COPING WITH COMPLEX ENVIRONMENTS: THE CASE OF DIGITAL HEALTHCARE TECHNOLOGY PRODUCERS

LORENA MACNAUGHTAN, MBA

Thesis submitted to the University of Nottingham for the degree of Doctor of Philosophy

July 2018

Last edited, April 2019

To my children,

Mia and Tod

ACKNOWLEDGMENTS

I am grateful to the Horizon Centre for Doctoral Training for the opportunity to join a multidisciplinary PhD degree and for their support throughout my years of enrolment. I am also thankful to the Horizon Digital Economy Institute and the School of Medicine for their support in the development of my research.

My warmest thoughts go to Prof. Lorraine Pinnington for always being there for me. It has always meant so much and I want you to know it. Forever grateful to all my supervisors, Prof. Pinnington, Prof. Gerardo Patriotta and Dr. Sujatha Raman, for your kindness, guidance and insights.

Very special regards go to Emma Juggins (Horizon Centre for Doctoral Training) and Christine Fletcher (School of Computer Science) for their excellent support.

I am very greatful to all participants in the research for the great time and valuable insights. It was an honour and a pleasure to know each and everyone of you!

There are many people and organisations who inspired my work. My thoughts right now go to: Emily Kramer-Golinkoff, Susannah Fox, Yoko K. Sen, Denise Silber, Prof. Larry Chu, Prof. Shafi Ahmed, Eugene Borukhovich and Dragos Stanca.

I am forever indebt to my sister, Mari, who put my kids to bed, picked them up from school sometimes! And greatful to my best friend, Monica Florescu, for good mood and patience.

Above all, I thank my husband, Alistair. For being my friend and my critique, but always, always believing in me. You make me feel I can do anything!

This research was supported by the University of Nottingham and the RCUK grants EP/G037574/1 and EP/G065802/1.

ABSTRACT

The aim of this thesis is to enrich the understanding of institutional complexity. To that end, my research focuses on an emergent field, as the most acute instantiation of institutional complexity, in addition to being an understudied phenomenon. Theoretically, the approach is anchored in the institutional logics perspective and the concept of institutional work. My research design is an inductive multi-level, multi-case study, found adequate to investigate a poorly understood and complex phenomenon. The research setting is the emerging field of digital health, at the intersection of healthcare and consumer digital technologies fields.

By means of the theoretical framework and the operational methodology, the research offers a robust understanding of the field emergence and of the institutional work undertaken by organisations in the midst of high institutional complexity. At field level, findings reveal the logics at play: the state, medical profession, market, science and citizen logics, as well as how the emerging role of the empowered patient mediates institutionalisation. A significant contribution of my research is a new theoretical model for field emergence.

This research provides insights on the understudied phenomenon of bottom up institutionalisation through the organisational level analysis. The study reveals the institutional work new organisations undertake in an emergent field, depending on their position, plurality and ambiguity and their own identity. It shows how organisations hybridise logics, often by co-creating digital solutions with stakeholders and by acting as institutionalisation agents. This research makes significant contributions towards the role trust and leadership play in organisation's success and the field institutionalisation itself. In addition, it reveals how new organisations contribute towards field emergence by adhering to distinctive categories and the promulgation of the new role of the empowered patient. Not last, my research contributes to the understanding of how digital technologies, by the virtue of their unfinished character, play a significant part in institutionalisation.

ACRONYMS

ACA – Affordable Care Act

ACO – Accountable Care Organisation

B2B - Business to business

B2B2C - Business to business to consumer

B2C - Business to consumer

CE - Conformité Européene (European Conformity)

CDHT - Collaborative digital health technologies

CEO - Chief Executive Officer

DH - Digital health

DIY – Do it yourself

DoH – Department of Health (US)

EC - European Commission

EHR - Electronic Health Record

EMR - Electronic medical records

EU - European Union

FDA - US Food and Drug Administration

GP – General Practitioner (Family/Primary Doctor in other countries)

HIMSS - Healthcare Information and Management Systems Society

ICT - Information and communication technologies

IP – Intellectual property

IT - Information technology

LTC – Long term condition

MVP - Minimal viable product

NICE - National Institute for Health and Care Excellence

NHS - UK National Health System

ONC - Office of the National Coordinator for Health Information Technology (US)

PHD - Personal health data

PR - Public Relations

RCT - Randomized controlled trials

SBRI - Small Business Research Initiative (UK)

STS - Science and Technology Studies

UK - United Kingdom

US - United States

VC - Venture capital

TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

CHAPTER 1. INTRODUCTION

1.1. STATEMENT OF MULTIDISCIPLINARITY

My research is by mandate, as well as necessity, a multidisciplinary research. As a student of the Horizon Centre of Doctoral Training at the University of Nottingham, I was both trained and encouraged to draw connections between different disciplines in order to better understand various aspects of the digital economy. Moreover, the contemporary landscape, with digital technologies intertwined with all economic activities and everyday life, requires more lateral thinking, complex approaches in order to generate fresh insights.

1.1. MOTIVATION

My research is "open minded, problem-driven" (Santos & Eisenhardt, 2009, p. 505) and grounded in the digitally transformed social and economic landscape. More precisely, it is situated at the intersection of consumer digital technologies and healthcare fields, where a new economic and innovation space is forming, hereinafter referred to as digital health. For the purpose of this thesis, digital health represents all things health informatics.

The motivation for my research goes beyond the mandate I mentioned above and even my interests, to the fact that it is an emerging digital setting, which promises tremendous social, economic and scientific transformations, and therefore it is sitting high on political and innovation priorities in many countries. For instance, the European Union has recognised and nurtured its potential since 2004 (European Commission, 2014a).

My research addresses several significant gaps in the literature. First, digital health is an emerging field and such fields have only been studied retrospectively. This study is actually looking at an emerging field as it happens. Acknowledging that retrospective approaches provide valuable insights, limitations are not to be overlooked (Aldrich & Fiol, 1994; Fligstein & McAdam, 2011; Greenwood et al., 2011). First, retrospective approaches

may have significant biases: “left-censoring of data” (Aldrich & Fiol, 1994, p. 664) (not having insights in the early years of formation) and the survival bias (studying only fields that succeed, not those that fail in reaching maturity) (ibid., p. 665). Second, I look at early ventures in an emerging field. Not only has this not been done before, but also retrospective research may have the bias of only observing the fittest. In addition to looking retrospectively at organisations that survived long enough, there is little information in the literature on how entrepreneurial firms navigate an early stage of a field or on how they may contribute to collective action (Aldrich & Fiol, 1994; Greenwood, Raynard, Kodeih, Micelotta, & Lounsbury, 2011). Not last, healthcare technology producers have not received much attention, despite the fact that technology has always been a major factor in the professionalisation of this field (Leicht & Fennell, 2008). The scarcity of studies during early stages of field emergence is due primarily to their lack of visibility (Morrill, 2006), which implies that much is left to the researcher’s ability to discover and recognise it as a field in its own right.

1.2. WORKING DEFINITIONS

Before proceeding with the presentation of my research, I consider useful to provide definitions for the main terms: digital health, institutions, organisation, institutional logics and institutional work.

The research setting is the emerging field of *digital health*, which is an umbrella term for all information technology (IT) solutions developed for healthcare. Digital health emerges as an interstice between healthcare and consumer digital technologies fields. Examples of digital health solutions are apps, wearables, virtual reality, but also electronic health records (more about terminology in appendix C).

Institutions are “comprised of regulative, normative, and cultural-cognitive elements that, together with associated activities and resources, provide stability and meaning to social life” (Scott, 2008; p. 48). Our social life is guided, restricted and inspired by “social facts”, as Durkheim called institutions in 1895, which guide our way of thinking, acting as individuals and

as a society as a whole. Examples of institutions are marriage, religion, justice, family, or the state. Institutions, however resistant they may be, they do evolve over time. For instance, the institution of marriage has very deep roots, but in the modern society, it is predominantly understood a monogamous association. Until recently, marriage was allowed only if the partners had different sexes. Since 2001, when Netherlands was first to allow same sex marriage, many countries have modified the understanding and legal standing of "marriage" accordingly.

Organisations are forms of social and economic life, with a structure, roles and purpose. They have a licence to operate, in the sense that they have to comply with state regulations, amongst other rules (i.e. professional or industry standards). Organisations could be public, private or non-governmental (NGO) and examples are hospitals, schools, companies or associations.

Society can be understood as a "system consisting of institutional orders (fields) and their associated logics" (Gawer & Phillips 2013; p. 1038). As a mean to relate institutions to agency, materiality and structure, the institutional logics framework provided a modality to operationalise social life and processes of institutionalisation. Thornton and Ocasio (1999; p. 804) define *institutional logics* as the "socially constructed, historical patterns of material practices, assumptions, values, beliefs, and rules by which individuals produce and reproduce their material subsistence, organize time and space, and provide meaning to their social reality". Institutional logics most invoked by scholars in their research are the state, profession, market or family.

Institutions, although resistant to change, evolve over time via the actions of individuals, organisations or collective actors. In order to understand this evolution, institutional work is contributing to the institutional logics framework by connecting it to action. *Institutional work* refers to what individuals or collective actors actually do to create, maintain or disrupt institutions (Lawrence, Suddaby, & Leca, 2011) and therefore it brings an agentic perspective to balance the cognitive and normative understanding of institutions.

1.3. ABOUT THE RESEARCH

My research aims to make contributions towards institutional complexity. To that end, I focus on an emergent field, as being the most acute instantiation of as this phenomenon. Most importantly, I research field emergence as it unfolds, not retrospectively. An emerging field presents itself as an interstice between other fields (Morrill, 2006; Rao et al., 2000; Greenwood et al., 2011; Stinchcombe, 1965), it lacks "stable social relationships" (Fligstein & McAdam, 2011, p. 12) and has "no agreement on means and ends" (ibid.). It follows that organisations entering such a field, have not only the "liability of newness" (Stinchcombe, 1965), but also operate in an institutional vacuum, a highly complex institutional environment (Morrill, 2006; Fligstein & McAdam, 2011, Van de Ven & Garud, 1993; Aldrich & Fiol, 1994).

Theoretically, I anchor my approach in the institutional logics perspective and the concept of institutional work to understand institutional complexity. However, I draw from adjacent streams of literature, from institutional entrepreneurship or innovation studies, to science and technology studies (STS), and even insights from the medical literature, to add fresh insights to the understanding of a complex phenomenon. Gathering insights from other streams of literature is aligned to calls from inside the institutional theory itself (Fligstein & McAdam, 2011; Friedland, 2013; Greenwood et al., 2011; Kraatz & Block, 2008), as well as to calls emerging from studying contemporary settings of the digital economy (Gawer & Phillips, 2013; Nicolini, 2006; Orlikowski, 2010; Santos & Eisenhardt, 2009).

My study aims to foster the understanding of field emergence and complexity and of the institutional work organisations undertake in such context. These aspects were understudied or approached retrospectively, after a field was stabilised, or they were only theoreticised. In contrast, my study takes place during the field is in the process of emergence. The two questions of the study are:

How does a field emerge?

How do organisations navigate an emergent field?

Answers to each question inform the answers to the other. However, it is necessary to capture first the institutional complexity of the field in order to situate and therefore better understand the organisations' responses to complexity. It follows that my research design requires two levels of analysis: a field level (macro) and an organisational level (meso). Such complex studies are considered to bring rich theoretical insights (Aldrich & Fiol, 1994; Greenwood et al., 2011; Scott, 2008; Thornton, Ocasio, & Lounsbury, 2012). The macro level setting is the emergent field of digital health and the meso level is a collective case study (Stake, 2005) of three companies that are not "sheltered" (Aldrich & Fiol, 1994, p. 646) by a powerful actor. At the meso level, I look at *collaborative digital health technologies (CDHT) producers*, who build solutions that may (potentially) connect various stakeholders in digital health (chapter five and appendix C offer further terminology clarifications). It is relevant that these organisations are developing without the support of an influential actor, for two main reasons: they are not influenced by the institutional logic of the powerful organisation and they do no have easy access to resources.

My research design is an inductive multi-level, multi-case study, found appropriate for investigating both poorly understood and complex phenomena (Gawer & Phillips, 2013; Santos & Eisenhardt, 2009). Such an approach provides a rich context, satisfying the need for a broad and an in-depth understanding. In addition, it is a "theory-building approach that is deeply embedded in rich empirical data" (Eisenhardt & Graebner, 2007, p. 25).

1.4. CONTRIBUTIONS

The theoretical contributions, besides addressing theoretical gaps, are towards the institutional theory, although they may inform other theoretical streams, like science and technology, social movements, institutional entrepreneurship or innovation studies. My findings allow for the rich theorisation of five institutional logics in digital health (state, medical profession, market, science and citizen), some not being previously defined in the literature. My research also shows how a new institutional logic, the citizen logic, is the beneficiary of the tensions generated by the plurality of logics at play. The rise of this new

logic is mediated by the emergence of a new role: the empowered patient. Most importantly, I enrich the understanding of field emergence by building a new theoretical model of emergence with four distinctive phases: the ingenuous, legitimation, mobilisation and stabilisation stages. This model brings forth the granularity attribute of the mobilisation stage and the role of legitimising actors for field institutionalisation.

This research enriches the understanding of institutional complexity and institutionalisation by revealing how organisations engage with various stakeholders in the field, based on their position, plurality and ambiguity, as well as their own identity project. It makes contributions towards the role that trust and leadership play in institutionalisation. It reveals how such organisations contribute towards the field emergence mainly by adhering to new distinctive categories, acting as institutional brokers and supporting the new role of the empowered patient. Significant insights regard the understanding of how digital technologies, by the virtue of their unfinished character (Garud, Jain, & Tuertscher, 2008) and compartmentalisation, play a role in institutionalisation, adding to insights from previous studies (Gawer & Phillips, 2013; Nicolini, 2006, 2007; Petrakaki, Barber, & Waring, 2012). Not last, I reflect on the merits of integrating values and materiality in research for the institutional theory at large and specifically for the institutional logics framework (Friedland, 2013; Hirsch, 2008; Kraatz & Block, 2008; Orlikowski, 2010; Patriotta, Gond, & Schultz, 2011).

Because my research is driven by a problem and it is rich in empirical data, there are several contributions of practical interest. Amongst them, it informs on the role of leadership on organisation's resilience, with material effects on its performance. I offer practical tools for entrepreneurs to develop strategy and a model of evaluation for digital health startups. There are a few recommendations for policy makers in respect to fostering and regulating innovation.

1.5. THESIS STRUCTURE

My work unfolds over nine chapters, with this first chapter presenting an overview. Chapter 2 provides the theoretical background on institutional complexity, the institutional logics perspective and the concept of and of institutional work. I give a significant space to the literature relevant to field emergence and I show how other theoretical streams of research inform this study. This chapter also presents previous contributions pertaining to technology and institutionalisation, as well as technology and healthcare.

Chapter 3 describes my theoretical framework, as a middle ground sociological approach. I draw on the institutional logics framework and institutional work to research institutional complexity and guide interpretation for this multilevel study. In this chapter, I explain the constructivism approach, where both organisations and their institutional field are relevant for the institutionalisation process. Chapter 4 proceeds with establishing the aims and the research questions, and it describes the methodological approach, as well as the operational steps taken for data collection and analysis.

Chapter 5 is a prerequisite stage primarily, which offers an overview of the historical institutional context of the main fields that converge into digital health – consumer digital technologies and healthcare. I found this stage of the research necessary, similar to other researchers that approached institutional transformation (Scott, Ruef, Mendel, & Caronna, 2000), because the phenomena in focus is both complex and understudied.

Chapter 6 and 7 are dedicated to the field level findings. Chapter 6 provides an overview of the institutional logics at play in this field – the market, the state, the medical profession, the science and the citizen logics – and their representative stakeholders. Having established that, chapter 7 goes into revealing the institutionalisation process of the field emergence, as interplay of hybridisation and conflict between actors, and explores the stages of emergence: the ingenious, the legitimation, and the mobilisation and stabilisation phases. The last phase is only referred to based on previous theorisation of the field emergence (Morrill, 2006), because, by the end of data collection, the digital health field only just entered the mobilisation phase.

Chapter 8 focuses on the meso level of analysis and presents how organisations navigate the complexity of digital health, based on their position, plurality and ambiguity, as well as their own identity project. It highlights how both actions and theorisation contribute to the field institutionalisation process. The variability of the cases offers additional insights of theoretical and practical relevance. Chapter 9 summarises the findings and presents the main theoretical and practical contributions of the research. In closing, there are reflections of the possible limitations and discussion of future directions of research.

This thesis builds upon and expands the preliminary findings of analysing the macro level, presented in a conference paper at the 31st EGOS Colloquium, July 2–4, 2015, Athens, Greece, accepted under the sub-theme 55: "Re-examining the organization of healthcare: institutional, technological and clinical challenges", but not published in the conference proceedings. The paper, "Plurality of institutional logics in digital healthcare: The rise of the hybrid patient", was co-authored with Gerardo Patriotta, Lorraine Pinnington and Sujatha Raman (Macnaughtan, Patriotta, Pinnington, & Sujatha Raman, 2015). As the first and main author, my contributions were significant and included the ground research, theoretical approach, methods, theoretical insights and conclusions. However, I acknowledge the invaluable guidance and input from all co-authors, who, at that time, were all my supervisors. Elements of this previous and preliminary work are mainly found in chapters 2, 6, 7, and 9.

Finally, the diagram below represents intuitively how the thesis is constructed.

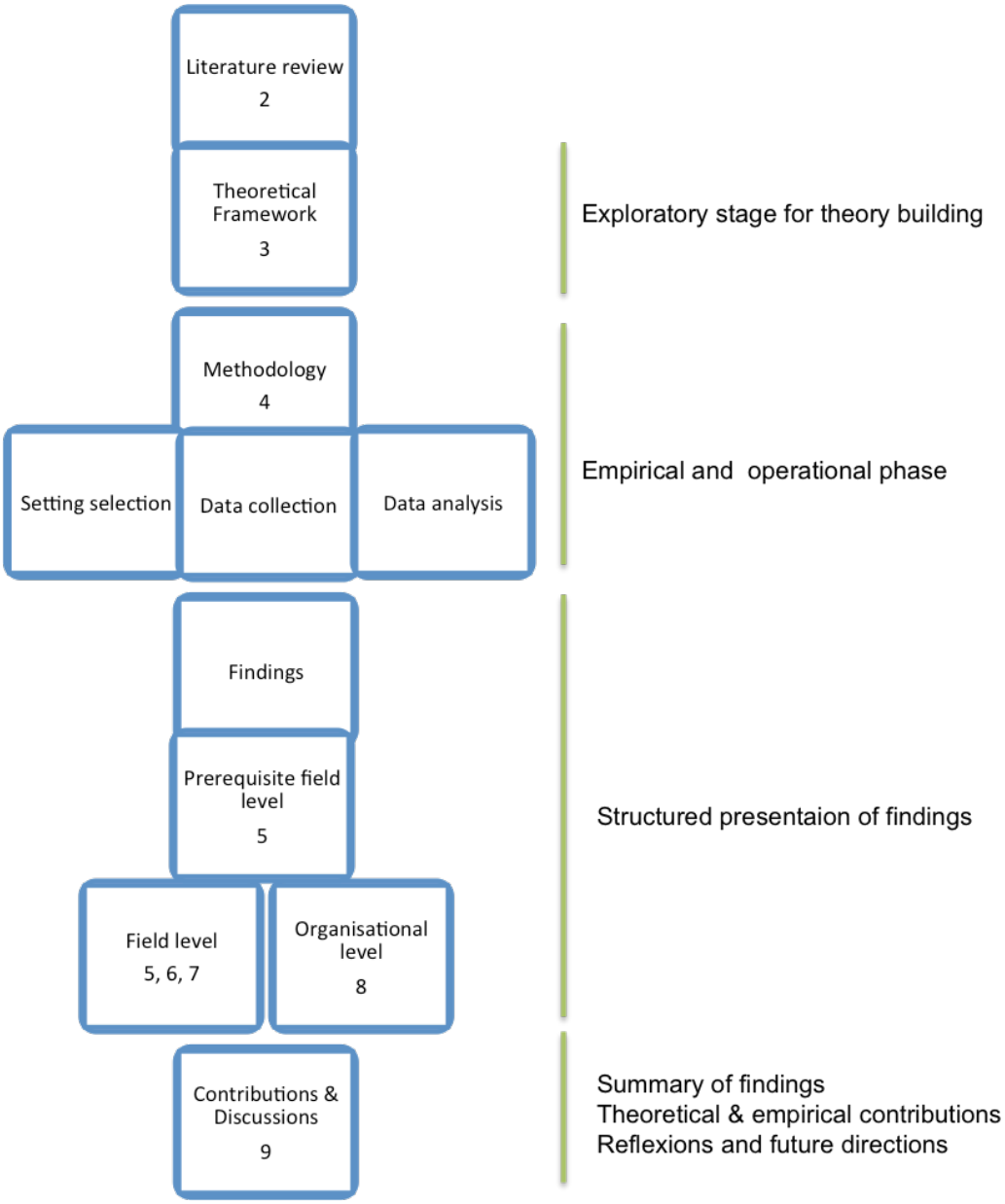

Fig. 1. Thesis structure

CHAPTER 2. LITERATURE REVIEW

2.1. INTRODUCTION

This chapter sets the theoretical background of my research. Theoretically, it is anchored in the institutional logics perspective and the concept of institutional work, as found relevant for understanding institutional complexity. However, I draw on adjacent streams of literature, from institutional entrepreneurship to science and technology studies, and even insights from the medical literature, to add to the understanding of a complex phenomenon. It is, in essence, a multidisciplinary approach to allow for a deeper understanding of contemporary complexities of the digital economy.

2.2. INTEGRATING INSIGHTS FROM SEVERAL THEORETICAL STREAMS

In order to understand the contemporary socio-economic environment and to provide fresh theoretical insights, developments in the institutional theory are calling for perspectives that on one hand reconcile action and structure (Barley, 2008; Barley & Tolbert, 1997; Beckert, 1999; Hirsch, 2008; Lawrence, Suddaby, & Leca, 2009; Orlikowski, 2010) and on the other hand are "open minded, problem-driven" (Santos & Eisenhardt, 2009, p. 505). Existing theories explain and guide stable environments very well, however the digital economy context may require lateral thinking, meta-theoretical approaches, because it may present characteristics that are not well explained or addressed by current theories or empirical research. Over the last decade, such meta-theoretical approaches applied to the digital economy revealed significant insights related to the emergence of technological platform (Gawer & Phillips, 2013), relationships with other organisations (Ozcan & Eisenhardt, 2009), digital market creation (Santos & Eisenhardt, 2009) and the continuous "morphing" of digital companies (Rindova & Kotha, 2001).

Both the institutional logics framework and institutional work allow for meta-theoretical approaches and have proven their usefulness to integrate broader perspectives over complex phenomena, as shown in this chapter. Additionally,

the institutional work approach offers a critical perspective over the interaction between agency and institutions, "one that avoids depicting actors either as cultural dopes trapped by institutional arrangements, or as hyper muscular institutional entrepreneurs" (Lawrence et. al., 2009, p. 1).

2.3. INSTITUTIONAL LOGICS

Institutional logics are "socially constructed, historical patterns of material practices, assumptions, values, beliefs, and rules by which individuals produce and reproduce their material subsistence, organize time and space, and provide meaning" (Thornton & Ocasio, 1999, p. 804). In other words, they are guidelines for how to make sense and engage in social situations, but they are also embedded in practices and material structures (Friedland & Alford, 1991; Gawer & Phillips, 2013; Greenwood et al., 2011; Jones, Boxenbaum, & Anthony, 2013; Thornton et al., 2012).

These "rules of the game" (Fligstein & McAdam, 2011, p. 5), although resistant to change, are still evolving through cross-semination with rules from adjacent areas or through peak moments (field crisis) - wars, legislation, technological breakthroughs or economic depression (Aldrich & Fiol, 1994; Nigam & Ocasio, 2009; Scott, 2008).

If our rationality is bounded by cultural norms we take for granted (Meyer & Rowan, 1977), where is change coming from? In 1991, Friedland and Alford introduce the 'institutional logics' term and provide a solution for what was becoming a problematic struggle for institutional scholars: the conciliation between structure and agency, stability and change. This view proposes the understanding of social life as intertwine of institutional orders, sometimes exerting conflicting expectations, nonetheless allowing for both continuation of social life and change. The institutional logics initially proposed by Friedland and Alford for the Western world were: bureaucratic state, democracy, capitalist market, Christian religion and the nuclear family. Scholars have either taken these into account or identified others, for instance the professional logic (Scott et al., 2000; Thornton, 2002) or the community logic (Thornton et al., 2012; Waldorff, Reay, & Goodrick, 2013). Many researchers combine the

societal level logics with more specific logics or field level logics (Dunn & Jones, 2010; Gawer & Phillips, 2013).

Institutional scholars embraced this view, but only in the early 2000s it benefits from theoretical revisiting. As a consequence of the increased acknowledgment that institutional life is not limited to periodic drifts from one logic to another, Greenwood et al. (2011) propose a framework for addressing institutional pluralism and complexity. In 2012, Thornton et al. crystallise the overall streams of research in institutional logics and propose a multi-level theoretical framework and fleshed out further research directions. More recently, Jones et al. (2013) call for a timely revisitation of the original acceptation of institutional logics offered by Friedland and Alford (1991), which includes materiality alongside structure and practices. Friedland (2013) himself supports the necessity of bringing in both materiality (Orlikowski, 2010; Scott, 2008) and values (Patriotta et al., 2011) into the institutional logics approach.

2.4. INSTITUTIONAL WORK

To recognize the importance of both action and agency in institutional processes, a stream of research has emerged. The concept of institutional work – "practices of individual and collective actors aimed at creating, maintaining, and disrupting institutions" (Lawrence et. al., 2011, p. 52) - is enriching the institutional logics framework by bringing human action and agency more to the forefront of research. Likewise the institutional logics framework, the institutional work concept allows for the combination of different theoretical streams (ibid.).

At the institutional field level, the institutional work approach was employed to study change, maintenance and even emergence. Several studies focus on the institutional work of maintaining and repairing institutions (Hirsch & Bermiss, 2009; Zilber, 2009). Others bring insights into how change happens in a field with a moderately centralised structure, showing how scientists can be institutional entrepreneurs (Ritvala & Kleymann, 2012), or in a less centralised field, where a technology company succeeds to change institutional

arrangements by forging collaborative practices and moving towards a platform logic (Gawer & Phillips, 2013).

Another relevant study (Zietsma & Lawrence, 2010) shows that some fields have change more embedded in their logic, hence institutional change is a constant, rather then an institutional crisis, as it is conceived most of the time. Such field movements can be understood as like lifecycles – "change and stability were the norm at different times, and transitions between cycles depended on particular mechanisms that shifted more gradually" (ibid., p. 216). An important insight this study brings is that different theoretical streams focus on certain institutional change aspects only; therefore much is left to understand by employing a unifying approach. For instance, "[t]he innovation cycle we found corresponds to research on institutional entrepreneurship or institutional design, which focuses on the creation of new institutions by interested actors, and their promotion to diverse constituencies" (ibid., p. 215). Another significant insight is the importance of situating the research more broadly in order to understand the field's nature, as well as its development stage in order to shed light over the actors' actions and the institutional processes.

Studies like the examples above have employed the concept of institutional work both at field and organisational levels and they proved its usefulness in explaining complex institutional contexts and processes.

2.5. INSTITUTIONAL FIELDS

An institutional field contains all stakeholders who, "in the aggregate, constitute a recognized area of institutional life" (DiMaggio & Powell, 1983, p. 148) and a field level logic (Scott, 2008, pp. 186–187) or "constellations of logics" (Goodrick & Reay, 2011).

My understanding of a field is different from that of a market, in the sense that even though a market can be conceptualised as an instantiation of a field (Fligstein & McAdam, 2011), it is only a part of it (Scott, 2008). An institutional field is not limited to exchanges of goods and money between producers and consumers (Fligstein, 2002). One essential element in the

delineation of a field is the relationship between actors, and therefore fields develop around issues (i.e. technologies, markets, as well as social, political or cultural aspects) that bring actors together, not around needs. Moreover, "[o]rganizations may make claims about being` or not being part of the field, but their membership is defined through social interaction patterns (…) Field membership may also be for a finite time period, coinciding with an issue emergence, growth, and decline" (Hoffman, 1999 in Scott, 2008, p. 183). It follows that field boundaries can change, as well as the boundaries between the actors inside the field (Fligstein & McAdam, 2011; Scott, 2008). Boundaries of an institutional field are cultural and functional (Scott, 2008) and are subject to constraints - technologies, resources or regulations (Fligstein & McAdam, 2011; Van de Ven & Gardu, 1993).

Stakeholders engage with others in various forms: from symbolic acts to more formal relationships (commercial activities, associations, governing and regulatory bodies, conferences). Recently, the serendipitous associations via social media represent another form of stakeholders' engagement (Beverungen, Böhm, & Land, 2015). The "thickness of ties" (Selznick 1992) reflects on stakeholders' connection to the institutional infrastructure, and their commitment to particular logics.

Various stakeholders carry their own logics in less pure forms. A field level logic is understood as presiding a field over a certain historical period (Scott 2008). The more mature the field is, its logic becomes more "objectified" as consensus appears. A "thick socialization" (Selzenick, 1992, in Scott, 2008) relies not only on regulations, laws and standards, but also on taken for granted assumptions and deep network relations entangled in "reputation, friendships, interdependence, and altruism" (Scott 2008 p.) or salient conflict (Dunn & Jones, 2010; Reay & Hinings, 2009; Scott et al., 2000). Friedland (2013) highlights value substances and Patriotta et al. (2011) refer to higher orders of worth as additional repertoires in which institutional logics are anchored, that could explain both resilience and change.

Much research developed at the field level is preoccupied with how a dominant field level logic transitions to another; change ignited by tensions between

society level logics (Thornton, 2002; Thornton & Ocasio, 1999), by actions of powerful actors (Scott et al., 2000) or even by actions of less powerful actors (Gurses & Ozcan, 2014; Haveman & Rao, 1997).

The table below is synthesising forms of changes of institutional logics at field level, depending on the amplitude of change. It is based on and adds to the table offered by Thornton et al. (2010, p. 164).

Forms of Change	Definition	Sample Studies
Transformational Change	*More radical changes of symbols and practices*	
Replacement	One institutional logic replaces another	Rao, Monin, and Durand (2003) Gawer and Philips (2013)
Hybridisation - Blending	Combining dimensions of diverse logics	Glynn and Lounsbury (2005)
Segregation	Separation of logics from a common origin	Purdy and Gray (2009) Dunn and Jones (2010)
Developmental Change	*Majority of prevailing practices and symbols remain, while others change or appear (hybridisation and plurality).*	
Hybridisation - Assimilation	Incorporation of external dimensions	Murray (2010)
Hybridisation - Elaboration	Endogenous reinforcement	Shipilov, Creve, and Rowley (2010)
Plurality - Expansion	Shift from one logic to another	Nigam and Ocasio (2010)
Plurality - Contraction	Decrease in logic's scope	Reay and Hinings (2009) Dunn and Jones (2010)
Plurality – Persisting conflict	New "beneficiary" logic	Scott et all (2000) Pouthier et al. (2013)

Table 1. Forms of institutional logics change at field level

2.5.1. FIELD EMERGENCE

An emergent field is a social space, an interstice (Greenwood et al., 2011; Morrill, 2006; Rao et al., 2000; Stinchcombe, 1965) between other institutional fields, where various stakeholders acknowledge each other, relate and take actions towards each other, but there are "no stable social relationships, and no

agreement on means and ends" (Fligstein & McAdam, 2011, p. 12). Therefore there is high uncertainty (Aldrich & Fiol, 1994; Fligstein & McAdam, 2011; Rao et al., 2000; Santos & Eisenhardt, 2009). Emergent fields, due to their blurred boundaries, invite and attract various actors and therefore there are multiple institutional logics vying for dominance (Pache & Santos, 2010; Thornton et al., 2012).

The usual triggers for crisis in institutional fields, which sometimes may cause new fields to emerge, are the actions of the state, wars or economic depressions (Fligstein & McAdam, 2011). However, Morrill (2007) signals that usually fields emerge around an innovation, a practical approach to problems in adjacent fields. Morrill considers that, at the very beginning, nascent fields are not very visible, but, as they develop, they redirect resources or support from established fields, causing contention (Fligstein & McAdam, 2011). Some actors in adjacent fields show resistance and hostility, whilst others show support (Greenwood et al., 2011; Morrill, 2006; Stinchcombe, 1965). The new space is characterised by intense competition over scarce resources (Aldrich & Fiol, 1994), a "shared sense of uncertainty" (Fligstein & McAdam, 2011, p. 9), intense segregation of stakeholders in incumbents and challengers and a general focus on the state's actions (ibid.).

"When a significant technological breakthrough appears in the public sphere, opinions tend to polarize between optimists, who emphasize the potentialities of the new technology, and pessimists, who tend on the contrary to stress the difficulties and the potential barriers to the adoption of the new instrumentality" (Nicolini, 2006, p. 2755). This leaves in between a liminal space characteristic to emerging activities and fields. The "liminal space" (Hirsch & Lungeanu, 2012, p. 9), at the confluence of existing and emerging social structures, is where rules, performances and regulations are uncertain. A liminal space or "space of uncertainty" (Beckert, 1999, p. 787) is characteristic to the emergent phase of an activity.

Institutional stabilisation happens as a consolidation of logics and may spread over a few years or even over decades (Aldrich & Fiol, 1994; Van de Ven & Garud, 1993). Eventually, the outcome is a new hybrid field logic (Glynn &

Lounsbury, 2005; Thornton & Ocasio, 1999), a winning logic (Scott et al., 2000) or a "constellation of logics" (Dunn & Jones, 2010; Waldorff et al., 2013). Once stable, a field can still go through periods of contestations and crisis (Fligstein & McAdam, 2011).

2.6. Institutional complexity and pluralism

Institutional pluralism and institutional complexity become a central interest for institutional scholars (Greenwood et al., 2011). Institutional complexity rises primarily from pluralism, from conflicting institutional demands from at least two logics (Kraatz & Block, 2008). Institutional demands consist of "various pressures for conformity exerted by institutional referents on organizations in a given field" (Pache & Santos, 2010, p. 455).

Greenwood et al. (2011, p. 325 - 331) offer an extensive summary of research conducted in institutional complexity, at different levels of analysis. They point out that most studies look at two logics only and that most of the times there are more logics at play. Consequently, some of the findings may not be generalisable because "the extent of complexity experienced may be underestimated or misinterpreted; and, the particular responses observed may not be properly understood" (ibid., p. 332). Greenwood et al. (2011) also plead for researchers to consider all logics at play and be clear in respect to the reasons they have included only certain logics in their analysis (ibid.).

2.6.1. At field level

Since the dawn of the institutional logics perspective, studies focused on transitions of field level logics and on how logics promoted conformity across their fields (Nigam & Ocasio, 2009; Reay & Hinings, 2005; Scott et al., 2000; Thornton, 2002). They were primarily historical accounts, often spreading over decades. Consequently, they took into account only a few logics, as they proved to be important over time. For instance, in her account of institutional change in publishing, Thornton (2002) considers only two logics: the editorial logic (as instantiation of professional logic) and the market logic. Scott et al. (2000) in their historic overview of healthcare institutional change take into

account the interplay between three logics: medical profession, bureaucratic state and managerial logic (steamed from the market logic).

Over time, acknowledgement arises for the rivalry between logics (Reay & Hinings, 2005) as a source of institutional change. Additionally, it becomes clear that some fields have persistent rivalry between logics, leading to an "uneasy truce" (Reay & Hinings, 2005, p. 364) rather than a single, victorious field logic. However, this tension between logics is considered unsustainable, and so one of them would eventually dominate. The authors themselves review this assumption through a later study (2009), showing that the co-existence of rival logics can continue as an uneasy truce for long periods of time and that mechanisms are developed to accommodate both logics. Interestingly, one mechanism identified by authors is the creation of experimental sites where actors of rival logics came together to approach certain issues innovatively, and thus create change at practice level. Additionally, one motivation for collaboration is the counterbalancing of the more powerful state logic.

Although not explicitly drawing on pluralism, Scott et al. (2000) show how the healthcare field logic changed in the US between 1945 and 2000, moving from an era of professional authority centred on quality (1945 - 1965) to an era of federal regulations (1966 - 1982) and, finally, to an era of managerial control and market forces (1983 - 2000). They show how the era of federal involvement fostering the logic of equity causes intense fragmentation, thus subsequently making space for the managerial and market logics to enter. "Market mechanisms have joined, but not replaced, state controls. What we see is a change in rhetoric and in the policy mechanisms that governmental actors employ as they attempt to steer the development of this sector specifically and govern the welfare state more generally" (ibid., p. 344). This shows how fragmentation and weak ties create a favourable environment for field level contestations (Dunn & Jones, 2010; Nigam & Ocasio, 2009; Scott et al., 2000). The conclusion of the study is that, paradoxically, different logics co-exist over time (institutional pluralism), with the medical profession logic being in decline. Moreover, the managerial logic in healthcare proves to be the beneficiary of the resistance of the medical professional logic against the state logic. Hence, none of the two competing logic wins, rather a third one

(managerial logic) emerges as a result. In this sense, managers "appear to have been the beneficiaries, not the agents, of the deinstitutionalization" (Scott et al., 2000, p. 328).

Similar findings showing resistance towards a cost effective approach in healthcare are presented by Nigam and Ocasio (2010) in their analysis of the Clinton's healthcare reform initiative in the US (1992 - 1994). They show how, despite the intense push of the state towards a "managed care" approach, both physicians and patients resist and "the competing logic of physician authority was invoked to threaten legislative changes" (Thornton et el. 2010, p. 167). This time, a field crisis caused by a state's action results in the strengthening of the medical profession logic, even if only for a while.

Studies, like those presented above, show that sometimes less powerful actors can impose institutional arrangements at field level. However, they also show that the entrance of new actors and the actions of powerful ones caused over time the decline of the medical profession logic.

Dunn and Jones (2010) acknowledge the competing logics of science (better represented by specialist doctors) and care (mainly carried by primary care doctors) in medical education and how these logics not only changed the medical schools over time, but they also created fragmentation, plurality and conflict inside the medical profession itself. Other authors show how multiple logics can co-exist in a certain field based on professional fragmentation (Dunn & Jones, 2010; Pouthier, Steele, & Ocasio, 2013), types of actors (Goodrick & Reay, 2011; Reay & Hinings, 2009) and geographical location (Greenwood, Diaz, Li, & Lorente, 2010). The complexity and the internal fragmentation of the medical profession logic itself make it more vulnerable to other logics (Dunn & Jones, 2010; Scott et al., 2000; Leicht & Fennell, 2008).

Most studies in pluralism illustrate the irreconcilable differences between logics, but more recent work show that in a "constellation of logics" (Goodrick & Reay, 2011) there is not only rivalry, but also similarities between logics. Greenwood et al. (2010) point towards the facilitative effect logics can exert upon each other. Waldorff et al. (2013) show that logics could produce both constraining and facilitative effects over actions. This is consistent with the

idea that the existence of multiple logics opens up space for change, because stakeholders may access a wider range of possible justifications, actions, or paths (Friedland & Alford, 1991; Greenwood et al., 2011; Thornton & Ocasio, 1999).

Greenwood et al. (2011) remark that there are or could be significant differences in how institutional complexity manifests and is experienced in mature versus nascent fields. Most studies in institutional complexity are either focused on mature fields, or are historical and therefore consider a limited number of stakeholders and logics, as they proved to be important over time. In this light, there is a recognized need for exploration of emergent fields to test and enrich existing theorization (Aldrich & Fiol, 1994; Fligstein & McAdam, 2011; Greenwood et al., 2011; Wooten & Hoffman, 2008).

2.6.2. AT ORGANISATIONAL LEVEL

Accepting the view of organisations as "sites where multiple institutional logics vie for dominance" (Thornton et al., 2012, p. 183) may bring new understandings of the organisational behaviour, including strategy and form, and therefore would enrich and refresh sociological insights. Similarly, it may lead to insights on field institutionalisation processes (Dunn & Jones, 2010; Gawer & Phillips, 2013; Santos & Eisenhardt, 2009; Van de Ven & Gardu, 1993).

Advancing the research agenda on institutional work proposed by Lawrence et al. (2009), as well as Thornton et al. (2012), should consider the cognitive and cultural dimensions, carried through by institutional logics. Such dimensions would contribute to a richer understanding of the institutional work at organisational level, not only at field level. Skilled actors use symbolic and cultural acts to undertake institutional work (Thornton et al., 2012; Greenwood et al., 2011; Kraatz & Block, 2008; Fligstein, 2001). Cultural and cognitive frames prove to have material impact on organisations and their access to resources, as showed for instance by the seminal work on categorisation (Santos & Eisenhardt, 2009; Tyler Wry & Lounsbury, 2013). Both studies show that organisations are more likely to access resources if they are satisfying existing industry categories. However, Navis and Glynn (2011) show

that in a nascent market, where categories are maladapted and emerging, new categories are actively constructed by entrepreneurial organisations and are used strategically to access resources.

Cultural and institutional entrepreneurship traditions show that building legitimacy, one of the main undertakings of new organisations in the midst of institutional change or complexity, cannot be reduced to a power exercise. Legitimacy "is a generalized perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions" (Suchman, 1995; p. 574). Legitimacy is "something" (Deephouse & Suchman 2008; p. 59) that affects the organisation's access to resources (Aldrich and Fiol, 1995; Suchman, 1995; Beckert, 1999). Suchman (1995) considers that legitimacy was approached from strategic and institutional perspectives, but these should not be exclusive (Deephouse & Suchman, 2008; Pfeffer & Salanick, 2003; Suchman, 1995), because in order to obtain resources, one needs legitimacy and in order to obtain it, one needs to allocate resources - otherwise put, to undertake institutional work.

Studies of nascent fields highlight that it is important for innovation entrepreneurs (individuals or organisations) to undertake institutional work, because of ambiguity and uncertainty. Aldrich and Fiol (1994) claim that in an emerging field, organisations' actions require different strategies at different levels: institutional, interindustry, intraindustry and organisational. The authors focus on strategies for obtaining legitimacy. Aldrich and Fiol (1994) stress how different the strategies can be in a nascent field as opposed to a mature one. Although they recognise the struggle for resources for all enterprises, the authors believe that in nascent activities it is important to create legitimacy as the foundation for exchanges with the environment.

Emergent fields are characterised by change, novelty and risk due to ambiguity. In this way, the organisations entering or starting up in such fields are entrepreneurial in nature. Entrepreneurial behaviour "always searches for change, responds to it and exploits it as an opportunity" (Drucker, 1994, p. 25). Studies of entrepreneurial actions either have a strategic or an institutional

perspective (Deephouse & Suchman, 2008; Hirsch & Wohlgezogen, 2009). These perspectives are not necessarily dichotomous; one emphasises resources and material constraints, whilst the other focuses on institutions (Suchman, 1995).

Various studies in entrepreneurship focusing on emerging worlds have analysed singular aspects of entrepreneurial firms: identity and legitimacy formation (Navis & Glynn, 2011), legitimacy building through design (Garud, Jain, & Kumaraswamy, 2002; Hargadon & Douglas, 2001; Rindova & Kotha, 2001), formation of alliance portfolios (Ozcan & Eisenhardt, 2009) and networks (Gulati & Higgins, 2002), and alliance decisions for accessing or defending resources (Katila, Rosenberger, & Eisenhardt, 2008). Without underestimating the tremendous theoretical and practical insights of these researches, they maintain an atomistic view either by focusing on singular elements, or by focusing either on the internal aspects of the organisation or on its relations.

Boundary is another overarching concept for investigating the entrepreneurial activities, in many ways similar to that of institutional work. Santos and Eisenhardt (2009) define organisational boundaries simply as "demarcations" with the environment. And so, boundaries serve as signposts or "tools by which individuals and groups struggle over and come to agree upon definitions of reality" (Lamont & Molnár, 2002, p. 168). Boundaries reduce ambiguity and uncertainty, support sense making and rule creation, and offer sense of belonging (insiders and outsiders) and legitimacy. Overall, boundaries point mainly to matters of governance and I define *governance* as concept related to purpose and control (Kraatz & Block, 2008, pp. 253–256), which has relevance for both the organisation and the field, as it reflects internal and external negotiations over institutional arrangements. Boundary work is often studied in the context of innovation, strategy or entrepreneurial activities, because it has profound material effects in acquiring resources and power (Lamont & Molnár, 2002; Santos & Eisenhardt, 2005, 2009; Zietsma & Lawrence, 2010). Boundaries are particularly important in the formative stages of an activity. Santos and Eisenhardt (2005) propose four different types of boundaries: efficiency, power, competence and identity. The efficiency boundaries aim to

minimize the transaction costs, the power boundaries maximize the control over the organisation's exchanges with the environment, the competence boundaries maximize resources and the identity boundaries ensure the coherence between what an organisation does and what it claims to be. Apart from contributing to the existent literature on boundaries with an integrative, meta-theoretical approach, the authors call for a "problem-driven boundary phenomena" (Santos & Eisenhardt, 2005, p. 505) as opposed to a theory driven approach, because of the new settings presented by the contemporary economic landscape. Santos and Eisenhardt (2009) actually use such an approach when looking at how entrepreneurial action unfolds in nascent fields (the confluence of IT and communication industries in the mid nineties). The study reveals that entrepreneurs do not always act rationally, but through a "blend of emergent and deliberate actions, together with mistakes and serendipitous learning" (Santos & Eisenhardt, 2009, p. 664). However, the authors do not explicitly address the nature of boundaries (power, efficiency, resources and identity) and the relation between these types of boundaries and the organisations' relations with other stakeholders. Also, the setting is not an institutionally fragmented field, where institutional conflicts compound the problem of legitimacy and boundaries.

However, one of the many contributions of this article is the view of interorganisational power through both institutional and competitive lenses. The soft-power techniques (persuasion) are more likely to be employed than hard-power ones based on competitive advantage (Santos & Eisenhardt, 2009). The use of soft power is similar to what Selznick calls co-optation – "the process of absorbing new elements into the leadership or policy-determining structure of an organization as a means of averting threats to its stability or existence" (Selznick, 1948, p. 34). Santos & Eisenhardt (2009) refer mainly to informal co-optation, bringing in constituencies that have some power to enforce demands. However, the authors have shown that co-optation can be employed strategically to obtain advantages, not only to annihilate threats. In this thesis, I use the term co-optation to refer to mechanisms of bringing in stakeholders, formally or informally, in order to either diminish pressures or to advance specific interests from a position of scared resources or of lack of

authority. In the context of soft power, the concept of *coopetition* is similarly relevant – when organisations simultaneously compete and collaborate (Walley, 2007). Coopetition in the emergent phase of a field is essential not only to obtain economic advantages, but also to survive (Aldrich & Fiol, 1994; Santos & Eisenhardt, 2009).

2.7. TECHNOLOGY AND INSTITUTIONAL CHANGE

Although the original article of Friedland and Alford (1991) pointed towards the material aspects of institutional logics, there are not many organisational studies that take material aspects into account. In his recent article, Friedland (2013) insists on the significance of materiality for the understanding of institutional logics. "Unobservable substances must be transmuted into observable objects – nested and interlocked – which are the means by which practices are anchored" (ibid., p. 37).

Digital technologies have always escaped the rules of traditional technology markets, not only due to their constant morphing (Rindova & Kotha, 2001), but also due to their inherently unfinished and intangible character (Garud et al., 2008; Orlikowski, 2010). These technologies morph with the user's input, or they are rendered insignificant in its absence. With digital technologies, we find that "operations are emergent and fluid, goods and services are intangible and informational, authority is distributed and diverse, and accountability is multiple and shifting" (Orlikowski, 2010, p. 243).

Gawer and Phillips (2013) show that "technological design of an interface allowed the conversation between social actors to happen, and during this process (characterized by a continuum of stages including recursive instances of design, testing, implementation and stimulation of complementary innovation), collective identities were specified and reinforced" (p. 1063). In other words, the interface design became an institutional work for social realignment, mediating a new institutional logic.

2.7.1. TECHNOLOGY AND HEALTHCARE CHANGE

Healthcare is inherently slow in adopting technology because it is regulated, from professional standards and treatment protocols to reimbursements

(Christensen, Grossman, & Hwang, 2009). Scott et al. (2000) reveal that healthcare has the ability to embrace technical complexity, but does not respond well to cost efficiency approaches (ibid., p. 333). An explanation could be that the medical profession logic is a blended logic of science (and technology) and care (Dunn & Jones, 2010; Oborn, Barrett, & Racko, 2013).

Research in the use of information and communications technology (ICT) in healthcare is predominantly preoccupied with evidence for clinical, economic and social benefits from the perspective of healthcare service providers (organisations that deliver healthcare services, i.e. hospitals, general practitioners). "Several systematic reviews indicate that there have been few evaluations of sufficient quality to determine effectiveness" (Davies & Newman, 2011, p. 12), because such studies are either done on a small scale, or are focused on a single aspect, a single condition, or a single beneficiary, or they have small samples or are using methods that make their results difficult to compare and generalise (Davies & Newman, 2011; Jennett et al., 2003). Another limitation is represented by the assumption that benefits remain static, whilst in fact they are evolving with the interaction between beneficiaries and producers (Gawer & Phillips, 2013; Jacobides, Cennamo, & Gawer, 2018; Orlikowski, 2010). Although such literature sometimes points to the organisational issues related to the introduction of digital solutions, they have not benefited from similar attention (Waring, 2015). Healthcare innovation is a political process and scientific evidence represents only one forum for debates (Nicolini, 2010; Pearce & Raman, 2014).

ICT has the effect of making objects, people, roles and relationships visible and explicit (Nicolini, 2006, 2007, 2009; Petrakaki et al., 2012). In this way, it has the potential to unveil unresolved, existent problems. In healthcare, for instance, an on-going debate is over the patient data: who owns it, who accesses it, who uses it and under what circumstances. Similarly, ICT potentially transforms existing social arrangements mediated by professional roles, because such roles may lose their distinctiveness through the introduction of expert systems, which emphasize efficiency or customer relations (Petrakaki et al., 2012). Nicolini (2006) reveals the consequences of the mismatch between the technological script and the existing work practices

in the field of telemedicine. The future script embedded in technology is based on the innovator's view of the stakeholders and is pointing to an envisioned value/risk, practices and it "assumes that morality, technology, science, and economy will evolve in particular ways" (Akrich, 1992, p. 208).

Acknowledging the social effects of ICT does not necessarily mean adopting a unidirectional or deterministic perspective on technology (Petrakaki et al., 2012; Nicolini 2006, 2010; Orlikowski, 2007). More recently, based on insights from Science, Technology and Society (STS) studies, the relationship between technology and organisational structure is understood as being "constitutively entangled" (Orlikowski, 2007, p. 1437). I would add to this also the relationship between the technology and person (Prout, 1996). Adopting such a perspective seems particularly relevant when looking at dynamic and cross-disciplinary contexts like technology, biotechnology, nanotechnology or digital technologies (Orlikowski, 2010).

Most of the studies on healthcare innovation focus on the service provider. The need to include other stakeholders apart from the service providers in researching innovation in the medical field is recognised by recent research. Service providers, patients and policy makers are included in the Neo-Schumpeterian model of healthcare innovation by Windrum and Garcia-Goñi (2008). Studies of ICT in telemedicine and telehealth (Petrakaki et al., 2012) point out that in order to understand ICT innovation in healthcare there is a need to expand the attention to other stakeholders, such as technology producers, associations or reimbursement agents.

Morrill (2007) signals that usually fields emerge around an innovation, a practical approach to problems in adjacent fields. Technology played a significant role in the professionalization and fragmentation of healthcare, and presently it is considered to be an imperative (Leicht & Fennel, 2008). However, technology producers remains an understudied segment, with few exceptions (Lebret, 2018; Lim & Anderson, 2016), despite technology having an increased impact on the healthcare environment: "there have been few analysis of that portion of the industry that has become increasingly more

important to the material/resource/technical environment: the producers of new healthcare technology" (Leicht & Fennell, 2008, p. 440).

2.8. CONCLUSIONS

In this chapter, I review the literature relevant to the theoretical approach, and the main concepts like institutional complexity, institutional logics and institutional work. I point out to their usefulness for unifying research from other theoretical backgrounds. I show that they are suited for researching a new phenomenon in an institutionally complex environment, both at field and organisational levels. Moreover, they allow for connecting meaningfully the two levels. I close the chapter with a brief overview of technology and its institutional relevance, in the spirit of considering the material aspects of institutions, an area that is understudied. In addition, several relevant concepts are also explained: boundary, legitimacy, governance, coopetition and co-optation. The literature review points out several theoretical gaps, mainly in studying field emergence, institutional complexity and technology producers in healthcare:

- Lack of research during an emergent phase of a field, as opposed to retrospective studies
- Institutional complexity analysed by taking into account only some of the institutional logics at play
- Scarcity of studies of medical technology producers, despite the technology becoming an imperative in healthcare.

CHAPTER 3 – THEORETICAL FRAMEWORK

3.1. INTRODUCTION

Having set the basis of the theoretical background for this research, as well as showing several theoretical gaps, in this chapter I synthesise my theoretical approach that allows me to answer the research questions. A middle ground sociological approach is taken, heterogeneous in nature, accepting that "technical, scientific, economic and political considerations are inextricably bound into an organic whole" (Nicolini, 2009, p. 15). By considering both action and structure, the research attempts to reveal explanations for phenomena in the richness of their context. To that end, I draw on the institutional logics framework and institutional work to research institutional complexity and guide interpretation for this multilevel study.

3.2. INSTITUTIONAL LOGICS

Institutional theory at large offers a template to understand broader environments, as well as the organisations populating them. To reiterate, institutional logics are "socially constructed, historical patterns of material practices, assumptions, values, beliefs, and rules by which individuals produce and reproduce their material subsistence, organize time and space, and provide meaning" (Thornton & Ocasio, 1999, p. 804). They offer templates and "rules of the game" (Fligstein & McAdam, 2011, p. 5) to organise social life and activity, which show endurance over time.

3.2.1. IDEAL TYPES

Ever since institutional logics were introduced by Friedland and Alford (1991), it was acknowledged that they operate on different levels and that there are inter-institutional systems in action. The higher the level, the more "pure" the logics are, the so called "ideal types" (Friedland & Alford, 1991; Thornton et al., 2012), such of those initially introduced by Friedland and Alford (1991) - religion, family, bureaucratic state, capitalist market, democracy – or the ones

proposed by Thornton et al. (2012, p. 72) – family, community, religion, state, market, profession, corporation. It is important to understand that the ideal types convey the essence, and that their manifestation in action is more complex. For instance, Dunn and Jones (2010) show in their study on medical education that this combines the logic of care with the logic of science.

I conceptualize the ideal types as being instantiations of social, technical and institutional arrangements, which are linked to higher value spheres. Instantiation means that ideal types are still subject to change, evolution or even replacement. The ideal types manifest at field, organisational or individual levels, and provide principles, practices and symbols. Ideal types, in research and theory, are valuable constructs to allow for both understanding and generalising "observed institutional outcomes" (Thornton et al., 2012, p. 53). They are also useful when using multiple levels of analysis to connect them, as it is the case with this research, which spreads between the field and organisational levels.

3.2.2. Institutional logics as a triad of materiality, practices and values

In a recent study, Patriotta et al. (2011) showed how "orders of worth" in societies provide equally legitimate, universal understandings for the common good. "Orders of worth are legitimate forms of common good, which provide universal principles of logical coherence as well as justice. Being universal, such orders of worth are symmetrical, i.e. they carry equal weight" (ibid., p. 1809). This study resonates with the Friedland's (2013) recent essay, drawing as well on Boltansky and Thévenot's (2006) orders of worth and on Weber's (1948) "value spheres", which calls to bringing value back into institutional theory as a mean to better explain institutional life as well as change. "Institution is required to fix a type of action and its referential relation to a situation as a token of that type. This normative fixing is the core of institution, a primordially semantic function. This appears to undercut the previous insistence that orders of worth should not be socially located either in a group or a sector" (Friedland, 2013, p. 43). Looping back to Patriotta et al. (2011), their study show how these universal values offer a repertoire for institutional

work and that institutions are both rooted in and made fragile by these higher value orders.

Values are carried and reproduced by people, but also by organisations and society at large. Selznick talks of an "organizational self" and "identity" to show that an organisation becomes not only distinctive in its technical capabilities, but also in its "character". An organisation becomes "value-infused" in itself. "The terms "institution", "organization character" and "distinctive competence" all refer to the same basic process – the transformation of an engineered, technical arrangement of building blocks into a social organism" (Selznick, 1984, p. 120).

Voronov and Vince (2012) propose a framework to include emotions when studying institutional work, given the increasing number of studies showing "that being cognitively aware that the current institutional order is suboptimal may often be insufficient to motivate agents to engage in institutional disruption or creation" (ibid., p. 2012) or maintenance. The authors consider useful to consider alongside a cognitive frame, a fantasmic one, that could be individual or collective. Such a frame is value and emotion infused and it is relevant for the formation of the organisational identity and for the new institutional arrangement of a field (Patriotta et al., 2011; Friedland, 2013).

Technology is regularly considered a factor of production that increases efficiency or reduces costs. When it comes to ICT, technology is an aim in itself (Jacobides et al., 2018; Mulligan, 2011; Rindova & Kotha, 2001), therefore there are different selection and validation criteria. Digital technologies are complex artefacts, which challenge the separation between the organisation and its environment (Gawer & Phillips, 2013; Nicolini, 2007; Orlikowski, 2010; Petrakaki et al., 2012). Digital technologies bring complex social, economic and institutional change via democratisation of specialist knowledge, alternative channels for action and information through peer-to-peer communications, and therefore they challenge temporary, spatial, ownership and governance conventions. Introduction of digital technologies also shape practices, sometimes leading to significant institutional processes, like simultaneous de-professionalisation and re-professionalisation (Petrakaki

et al., 2012). It follows that the introduction of digital solutions has material effects and involves institutional work, due to the emergence of new practices, and sometimes even new roles and governance conventions.

Restating that healthcare is a technology intensive field and in the light of the increased acknowledgement of both materiality (Gawer & Phillips, 2013; Morrill, 2006; Thornton et al., 2012) and value in institutional logics research (Friedland, 2013; Kraatz, 2009; Kraatz & Block, 2008), I consider institutional logics as a triad of materiality, action and values.

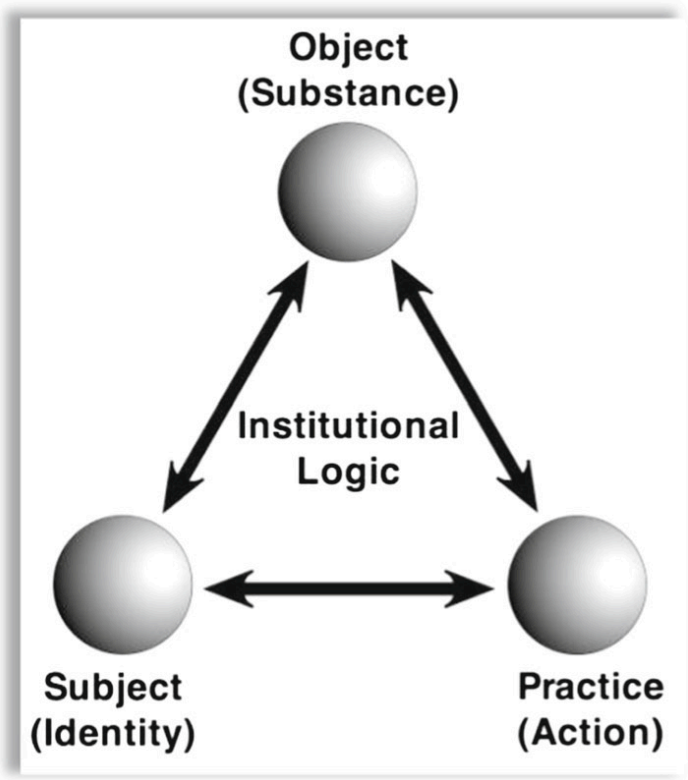

Fig. 2. "Institutional logics: duality articulations linking troika of object-practice-Subject" (Friedland, Mohr, Roose, & Gardinali, 2014, p. 338)

3.3. INSTITUTIONAL COMPLEXITY

Institutional complexity rises from conflicting institutional demands from stakeholders participating in a field (Pache & Santos, 2010, p. 455). The more institutional logics there are, the more complexity increases. Therefore, pluralism is one of the main sources of complexity.

Below, I will add to pluralism other sources of complexity that are relevant to this research – fragmentation, centralisation and field structuration/stage (emergence in this case). Their importance for research was first underlined thoroughly by Greenwood et al. (2011) in their synthetic article and I find them particularly useful for my research embedded in a high complexity context.

3.3.1. INSTITUTIONAL FIELDS AND COMPLEXITY

An *institutional field* contains all stakeholders who, "in the aggregate, constitute a recognized area of institutional life" (DiMaggio & Powell, 1983, p. 148). It may have a field level logic (Scott, 2008, pp. 186–187) or "constellation of logics" (Goodrick & Reay, 2011) that binds together meaningfully the social, technical and material arrangements.

In that sense, I find conceptually useful the description of a social system offered by Van de Ven and Garud (1993) to reflect how I conceptualize an institutional field in this thesis. In the table below, I represent an institutional field as a complex connection of social, technical/material and institutional arrangements.

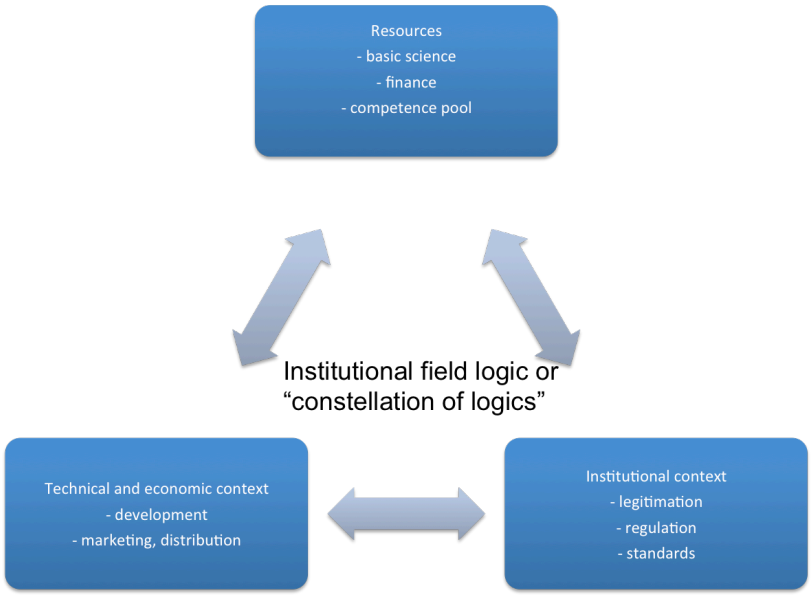

Fig. 3. Elements of an institutional field (adapted from Van de Ven and Garud, 1993)

It is no coincidence that studies on institutional pluralism evolve around healthcare, education and culture, because they provide a public service/good. They are often regulated (degree of centralisation) and accommodate many,

uncoordinated stakeholders. Such fields are *fragmented*, meaning they are entangled in conflicting demands (Pache & Santos, 2010), because the "collective nature of these goods places their producers at the intersection of a fragmented web of interests (direct and indirect beneficiaries, specialized interests groups, professionals, funders, local and national governments, regulatory agencies etc.)" (Pache & Santos, 2010, p. 472). The degree of *fragmentation* can evolve over time, due to pressure to access resources or the involvement of the state (Pache & Santos, 2010). Stakeholders can experience conflicting demands in fragmented fields in various degrees depending on both the compatibility between logics (Pache & Santos, 2010) and the degree of prescriptiveness (Goodrick & Salancik, 1996).

Centralisation refers to the number of actors that can impose a normative thickness (Pache & Santos, 2010). Highly centralised fields are dependent on one authority, whilst the decentralised ones are loosely regulated. It is the moderately centralised fields that present the most challenging institutional context for its participants, as demands are issued by various stakeholders who hold enough influence that cannot be ignored (ibid.).

The conflict may be over goals or means (ibid.), and sometimes it may take time for stakeholders to clarify where precisely differences lie (Pouthier et al., 2013; Scott et al., 2000). This differentiation between conflict over goals and means is particularly relevant, because it explains how logics, however thick they may be, leave room for change. It also offers a more nuanced explanation of hybridisation and conflict between logics. Often the means are where negotiation mostly happens and goals where conflict is most enduring (Pache & Santos, 2010; Santos & Eisenhardt, 2009). An excellent example is given by Scott et al. (2000) study on healthcare transformation towards the logic of managed care, where this new logic was the non-intended beneficiary of the enduring conflict over goals between the medical profession and state logics. Interestingly, Pouthier et al. (2013) show how the managed care logic did not fully resist the medical profession logic and so, this time by the intentional mobilisation of actors, it was undermined and a new logic emerged as retaliation – the "hospitalist logic". The enduring conflict was over goals – the

managed care logic prioritise financial objectives, whilst the medical professional logic prioritise patients' best possible health outcomes.

These two studies, when taken together, are particularly interesting as they cast three major insights. First, they show how complex and subject to crisis fragmented and moderately centralised fields are. Healthcare perhaps is one of the best examples of such fields and this may explain the volume of studies in this area. It is a territory where several logics co-exist under an "uneasy truce" (Reay & Hinings, 2005), with many moments of institutional turmoil at field, regional and organisational levels. "Patients receive diagnoses and treatments. Physicians carry out their practice. However, the two logics [n.b. medical profession and managerial logic] continue to co-exist and neither one can be considered dominant" (ibid., p. 630). Second, they reveal how conflict over goals can be persistent and how it gets to be revisited by moments of institutional crisis at various levels (Dunn & Jones, 2010; Goodrick & Reay, 2011; Pouthier et al., 2013; Reay & Hinings, 2009, 2005; Scott et al., 2000; Waldorff et al., 2013). And third, they prove that new logics or new institutional arrangements can come into existence or demise by both intentional and unintentional actions of stakeholders.

This last point would probably allow for a forth insight, the fact that sometimes less powerful actors can cause massive institutional change. Such individual actors are institutional entrepreneurs, as described by Schumpeter (1942), Drucker (2001) or Selznick (1948). In the example at hand (Pouthier et al., 2013), in the early '90s, when the logic of managed care was enjoying a great support from very powerful actors, state being one of them, "several physicians began creating lists of those peers that they considered to be part of an emerging specialty – a body of physicians who spent most of their time, if not all of it, working with acutely ill hospitalised patients, as opposed to splitting their time between care in the hospital and care in the community. This emerging consciousness of a shared style of work, and perhaps even a shared set of problems and concerns, gave rise to a key 1996 article in the New England Journal of Medicine (Wachter & Goldman, 1996). It was in this article that the ''hospitalist'' was first named, and identified to a broad audience as part of an emergent and coherent specialty; one that was articulated largely

through the rhetoric of managed care" (Pouthier et al., 2013, p. 214). The use of the managed care rhetoric was used skilfully to gain acceptance and co-opt powerful actors. However, later on, the same actors offered other meanings, rationales and differentiations, for instance reframing "managed care" as "rationing of care", undermining its legitimacy. The hospitalist movement was successful in gaining back some of the medical profession authority, strengthening its logic.

3.3.2. FIELD EMERGENCE

Institutional fields can be emergent, stable or in crisis (deinstitutionalisation that can lead either to repair, to the radical transformation of a field, or even to its disappearance) (Fligstein & McAdam, 2011; Gawer & Phillips, 2013; Patriotta et al., 2011; Scott et al., 2000). Morrill (2006, p. 6) defines an emergent field as "a mesolevel location that forms from overlapping resource networks across multiple organisational fields in which the authority of the dominant resource network does not prevail".

"One can conceive of emerging fields as a social space where rules do not yet exist, but where actors, by virtue of emerging, dependent interests, are being forced increasingly to take one another into account in their actions" (Fligstein & McAdam, 2011, p. 11). Emergent fields are institutional projects and therefore they have the most acute characteristics of an institutional crisis, contestations over goals, means, identities, legitimacy and governance. "The crisis of new fields reflects the fact that stable rules of interaction have not emerged and groups are threatened with extinction" (Fligstein, 2001, p. 115).

A new field comes to life when several actors perceive new opportunities brought by unresolved issues of adjacent fields (Fligstein, 2001; Purdy & Gray, 2009), technical innovation (Morrill, 2006; Van de Ven & Gardu, 1993), state interventions or significant social event (wars, economic recessions, acts of God). Several studies reveal how new fields emerge with the introduction of innovative technologies (Garud et al., 2002; Rindova & Kotha, 2001; Van de Ven & Gardu, 1993; T. Wry, Lounsbury, & Jennings, 2014), reflecting the profound socio-material consequences of technology adoption in various contexts: carbon nanotechnology, medicine or IT. Rindova and Kotha (2001),

through a two case inductive study of two internet search engine companies, explore the relation between structure and function in nascent fields. Other studies of nascent technological fields bring insights into an organisation's struggle for clear boundaries of identity, i.e. studies on categorisation (Wry & Lounsbury 2013) and distinctiveness (Navis & Glynn, 2011). Such studies suggest that nascent and fragmented fields pose interesting settings and that organisational action in complex institutional environments still remains to be explored.

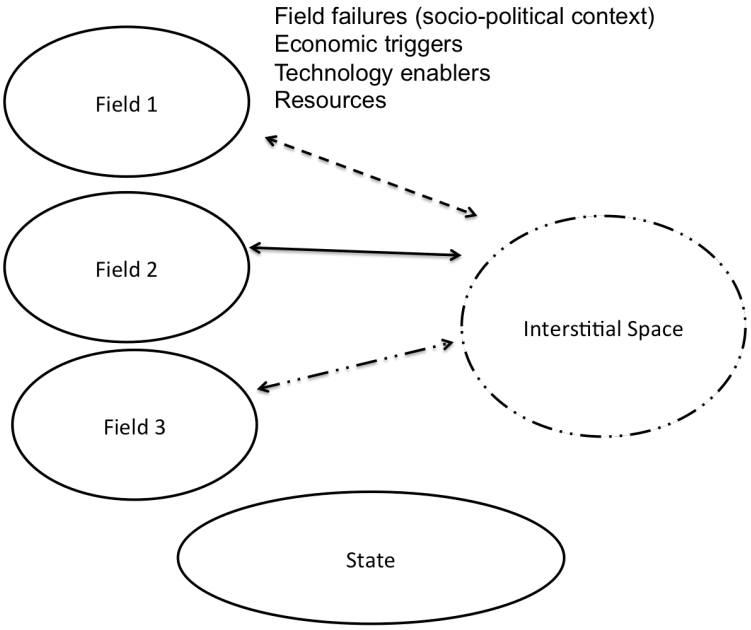

Fig. 4. Representation of field emergence as liminal space, potential triggers and ties with other fields

Purdy and Gray (2009) and Morrill (2006) describe the emergence of alternative dispute resolution field in the US as a response to failures of the judicial system to address timely and transparently conflicts, in addition to providing good decision that allows for disputants to be more involved. The studies highlight innovative practices creation, diffusion mechanisms that included champions or institutional entrepreneurs, industry association creation, and regulations amongst others. The emergence is analysed for almost thirty years, and yet, the field is not mature. "Still, the question remains, Just how long is long enough?" (Purdy & Gray, 2009; p. 376).

It is important to acknowledge that fields evolve over time, sometimes over decades (Purdy & Gray, 2009; Van de Ven & Gardu, 1993); some reaching stability, if the institutionalisation project is successful. Morrill (2006) identifies three stages of emergence: innovation, mobilisation and structuration (see figure 5 below). The first phase is mainly characterized by the isolation of actors as well as intense experimentation, mobilisation by accumulation of a critical mass of actors and better visibility, and structuration by the emergence of patterns of action and interaction, governance (Morrill, 2006; Van de Ven & Gardu, 1993).

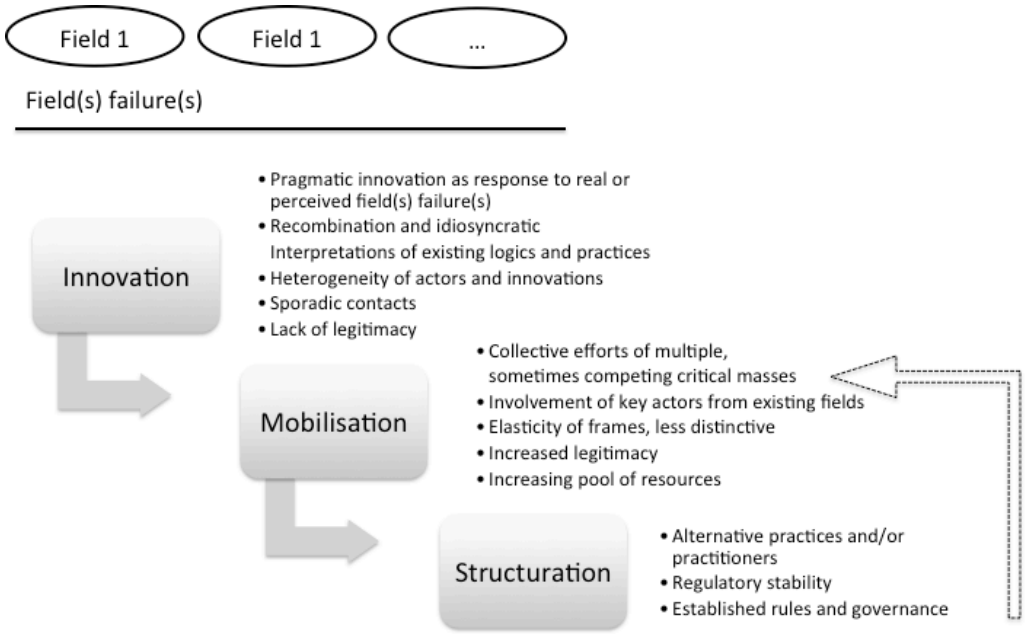

Fig. 5. Emergence stages based on Morrill (2006)

Nascent fields are "liminal spaces" (Hirsch & Lungeanu, 2012) because they are unstructured and characterized by extreme uncertainty (Fligstein & McAdam, 2011). Some authors (Aldrich & Fiol, 1994; Santos & Eisenhardt 2005) looking at nascent fields use the term *ambiguity* as well. Ambiguity is the "lack of clarity about the meaning and implications of particular events or situations. Ambiguity arises from unknown cause-effect relations and lack of recurrent, institutionalized patterns of relations and actions" (Santos & Eisenhardt, 2009, p. 644). The difference between uncertainty and ambiguity is justified by Santos and Eisenhardt (2005, 2009) as being related to the

institutional structure, in the sense that uncertainty would involve a relatively stable structure as opposed to ambiguity where there is no structure. Ambiguity requires experimentation, learning, and sense making. "Sensemaking: an iterative cycle of action and retrospective interpretation to generate stable meaning and organized action" (Jay, 2013, p. 140).

It is for all of the above reasons that emerging fields are the most challenging institutional contexts. In order to understand them, one has to understand their origins, their ties with the adjacent fields and their evolution (stages).

3.3.3. Organisations and complexity

Organisations participate in a field and can be conceived as "sites where multiple institutional logics vie for dominance" (Thornton et al. 2012, p. 183). Similar to fields, they are part of a complex system with social, technical/material, and institutional elements (see figure 3 in this chapter). Organisations are developing identities to allow the co-existence of multiple logics and provide coherence. Therefore, a new organization in a new field is an institutional project, not just a form of economic activity. Moreover, an organisation, through its institutional work, contributes to the structuration and institutionalisation of the field (Greenwood et al., 2011; Kraatz & Block, 2008; Selznick, 1984).

The institutional work concept reconciles different streams of research and bridges institutionalism and agency, responding to multiple calls (Greenwood et al., 2011; Hirsch, 2008; Hirsch & Wohlgezogen, 2009; Santos & Eisenhardt, 2009; Suchman, 1995)

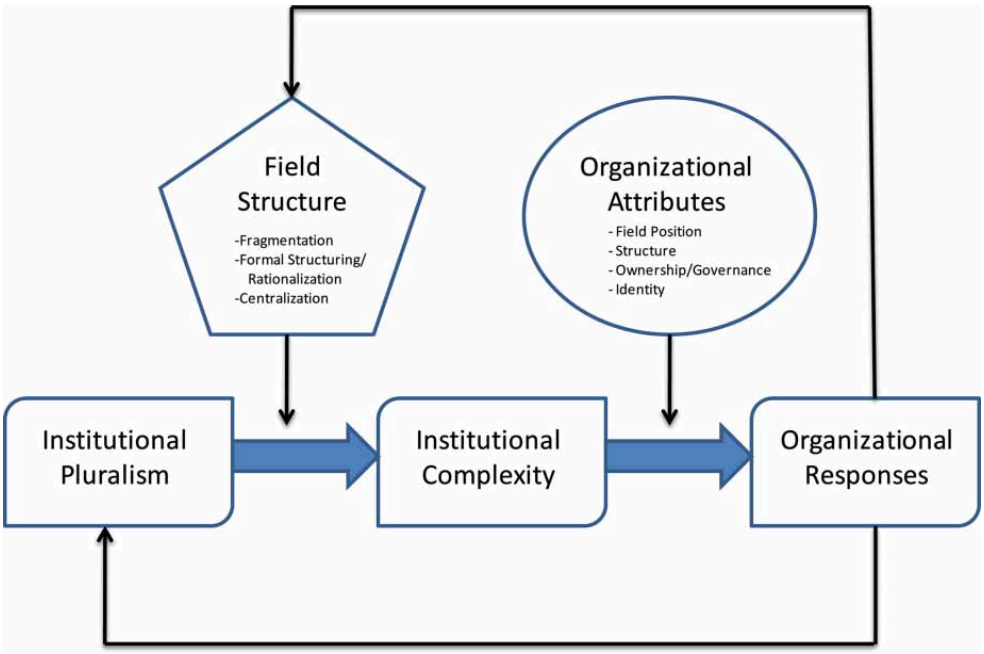

Fig. 6. Framework for understanding organisational responses to institutional complexity (Greenwood et al., 2011, p. 324)

In the figure above, Greenwood et al. (2011) represent how multiplicity of logics leads to complexity and that instigates organizations to adaptive responses that depend on several organisational characteristics, like position in the field, structure and governance, and, not last, identity. Organisations will face different challenges and perceive them differently depending on fragmentation, centralisation and the structuration stage (field emergence in this case).

All organisations in complex environments are pluralistic organisations themselves. Kraatz (2009) considers that for understanding organisations facing pluralism, therefore complexity, researchers should consider the struggles for legitimacy, governance and organisational change, in their *evolving* institutional context. Legitimacy is often contested, as a pluralistic organisation has to satisfy various institutional demands, and shifts in the stakeholders' institutional arrangement make it vulnerable. Such an organisation has to develop integrity by accommodating competing institutional logics internally and externally. Moreover, it has to possess capabilities to respond and adapt when various institutional logics change, whilst maintaining integrity, purpose and legitimacy.

One of the main concerns Kraatz (2009) has is that organisations reflect the institutionalisation process of the field, and therefore *leadership*, as in Selznick's conception, should have a greater bearing when looking at such organisations. "The pluralistic organization does not automatically hold itself together. Naturally occurring social and political processes may facilitate institutionalization and the formation of an organizational-self" (ibid., p. 263). According to Selznick (1984), becoming a leader begins when one becomes preoccupied with missions and values, creates structures that embody them, and builds adaptive capabilities to a changing environment. A leader is concerned with the integrity of the organisation, identifies with it beyond their own interests. Rising above rivalries, a leader is still and at least a politician. "He may succeed in rising above this game (the very mark of statesmanship), but he must remain fully in it at the same time. This is a difficult (some would say impossible) trick" (Kraatz & Bloch, 2008, p. 66). This implies that leaders are simultaneously realists and idealists and not at last hold high moral standards. The morality of the leader would pay off in the long run, by guarding organisation's integrity and by fostering the development of distinctive competencies, as it is mostly agreed in the leadership literature.

The importance of leadership is enforced by other authors too, albeit not so forcefully (Aldrich & Fiol, 1994; Fligstein, 2001; Gawer & Phillips, 2013). However, studies rarely mention leaders that have a significant impact on institutional changes. Pouthier et al. (2013) identify Bob Wachter as "the hospitalists' original theorist" (p. 216). Another exception is made by Purdy and Gray (2009) who mention Lawrence Susskind and Frank Sander as institutional entrepreneurs promoting new logics and defending them from incumbents.

As also discussed in the previous section, emergent fields are characterized by ambiguity. "Liminality allows for the amalgamation of different realities. Defined as the ambiguous condition of "being 'in between', at the limits of existing social structures where new structures are emerging", a liminal space blurs the means of identification with previously established identities" (Hirsch & Lungeanu, 2012, p. 9). Therefore, organisations acting in this space face the most complex environment. The lack of clarity and structuration makes them

"be more opened to possibilities and less tied to theory" (Van de Ven & Gardu, 1993, p. 38) or, I would add, less tied to an institutional "iron cage". Therefore, the representation of the future becomes an on-going determinant of organisational action too and the lack o visibility brings forth a lot of serendipity and the need to continuously revisit their trajectory (Rindova & Kotha, 2001). Studies highlighting the role or institutional entrepreneurs, leaders beyond their own organisation, reveal their relevance in complex environments, like emergent fields where there is ambiguity. That is because uncertainty and ambiguity amplify the need of sense making and sense giving, and institutional entrepreneurs play a crucial role in field orientation and negotiation.

Insights from STS studies show that the introduction of new technologies calls for "lateral thinking, away from the present functionalities and prospects of the product" (Rip & Schot, 2002, p. 164). In order for a firm to create a meaningful value proposition in a shifting landscape, it should aim to "understand the value-creating system of offering, affordance, context, agency and resources and all its social, material and technological influences with other actors in the system" (Ng & Smith, 2012, p. 235). In other words, organisations are shaping from bottom up the institutional field by creating boundaries and relationships and so governance structures for themselves and the field. Anticipation based on scenarios of the future in conditions of ambiguity is another motivation for action or at least for readiness for action. In the case of nascent activities, anticipation is part of the learning process (Rip & Schot, 2002), just as much as of the institutionalisation process.

It follows that

- organisations reflect and contribute actively to institutional processes, at least as much as they are influenced by them
- the higher complexity, the larger palette for choices
- the higher complexity, the more relevant leadership becomes
- organisations introducing technological innovation will guide themselves based on scenarios of the future as well.

3.3.4. Organisations in a new field – visionary or foolish?

It becomes clear that organisations entering an emerging field, with little recipes to follow, face the most challenging environment, economically and institutionally. Such space has one stable feature: paradoxically, instability. "The status quo should be viewed as an ongoing, negotiated accomplishment, threatened at all times by challenger resistance and exogenous change processes. As such, this constantly produces shifts in the nature of the relationships, the tactics organised groups use to attain their goals, and the worldviews they use to make sense of their situations." (Fligstein & McAdam, 2011, p. 15)

This leads to the straight question Aldrich and Fiol (1994, p. 465) ask: "Such foundings are risky, but are they also foolish?". They explain further that "founders of new ventures appear to be fools, for they are navigating, at best, in an institutional vacuum of indifferent munificence and, at worst, in a hostile environment impervious to individual action. In addition to the normal pressures facing any new organisations, they also must carve out a new market, raise capital from skeptical sources, recruit untrained employees, and cope with other difficulties stemming from their nascent status" (ibid.). They are also knowledge and new competencies generators (Gawer & Phillips, 2013; Van de Ven & Gardu, 1993).

Most importantly, perhaps, is that during all of the above, a new organisation in a new field "develops a logic of its own and attains the ability to give identity to its members, it accepts identities and logics" (Kraatz & Block, 2008, p. 252) from its constituents too. In other words, new organisations in new fields are building identities without a blueprint and that in itself is a significant institutional work. Kraatz and Block (2008) highlight the impact of organisations in complex environments over the institutionalisation of the field, embracing Selznick's view that institutionalisation happens bottom-up, as a response to the anxiety experienced in the midst of complexity - "it is possible that some organizations may be able to forge durable identities of their own and to emerge as institutions in their own right" (ibid., p. 251).

Many authors highlight legitimacy as one of the most important assets an organisation needs for both strategic and institutional rationales (Aldrich & Fiol, 1994; Suchman, 1995). Whilst not disagreeing, Kraatz and Block (2008) show that organisations with a strong "self", as Selznick conceives it, are less exposed to institutional pressure, to problems of legitimacy, demonstrate more endurance, and have a significant impact over the field structuration.

This view is complementary to the "proto-institution" concept advanced by Lawrence, Hardy & Phillips (2002, p. 283) – "practices, technologies, and rules that are narrowly diffused and only weakly entrenched, but that have the potential to become widely institutionalized". New organisations in new fields are in fact proposing institutionalisation models. If and to what extent these models diffuse would contribute to the field structuration. In respect to Selznick's view, an organisation that can both integrate its constituents and develop distinctively becomes an institution in its own right (what he calls "*entitativity*") and will be one of the main drivers of field institutionalisation.

3.4. INSTITUTIONAL WORK

I found the concept of institutional work appropriate for this research, because it is suitable to research complex problems and allows me to address meaningfully major theoretical gaps identified in the previous chapter.

- Emerging fields – most studies have a historical approach; there is no study of emergent fields in their early phase
- Organisations in the highest institutional complexity - field emergence at the confluence of several fields; one of them, healthcare, being a fragmented and moderately centralised field, therefore, very complex
- Medical technology producers - understudied, although the impact of technology in healthcare has been studied from the medical provider's perspective, only few studies consider the medical technology producer.

Whilst lateral streams of research, particularly STS, inform my work, I take a middle ground sociological approach, where both action and institutions determine social and economic realities. "A significant part of the promise of

institutional work as a research area is to establish a broader vision of agency in relationship to institutions" (Lawrence et al., 2009, p. 1) that avoids extremes, like agents simply following institutional prescriptions or having superpowers.

The institutional work concept is adequate in studying contemporary life in the digital economy context. The digital economy requires meta-theoretical approaches, because it presents new layers of complexity, which are not well explained by current theories. Examples of complexity would be the rapid and constant changes (Orlikowski, 2010; Rindova & Kotha, 2001; Zietsma & Lawrence, 2010), technology development as raison d'être instead of production support (Mulligan, 2011), or the development of platforms and ecosystems (Gawer & Phillips, 2013; Jacobides et al., 2018). As shown in the literature review chapter, such meta-theoretical approaches reveal valuable insights about social and economic life driven by digital technologies (Gawer & Phillips, 2013; Nicolini, 2006; Petrakaki et al., 2012; Rindova & Kotha, 2001; Santos & Eisenhardt, 2009).

Hence, I consider that the digital economy may "demand a more holistic account of institutional action that moves beyond simple dyadic relationships and discrete logics, toward the assumption that actors, at any given time, are subject to pressures from many different institutions and are often responding locally, creatively, incrementally, and more or less reflexively" (Lawrence et al., 2011, p. 57).

3.5. Theoretical framework in a shell

One of the remarkable insights of the institutional logics framework is that it recognizes that the institutional arrangement, composed by multiple logics, offers not only constraints, but also a repertoire for action. Therefore, it breaks from the traditional conception of institutions as "iron cages" (DiMaggio & Powell, 1983) that demand conformity and isomorphism from participants in a field. It makes space for agency and action, allowing for a nuanced explanation of social change.

Thus, I connect the institutional logics framework with the institutional work concept to investigate the complexity of being a new organisation in an emerging field, because it allows me for a more holistic approach. "Connecting, bridging, and extending work on institutional entrepreneurship, institutional change and innovation, and deinstitutionalization, the study of institutional work is concerned with the practical actions through which institutions are created, maintained, and disrupted" (Lawrence et al., 2009, p. 1).

In order to understand the institutional work organisations undertake in what I have identified with a degree of certainty from existing literature as being the most institutionally complex environment – field emergence, my task presents as a two folds endeavour: to capture the institutional complexity and the organisational responses. And so, the research develops on two levels – field and organisation.

An emerging field can be considered as the most acute instantiation of institutional complexity. It is an interstice (Morrill, 2006; Rao et al., 2000; Greenwood et al., 2011; Stinchcombe, 1965) between other fields, with "no stable social relationships, and no agreement on means and ends" (Fligstein & McAdam, 2011, p. 12). As the result of this interstitial activity, adjacent fields may or may not experience institutional crisis to the far end of deinstitutionalisation.

For the task at hand, at the field level, the focus is to capture the institutionalisation processes (stakeholders and logics, as well as their interplay via hybridisation and conflict) and the stages of the emergent field, in acknowledgement of its interactions with the adjacent fields. It is important for my research to understand not only the context of field emergence, but also the stage to better situate the organisational analysis. At organisational level, to capture and interpret the institutional work, it is relevant to understand the position in the field, their representation of pluralism and ambiguity, and their governance (in relation to ownership and leadership) as it unfolds.

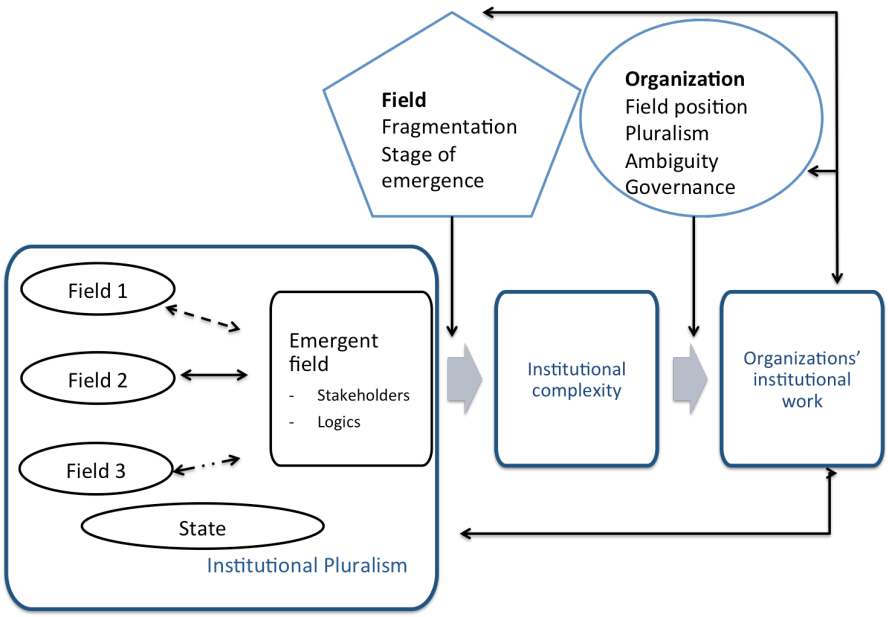

Fig. 7. Theoretical framework for understanding complexity of an emergent field

The diagram above builds upon the one offered by Greenwood et al. (2011, p. 324) and it reflects a stronger interactionism stance. My approach reflects the importance of organisational responses both upon the institutionalisation of an emergent field and upon the organisation itself. I also readdress the field and organisational attributes that contribute to the dynamic, in the sense that I consider that in an emergent field, there is no centralisation just yet, and the degree of structuration/institutionalisation depends on the emergence stage of the field. Therefore, it is important to determine that stage. On the organisational attributes, I consider relevant the position in the field, the internal representation of pluralism and ambiguity (to the extent they are acknowledged), and its governance. The organisation identity attribute is not present, because new ventures are institutional projects, proto-institutions, so they do not have models to develop identities fast. Their identity is in flux and its formation constitutes a significant institutional work (Gawer & Phillips, 2013) upon which their survival depends, and ultimately, collectively, the survival of the field.

The interactionism and constructivism approach is in line with the conception of institutional work. Other authors employed the "negotiation" metaphor, referring to similar perspective, to understand the way innovating organisations are acting to mitigate the ambiguities of an emergent fragmented field, build

legitimacy and mobilize resources (Hirsch & Lungeanu, 2012; Hirsch & Wohlgezogen, 2009; Santos & Eisenhardt, 2009). The negotiation reflects that actions are directed both inward and outward and have effect upon the environment and the organisation itself.

From the theoretical framework, it derives that in order to investigate organisations in the complexity of the field emergence, these three research stages are needed.

- Understand what leads to the field emergence - precursors of change, as a prerequisite first stage
- Understand the field institutional complexity
    - Identify institutional logics and their main carriers (stakeholders)
    - Identify the institutional stage of emergence, by looking at stakeholders interactions that reveal processes of hybridisation and conflict
- Understand organisations' institutional work in their situated evolving context

In the structure of the thesis, the following chapters will unfold the theoretical framework, based on the methodology presented in chapter 4. Chapter 5 offers a brief overview of precursors of change, similar to how Scott et al. (2000) found necessary to provide for their healthcare field level change. Chapter 6 identifies the main stakeholders and the institutional logics at play in digital health. Chapter 7 analysis the stages of emergence and identifies an emergent new field logic, and, after establishing the institutional setting in a comprehensive manner, chapter 8 presents organisations' institutional work. The last chapter, linking back to the theoretical framework, integrates the main findings, presents the theoretical and practical contributions, the research limitations and further directions of research.

3.6. Conclusions

Before proceeding to the methodological approach, this chapter sets the theoretical stance and the main constructs deployed in this research. The

institutional logics, carried by stakeholders and represented as ideal types, are understood as a triad between materiality, practices and values, responding to recent calls for research to consider more such interactions. Leadership is also given attention, particularly because it is relevant in the midst of institutional contestations. Institutional complexity is grounded in the number of institutional logics at play, which may compete over goals and means, and also in the degree of fragmentation and centralisation. Field emergence is the most complex situation because it has a high degree of uncertainty and ambiguity. Moreover, it is the most complex when the new field overlaps a fragmented and semi-centralised field, like in the case of digital health. Organisations facing complexity deploy institutional work depending on the characteristics of the field and on their own attributes.

The theoretical framework is synthesised at the end, accompanied by the research stages and a description of how it will unfold in the chapters of this thesis. The theoretical framework reflects a middle ground sociological approach, which is informed by other theoretical streams, i.e. STS or entrepreneurship studies. This framework connects the institutional logics and institutional work and most importantly connects theoretically and epistemologically the two levels of this research – field and organisation. It grounds the constructivism approach, where organisations and their institutional field are mutually relevant for the institutionalisation process. The theoretical approach combines the institutional logics approach with the concept of institutional work considered rich and valuable in researching complex and understudied phenomena.

CHAPTER 4. METHODOLOGICAL APPROACH

4.1. INTRODUCTION

The previous chapters established the literature on which this research is based upon. In this chapter I elaborated on the aims and questions of the study, and I describe the methodological approach, as well as the operational process employed for data collection and analysis.

4.2 RESEARCH OBJECTIVES AND QUESTIONS

The primary aim of this research is to enrich the theoretical understanding of institutional complexity at its most acute instantiation – field emergence - and the institutionalisation work undertaken by organisations in a complex environment. An emerging field is an interstice (Morrill, 2006; Rao et al., 2000; Greenwood et al., 2011; Stinchcombe, 1965) between other fields, with "no stable social relationships, and no agreement on means and ends" (Fligstein & McAdam, 2011, p. 12). It means that organisations entering such a field, not only have the "liability of newness" (Stinchcombe, 1965), but they also operate in an institutional vacuum, an environment of high uncertainty and ambiguity (Morrill, 2006; Fligstein & McAdam, 2011, Van de Ven & Garud, 1993; Aldrich & Fiol, 1994).

This study aims to foster the understanding of field emergence and of the institutional work organisations undertake during field emergence. Both areas are understudied or have been approached retrospectively when the field was already stabilised, or were only theoreticised.

The two objectives are connected, in the sense that it is necessary to capture the institutional complexity at the field level in order to understand the organisations' responses in their specific context (Aldrich & Fiol, 1994, p. 646), and also to understand how institutionalisation happens as a bottom up phenomenon. It follows that the research has to reveal both the field emergence and the organisations' institutional work. The two questions of the study are:

How does a field emerge?

How do organisations navigate an emergent field?

The first question, *How does a field emerge?*, aims to present a rich picture at the macro level, whilst the second one, *How do organisations navigate an emergent field?*, zooms in at the meso level.

In order to answer the first question, I take an analytical and historical approach. I identify the institutional logics, the representative stakeholders and their interactions as revealed over time. Given that the focus is an emergent field, in order to be able to provide an understanding of the origin of emergence, I investigate the precursors of change in the adjacent fields. To cope with the complexity of the research itself, I limit the analysis to the main fields that overlap in the emergence process. Therefore, for clarity, I added the following empirical questions*:*

- What caused the emergence of a new field? (prerequisite for field emergence)
- What is the institutional complexity of the emergent field? (institutional logics and stakeholders)
- What are the stages of emergence? (determined by interactions and institutionalisation processes, turning points)

The unfolding of institutional processes and the historical approach helps better understand the institutional phases of emergence. It has been established that organisational processes may be different at certain stages of field existence: emergence, maturity or crisis. Furthermore, during field emergence the context and challenge may change in nature for entrepreneurial organisations (Fligstein & McAdam, 2011; Morrill, 2006; Van de Ven & Gardu, 1993), depending on how far towards maturity the field is.

In order to answer the second main question, *How do organisations navigate an emergent field?,* I take a similar approach - historical and analytical. Some of the guiding empirical questions were:

- How were they founded?

- What was their purpose?
- How did they evolve over time?
- Who were their main stakeholders?
- What were the institutional logics at play?

It is important to say that my research does not aim to forecast the evolution of the field or of the organisations themselves, as the field emergence did not reach stabilisation, and many aspects are still to be negotiated.

4.3. Epistemological approach

Epistemologically, this research aligns with its theoretical framework - it has a social constructivist stance. More precisely, I see social life as the result of interactions in instantiated spaces, which filter and crystallise over time in certain institutional logics and institutional spheres. As such spaces are co-created through social interaction, they maintain various degrees of vulnerability (Friedland, 2013). Such epistemological stand is embraced largely by social and organisational scholars, who agree "that much of the world with which we deal is essentially socially constructed" (Gioia, Corley, & Hamilton, 2012a, p. 2).

4.4. Research design

The research is qualitative and the design is based on two levels of analysis – macro (field level) and meso (organisational level), and so it responds to calls for multilevel studies to better understand institutional processes (Greenwood et al., 2011; Thornton & Ocasio, 1999). The methodological choice is motivated by limited theories to address the research questions and the scarcity of empirical research (Rindova & Kotha, 2001; Santos & Eisenhardt, 2005, 2009; Eisenhardt & Graebner, 2007). Such methods allow for the understanding of complex processes that develop over time, and, in addition, at organisational level, by revealing the rationales for decision making (Santos &, Eisenhardt 2005; Eisenhardt & Graebner, 2007). Multiple case approaches retain the replicating relations and characteristics of the investigated phenomenon and therefore they result in more robust and generalisable theory (Stake, 2003; Eisenhardt & Graebner, 2007).

Theoretically, the field level can be considered a single case study, and the organisational level a multiple case study (Yin, 2009) or a collective case study (Stake, 2005). "Researchers that combine multiple levels of analysis in their research are more likely to observe a more accurate picture because, by observing across levels, they can see the workings of mechanisms and – according to the institutional logics perspective – the contradictory nature of the institutional logics" (Thornton et al., 2012, p. 14). Beyond this, it became clear from an early stage of my investigation that a multilevel approach would be appropriate to render much needed theoretical insights. Institutional scholars make similar arguments when discussing field emergence and institutionalisation (Aldrich & Fiol, 1994; Fligstein & McAdam, 2011; Thornton et al., 2012).

Fig. 8. Multilevel research design

My research follows an inductive research design. This choice resides primarily in the fact that I explore an area – field emergence - known only retrospectively or simply theorised by extrapolation. The logic of inductive inquiry is valuable when investigating poorly understood, as well as complex phenomena (Gawer & Phillips, 2013; Santos & Eisenhardt, 2009). An inductive approach provides by design a rich context, satisfying the need for both a broad and in depth understanding.

An inductive inquiry is not just a description of a realm of social and economic life, but it is a "theory-building approach that is deeply embedded in rich empirical data" (Eisenhardt & Graebner, 2007, p. 25). My research is also phenomenon-driven, with two immediate consequences: the research questions remain broadly defined and it has a relatively opportunistic characteristic. The

research questions are maintained at a high level of specificity to allow for discovery, and therefore to benefit from the richness of data, characteristic of qualitative studies. The opportunistic characteristic will be further explained in the research setting and case sampling.

The field level of analysis aims to reveal the institutional landscape of the emergent field. In that sense, I employ a narrative approach to understand its evolution by looking at the turning points reflected by new entrants, (de)regulations, events, industry associations, even vocabulary. To understand the institutional context of the new field, I analyse the adjacent fields, the institutional logics at play, the stakeholders and their interactions, as well as the evolution of innovations that fuel its emergence.

The organisational level consists of three case studies of organisations. Here, I employ the institutional work concept to look at how they navigate the institutional complexity of the emergent field. Having identified the institutional logics, the institutional work concept allows me to analyse the narratives and actions of these producers as a problem solving process to cope with a complex, novel and ever-changing environment. In order to understand organisations in their context, I consider their history and the stage of field emergence when they entered.

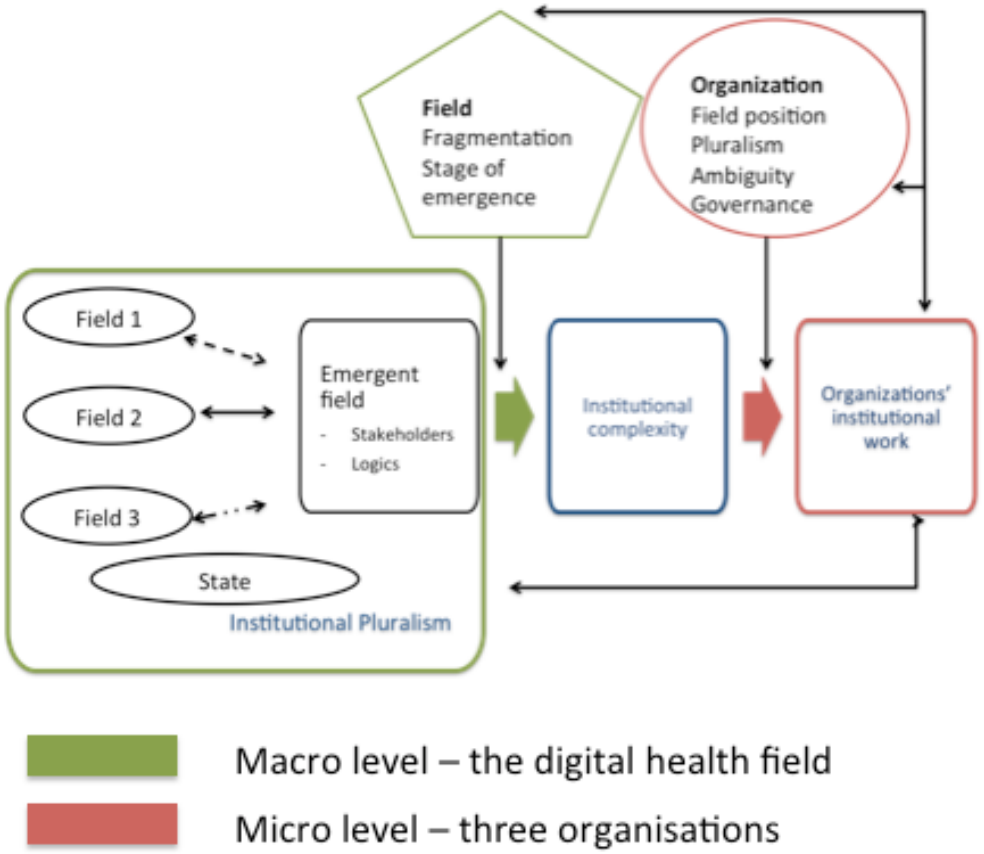

Fig. 9. Empirical framework highlighting both levels of research - field and organisation

4.5. RESEARCH SETTING

Due to the nature of my programme, which is digital economy, naturally, my discovery was guided by innovation – smart digital technologies. Secondly, I had an interest in healthcare and technology that preceded my admission in the programme, so I was actively scanning the intersection of the two fields.

The digital economy transformed the social and economic landscape over the last three decades and it is presenting us with new settings (Gawer & Phillips, 2013; Jacobides et al., 2018; Nicolini, 2006; Rindova & Kotha, 2001; Santos & Eisenhardt, 2009) that call for a "problem driven approach" (Santos & Eisenhardt, 2005, p. 505). Digital technologies, along with other socio-economical factors, contributed significantly to "a fundamental shift in the rules of competition and the way the game of competition is played" (Ilinitch, D'Aveni, & Lewin, 1996, p. 211) across industries.

Following my research mandate as well as my interest, in 2010 I ran a small research project aimed at understanding Assistive Technologies (how they were called at that time, basically technologies used in telemonitoring). I focused on business models for private and public sectors. In that research, I had two organisations, one public and one private, both based in the UK. The private company developed a wireless pregnancy monitor. The traditional ones were used only in hospital settings, whilst the new ones allowed for remote monitoring of risk pregnancies, and also allowed a carer or partner as a user. For healthcare providers, they offered continued monitoring, reduced hospitalisation and better health outcomes. The last two benefits were relevant for payers (insurers) too, as they were reducing care costs for mother and potentially for the infant. The public organisation ran a pilot remote monitoring programme, using fall sensors and alarm buttons mainly. The programme was originated in social services due to the increased demand for elderly assistance, but also involved general practitioners (GPs). It was during that time when I realized that it was indeed the beginning of a new era at the intersection of digital solutions and healthcare. The two cases offered me great insights on the potential and the demand for digital products in healthcare, some of the obstacles and some of the main stakeholders. In addition, they made it clear that the intersection of health, social services and digital technologies will create an emergence of a field in its own right, which came later to be known mainly as *digital health*.

The research setting discovery, the research opportunity, was serendipitous, opportunistic, however, it was "problem driven" (Santos & Eisenhardt, 2005, p. 505). One of the main reasons there is not much research at an early stage of a field/industry, is because it is hard "to see" it (Aldrich & Fiol, 1994; Fligstein & McAdam, 2011; Van de Ven & Gardu, 1993). In that sense, I had to "test" my assumption by heavily researching this field further and by returning to the existing literature on field and industry emergence (Fligstein, 2002; Fligstein & McAdam, 2011; Hirsch & Wohlgezogen, 2009; Klepper & Graddy, 1990; Mulligan, 2011; Van de Ven & Gardu, 1993).

Often, a field emerges following a technical innovation (Morrill, 2006; Van de Ven & Gardu, 1993), in this case digital smart technologies. Digital health's

emergence was also fuelled by institutional tensions in the healthcare field (Nicolini, 2006; Nigam & Ocasio, 2009; Pouthier et al., 2013; Scott et al., 2000), a highly fragmented and moderately centralised field. The role of the state cannot be overlooked, as its interventions caused historically several institutional changes in healthcare (Nigam & Ocasio, 2009; Pouthier et al., 2013; Scott et al., 2000). In respect to digital health, the state sees it as a way to respond to the demographic changes and the rampant costs of care. There are three main political consequences: reforms or pressures to reform healthcare systems and governments searching to reduce healthcare costs and, more broadly, for creating new areas of economic growth.

In sum, in order to research institutional complexity, my research setting is an interstitial field between healthcare and healthcare related fields (pharma, medical devices, even social services or academia) and the consumer digital technologies field. To reduce the complexity of the research itself, although acknowledging the other fields, I have conceptually looked at the two main ones (healthcare and digital technologies), but I acknowledge all stakeholders (streaming from other fields) as they enter the field of digital health. As the result of this interstitial activity, adjacent fields may or may not experience institutional crisis to the far end of deinstitutionalisation, however the focus remains the institutionalisation processes of the emergent field alone, although acknowledging the interaction with the others. In order to understand better the process of emergence, the institutional tensions and processes, it became necessary to track down the institutional transformations of healthcare and digital technologies field (see chapter 5).

4.6. CASE SELECTION

As stated previously, there are two levels of my research, the field level and the organisational level.

I use the term "**digital health**" to designate the broad field where healthcare meets digital technologies, the focus of this research. This term covers all things health IT, similar to its use in the industry. At the organisational level, my research is looking only at collaborative digital health technologies

(CDHT) producers, so those who build interactive solutions for various stakeholders in digital health. (For more clarifications on terminology in this research, see chapter five, and for the terminology evolution, see appendix C.)

4.6.1. Field level

Digital health was chosen for its relevance to my theoretical aims (Yin, 2009): it presents institutional complexity (Greenwood et al., 2011; Pache & Santos, 2010), from fragmentation to the high end of emergence. Most importantly, for both empirical and theoretical reasons, it is still in a nascent phase (Aldrich & Fiol, 1994; Fligstein & McAdam, 2011; Santos & Eisenhardt, 2009), allowing for conducting research during emergence. This addresses a major gap in our theoretical understanding both of institutionalisation in this phase (Aldrich & Fiol, 1994; Fligstein & McAdam, 2011) and of organisational behaviour in such an environment (Greenwood et al., 2011; Kraatz & Block, 2008).

Digital health fragmentation is given by its proximity to healthcare related fields and it is enhanced by the intersection with the consumer digital technologies field. Healthcare is a highly regulated field where powerful actors vie for dominance (Nicolini, 2006; Nigam & Ocasio, 2009; Pouthier et al., 2013; Reay & Hinings, 2009; Scott et al., 2000; Van de Ven & Gardu, 1993). Therefore change does not happen fast; it is often the consequence of political debate (Christensen et al., 2009; Nicolini, 2009; Scott et al., 2000). In contrast, digital technologies field is a low centralised space where technologies, preferences and resources move fast, with minimal regulation (i.e. data privacy, competition laws, intellectual properties), and it is mainly coordinated by industry standards (Gawer & Phillips, 2013; Jacobides et al., 2018; C. Mulligan, 2011; Rindova & Kotha, 2001; Santos & Eisenhardt, 2009).

The digital health emergence is reflected by new organisations (startups mainly), new industry associations, private public associations (i.e. for research), increased funding from state and non-corporate investors, the evolving vocabulary and meanings (Macnaughtan, 2015b), the presence of opinion leaders (similar to social movements), overall sense of ambiguity, regulatory hesitations (Macnaughtan, 2014), the entrance of new stakeholders, and the changing debates over legitimacy, ownership, privacy and

accountability. This setting presents distinctive features, like an ever-increasing entrepreneurial activity, reflected in the numerous startups and the nature of funding (intense angel, venture capitalist funding), all indicative of an intense institutionalisation process. The timing of the research is perfect in the sense that it coincides with intensified activities in the field, accompanied by a high level of ambiguity (a liminal state).

The context of field emergence is offered in chapter 5 and chapter 7 reveals its evolution. A summary of digital health evolution to the date data collection ended is available in the appendix D.

4.6.2. Organisational level

The organisational level can be conceived as a collective case (Stake, 2005). I looked to identify cases exemplary for this field (Eisenhardt & Graebner, 2007; Stake, 2005; Yin, 2009). To ensure the theoretical relevance, the guiding principles were the product developed and its intended audience. To elaborate, the product had to be a digital product, which connects or intends to connect or mediate the connection between at least two healthcare participants (i.e. patients, doctors, non-doctors personnel, insurers). It is important to mention that the recruitment remained focused on the aforementioned requirements, and it was not guided by geographies. Despite differences between healthcare systems (regulatory, insurance, public - private), these companies aimed, in different ways, to compensate for common perceived failures or tap into new areas in healthcare: low uptake of digital technologies, connections between stakeholders, prevention, health education etc. Selection also took into account their willingness to allow for multiple in depth interviews with several respondents inside the organisation.

Another criteria for selection was for organisations not to be "sheltered by sponsoring organizations" (Aldrich & Fiol, 1994). This is relevant for theoretical reasons, because exploring the institutional work of organisations entering in an emergent field with limited resources and without a big institutional or corporate "shelter" is most relevant. Such organisations experience all the complexity of being a new organisation in a new field – scarcity of resources, uncertainty, lack of legitimacy and so on. In addition, the

companies should have had at least two years of existing at the end of my data collection, to allow them to experience and evolve inside the institutional complexity.

In sum, organisations were selected based on their theoretical relevance, representativeness for the field and willingness to participate in research. Their variability ensures theoretical representativeness, generalisability and flexibility (Eisenhardt & Graebner, 2007).

4.6.2.1. Recruiting

A market report showed that the average age of a company in the field of digital health is 2.7 years (research2guidance, 2012). This means that when I started the research, such companies were difficult to find, due to lack of visibility. Many startups appeared in 2010 - 2012 and, alongside a big influx of investments, they came eventually to the forefront of innovation conversation. Adding to the discoverability problem, most companies were operating under scarce resources, with little to no willingness to invest in relations that were not perceived to bring them value.

Therefore, the recruitment period was lengthy - between May 2014 and May 2015. The targeted number of cases was minimum two, maximum three. All attempts to enrol organisations in my research via email were unsuccessful. I soon came to understand that I had to have a "presence" in the field for these companies to see value in engaging in my research and to make direct approaches to them. My academic program requested me to have an internship; therefore I took this opportunity to establish a "presence". And so, I began a collaboration with nuviun (currently Innovate Medtech), a digital platform for the emerging digital health community founded in 2014. During and after my internship, I have published six articles, three of them "featured" by the platform for being relevant to the industry. I was already participating in conferences since early 2012, but during the recruitment phase, I intensified my presence to industry events.

The recruitment of all organisations had the same pattern - I have made the acquaintance of the founders or the CEOs during my participation to industry

events (for a list of industry events attended, see appendix E). By May 2015, I had three companies enrolled. Due to lack of access to respondents, after conducting only three interviews, it became clear that there was not enough data to construct a case study for one of them. As a result, I have enrolled one more company, YouLife.

At the end of the recruitment, I had three CDHT organisations: 11 Health, YouLife, and Mira Rehab. In all three cases, the initial contact was with founders and/or CEOs during an event. As part of the agreement to join the research, I offered and produced a business report for two organisations (YouLife and 11 Health) and an article that was published online for Mira Rehab (Macnaughtan, 2016).

This sample offered a good degree of diversity in terms of type of product developed, source of funding, founding contexts and entrepreneurial profile. Having such a diverse set of organisations offered a firm grounding for developing theory (Eisenhardt & Graebner, 2007; Santos & Eisenhardt, 2009). Moreover, in the context of an emerging field, it would be challenging and less fruitful to pursue similar cases which may, in the future, be representative or not for a specific aim. As my approach is purposefully broad, the variety of the sample is beneficial as it allows for the emergence of theoretical insights that surpass specific contexts.

Although the field data analysis was mainly documentarian, it was supplemented by observations during my participation to events and by ten opinion leaders interviews (see appendix A). Their identification was based on their presence online (articles, interviews, followers, quotations by articles written by other authors) and on their presence at industry events as speakers. I have met in person all opinion leaders prior to asking them to participate in research during industry events and similar occasions, with very few exceptions (i.e. Lisa Suennen with whom I first made first contact via email as when recruiting for this research). A decisive factor was their willingness to participate in research in the subject matter, as well as taking the time for an interview.

4.6.2.2. Brief presentation of the three organisations

Mira Rehab is developing exergames, clinically based video games that incorporate exercises and movements with game interaction. To that end, they integrate sensors, at the time of study Microsoft Kinect, to support clinical physiotherapy, initially.

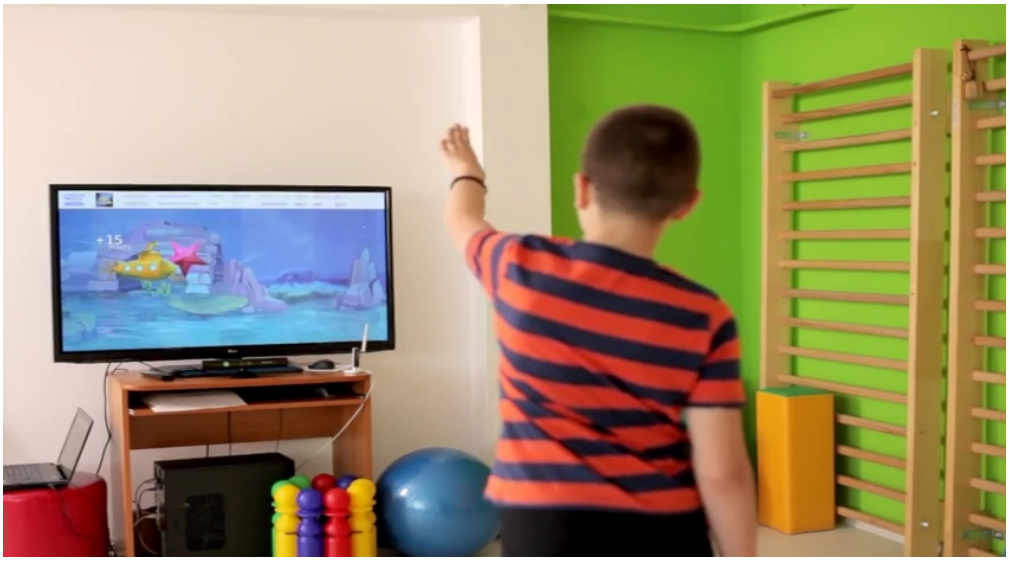

Fig. 10. Mira Rehab rehabilitation games[1]

The company was established in 2012 by four Romanian master level students (business and IT) who were part of the finalist teams of the international competition Microsoft Imagine Cup 2011. Following an invitation by HealthBox, a London digital health accelerator programme, they founded the company in 2012. Mira Rehab has been operating ever since in both the UK and Romania. Products were sold mainly in the UK and Romania, with commercial interest from other countries in Europe, mainly via a B2B model, although a B2C model was not dismissed, just not actively pursued as a line of business at the time of the study.

YouLife is a company founded in the UK, in the early 2000s, which provided corporate clients (employers and insurers) tools for assessing personal health risks. Over the years, they have developed specific questionnaires, based on clinical guidelines for specific health risks. i.e. chronic diseases, cancer. Some

[1] Source (Geels, 2005, p. 18) (retrieved July 14)

of the tools were validated with UK universities. In 2014, the board decided to pivot into digital and change completely the business model – from business to business (B2B), to a business to consumer (B2C) model. YouLife had previously produced digital products like a website, with specific access for management and personnel, and an app, for corporate clients. Despite that, they considered the transformation as a radical change. And therefore, they have started a complete new product and business model, here named NewLife. The company self funded the development by diverting revenue from the legacy business. The NewLife app was first available to consumers late 2015, via app stores, with a B2C model.

11 Health is a company based in the UK, founded in 2013. In 2015, it started operations in the US as well. The company produces a device containing a sensor that attaches to a stoma bag, and, via an app, it supports the health condition management for patients and later for medical professionals. Around this product, other digital products were developed – apps for different stakeholders. It was co-founded by Michael Seres, who came up with the idea following his own experience as a patient using a stoma.

Fig. 11. 11 Health main product (first generation)[2]

[2] Image retrieved from company's website (on may 2015).

An angel investor, who became a co-founder, funded the company initially and it launched in 2013, with a B2C model, followed later by a B2B and a B2B2C model.

Characteristic	11 Health	YouLife	Mira Rehab
Product	A sensor which, via apps, supports patients with stoma bags, later medical professionals too	An app which allows people to self asses their health risks	A platform which integrates sensors (i.e. Microsoft Kinect) to support physical therapy
Targeted users	Patients Doctors Non-physician personnel Potential: Carer	People Insurer Potential: Doctors or Public Health organisations	Patients Doctors Physiotherapists Payers
Year of founding	2013	Early 2000s Year of starting NewLife 2014, January	2012
Country of founding	UK	UK	UK
Maine countries of operations	UK and US since 2015	UK Recently entering US	Romania and UK
Context of Founding	A patient teamed up with a more experienced business man, Adam to bring to life a devise conceived on the hospital ward	Due to the gradual shrinking of the business opportunities in the existing field, it was decided pivoting the business model into digital.	A team of four master students following the success of their idea at an international student competition – Microsoft Imagine Cup, 2011
Maturity	Startup	Mature business pivoting in digital	Startup
Funding	Angel investments SBRI grant of 89 450 GBP, spring 2015 In discussion with	Self-funded initially Corporate investor end of 2015	Self-funded initially Two angels investors in Romania Healthbox in 2012

Characteristic	11 Health	YouLife	Mira Rehab
	VC funds		SBRI grant of 780 000 GBP, spring 2014 Three more rounds of angel investments by the end of 2015
Entrepreneurial profile	Second time entrepreneur Long term patient Previous experience primarily in marketing	Long term entrepreneurial experience Experience in insurance and employee benefits Board with experience in insurance, corporate wellness programs	First time entrepreneurs IT and business students, master level degrees
Advisory Board	Two doctors, one digital health influencer, one health policy/insurance expert, one dietician	5 healthcare advisors	One clinical advisor, one business advisor, one technical advisor
Human Resources	Permanent 7 Outsourced: less than 5	Permanent: under 30 Outsourced collaborators: about 25 external developers	Permanent 5 Permanent outsourced developers 5
Initial contact for research recruiting	Digital Health Pit Shop Week, Dec 2014, London UK Organiser: Digital Catapult	The Role of Psychology in Digital Health Mar. 2015, London, UK Organiser: D Health Europe	INTERFACE 2015 September 2015, Vancouver, Canada Organiser: Interface Health Society

Table 2. Organisations overview

Only YouLife is a mature company. What is important here are that its undergoing efforts to pivot into digital gives it many of the characteristics of a startup. The notable differences are that there is an on-going stream of business generating a stream of revenue, more employees and a relative double goal. It is still self-funded, with limited resources and it is not “sheltered”. Funding of

the new company project continued to rely on internal sources until late 2015, when a corporate investor came in. Although the company has a long history, it manifests many of the characteristics of new ventures – limited resources, great uncertainty, long term and on-going organisational changes, regular visitation of strategy. My focus is the pivoting side of the business, YouLife, rather than the consequences of having two concurrent work streams.

YouLife is also the only company that required a formal confidentiality agreement. Data pertaining to it is anonymised, not due to the confidentiality agreement, but mainly because participants requested often anonymisation of parts or entire interviews. Other companies did not demand formal agreements besides than the research consent form, but several participants were cautious in answering certain questions, or they highlighted the confidential nature of particular information whenever they deemed necessary: for instance, future product features, potential commercial or investment deals which were not finalised. All such concerns were treated based on the interviewee's desire. The respondents' desire to maintain anonymity was respected.

4.7. DATA COLLECTION

Data analysed in this research is collected between 2011 and February 2016.

4.7.1. FIELD LEVEL

For the field level case, the documentarian data represents the main source. This was supplemented by data collected during participation at industry events, by social media listening and through opinion leaders interviews.

4.7.1.1. Documentarian data

Archival data was collected from various sources: proceedings from industry conferences and events, academic and public articles, commercial and public organisations' websites, webinars, video presentations and interviews, blogs, industry reports, and regulatory documents. I used a snowball approach to sample documentary data, guided by observations, industry events and materials available (Gawer & Phillips, 2013; Jay, 2013). For instance, if a document referred to a report, I analysed that report too; if a technology was

discussed along others, I investigated them as well; if a website referred to a patient blog or community, that would be consulted too, and, if relevant, such sources were included. This technique proved particularly useful when examining an emerging field, simply because boundaries of the field are not yet formed, they expand slowly and overlap on various degrees with those of the adjacent fields, therefore the snowball approach allowed me to track significant developments in other fields, which proved to have had an impact on digital health (i.e. the relation between Obamacare and the drive for interoperability in the US).

Data originates mainly in the US and parts of the EU (i.e. UK, Sweden, Denmark, The Netherlands, Germany, France, Romania) and was derived predominantly from English written sources, and several in French and Romanian. Some sources date back to 1999, however the focus is on sources from 2007 onwards, when the launch of the first smartphone marked the proliferation of pervasive and sensing consumer technologies.

Of course, the Internet has proven to be a rich source of documentary data. As the field is still emerging, many of my searches led to the discovery of niche websites: MedCityNews, mobihealthnews, nuviun (currently Innovate Medtech), Medtech Engine, to name a few. Over time, the mainstream news or opinion websites began to offer more content on Digital Health: Forbes, The Wall Street Journal, The Guardian, or the BBC. To identify relevant news and opinion articles, I have used search engines like Google, Google Scholar, however many relevant articles have been identified via social media listening.

4.7.1.2. Social media

I have been involved with digital health social platforms (LinkedIn groups: Digital Health, Digital Health UK, Healthcare Denmark, eHealth Romania, mHealth; Nuviun), I followed Twitter hashtags and a number of accounts of private individuals and companies – i.e. HIMSS15, Data4health, digital health, wearables, patientsincluded, DHL2015, doctors20). In doing so, I was able to identify more sources of information, news and opinion articles. Social media platforms represent a public forum for debates and they prove to be useful in

analysing emerging social and economic realities (Beverungen et al., 2015; Lupton, 2014a, 2014b).

Perhaps, in the last two years of the research, social media listening became one of the main tools to select relevant documents for digital health. This social media listening only guided identification of current issues, stakeholders, themes and, occasionally, of relevant archival data (Swirsky, Hoop, & Labott, 2014), similar to my participation at industry events. It also helped identify opinion leaders, which led to supplementing the documentary data with several interviews.

4.7.1.3. Industry events

Data at field level was supplemented by data collected by my participation at industry events (see appendix E), where I observed the profile of participants (i.e. medical technology providers, doctors, regulators, pharma, CHDT produces), agendas, as well as significant topics raised by presenters or panels. All observations pertained to the public space, and therefore it can be considered a passive observation of the public space. Some of the events opened have made presentations available online. Several others have offered interviews or session recordings. Some of these online sources were used.

4.7.1.4. Opinion leaders interviews

Field data was enriched by ten opinion leaders interviews (see appendix A). Their identification was based on their presence online (social media, followers, articles, referrals to them inside events or articles) and at industry events.

Interviews were semi-structured to allow for themes to emerge and were conducted mainly like conversations. In the case of opinion leaders, the opening question was to talk about themselves prior to their involvement in digital health. These interviews maintain a broader level of assertions in respect to the field evolution (see appendix F for an example). Most interviews with opinion leaders were taken over the phone or Skype, and lasted 30 - 40 minutes. Majority were recorded, except two. One was returned in a written format and the other one was partially written, partially recorded. Michael

Seres was the only opinion leader who was also a participant in the organisational level, as co-founder and CEO of 11 Health.

4.7.2. ORGANISATIONAL LEVEL

In the case of organisation case studies, the main data source is interviews. As a primary source I also included presentations at industry events where I took part.

4.7.2.1. Documentarian data

Documentarian data varied from articles in the written press, company websites, online interviews and articles in which the company or founders were mentioned, competitor websites (where applicable). To observe changes in their public discourse, I have used the Wayback Machine website (an online archive that maintains selected images of websites over time) to track the changes companies brought to their websites. In the case of YouLife, I focused mainly on its evolution since the beginning of the pivoting phase.

4.7.2.2. Social media

For organisations, I have also followed their social media accounts (LinkedIn, Twitter and Facebook), also as another modality to analyse their public rhetoric. It is important to highlight that social media is enhancing what was previously achieved via Public Relations efforts only. Through their shares and endorsements on social media, companies are both enhancing their discourse and indirectly legitimise by association with reports, opinion pieces, and authority or influential figures (Brown, 2006).

4.7.2.3. Industry events

In several occasions, I participated to conference or events where talks were given by organisations' representatives – Mira Rehab and 11 Health.

4.7.2.4. Interviews

Interviews conducted for organisations took place in person, over the phone, or via Skype (video or audio calls). Most of the interviewees were part of the company, most of them in middle, top management and board or founder level.

I would like to highlight that compared to the size of companies, their history, the degree of adequacy (Bowen, 2008), the number of respondents is satisfactory. Of course, inside of two of the companies, Mira Rehab and 11 Health, respondents had more overlapping roles and most of them having great level of empowerment compared to similar roles in big companies. In addition to that, the high level of interaction led to the fact that most respondents had a very rounded understanding of their company. A few interviews were conducted with interviewees from outside the company – advisors or former advisors. Most respondents were interviewed twice. The second round (sometimes the third round of interviews) aimed to either clarify, expand on previously discussed topics, or to generate additional data on company developments. Most interviews lasted 60 minutes, although the second round usually lasted on average 30 minutes. In a few occasions, some clarifications via email were obtained in relation to specific issues and some drawings were used.

	11 Health	**YouLife**	**Mira Rehab**
Number of interviews	13	23	10
Non-company representatives	1 advisor	1 consultant	1 advisor 1 investor
Number of individual interviewees	7	13	7
Language of interviews	English	English	English Romanian

Table 3. Interviews in organisations

Interviews were semi-structured to allow for the themes and topics to emerge (see appendix B). They usually started by asking the interviewee to talk about their experience prior to joining or founding their company. Interviews inside organisations started more broadly and ended up focusing on company strategy, product and more specific aspects (see appendix G for an example), but there were questions about the field aimed to elicit their understanding and perception over it and over the position of their company's inside it. Interviews with company representatives ranged between 15 minutes to 90 minutes, on average 50 minutes.

4.7.3. SUMMARY OF DATA SOURCES

The table below synthesizes data sources used for this research, for both field and organisational levels.

Data source type	**Digital Health** **Macro level**	**11 Health** **Meso level**	**YouLife** **Meso level**	**Mira Rehab** **Meso level**
Industry events	11	3	1	1
Interviews	10	13	23	10
Company websites	30	1	2 Competitors: 3	1 NGO website: 1
Press or online articles	150	8	N/A	5
Languages	English, French, Romanian	English	English	Romanian and English
Countries	US, UK, France, Canada, Romania, Netherlands, Denmark	UK US	UK	Romania UK
Recordings (interviews, TEDx talks, conference talks, podcasts)	35	Presentations: 4 Panel discussions: 2 Interviews: 3 "How to" recordings: 3 Promotional: 2 TV: 1 Others: 2	Promotional: 2	Tedx: 1 TV: 1 Promotional: 1
Social pages	Twitter: 40 accounts related to digital health LinkedIn Groups: 3	Facebook, Twitter, LinkedIn	Facebook, Twitter, LinkedIn	Facebook, twitter, LinkedIn
Related online content	Various sources (personal websites, news websites, social platforms) 50	On company website 16 On founder's website 20 On other websites: 3	On company website 2	N/A
Books	5	N/A	N/A	N/A
Market reports	30	N/A	N/A	N/A
Regulatory documents	8	N/A	N/A	N/A

Table 4. Summary of data sources

4.8. DATA ANALYSIS

Data collection followed a concurrent and iterative approach (Eisenhardt & Graebner, 2007; Yin, 2009) between field data and theory, to allow for the emergence of themes and identification of additional sources. The high volume of data obtained was reviewed in its entirety. It was organised historically for longitudinal analysis in all cases, and, following several qualitative iterations, it was analysed based on the units of analysis and on the key themes, as they emerged over time.

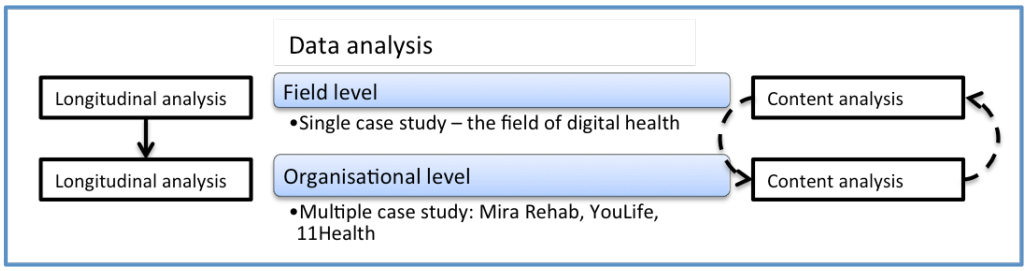

Fig. 12. Representation of how data analysis on each level informed the other

The main units of analysis used in this research are institutional logics as ideal types and institutional work as defined in chapter 3. Institutional work is a useful concept because, as I have mentioned before, it allows me to refer to both actions and rationales. Action is important because, on one hand, it often embodies meanings, on the other hand, it can lead to a change in meaning. Actions can embody, in conditions of ambiguity, sometimes less intended reactions or irrational attachments (Santos & Eisenhardt, 2009), what Weick (1988) referred to as "enacted sensemaking". Rationales (retrospective as well as anticipative) are captured through narratives and theorisations. Rationales "provide sufficient structure for people to get their bearings and then create fuller, more accurate views of what is happening and what their options are" (ibid., p. 310). Examples of such actions at the organisational level are hiring, alliances, subscriptions to professional associations, product development, branding etc. At the field level, a few examples of such actions would be formation of new associations, new social media groups or hashtags, market reports, regulations, events, prizes, contestations…The secondary units of analysis related to institutionalisation are hybridisation and conflict.

Hybridisation is understood as a process where logics combine and *conflict* represents a process where logics at best ignore and worst oppose each other.

Analytic Level	Activity	Approach and supporting tools
Field level	Timeline for the field	Table based on documentarian data and conferences notes organised in Zotero on categories (i.e. article, market report, startup, association, regulation)
	Reiteration between data and theory for institutional logics and stakeholders	Tagging in Zotero of documentarian data and conferences notes, alongside with theoretical articles Tagging of interviews in NVivo guided by preliminary work on documentarian data Tables to represent logics and stakeholders as they emerged
	Reiteration between data and theory for institutionalisation processes	Tagging in Zotero of documentarian data and conferences notes, alongside with theoretical articles Tagging of interviews in NVivo guided by preliminary work on documentarian data At this stage, the process was better informed by the previous stage and guided by certain units. Graphs to represent institutionalisation processes in various contexts.
	Reiterations between timeline, processes of institutionalisation and stakeholders, as well as existing theory, to generate field emergence stages	Supported by the timeline and the previous stages of content analysis Tables and graphs were used to support findings
	Reiteration between data and theory led to identification of aggregation units for organisational level	Tables and graphs, based on themes emerged and theoretical insights
Organisational level	Timeline for each organisation	Table based on both documentarian data and interviews
	Reiterations of data analysis guided by the content of institutional logics derived from previous level	Tagging of interviews and documentarian data in NVivo
	Reiteration between data and theory for processes of institutionalisation	Tagging of interviews and documentarian data in NVivo Tables to organise themes
	Open minded tagging for themes regarding institutional work	Tagging of interviews and documentarian data in NVivo
	Iteration between theory and findings	Graphs and table to represent and connect emerging themes with theory and allow for insights
	Grouping of emerged institutional work themes under the aggregation units identified at previous level	Organisation of tags in NVivo Graphs and table to support ideas, organisation of categories and theory
Abducting phase Connect the two levels & build theory	Reconnect institutional logics content from both levels to enrich findings and generate theory	Facilitated by previously generated theorisation, tables and graphs
	Reconnect processes of institutionalisation and institutional work between levels to generate theory	Facilitated by previously generated theorisation, tables and graphs
	Build upon theory and findings to generate practical insights	Tables and graphs

Table 5. Summary of analytical steps

The above table summarises the main steps of data analysis. However, the process was not as linear as it may seem from the table above; there were significant iterations at each level of analysis, as well as during the abducting phase. It is important to highlight that the two levels of analysis informed each

other, as my research takes both a top-down and a bottom-up approach (Scott, 2008).

4.8.1 LONGITUDINAL ANALYSIS

Data was first organised historically and then synthesised based on milestones. Historical stages have been used previously to depict and explain institutionalisation processes (Morrill, 2006; Pouthier et al., 2013; Scott et al., 2000; Thornton & Ocasio, 1999). At the field level, after several iterations, data was organised in two blocs: precursors of change and the phases of digital health emergence: the ingenuous phase (2007 - 2009), the legitimation phase (2010 - 2012) and the mobilization phase (2012 - present). At the organisational level, the history was constructed from online sources and interviews. Given the relative short lifespans, it was not difficult to build a brief history based on milestones (founding, product, funding…). One of the companies, 11 Health, has developed its own history on the website, which was very useful to see what the company recognised as milestones.

4.8.2. CONTENT ANALYSIS

Throughout my research, I engaged in numerous meetings, discussed the history of the case, themes and processes as they emerged, and sought to develop underlying explanations. These meetings included my supervisors, and also other academics and researchers. Moreover, through my participation at conferences, I had the opportunity to discuss my work with a variety of industry representatives. This iterative process allowed me to select data, display it in tables and diagrams, build narratives and develop and verify conclusions (Eisenhardt & Graebner, 2007; Miles & Huberman, 1994).

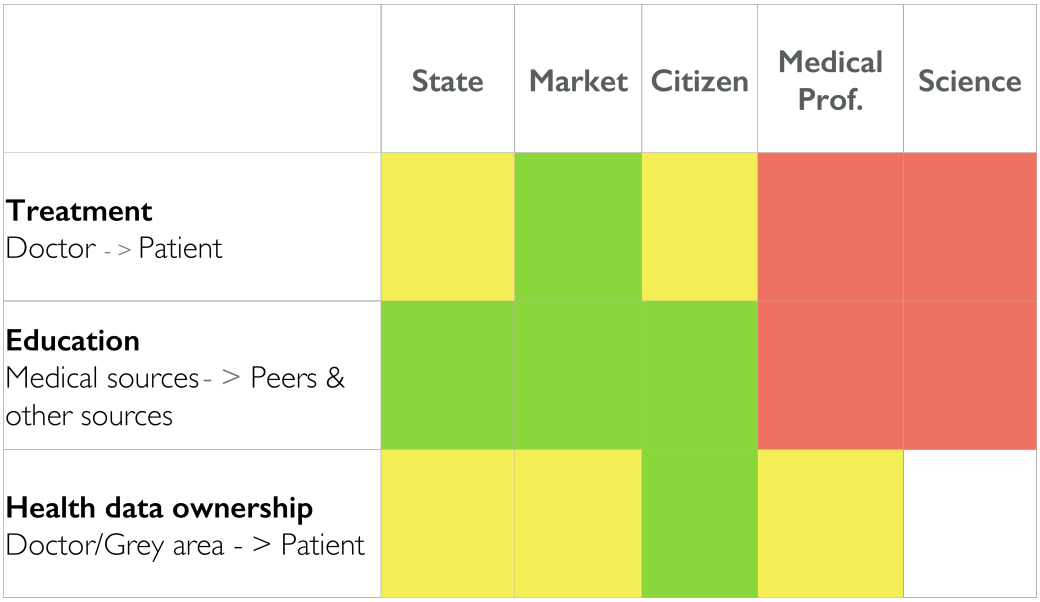

Fig. 13. Sample diagram presented at Interface conference (Vancouver, Canada, 2015)

Due to the large amount of data, I used hand notes, tables and graphs, as well as softwares like NVIVO 11 and Zotero 4. Initially, I relied on Zotero 4, and later I found NVIVO to be helpful to manage interviews in particular. This allowed me to cope with the amount of data and cross-analyse the case studies. I used a multitude of means to support emerging processes of theory creation, but, in the end, I relied primarily on hand notes, tables, and diagrams to simplify and synthesise my analysis. That was the case mainly for the inductive approach when I determined broader themes, and when I undertook an intense adductive stance to build the theoretical insights.

4.8.2.1. Field level

The historical narrative allowed me to identify themes and to generate explanations and theoretical insights. At first, I used a multitude of codes, as they appeared to be relevant over time. I started doing that using Zotero 4, and then I added also NVIVO 11, particularly for interview data.

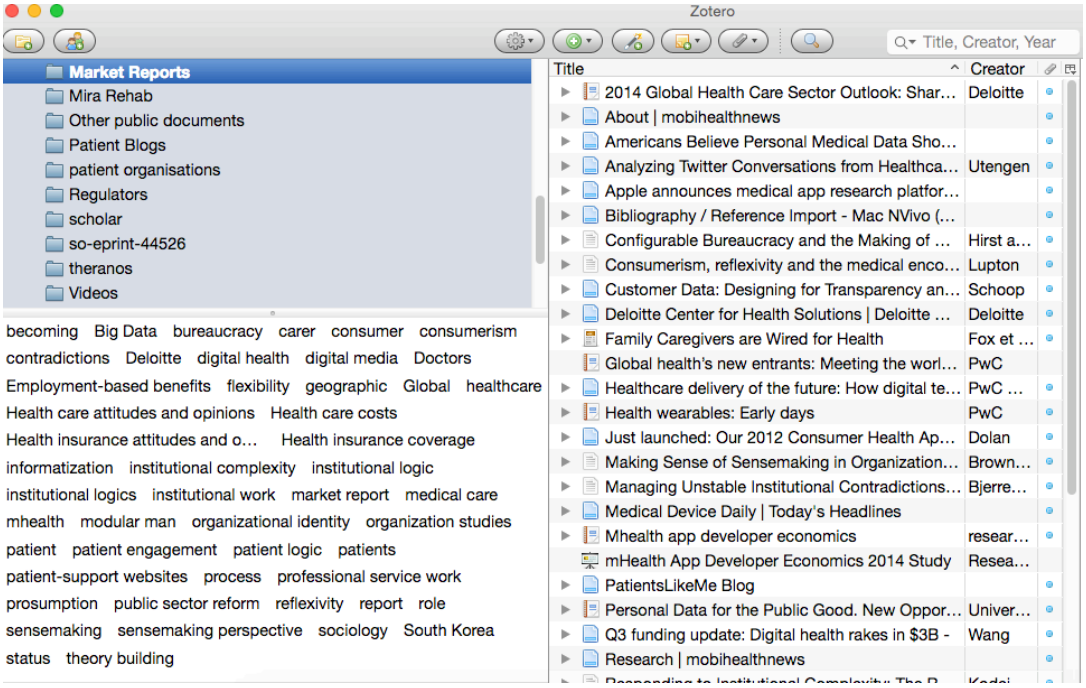

Fig. 14. Sample coding, as inductive approach, in Zotero 4 for field level analysis

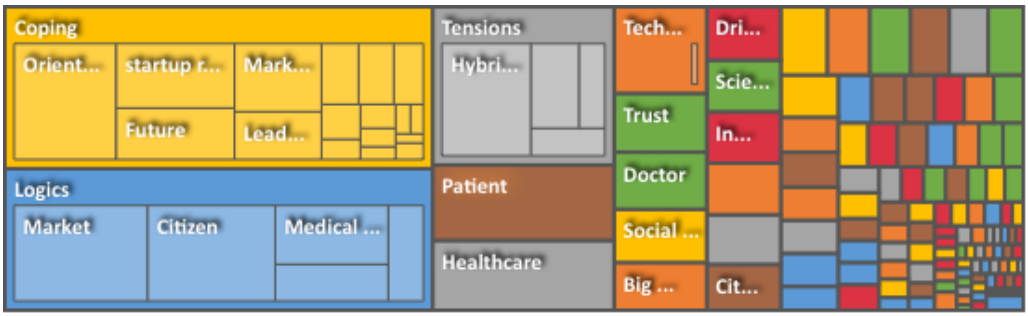

Fig. 15. NVIVO codes represented based on number of coding references

Data was analysed through several iterations as themes emerged: institutional logics and stakeholders, hybridisation and conflict, and the hybrid role of the empowered patient. Data was tagged based on themes to allow for comparisons and formulation of theoretical contributions.

The content of the institutional logics was derived through an iterative process between data collected and the institutional literature and it is explained extensively in chapter 6, along with representative stakeholders. For instance, professional logic means that their representatives have access to a body of knowledge, are licensed to employ it and have autonomy in their decisions (Abbot, 1988; Leicht & Fennell, 2008; Scott, 2008). Additionally, I consulted existing institutional logics studies in healthcare to guide both the identification and the formulation of logics. A special regard is owed to the identification and

formulation of the citizen logic. Although it is invoked by other healthcare studies (Dunn & Jones, 2010; Scott et al., 2000; Waldorff et al., 2013), it has not been formulated as such before. I guided my formulation more heavily on data collected in this case. Sample themes for this logic were "connected health", "empowerment", "patient participation", "self management", "patient management", "collaboration", "population health", "quantified self", "weareables", or "personalized health". Related to the citizen logic, the emerging role of the "empowered patient", as ideal type, was also described.

At the field level, the inductive approach was used to identify recurrent and emerging themes pertaining to the institutionalisation processes. My search was guided by new activities, declared needs, missions, resistance, target audience, delivery and communication channels, founders, hiring practices, board members, affiliations with industry or professional associations, engagement with or co-optation of stakeholders, and governing bodies. These aspects varied depending on stakeholders. For instance, when examining regulators, I looked at how they approached digital health, their declared intention versus actions, who do they recognise as other stakeholders, how they engage with them, or how they direct financial support and incentives.

I will offer here an interesting example of how a stakeholder, by promoting a certain rhetoric, creates institutional logics hybridisation and conflict with different stakeholders. "This is not just about a change in service provision, but about a cultural change, allowing patients to be partners in their care, letting them decide what support they need, when they need it and how" (UK Department of Health, 2006). States' push for consumerism stimulates in lay people the hybridisation of the medical profession and citizen logics. But enforcing the same idea to healthcare professionals, causes conflict with the market logic.

Processes of hybridisation and conflict happen in the same time for many of the digital health stakeholders. CDHT producers though are one great example, as they try to hybridise with both medical profession citizen logic, but they also go at times into conflicts with both. "In this day and age, where the explosion of apps, etc., if you don't walk in the shoes of the patient, that is going to be

using your technology, you're gonna fail. You're gonna absolutely fail!" (Michael Seres, patient entrepreneur, opinion leader). I have called *ambivalence* this process of simultaneous conflict and hybridisation that proved to be most common amongst stakeholders. It is perhaps explained by the uncertainty and ambiguity of the field emergence, as well as by the "uneasy truce" amongst market, state and medical profession logics present in the healthcare field.

4.8.2.2. Organisational level

It is relevant to say that this analysis started later in the research, and therefore the field level analysis informed and guided heavily the analysis at the organisational level. More specifically, the content of institutional logics were broadly identified along with other themes during the field level analysis and they guided the identification of these logics inside organisations. However, both levels of analysis continued to inform each other (Scott, 2008).

For the organisational level, although Zotero 4 was still used, NVIVO was preferred due to better management of interview data.

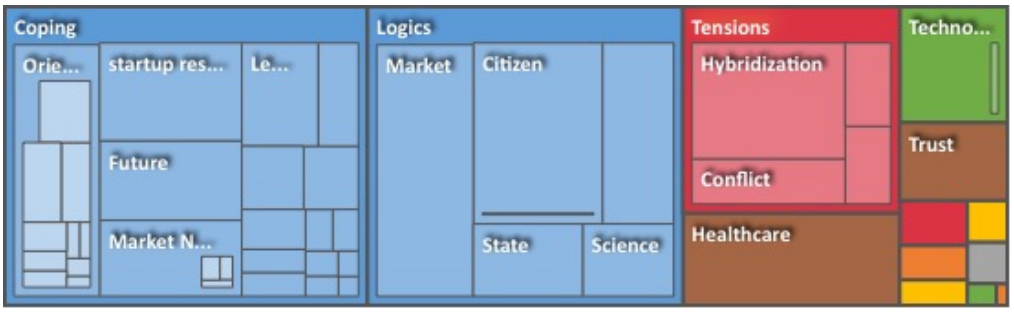

Fig. 16. NVIVO codes represented based on number of coding references for organisational level

At this level, I looked to identify institutional logics (based on the field level work) and processes of institutionalisation (hybridisation, conflict and ambivalence) and institutional work. For the institutional work, I paid attention to symbolic acts, theorisation and actions, as resulted from the data gathered. Examples of such actions are hiring, partnerships, subscriptions to professional associations, product development, branding, funding, or presence at events.

Institutional logics were identified for each participant based on their previous experience and role in the company (founder, employee, investor, advisor), as well as based on the content of the logics as emerged through the field analysis (see chapter 6). This process was relevant to understand the prevalent or emerging institutional logic or logics at the organisational level, as well as to assess certain types of institutional work and understand the bottom-up institutionalisation.

Institutional logic	Example	Institutionalisation process
State logic	"But after you've tested it, can it be prescribed? No! You can pay for it? Don't know. So what's the point? That's what I mean about the disconnect between the big idea and stuff on the ground. I work very closely with NHS in the digital health thing. I think there are some fantastic people there who really have great visions, but they cannot solve everything. And that's the problem. And sometimes, they don't even understand the issues on the ground. (Michael Seres, CEO, founder 11 Health)	Conflict - market and state logics.
	"Because, you can't avoid the issue of data privacy, but it's the people that don't pay attention to data privacy won't be around for very long." (M. B., co-founder YouLife)	Ambivalence – citizen, state and market logics
Medical profession logic	"It was from bags that leaked, it was from watching nurses. (…) I would time how long it took them to come in, empty the bags, measure it, put it on a flow balance chart and put it back again. And it was quite a lengthy process for them and also a difficult process for them… It's not just about me, it's about them managing it." (Michael Seres, CEO, founder 11 Health)	Hybridisation – citizen and medical profession logics
	"Yes, it's the infrastructure and the staffing of the hospitals. Here they have enough difficulty having enough beds, let alone managing a new technology like this. It doesn't seem to be a priority." (D. B., communications, 11 Health)	Hybridisation – citizen and medical profession logics
Citizen logic	"Being a participant patient is vital, in my opinion, in healthcare." (Michael Seres, CEO, founder 11 Health)	Ambivalence – citizen and medical profession logics
	"Especially with healthcare, I found a lot of patients don't really want to deal with an app, they don't want to experience 17:52 want to get things done." (A. C., technical lead, 11 Health)	Conflict – citizen and market logics
	"And I think educating people is the really important part of all of that, and I think that's what excites me. I want to help people understand how healthy they really are, and I think that's why I really like what we're doing." (I. D., business development, YouLife)	Hybridisation - citizen and medical profession logics
Market logic	"The patient is not necessarily the forefront from the hospital's perspective. Unfortunately, that's the case, the hospitals may voice that they care about the patient, which they do, but not as much as they should. The hospital is a business." (K.P., US business lead, 11 Health)	Conflict – citizen, medical profession and market logics
	"I am a big fan of gamification as principle. I believe it is a necessity to transform a boring process in a more interesting one is a very good thing. On the other hand I	Conflict – citizen and medical profession logics

Institutional logic	Example	Institutionalisation process
	find it overused, it's applied in anything. I find serious games a wrong definition. It seems you need serious because games would point to something that it's not essential. From my point of view, games are essential to everything." (Cosmin Mihaiu, co-founder Mira Rehab)	Hybridisation – market and citizen logics
Science logic	"How many companies have actually done the research into the psychology of the way you ask the question, or the psychology of where a question appears in the list, or the psychology of the colour you write the letters in? How many companies are doing that? Because that takes a long time to do. And that's what I mean about the validation work." (M. B., co-founder YouLife)	Conflict – market and science logics
	"We can follow what a patient does based on some parameters that could not have been monitored before. In that sense, we are bringing medical innovation." (Alina Călin, co-founder Mira Rehab)	Hybridisation – science, citizen and market logics

Table 6. Institutional logics and institutionalisation processes at organisation level

As observed in table above, each logic is accompanied by the institutionalisation process reflected in the quotation. The explanation is in the fact that institutional logics are ideal types and they are carried out in less pure forms and in greater diversity by field participants. Given the very nature of emergence, it is expected that institutional logics be represented at individual level in less pure forms, particularly because meanings and rules of the game are still negotiated. This is also relevant to show how field level analysis informed the organisational level, as an interpretation schema.

For analysing institutional work, I used an iterative process to allow categories to emerge until I had a clear understanding of their relationship and their fit into the parameters set by the theoretical framework: position in the field, pluralism and ambiguity, and governance. As themes and relations emerged, I referred back to existing theories and literature, as highlighted in chapters 2 and 3. I followed recommendations on coding (Gioia, Corley, & Hamilton, 2012b) that provide guidance on organising and order of abstractions, which al facilitate theorising phase. However, due to the complexity of this research and the theoretical approach, I did not use the 1st and 2nd orders terminology, to avoid confusions. I have followed the coding and abduction strategy, but my aggregation themes were predetermined by my theoretical framework and research design. As Gioia et al. recognise, "different methodological

approaches will naturally rely on different conceptualizations of data" (ibid., p. 25).

Aggregation themes	Institutional work	Mechanisms	Examples
Taming liminality (Position)	Incumbent (mis)alignments	Recognition of regulations or expectations that may or may not apply Conflict or ambivalence – avoidance of certain requirements, at least temporisation Preparation for the future changes in regulations or expectations	Recognition of regulations or expectations that may or may not apply: "But after you've tested it, can it be prescribed? No! You can pay for it? Don't know. So what's the point? That's what I mean about the disconnect between the big idea and stuff on the ground. I work very closely with NHS in the digital health thing. I think there are some fantastic people there who really have great visions, but they cannot solve everything. And that's the problem. And sometimes, they don't even understand the issues on the ground. (Michael Seres, CEO, founder 11 Health) Conflict or ambivalence – avoidance of certain requirements, at least temporisation: "If you are really agile and grow really fast, ahead of the curve, my advice is to stay away from the NHS. Because it will bog you down, absolutely drag you down, drain you every penny and the few resources you've got and you'll end up with nothing." (M. B., co-founder YouLife) Preparation for expected changes in regulations or expectations: "We prepare to test with a trust in UK. We work after a set of rules from the UK. We want to launch the online version that would link the home version to the hospital one and to secure them both. Here there are many aspects to take into account that are not necessarily related to usability, but they are necessary. (...) For now, for data security, we follow a set of UK guidelines." (Andrei Cantea, co-founder Mira Rehab)
	Legitimacy	Association with legitimising actors – academia, healthcare professionals or organisations (on partnerships or advisory boards) Display of public awards or recognitions Display of evidence Good cause	Association with legitimising actors: Mira Rehab dedicated since very early on a lead for their academic and scientific connections. All three companies engaged with such stakeholders. Display of evidence: Mira Rehab and YouLife had extensive articles with evidence on their websites. Establish trust/Good cause: "And he talks [n.b. the founder] in away that's not down to people, he's truly a patient and people need that. I think people will believe in the

		Establish trust	product because they believe in him. I mean, he's got nothing but the best interests at heart." (D. B., communications, 11 Health)
	Resource maximisation	Co-optation of various stakeholders Temporisation of actions or engagements with other stakeholders Develop capabilities	Co-optation of various stakeholders: "And it's beneficial to companies like ours who want good expertise in some ways that are often cheaper, because there is the reciprocal thing." – on working with academia (M. R., finance, YouLife) Temporisation of actions or engagements with other stakeholders: "… if I can get the efficacy and show I can do that, this business will be of immense value because you've got something that the NHS is been trying to get to for years and years." (M. B., co-founder YouLife) Develop capabilities, depending on perception of needs: For internal capabilities, 11 Health looks to invest in technical resources, whilst YouLife headhunting for Digital Experience Lead. For science capabilities, most companies established links with outsiders, particularly academia. For medical expertise, 11 Health and Mira Rehab developed long term, intense collaborations with healthcare organisations and co-opted doctors in the advisory boards.
	Forge a new market	Establish partnerships with incumbents (academia, healthcare) Promote new practices Turn partnerships into distribution channels	Establish partnerships with incumbents (academia, healthcare): Mira Rehab considers that healthcare professionals co-created with them their solution. Promote new practices: "We can follow what a patient does based on some parameters that could not have been monitored before." (Alina Călin, co-founder Mira Rehab) Turn partnerships into distribution channels: Mira Rehab and 11 Health were looking into developing B2B2C models via their partnerships with healthcare providers. Similarly, YouLife was looking for commercial partners from consumer areas to use as distribution.
Taming contradictions (plurality and ambiguity)	Scanning the environment	Co-opetition and competition Scan broader technological environment Monitor incumbents evolution (i.e. state and healthcare) Gain market insights	Co-opetition and competition: "Competitors… every month a few more. Competition validates the market. There is no dominant one. I am happy when I am told our product is better." (Cosmin Mihaiu, co-founder Mira Rehab) Scan broader technological environment: "I think Apple is making steps towards that with their health kit. Honestly, I haven't seen anything from Google, but I would say they're doing something. It really needs to be kind of led, the app industry tended to kind of wait for the big players, like

			Microsoft, Apple, Google to do things, and then they kind of moved on it." (A. C., technology lead, 11 Health) Monitor incumbents evolution (i.e. state and healthcare): All companies realised for instance that data privacy and security are coming to the forefront and that eventually, this will not only be a competitive edge, but a regulatory requirement. Gain market insights: "…we have learned a lot over time, from many people, and how to spend and what would be more beneficial, to respect our strategy. (Andrei Dascalu, co-founder Mira Rehab)
	Institutional brokerage	Compartmentalise by design for multiple logics Hold multiple identities	Compartmentalise by design for multiple logics: "Specifically talking about the device that we have, it certainly delivers a high level of quality of life, its convenience, that the patient just did not have before and that they achieve with this device. And in terms of how hospitals at C-level, surgeons, and nurses view quality of life of the patient... surgeons are focused on just the result of what the device actually does, nurses are probably most concerned with the quality of life of the patient, and hospital C-level administration, they will say that they're concerned about the quality of life of the patient, but their focus is internal on the hospital, they're concerned about making money and saving money. " (K. P., US business lead, 11 Health) Hold multiple identities: "So we had to build something that a patient would read, but also a doctor could read and a pharmaceutical distribution company could read, so we had to please a lot of different audiences." "We're dealing with professionals, and doctors, and nurses and patients come across the spectrum. It's such a diverse group and there are so many different, diverse areas. It's been really a challenge. I think the fact that people are still trying to catch up with it, and define it, and disrupt it that makes it really exciting." (D. B., communications, 11 Health)
	Build for the future	Flexibility in product and business model development Develop concurrent business models	Flexibility in product and business model development: Mira Rehab had designed their platform with inbuilt flexibility to be able interoperate with various technologies. Develop concurrent business models: Both Mira Rehab and 11 Health have a B2B and a B2B2C business models. 11 Health has also a B2C one, Mira Rehab aiming to get to develop that one. YouLife focused mainly on a B2C, but came to realisation that the B2B model was very important for monetisation.

Brave new world (Governance)	Distinctiveness	Use new categories (i.e. "patient led innovation", "digital health", "connected care") Use categories based on circumstances and stakeholders Separate from legacy health IT Use of stories to alleviate contradictions	Separate from legacy health IT: "If you have something that's digitally sound and something that's new, people typically will embrace that, more so than something that's been around for a while, something that's not necessarily you know, run through a digital platform." (K. P., US business lead, 11 Health) Use categories based on circumstances and stakeholders: "Digital health" for instance is often used when connecting with investors, to associate the company with the booming market. Another examples is Mira Rehab avoiding the "exergame" label, of fear of trivializing their solution. Use of stories to alleviate contradictions: "It was from experiences in the hospital bed. It was from bags that leaked, it was from watching nurses." (Michael Seres, CEO, founder 11 Health) Use of stories to alleviate contradictions – leverage social media: "Yes, but I'd say that the brand is owned by your audience. Your company, we don't even own the brand. Because they have so much influence on the way it's going to perform, that I'd say that they own the brand. They are the ones there are going out there and do social media or talk about it. So they have a lot more power. (D. B., communications, 11 Health)
	Leadership	Identity project based on scenario of the future Founding logic as catalyser or challenge From identity project to institutional change Adaptive strategy, with integrity	Identity project based on scenario of the future: "I don't believe that successful apps are necessarily the one that have lots and lots of features. I think that the apps that are really successful are the ones that have focused on what they do and do it very well." Founding logic as catalyser: "I tend to just look at what needs to be done right now, Michael is a visionary." (A. C., technical lead, 11 Health) Founding logic as challenge: "if we moved from getting people healthier into insurance, then I should know that" (J. K. technical lead, YouLife) From identity project to institutional change: "He [n. b. Michael Seres, 11 Health], in many ways typifies the humanity of the digital health movement - of the citizen scientist, of the empowered patient. What he's done is leverage that enthusiasm that perspective as patient combined in the context of business, medicine and created a great company from that." (John Nosta, opinion leader) Adaptive strategy, with integrity: "I'm very

			clear to try and keep the company focused on improving the life of the patient. If we are keeping focus on this, then the company is going to continue to make more money. The priority is 'What are we trying to do?' And that is a hard balance, as we grow." (Michael Seres, CEO, founder 11 Health)

Table 7. Institutional work at organisation level

4.8.2.3. Abducting phase

There were several iterations at each level, as I was following the insights provided by data, as well as theory. As well, findings at each level informed findings at the other. Moreover, having a unifying framework of analysis, it allowed for rich theoretical insights. The field level analysis informed the organisational level, as an interpretation schema, and the organisational level informed the field analysis, by making visible the bottom up institutionalisation.

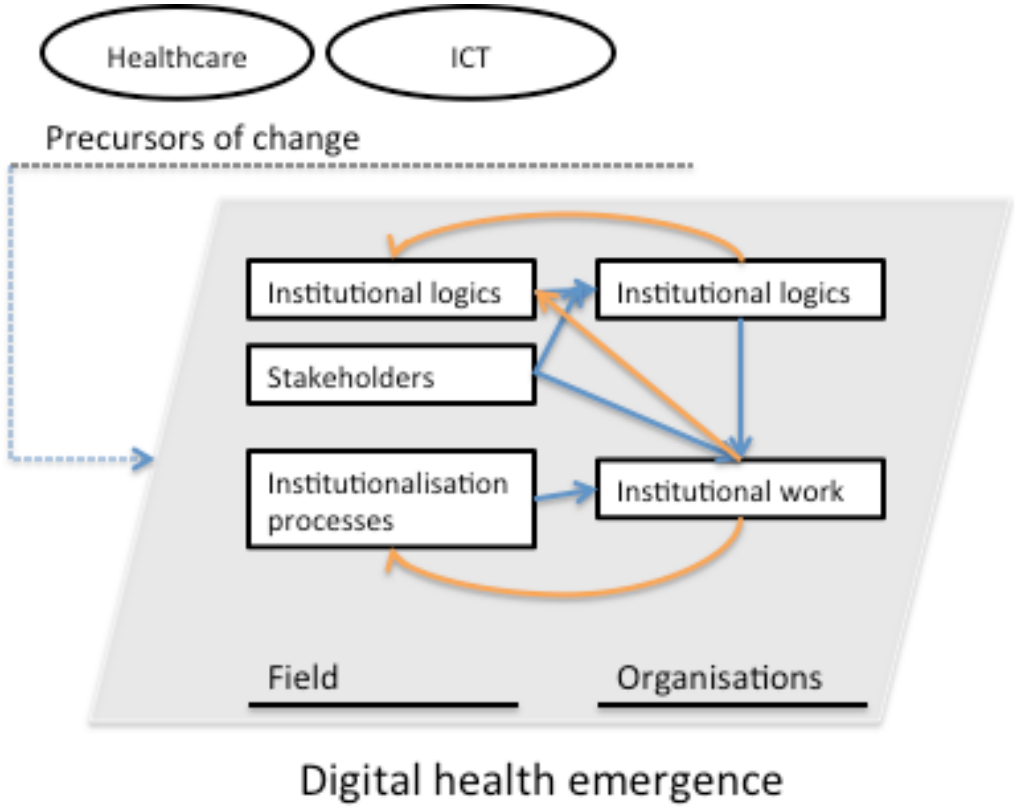

Fig. 17. Representation of how field and organisation levels informed each other

The figure above shows the connections between the levels of analysis. For instance, refining the institutional logics at field level, orientated the identification of institutional logics at play in organisations, as well as of the

institutional work. For instance, the state logic was not that well represented at organisational level, except in terms of institutional work, particularly via processes of conflict or ambivalence. However, having a good understanding of this logic, as well as of the main moves of the state during the field emergence, it helped with the understanding of the rationales and actions of the organisations.

The table below shows how institutional logics defined at the field level orientate the analysis of institutional logics at play in organisations. Further, alongside the institutional work at the organisation level, indications of the bottom up institutionalisation of the field are revealed. To illustrate this, in the table below, the organisation level processes and rationales are connected with field level themes.

Institutional logic	Example	Institutionalisation process	Field level theme
State logic	"But after you've tested it, can it be prescribed? No! You can pay for it? Don't know. So what's the point? That's what I mean about the disconnect between the big idea and staff on the ground. I work very closely with NHS in the digital health thing. I think there are some fantastic people there who really have great visions, but they cannot solve everything. And that's the problem. And sometimes, they don't even understand the issues on the ground. (Michael Seres, CEO, founder 11 Health)	Conflict - market and state logics.	Reimbursement of new technologies
	"Because, you can't avoid the issue of data privacy, but it's the people that don't pay attention to data privacy won't be around for very long." (M. B., co-founder YouLife)	Ambivalence – citizen, state and market logics	Privacy Ethics
Medical profession logic	"It was from bags that leaked, it was from watching nurses. (…) I would time how long it took them to come in, empty the bags, measure it, put it on a flow balance chart and put it back again. And it was quite a lengthy process for them and also a difficult process for them… It's not just about me, it's about them managing it." (Michael Seres, CEO, founder 11 Health)	Hybridisation – citizen and medical profession logics	Efficiency Patient experience
	"Yes, it's the infrastructure and the staffing of the hospitals. Here they have enough difficulty having enough beds, let alone managing a new technology like this. It doesn't seem to be a priority." (D.B., communications, 11 Health)	Hybridisation – citizen and medical profession logics	Adoption by healthcare professionals
Citizen logic	"Being a participant patient is vital, in my opinion, in healthcare." (Michael Seres, CEO, founder 11 Health)	Ambivalence – citizen and medical profession logics	Empowered patient
	"Especially with healthcare, I found a lot of patients don't really want to deal with an app, they don't want to experience 17:52 want to get things done." (A. C., technical lead, 11	Conflict – citizen and market logics	Adoption by patients

Institutional logic	Example	Institutionalisation process	Field level theme
	Health)		
	"And I think educating people is the really important part of all of that, and I think that's what excites me. I want to help people understand how healthy they really are, and I think that's why I really like what we're doing." (I. D., business development, YouLife)	Hybridisation - citizen and medical profession logics	Health literacy
Market logic	"The patient is not necessarily the forefront from the hospital's perspective. Unfortunately, that's the case, the hospitals may voice that they care about the patient, which they do, but not as much as they should. The hospital is a business." (K.P., US business lead, 11 Health)	Conflict – citizen, medical profession and market logics	Healthcare systemic failure Patient centricity
	"I am a big fan of gamification as principle. I believe it is a necessity to transform a boring process in a more interesting one is a very good thing. On the other hand I find it overused, it's applied in anything. I find serious games a wrong definition. It seems you need serious because games would point to something that it's not essential. From my point of view, games are essential to everything." (Cosmin Mihaiu, co-founder Mira Rehab)	Conflict – citizen and medical profession logics Hybridisation – market and citizen logics	Patient involvement Treatment adherence Legitimacy
Science logic	"How many companies have actually done the research into the psychology of the way you ask the question, or the psychology of where a question appears in the list, or the psychology of the colour you write the letters in? How many companies are doing that? Because that takes a long time to do. And that's what I mean about the validation work." (M. B., co-founder YouLife)	Conflict – market and science logics	Trust Legitimacy
	"We can follow what a patient does based on some parameters that could not have been monitored before. In that sense, we are bringing medical innovation." (Alina Călin, co-founder Mira Rehab)	Hybridisation – science, citizen and market logics	Legitimacy

Table 8. Institutional logics and institutionalisation processes reflected at organisation level and connections with broader field concerns (themes)

The last phase of data analysis, was aggregating findings for the theoretical insights to be formulated. This was a constant validation through referring to extant theories, re-examining data and obtaining feedback from other researches (Eisenhardt & Graebner, 2007; Rindova & Kotha, 2001; Santos & Eisenhardt, 2009; Yin, 2009). Overall, data analysis is an iterative process to select data, display it in tables and diagrams, build narratives and develop and draw theoretical insights (Eisenhardt & Graebner, 2007; Gioia et al., 2012b; Miles & Huberman, 1994).

4.9. CONSIDERATIONS OVER ETHICS, VALIDITY AND GENERALISABILITY

4.9.1. ETHICS AND VALIDITY

A common validity concern is the social desirability bias (Weaver, TreviÑo, & Cochran, 1999), which refers to the fact that people have the tendency to present themselves more as they believe they should, rather than how they are. This risk was higher when interviewing organisation members than in the case of opinion leaders. This may be due to the fact that organisational interviewees may feel that they are in the same time representing the organisation, or they may project what they would believe organisation outsiders would expect them to be like. In many cases, at the organisation level, I conducted two interviews, and this had a positive effect on establishing confidence and trust. In fact, on several occasions, respondents mentioned that they enjoyed the interview, as it offered them an opportunity to reflect on various matters.

> *It's been really interesting talking it through with you, because also you helped to make things more structured in my own mind. It's the first time really that I've had a chance to talk through where my vision is, and what we're trying to do. So it has been very interesting. (Michael Seres, CEO, founder 11 Health)*

For all respondents, I presented them the ethics consent form and I offered them the choice of being anonymised. For anonymised interviewees, I have used randomly assigned initials. Additionally, I stopped recording on request and I made notes on what was requested to remain out of records.

All organisations in the research participated on average with 80% of their teams and some outside collaborators were also interviewed. This offered a good saturation of the interview data at organisational level. In addition, the variety of both interviewees and the documentarian data ensured the triangulation and a comprehensive representation of the companies' contexts. At the field level, similarly, the data was gathered over a long period of time; it was rich and diverse to ensure both triangulation and saturation.

4.9.2. GENERALISABILITY

This is one of the most important attributes of a research. To that end, I purposefully looked to ensure representativeness of cases and data, and appropriate variability to allow for robust theoretical insights. For each level of analysis, I ensured triangulation of primary and documentarian data.

In respect to the research design, the aim of an inductive inquiry is not to describe an aspect of life, but to extract "accurate, interesting and testable" (ibid., p. 26) theoretical insights from "data collected from multiple sources, analysed through constant comparisons and validated both by extant theories and on-going re-examination of the data" (Rindova & Kotha, 2001, p. 1264).

4.10. REFLECTIONS AND LIMITATIONS

This methodology may not be perfect, but I found it adequate and well-adapted to the empirically unfolding of the theoretical framework. Additionally, I found it suitable for addressing a complex and understudied phenomenon. I therefore tried to render explicit most of my endeavours, as reasonably possible. I am certain, perhaps some sections would have benefited from more detailed descriptions.

One drawback of my study is that it is spread geographically. Although this provides richness and variability of data, it is difficult to manage at times. The main reason for not limiting it on a certain geographical area, i.e. a country, was the field emergence itself, which made discoverability and recruiting difficult and lengthy. However, the geographical variety reveals interesting situations, for instance, a company originated in the UK, 11 Health, found a better market in the US, whilst one originated in Romania, Mira Rehab, found the UK to be the main market to grow into. This shows that different solutions had different appeals to different healthcare systems, but also that serendipity played an important part. For instance, in the case or Mira Rehab, the early connection with an academic institution favoured its reach in the UK healthcare system, due to early access to evidence research developed with academia and healthcare organisations.

Finally, due to time, resources and complexity constraints, I had to contain my analysis, despite the richness the data provided. However, the outcomes of the study, and the fact that it addresses a major theoretical gap make it worthwhile.

4.11. METHODOLOGY REPRESENTATION

Through the figure below, I represent the methodological approach and the operational unfolding of my research activities. This diagram includes some of the activities and insights that led to this research.

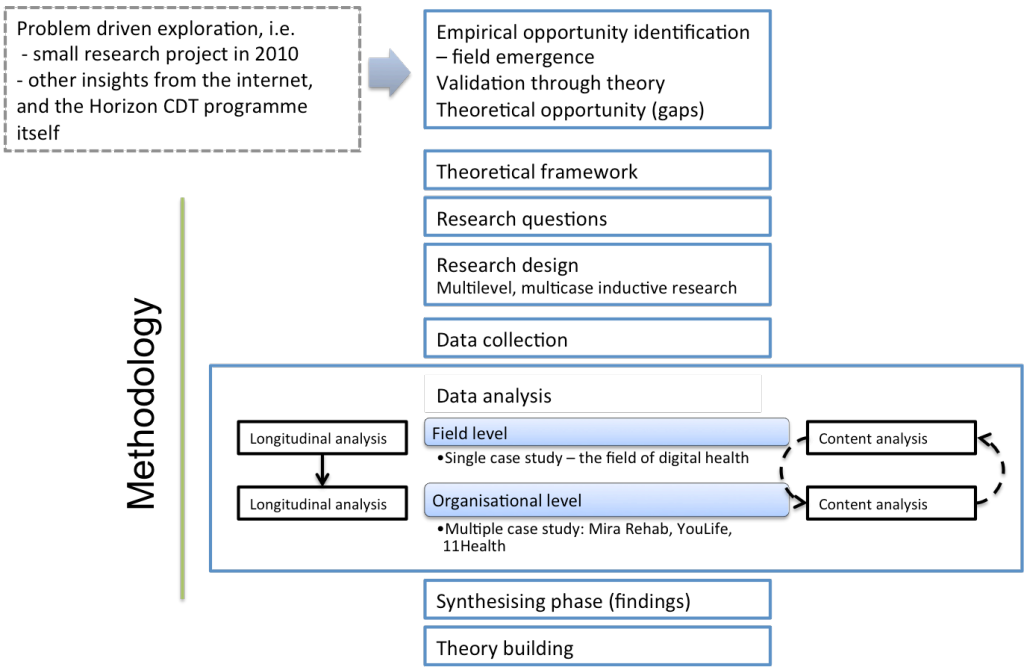

Fig. 18. Methodology overview

4.12. CONCLUSIONS

This chapter addresses the methodology employed in this research. In order to investigate the institutional complexity at its most acute instantiation – field emergence - and the institutional work organisation undertake, I employ an inductive approach. The research develops at two levels – field and organisational levels – and it is based on a variety of data to ensure reliable theoretical contributions.

CHAPTER 5. PRECURSORS OF CHANGE

5.1. INTRODUCTION

This chapter presents the main economic, technological and institutional changes that led to the emergence of digital health, at the confluence of the fast moving digital technology field and the slow paced, regulated field of healthcare. A historical timeline is provided to guide the accumulation of events. This chapter aims to ground a deep understanding of the digital health complexity and emergence.

5.2. DIGITAL TECHNOLOGIES

In the last thirty years, information and communication technologies (ICT) have penetrated many economic sectors, with promises of increased efficiency, streamline processes, optimized decision systems, integrated information management and even led to opening of new markets (e-Commerce for retailers, for instance).

ICT has a rationalisation effect on industries and organisations. For a business to be supported by an ICT system, it has to be broken down, more or less arbitrarily, to building blocks. With the penetration of the ERP (Enterprise Resource Planning) and subsequently CRM (Client Relationship Management) systems, more and more business activities were broken down and mapped as processes, entry and check points, roles and responsibilities. Initially, ERP systems took over production planning, logistics, accounting, financials, but then expanded into human resources, marketing, client management and even R&D activities. The ICT penetration introduces specific vocabularies, i.e. business modelling or six sigma (introduced by Motorola in 1986, refined in 1995 in General Electrics). For instance, Ghaziani and Ventresca (2005) found that between 1975 and 1994, the term “business model” occurred predominantly in association with computer/system modelling talk. This process of breaking down activities and processes also makes interactions between actors more visible inside and outside the focal organisation.

The ICT industries undergo a conversion phase (Mulligan, 2011), moving towards platform economics (Baldwin & Woodard, 2009; Gawer, 2011) and more recently, ecosystems (Jacobides et al., 2018).

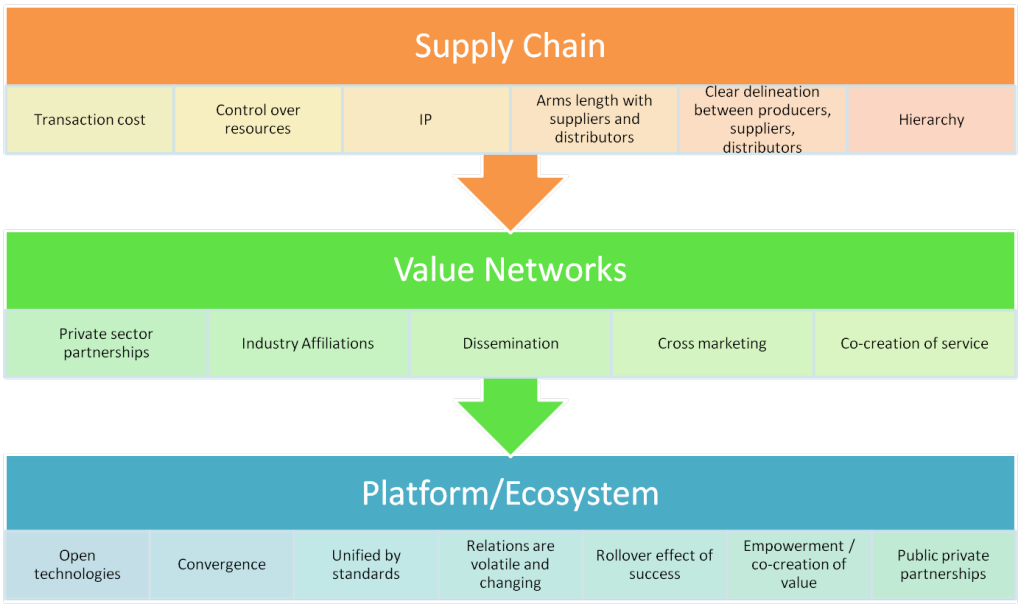

Fig. 19. Towards the digital economy

Until the 2000s, intellectual property (IP) rights were very important assets for an organisation. After this time, IP begins to be less a determinant of a company's value; platforms and ecosystems become more prevalent. Recent research on digital platforms shows that contrary to existing views from transaction economics and resource based theories, guarding technology and intellectual property is not necessarily the way to gain competitive advantage in the digital economy. Companies may use technological resources from a "common" pool and the competitive advantage emerges from value added solutions and business models rather than control over resources (Gawer, 2011; Jacobides et al., 2018). The old value chains become value networks where customers have a seat. The open source trend benefits of a lot of attention. In this age, e-services enhance tremendously due to the mobility brought in by tablets, smartphones, and improved infrastructure for digital services.

The ICT field gained a revived interest with the massive adoption of mobile phones and particularly of smartphones (since 2007 when the iPhone was launched). The iPhone was soon followed by other smartphones, and so the personal mini computer, truly mobile, proliferated.

None could have predicted that, certainly would not have predicted where we are today. I certainly would not have where we are today. (Denise Silber, Doctors 2.0 & You founder, opinion leader)

Smartphones came on the grounds of an increasingly democratised digital technology environment - with prices for ubiquitous, sensing technologies dropping rapidly and the emergence of platforms. This resulted in the fast uptake, proliferation and innovation surrounding these new digital products. The social and economic impact of smartphones is based on several factors: they are more intuitive, they can incorporate sensors, they are closer to minicomputers than phones (Boulos, Wheeler, Tavares, & Jones, 2011) and they are in your palm.

5.3. HEALTHCARE HISTORICAL CHANGE

It is difficult to understand digital health without a broader historical understanding of how healthcare developed and morphed.

Before the Second World War, healthcare was dominated by the medical profession logic, where medicine was illness centred. Vaccines created a logic shift and so preventive medicine came about. Preventive medicine, maybe along with socialist movements, created another shift in the healthcare logic - "medicine for all". And hence, the state became more involved in making the medical act more affordable and available. Before this time, healthcare was essentially a capitalist market, based on offer and demand.

Before the Second World War, healthcare was dominated by the medical profession logic, where medicine was illness centred. Vaccines created a logic shift and so preventive medicine came about. Preventive medicine, maybe along with socialist movements, created another shift in the healthcare logic - "medicine for all". And hence, the state became more involved in making the medical act more affordable and available. Before this time, healthcare was essentially a capitalist market, based on offer and demand.

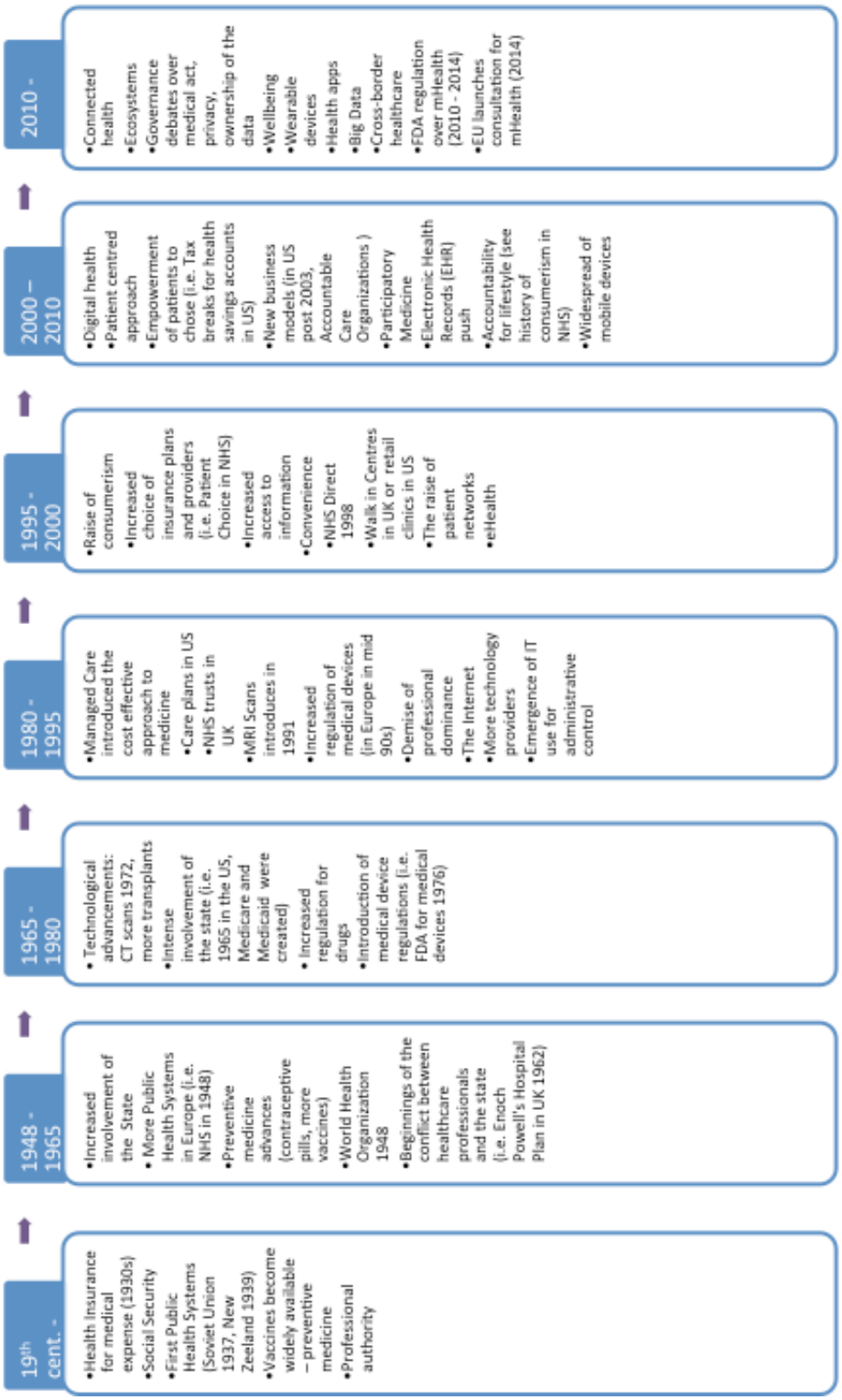

Fig. 20. Brief history of healthcare with highlights in governance changes

The next period, 1965 – 1980, is dominated by regulations (Scott et al., 2000, p. 385) related to insurance (again, interfering with the previous capitalist market dominated by professionals). Emergence of many healthcare technologies (in the broad sense - vaccines, drugs, contraceptive pills, radiology) increased awareness for associated risks, and therefore regulations were expanded to medical devices and drugs. Regulation in healthcare did not always have the focus to constrain, but it was concerned with innovation too. "Patient advocacy groups influenced a law to stimulate industry interest in developing so-called orphan drugs for rare diseases, and they played a role in the agency's development of accelerated techniques for drug approval, beginning with drugs for AIDS" (Swann, 2003, p. 14). And so, regulations in this period facilitated the production of generic drugs (ibid.). These are also the times when patient voices began to be heard.

In the 80s, managerial theories penetrated the healthcare sector. "...[F]ederal involvement in healthcare, designed to be compatible with professional interests, unseated professional dominance indirectly through the profusion of conflicting governance structures that followed the federal program" (Scott et al., 2000, p. 386). Adding to this, the state, which took upon itself the cost of most healthcare expense, realised that demand had to be controlled. "Managerial-market logics were not directly related to either of the two primary logics or to fragmentation. Legitimated by the rise of the medical costs, business interests appear to have been the beneficiaries rather than the cause of the decline in professional dominance" (ibid.). Managerial theories were dominated by value chain, efficiency, centralised procurement, and resource scarcity. This time marks the divide between the professional and managerial personnel in healthcare.

In the mid-90s, the internet changes the rules of the game and terms like eHealth emerge. Information and knowledge become commoditized, democratised. The doctor – patient relationship is less asymmetrical when it comes to information, due to its escape into the digital space. What used to be knowledge accessible to elites only now becomes available to all. Managerial mind-set changes again, partially due to conflicts with healthcare personnel, partially due to discontent from patients. Patients become consumers with

expectations and healthcare is looking again for ways to satisfy doctors, patients and payers.

In this context, the 2000 – 2010 period is characterized by an information afflux and is dominated by changes caused by the digital economy. Customers in all industries become more empowered. Partially due to the massive increase in healthcare costs due to change in demographics - aging population and huge increases in chronic diseases (diabetes, asthma, chronic congestive heart failure etc.) - and partially due to the widespread use of digital technologies (including the fast spread of mobile devices), the debates over the role of the patient intensify. Patients are seen as customers, drivers of change, resources for managing illnesses, contributors of data for research... The repositioning of the patients challenged again the relationship with healthcare professionals and the healthcare system as a whole.

5.4. How digital health came about

Around 2010, "eHealth", "mHealth" and "digital health" terms become prevalent and intrinsically related to healthcare.

5.4.1. Brief terminology clarification

Before I proceed, and even though this research does not aim to contribute to the terminological debate, acknowledgment of the main terms and the relationships between them is needed, in order to clarify the terms used in this thesis. I choose to use **digital health** to designate the broad field where healthcare meets digital technologies, as it became prevalent over the last decade. This is the emergent field that is the focus of my research. The term 'mHealth' was used at least since 2005 (Istepanian, Laxminarayan, & Pattichis, 2006), but it gained momentum once the smartphones were massively adopted. Although there are many years since the term 'digital health' emerged, 2007 could be its official birth. A search (on July 2014) on Google Scholar for articles containing the exact phrase "digital health" between 1990 and 2014 rendered 3310 results, of which 2740 are between 2007 and 2014. Similarly, eHealth term - used at least since 1999 (Della Mea, 2001) - for the same periods, Google Scholar returns 18,500 results and 17,300, respectively.

Except Twitter, "every platform including news publications favor digital health as the term" (Davis, 2015). Comprehensive explanations and definitions of the evolving terminology pertaining to this field are provided in appendix C.

> *It's a very broad field that involves everything from internet to apps to CT scanners, everything really. Every use of tech in healthcare, regardless of who uses it. (Sara Riggare, patient researcher, opinion leader)*
>
> *[Digital health is the] improvement of health and healthcare in the broad sense of the words, with the help of tools that are digitally connected. (Lucien Engelen, healthcare intrapreneur, opinion leader)*

Whilst I use the term "digital health" for all things health IT, in congruence with its use in the industry, it is important to point out that a distinction is needed between the administrative tools and tools employed for interacting with the patient (Djellal & Gallouj, 2005). At the organisational level, my research is looking at collaborative digital health technologies (CDHT) producers, who build interactive solutions for various stakeholders in digital health. These are digital technologies used in relation to health and wellness and involve (directly or indirectly) heterogeneous beneficiaries (herein called stakeholders) - amongst them technology producers, patients, carers, citizens, medical doctors, non-physician personnel, insurers, infrastructure providers, system integrators, technology service providers, health or social care providers, call centres, regulators… The definition of CDHT for the purpose of this thesis is *pervasive and/or sensing digital technologies that are intended to support people's wellbeing, either by helping them staying well physically, mentally or socially, or by helping manage medical conditions they are confronted with*. CDHT are technologies that help medical and other organisations deliver wellbeing and healthcare to people. CDHT could be ambient or ubiquitous, allow for multiple user categories (patient, carer, doctor, healthcare organisation, support organisation...), involve user management or engagement, and, possibly but not necessarily, monitoring of body functions.

5.4.2. STARTING FROM THE BEGINNING

It is beyond the purpose of this research to assess, predict or advocate the impact of digital technologies over the future of medicine and healthcare. What I present below is a broad picture of how ICT technologies impacted healthcare over time, with the purpose to situate the research, which begins from 2007 onward, having as time mark the introduction of smartphone.

> *„[T]he 'smartphone industry' is eating the world (...). As well as acting as the centralized repository for connected third-party devices the smartphone itself is packed with a range of intelligent sensors that can – and are – being used to help people improve their health". (Stephen Davis, consultant, Bionicly online article) (Davis, 2013).*
>
> *I think that the smartphone is one of the pivotal aspects of digital health. It's the conduit through which information flows, it can travel. And the development of the smartphone and its processing power has enabled people to create what I call "care at a distance". So now we can measure and manage wellness using telemedicine, or for people around the world, not only around the corner. So this smartphone is an important tool that is part of digital health. (John Nosta, digital health evangelist, opinion leader)*

In May 2015, I wrote a brief history of digital health that was well received by the industry, via two articles. Based on these articles, the infograph below was produced by the Digital Catapult Centre, a UK governmental agency dedicated to foster innovation and collaboration across digital industries and academia,.

Fig. 21. Digital health infograph by the Digital Catapult UK (2015), based on my original articles published on nuviun (Macnaughtan, 2015b, 2015c)

I will use some extracts from the article "The Curious Case of Digital Health" (Macnaughtan, 2015b) to briefly describe these stages.

5.4.2.1. Prehistory (1897 - 1985)

"First, there was telemedicine... Darkins and Cary (2000) find that the first remote diagnosis reported in a journal was in 1897, when a child is diagnosed with croup cough via the telephone. Between the mid '70s and the mid '90s, the interest in telemedicine is conserved for space and Antarctic expeditions, remote explorations or military interventions (ibid.). Imaging technology benefits most from digitization. Two significant industry associations are founded: COCIR (1959) and HIMSS (1961)." (Macnaughtan, 2015b)

5.4.2.2. The hit wave (1985-1999)

"This age is dominated by lateral creative thinking, the era of managerial visions and magic changes. "One size fits all" solutions are tested, not only related to information and communication technologies (ICT), but to many areas of healthcare. However, the ICT visionary bubble is not sustained because of a general disconnection between the main stakeholders - the ICT and medical community. (…)

New terms emerge: Health Informatics, Telemedicine, Telecare

Nonetheless, several professional associations appear, i.e. the International Medical Informatics Association (1989), the American Telemedicine Association (1993), the UK Telecare Services Association (1995), and EHTEL (1999). A few health information providers set ground as well (i.e. WebMD in 1996, Medline Plus in1998).

Towards the end of this period, the demise of managed care makes the patient more visible. 'The shift to consumerism is driven by a widespread scepticism of governmental, corporate, and professional dominance; unprecedented economic prosperity that reduces social tolerance for interference with individual autonomy; and the Internet technology revolution, which broadens access to information and facilitates the mass customization of insurance and delivery' (Robinson, 2001)." (Macnaughtan, 2015b)

5.4.2.3. The insights age (2000 - 2009)

"At this stage, there is a general impatience with digitizing healthcare. Several national Electronic Health Records initiatives are deployed with success (Israel), and relative success (Canada) — but mostly with sound failure (i.e. UK, Germany, Australia).

New terms emerge: eHealth, Digital Health, mHealth, Connected Health, Personalised Health, Telehealth.

A lot of effort is put into assessing the benefits of telehealth and telecare programs. 'Evidence is the name of a battle that has been won' concludes Nicolini (2009, [my addition p. 15]) - because healthcare innovation is a political process in which scientific arguments represent only a forum for debates (…).

In January 2008, the European Union (EU) launches the Lead Market Initiative, where eHealth is identified as one of the most promising markets. The Health Information Technology for Economic and Clinical Health Act (2009) sets an agenda for the US to invest in promoting the use of ICT in healthcare. In the same year, a first of its kind industry event, the mHealth Summit (US) gives the market a positive indicator.

Starting in 2006, the first niche market report on Digital Health is produced by Parks Associates. Several professional associations are formed, i.e. Continua (2006) and mHealth Alliance (2008). (…)

Imaging technologies, health content providers (i.e. WellDoc founded in 2005) and patient networks (i.e. PatientsLikeMe founded in 2004) are the main beneficiaries of this period. There are only a few wireless sensing device companies, i.e. Monica Healthcare (2005) in the UK, or Fitbit (2007) in the US.

'Issues of scale and complexity in healthcare are only just beginning to be understood in relation to eHealth' (EHTEL 2009). During this age, it is acknowledged that despite notable national ICT failures, the future of healthcare will require a digital framework. Additionally, there is a realisation

and understanding that the use of ICT in healthcare will include the need to address specific requirements - such as infrastructure, interoperability, legal issues, etc. There is an overall sense of disillusionment, which carries over to the next age." (Macnaughtan, 2015b)

5.4.2.4. The great expectations age (2010 – ...)

The idea of patients being an underused resource in healthcare was launched long ago (Lott, Blazey, & West, 1992), but it is now that it becomes a political priority. This is a consequence of the demographic trends showing that more people are living longer with chronic conditions and of the rising costs of healthcare. In 2004, the EU eHealth Action Plan (European Commission, 2004) highlights some of the barriers for adopting digital technology in health, i.e. regulations or infrastructure.

"The pervasiveness of technology (mobile devices, open source, APIs...) converging with the urgency of overwhelmed governments burdened by demographic issues leads to the emergence of lay-people at the forefront of the Digital Health vision. What we see now is an intense interaction between stakeholders and industries, and an emerging/exploding market at the crossroads between consumer digital technologies, medical devices and healthcare. New terms emerge: Wellbeing, Wearables, Insideables, Apps, Quantified Self, Gamification, Health 2.0, Big (Health) Data. Presently, Digital Health is emerging as a standalone market, with multiple stakeholders stumbling in uncertainties and debates. Whilst the digitally geared up patient/person is still waiting for a role to be written, Digital Health will find its way only by negotiating a new logic of health, wellness and care." (Macnaughtan, 2015b)

The launch of the iPhone (2007) was a game changer not only for digital health, but for other industries too. However, there were many factors that stimulated a new wave of interest in using digital technology for health. Mobile, sensing and affordable technology was not the only factor responsible for the digital health rise, there were also economic, politic and even social factors.

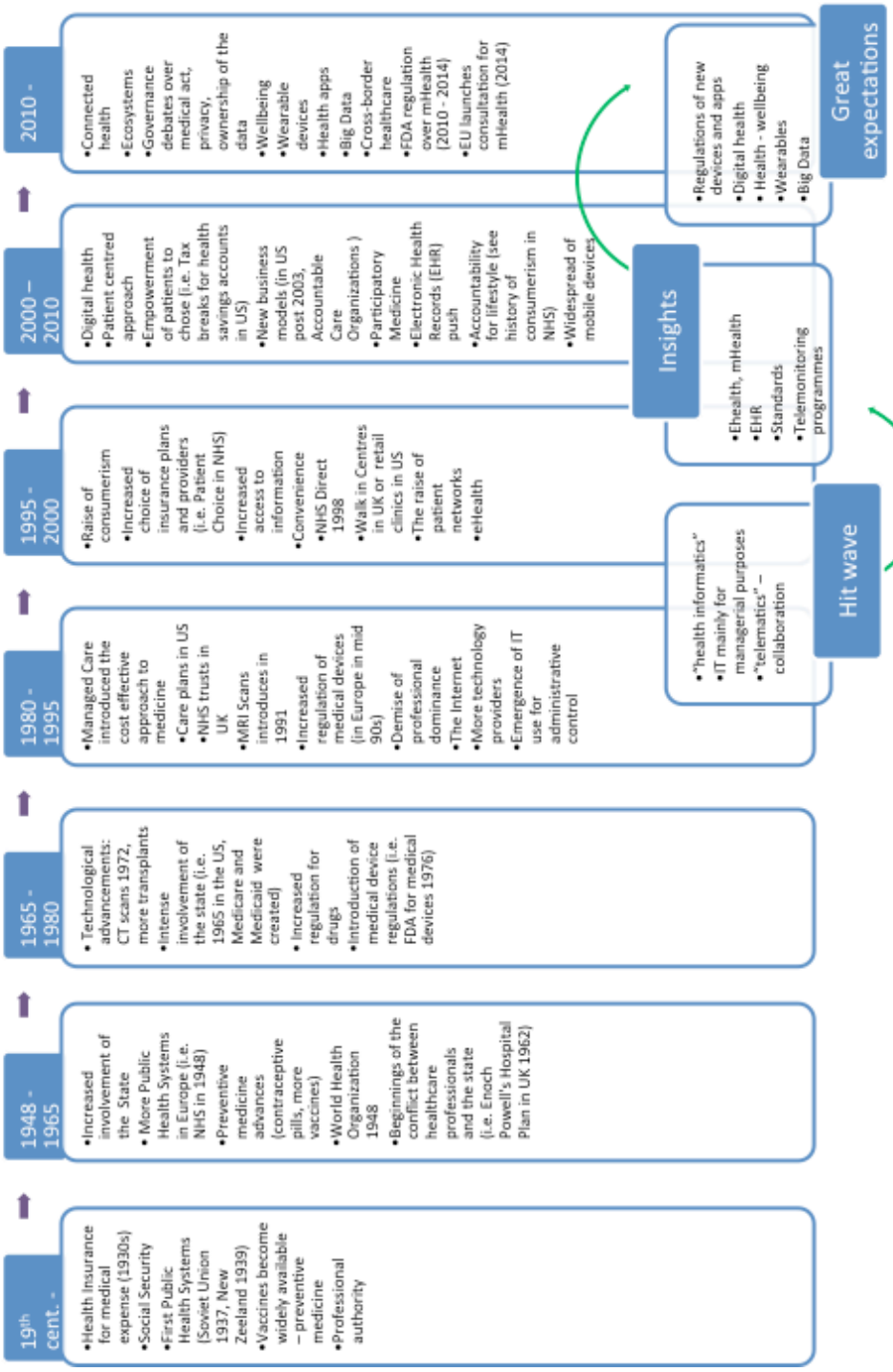

Fig. 22. Synthetic view of healthcare and digital health history

5.5. CONCLUSIONS

In this chapter, I present a broad overview of the changes in the digital technologies and healthcare fields to reveal the institutional context of digital health emergence. I make a few terminological clarifications and I build a brief history of healthcare encounter with digital technologies. I have therefore completed the prerequisite for the analysis of the field, which unfolds in the next two chapters.

CHAPTER 6. DIGITAL HEALTH INSTITUTIONAL LOGICS AND STAKEHOLDERS

6.1. INTRODUCTION

Having laid out in the previous chapter the broad picture of what led to the emergence of digital health, this chapter focuses with one component of its institutional complexity – pluralism. This is exemplified by the multitude of institutional logics at play and their representatives. As discussed in the theoretical framework chapter, it is important that logics are documented as they unfold, with no prior preference for a limited number. Presenting all logics at play has theoretical relevance, particularly because the field is in a formative stage and any selection might present an undesirable bias. I describe each of the five logics identified – state, medical profession, citizen, market and science - and their representative stakeholders with their relative power – incumbent or challenging. Chapter 7 will continue with the other element of complexity, the field emergence, by describing the process of institutionalisation as it unfolds via concurrent processes of hybridisation and conflict.

6.2. MAIN HISTORICAL INSTITUTIONAL CHANGES IN HEALTHCARE

It is at the field level "where organizations in interactions construct their 'collective rationality'" (Scott, 2008, p. 217). This 'collective rationality' relates to the neoinstitutionalist understanding of institutions as "irrational influences... [and] frameworks for rational action" (ibid.). Understanding the logics of digital health will deepen and contextualise the understanding of how CDHT producers navigate the fragmentation and ambiguity of this field. "Just as the attributes and actions of a character in a play are not fully comprehensible apart from knowledge of the wider drama being enacted – including the nature and interest of the other players, their relationships, and the logics that guide their actions – so we can better phantom an organisation's

behaviour by seeing it in the context of the larger action and meaning system in which it participates" (ibid., p. 209).

It is generally agreed that healthcare went through three major stages of institutional framing (Currie & Guah, 2007; Scott et al., 2000), albeit with significant fragility (Currie & Guah, 2007; Nigam & Ocasio, 2009; Pouthier et al., 2013; Scott et al., 2000).

	Institutional Ages		
US (Scott et al., 2000)	**Era of professional dominance** 1945–1965 Professional control Non-profit ethos	**Era of federal involvement** 1966– 1982 Passage of Medicare and Medicaid – government regulation Public control Equity of access Consumer health movement	**Managerial control and price competition** 1983– Market and managerial mechanisms Cost containment Efficiency
UK (Currie & Guah, 2007)	**Era of professional dominance** 1948–1971 Public sector ethos Professionalism Self-regulation	**Era of managerialism** 1972–1997 Private sector ethos Performance Government regulation	**Era of market mechanisms** 1998– Patient-centered ethos Consumerism Public value

Table 9. Change in the institutional context in two different systems – single and multi-payer health systems

Although the names of the ages may be different, they point to similar institutional changes, with a slight temporary delay. As shown in the previous chapter, the evolution of healthcare as institutional field has many commonalities across countries. The increased involvement of the state, as well as the technological advances led to fragmentation. This fragmentation happens also inside the healthcare profession itself, being one of the factors that led to the demise of the professional power. The increasing bearing of technology and the change in state's approach led to an increased number of stakeholders that make various claims.

In the case of digital health field, due to its state of flux, it would be unfruitful to attempt a definition of the field logic. Instead, I will describe the institutional context through the logics at play and their relative influence.

All participants in the emerging field of digital health are stakeholders, meaning they bring goals, expectations and institutional logics, which motivate

or constrain them. The figure below offers a simplified view of the changes in the dynamics between three of the main stakeholders in healthcare, doctors, payers and patients. However, many other stakeholders populate the healthcare field, even if they do not occupy such a central or visible place: technology producers, carers, pharmaceutical companies... The state, for instance, one of the main stakeholders, is not represented here. Nonetheless, it illustrates that changes in the institutional environment of healthcare are still on-going.

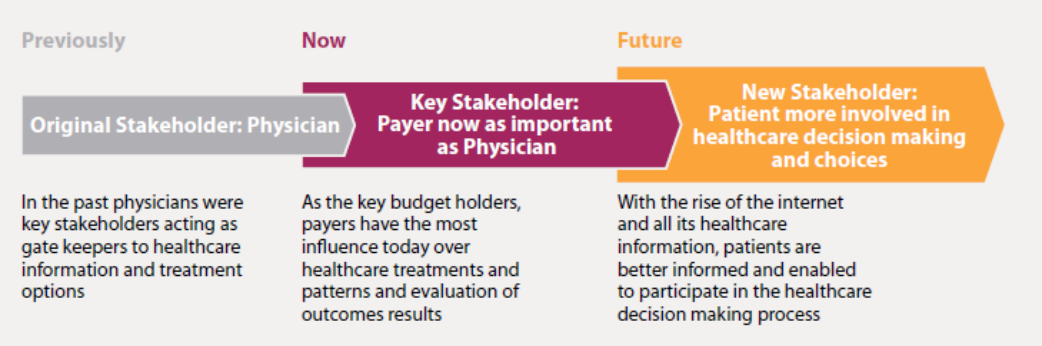

Fig. 23. Evolution of some of the healthcare stakeholders (IMS, 2013, p. 3)

6.3. Institutional logics and stakeholders in digital health

Digital health develops mainly at the intersection of healthcare and digital technology and is populated by diverse stakeholders. Imminently, the accumulation of stakeholders brings both a diversity of logics and great complexity. In this chapter, my only aim is to focus on the main logics and their representative stakeholders.

I have found and documented five institutional logics in the emerging digital health field: state, medical profession, citizen, market and science. As described in the methods chapter, the content of the institutional logics is derived through an iterative process between data collected and the institutional literature.

The institutional logics are described as ideal types, and stakeholders carry them in more or less pure forms (Scott, 2008; Thornton et al., 2012). For instance, doctors are dominated by their professional logic, but might make choices rooted as well in personal values (citizen logic). For example, along with the commitment to save lives, some medical professionals support the

assisted dying as a form of care and respect for the patient. Another example is that in the case of childbirth, some doctors consider natural birth safer; others favour caesarean interventions for the same reason. Stakeholders are identified through their field level interactions (Scott, 2008) and are relevant at the time of data collection. This is important to stress, because they may change with the evolution of the field.

6.3.1. The state logic

The state logic is focused on collective welfare through rationalisation and uniformity (Friedland & Alford, 1991; Scott, 2008). In the rational market view, the state should only guarantee the individual property (ownership) and the right to sell, and the market should be able to take care of the rest (Alford & Friedland, 1985; Fligstein, 2002). But, the welfare state doctrine has at its core the idea that capitalist markets are not capable to ensure the welfare of its citizens, and that disfranchised individuals (women, elderly, children, lately the unemployed) need protection. Therefore, the main function of the contemporary states remains to ensure a capitalist market and through a system of tax to redistribute wealth, despite the proliferation of the neoliberal agendas. The neoliberal philosophy is focused on the overall increased wealth of a state, rather than its redistribution. This economic approach had a slower uptake in sectors like education or healthcare, particularly in Europe (Beach, 2010). Or, when enforced, it did not prove necessarily a positive impact (Bates, 2014; Beach, 2010; Phillips, Henderson, Andor, & Hulme, 2006).

> *While new 'workfare' principles have often emerged, these have not always led to improved social conditions. Indeed, the opposite has often been true and, as a consequence, concern has been directed to the origin and nature of social policy change. (Phillips et al., 2006, p. 585)*
>
> *[A] lack of focus on redistribution has had a significant negative impact on many apparently wealthy societies in terms of both general wellbeing and economic growth and efficiency. It is clear that for many researchers in this field deepening inequality is not simply a moral issue, but one of social and economic inefficacy. (Bates, 2014, p. 389)*

The idea promoted by the neoliberal philosophy that there is no need to prioritise redistribution, as everyone will be better off simply by taking care of the bottom line wealth of the nation, leads to a shift from welfare to workfare including in healthcare.

> *The collision and confluence at the site that is known as the individual, of contemporary influences such as neo-liberal thought, market-based notions of health and health care, individual responsibility for health, the individual's right to choice and to choose, the quest for certainty (such as the evidence-based movement), and an increasingly uncertain world produce new and refracted understandings of health and health care. (Cheek, 2008, p. 980)*
>
> *Neoliberalism encourages individuals to give their lives a specific entrepreneurial form. (...). This participation has a 'pricetag': the individuals themselves have to assume responsibility for these activities and the possible failure thereof. (Swyngedouw, 2005, p. 1997)*

In healthcare, the neoliberal view translates in transferring more responsibility to the citizen, to the patient, who becomes a *consumer*. Not simply a consumer, but a responsible one - both entitled to and responsible for their health choices (Cheek, 2008; Crawford, 1980; Phillips et al., 2006).

> *Daily, governments and individuals speak of, or are spoken to, about pursuing health and/or healthy lifestyles, achieving health, having responsibility for and/or being responsible with respect to health. (Cheek, 2008, p. 974)*
>
> *Medical care, after all, is an area in which crucial decisions — life and death decisions — must be made. Yet making such decisions intelligently requires a vast amount of specialized knowledge. Furthermore, those decisions often must be made under conditions in which the patient is incapacitated, under severe stress, or needs action immediately, with no time for discussion, let alone comparison shopping. (Paul Krugman, 2011, The New York Times article)*

The state's influence on healthcare began after World War II and, at first, it was preoccupied with supporting medical professionalisation. Before the '70s, it became preoccupied with social inclusion and affordability of the medical

act, to end up being increasingly concerned with limiting costs. "Finally, as health expenditures [...] escalated rapidly during the 1970s, cost containment began to overshadow the concern for equity and even to challenge the value of quality" (Scott et al., 2000, p. 217). The neo-liberal agenda placed further pressure on healthcare systems, already under the mantra of "managed care" and limited further the professional autonomy (Leicht & Fennell, 2008).

> *I have faith that intelligent and educated people [n.b. doctors] understand by now that the sole difference between progressive and conservative agendas is a personal preference to have your serfdom managed either through a government intermediary, or directly by the business overlords. (Margalit Gur-Arie, doctor, Kevin.MD article, 2015)*
>
> *Go ahead, take over the cockpit and storm the O.R. Fly your own plane, remove your own tumour. [...] Give the carcass of expertise a good kick as you go by. (David L. Katz, doctor, LinkedIn article, 2015)*

The state is operating on the basis of consensus and tries to regulate activities based on resources and general contribution to collective good (Thornton et al., 2012). The greater good, however, is defined differently at different times in history. The participation of the electorate is discontinuous, through the democratic institution of vote. Sometimes, public organisations create ways for the citizens to get involved in a more continuous manner, other times, citizens get involved through activism, hacktivism (use of the digital to promote political change), non-governmental organisations (NGOs) or public manifestations. Current trends from governments to make public data available ("open data") may be seen as a way to counteract existing neoliberal philosophy across the board, but voices remain sceptical if disclosures are not being controlled to rekindle public trust in the commodification of public services (Bates, 2014). However, access to public big data and information is still in its infancy and it is difficult to predict its transformative effect on economic sectors, societies and governments.

Although perceived mainly in its coercive capacity, the state is also one important factor for facilitation of innovation, technical or social (Christensen et al., 2009; Fligstein, 2002; Mazzucato, 2013). Whilst there may be tensions

between the welfare and neoliberal doctrines, it may be that a new hybrid view is on the rise, at least when it comes to sectors like education or healthcare – the "entrepreneurial state" (Mazzucato, 2013). In this new view, the welfare supports the workfare function, as a function necessary for the expansion of capitalism, which converts "other value forms (e.g. the physical and emotional capital of education and care work) into objectively economic forms and their products" (Beach, 2010, p. 562). Arguably, the opposite is also true, in the very Schumpeterian sense that innovation, entrepreneurship is the engine of democracy and the overall social welfare (Mazzucato, 2013; Schumpeter, 1950). In this paper, I only underline such tensions as they become relevant for the development of digital health. Being one of the pillars of the healthcare system, as we know it, the state logic is an incumbent logic in the emerging field of digital health. The representative stakeholders are the payers (or insurers) and regulators.

6.3.1.1. Regulators

The state operates through a bureaucratic apparatus, which tries to rationalise and implement policies or safeguard laws. The increased involvement of the state creates difficulties for the private sector, because it "constraints the corporate responsiveness to the changing markets and also because of the uncertainties created by unstable political control over bureaucracy" (Alford & Friedland, 1985, p. 430). The various agencies upon which the state relies to rationalise resources and safeguard policies, also bread professionals who have incentives to "maintain their positions, enhance their careers, mark off their jurisdictions" (ibid., p. 430). Because in a democratic state, civic participation is important, these institutions have to create or at least offer the appearance that public voice is captured (i.e. the Health Watch in the UK health system). "In this process of increasing the predictability of their specific environment, public bureaucracies incorporate external constituencies, blurring the boundary line between private and public sectors, as they establish powerful interest groups inside and outside the state with a stake in the preservation of the agency" (Alford & Friedland, 1985, p. 436).

These entanglements of public – private sectors and civic participation result in very complicated fields, such as healthcare (Christensen et al., 2009; Harvard i-lab, 2014).

> *There could be too many people in between, kind of getting in the way, the doctors and their patients. I think we unnecessarily complicate that and I think we have incentivised the wrong things (medical interventions over human interactions lots of times) and that had a ripple effect on what the system wants to do. (Dave Chase, entrepreneur, opinion leader)*

Similarly, pharma or medical device companies are subject to time consuming and very expensive regulatory and certification processes. Moreover, in some countries, these are topped up by other endeavours to produce evidence for economic or clinical benefits in order to access the healthcare distribution channels (i.e. NICE in the UK). This traps healthcare "in the expertise-intensive world of high costs" (Christensen et al., 2009, p. xlviii), a market with high barriers to entry.

Christensen et al. (2009) consider that innovation is enabled by technology, new business models or new networks of value. The last one, points to the institutional change at field level. I am using their representation below to show the importance regulators have in any industry to stabilise it and create "rules of the game", but most importantly in regulated areas, like healthcare. The downside is that state agencies have a tendency to self-perpetuate. And so we have healthcare with regulations running so deep – reimbursements being only one aspect. "When the government is everywhere, innovators can't go where the regulators aren't, in order to initiate disruption" (Christensen et al., 2009, p. 399). Obamacare, by introducing a new form of reimbursement based on population outcomes instead of individual medical acts, is an attempt to innovate the reimbursement model.

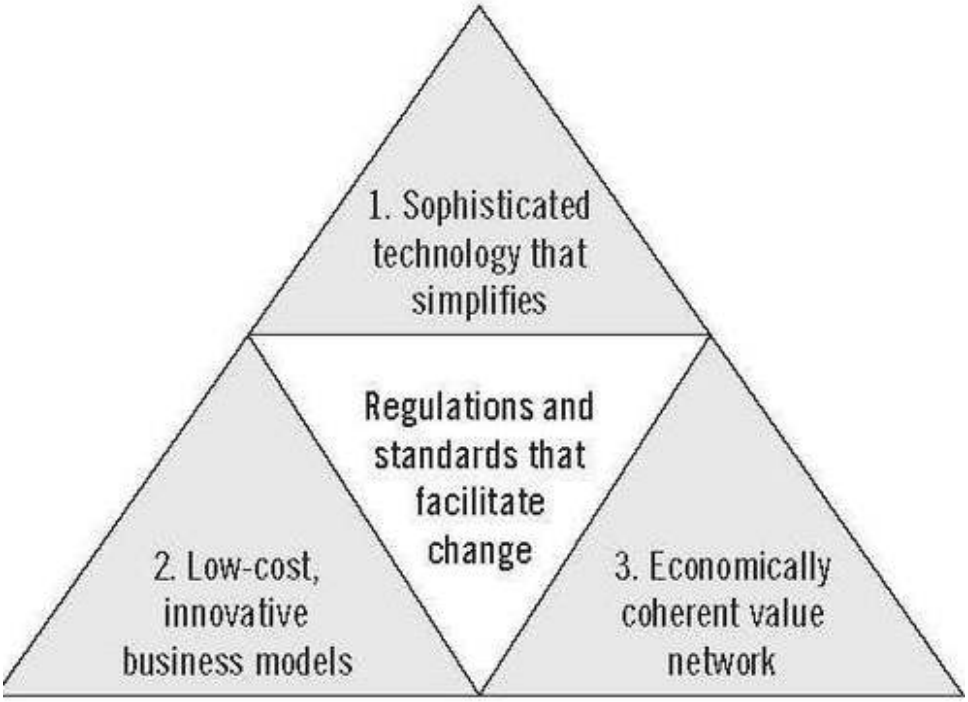

Fig. 24. "Elements of disruptive innovation" (Christensen et al., 2009, p. XX)

Regulation is only one reason to explain healthcare's resistance to change. Other reasons would be fragmentation of the field, safety and efficiency concerns, scarce resources, conflicting logics, but regulation remains one central concern. The same authors consider that regulators' concern should not just be to stabilise a field, but also to enable competition, and, even further, to facilitate "*disruptive* competition" (ibid., p. 393).

At the intersection of healthcare and technology, there is an on-going conversation about regulation and deregulation. There have been concerns that regulation would limit innovation, on the other hand supporters say that regulation could enhance it.

> *There are those who believe that government should stay out of health IT altogether: it can only mock things up. I disagree. First of all, no one else can enforce public goods like interoperability and security – the market just won't do it. (Bob Wachter, doctor and professor, opinion leader) (R. Wachter, 2015, p. 216)*
>
> *You can't have a blanket statement. Just because you have a regulation, doesn't mean it's an intelligent one and often it exists to*

protect incumbents and doesn't serve patients very well. (David Shaywitz, doctor entrepreneur and journalist, opinion leader)

Such opinions show that regulation is needed in healthcare and other markets, but it requires higher adaptability to the current economic and technological landscape.

6.3.1.2. Payers

Healthcare is expensive for all participants to the system: patients, carers, insurers, and, without the support of employers and the state, most people would not be able to afford it (Christensen et al., 2009). Regulators' tendency to overreach in healthcare manifests often through the iron cage of reimbursement (ibid.). Christensen et al. (2009) offer an interesting history of reimbursement in the US (ibid., pp. 223 - 230).

Payers are often state agencies, as most healthcare systems have a combination of state and private healthcare. Even when payers are entirely private, they have to comply with strict regulations and this makes them similar to public ones. Hence, payers mix the logics of the state (subject to regulations and/or budgets) and of the market, depending on how much their financial model relies on the state. They also have to embrace or create a relative equilibrium with the medical professional logic, and this depends on the proximity to healthcare providers. There are even healthcare providers that are also insurers (BUPA in the UK or Kaiser Permanente in the US).

The balancing act between coordination and co-optation (of patient groups, private sector organisations) results in fragmented authorities to the extent that none of these organisations have enough authority for the whole, and so this adds to uncertainty and irrationality (Alford & Friedland, 1985; King's Fund, 2013). A great representation of this complexity is provided by King's Fund representation of the NHS.

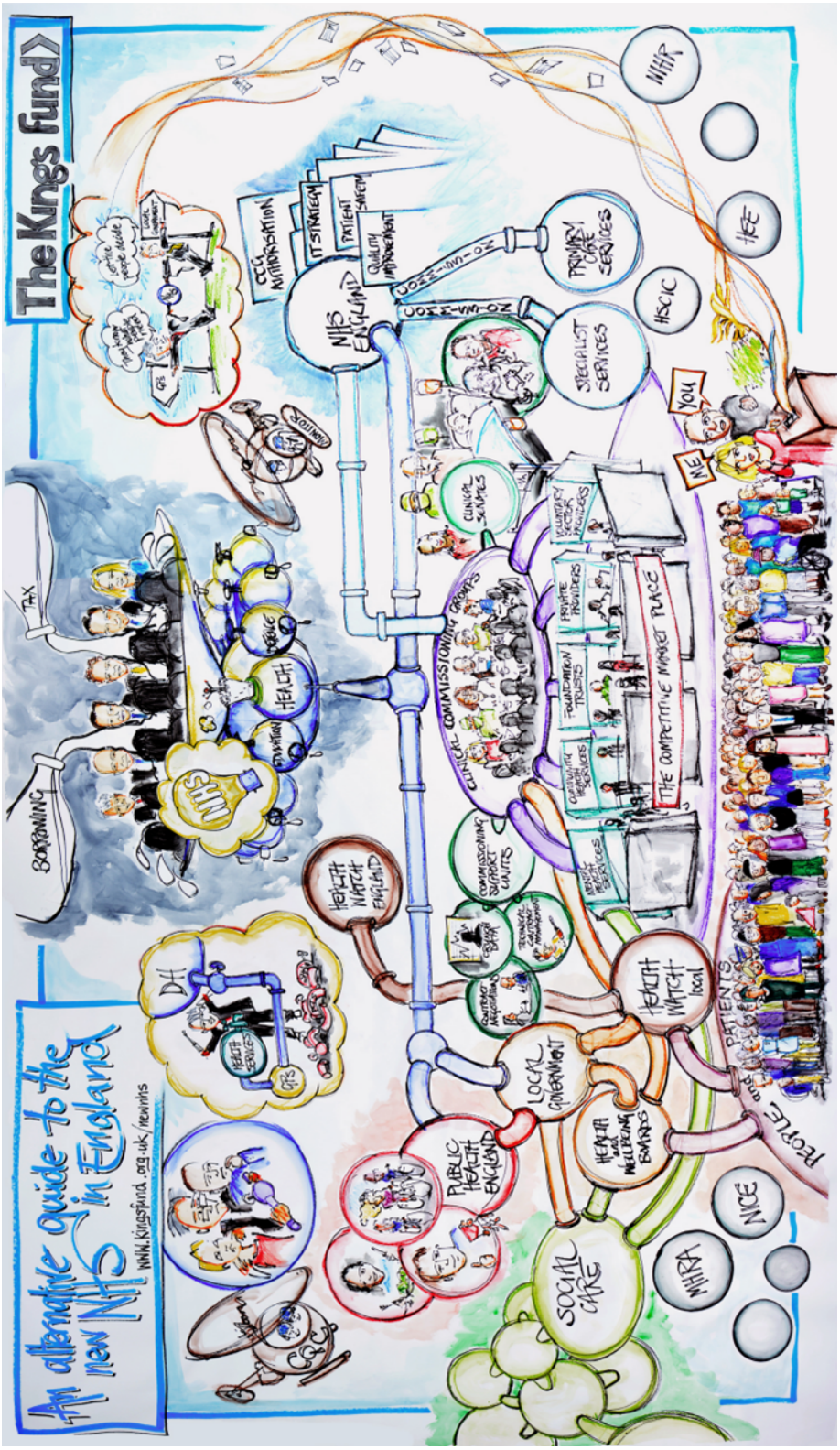

Fig. 25. An attempt to simplify the very complicated system of the new NHS (King's Fund, 2013)

The logic of the payers (state or private) is based on resource utilisation and efficiency (market), not aimed at personal, but rather population health outcomes (state). They manage demand and offer through rationalisation of resources, and therefore innovation is welcomed as long as it proves to reduce costs, not always better health outcomes, as valued by healthcare professionals.

6.3.2. The medical profession logic

A professional logic means that its representatives have access to a body of knowledge, are licensed to employ it and have autonomy in their decisions (Abbot, 1988; Leicht & Fennell, 2008; Scott, 2008). Traditionally, professionals are legally mandated guardians of a body of knowledge, upon which they have autonomy, and they are licensed and overseen by self appointed peers and arbiters, usually through a lengthy or costly process (Abbot, 1988; Leicht & Fennell, 2008; Scott, 2008). Professionals are considered to be one of the forces that oppose the power of the state (Alford & Friedland, 1985; Selznick, 1951).

6.3.2.1. Doctors (and other healthcare professionals)

Over time, various players have penetrated the healthcare field, and consequently, the professional authority and legitimacy of doctors has been challenged, contracted (Leicht & Fennell, 2008; Scott et al., 2000) and their professional realm has been fragmented (Dunn & Jones, 2010; Pouthier et al., 2013). Presently, the healthcare field is subject to a plurality of logics (Nigam & Ocasio, 2009; Pouthier et al., 2013; Waldorff et al., 2013), which gives space to vulnerabilities, lack of coordination, irrationalities (Alford & Friedland, 1985; Christensen et al., 2009; Waldorff et al., 2013). As shown in the previous section, "[t]he rationalization of each state agency renders the state bureaucracy as a whole increasingly irrational" (Alford & Friedland, 1985, p. 437).

The implication of the state in healthcare over time changed in scope: from making healthcare affordable and available, to making it efficient and, lately, to making it participatory.

I think that when you have the right processes in the right philosophy, I think you will have the patient naturally participate in that as a team member. (Dave Chase, entrepreneur, opinion leader)

We haven't understood the motivations well enough or there isn't the payment structure in place that participation can be rewarded to the carers. (Colleen Young, communications, opinion leader)

Healthcare, from a field where professional logic dictated what is best, became an arena where bureaucracy set in, as well as political struggle. This led to an increased fragmentation and politicisation of the medical profession, and to a salient conflict between the competing state, market and medical profession logics.

The relationship between a doctor and a patient does not feel transactional now and I don't think it will then. Rather it will remain vital, scary, ethically charged, and deeply human. (Bob Wachter, doctor and professor[3], opinion leader) (R. Wachter, 2015, p. 277)

Healthcare is really complicated, it's hard to make things happen, and also human physiology, human disease is really complicated. Look at chronic diseases - heart problems. (David Shaywitz, doctor entrepreneur, journalist, opinion leader)

Moreover, the digital changed profoundly the area of medicine, which used to be a confined space, reserved for professionals only (Lupton, 2013, 2014b; Nettleton, 2004).

Analogue medicine	Digital medicine
Body as a standalone machine	Cyborg
Disease – pathological problem	Disease – communication problem
Insides of body seen by surgeons mainly (doctors)	Insides of body seen possibly by all (internet)
Medical knowledge	Medical information
Art of medicine	Evidence based medicine - > Participative
Patients have lay beliefs	Patients produce medical knowledge
Doctors manage disease	Expert patients manage illness

Table 10. Digital transformation of medicine, adapted from "The Emergence of E-Scaped Medicine?", by Sarah Nettleton (Nettleton, 2004, p. 666)

[3] Interestingly, Bob Wachter, MD and Professor of Medicine (UCSF) is also the most known leader of the "hospitalist" movement, which went against the regulators (see Chapter 3 and Poulthier et al., 2013).

Apart from the exogenous factors like politics, markets and technologies, the medical profession logic has its own intricacies. For instance, although medicine is based on science, it can take a long time for scientific breakthroughs to enter clinical practice. For instance, it took 39 years for the cochlear implant to become marketable (Van de Ven & Gardu, 1993). Dunn and Jones (2010), in their analysis of the medical education, showed how doctors are performing under a blend of science and care logics. The science logic favours innovative and efficient diagnostic and treatments, whilst the logic of care represents "compassionate, preventive care to patients and treat them as whole people rather than simply diseases" (Dunn & Jones, 2010, p. 117). Even if these logics co-exist, the specialist doctors would favour the first, whilst primary care doctors the later. I will refer to the care logic as citizen logic in this thesis.

The gap between a scientific discovery and clinical practice is still debated, with focus on the endemic tribalism of the medical profession, where specialisation acts both as a fragmentation factor and as a barrier for knowledge sharing (Oborn et al., 2013).

> *[Healthcare is] operated almost by tribal knowledge, where you know the elders pass on information in their community. But this kind of stays in that area and a lot of how medical practice happens today is largely a function of where one receives medical training. (Dave Chase, entrepreneur, opinion leader)*
>
> *2004 is a long time ago, I would say no physical therapist knows this. (...) People are actually not getting treated according to the latest research. There is very little knowledge in Sweden of how much physical activity can help for Parkinson. Which means people are not as well as they could be. This is only in Parkinson, I expect this to be all over healthcare. (Sara Riggare, patient researcher, opinion leader)*

Specialised doctors are more likely to uptake the results of pure science, because it is the way they build up their status and power (Pouthier et al., 2013), in comparison to primary care doctors where the logic of care is dominant (Dunn & Jones, 2010).

Doctors are professionals, carrying the strong, complicated and fragmented institutional logic of their profession. Their professional logic is a hybridisation of science and citizen logic, and despite the resistance to managerial and state logics, there are hybridisation aspects. For instance, the financial incentives obliged doctors in time to rationalise to some extent the care act. The medical profession is a second incumbent logic in digital health. Carriers of this logic are doctors and other healthcare professionals, to the far end of healthcare managers.

6.3.2.2. Healthcare managers

This category of stakeholders embraces a highly hybrid logic over time, which combines the market, the state and the medical profession logics. It is important to mention that increasingly managers in healthcare have a medical background, and usually get additional qualifications in management (MBA or other healthcare management or public health degrees). Such qualifications became more available with the proliferation of the "managed care" logic, as a mean for doctors to have a say in running healthcare organisations. Consequently, healthcare managers are operating on the medical professional logic, the market logic, and the bureaucratic (state) one, with various degrees of balance or conflict. Managers inside traditional healthcare providers struggle not only with streamlining processes, legal requirements, contract management, but, most importantly, with deriving the maximum value from demand and resources.

There is also a constant adjustment around the reimbursement model and bureaucracy. The reimbursement models are still difficult to get right in healthcare. Girard (Harvard i-lab, 2014), doctor and President of Steward Health Care Network (US), considers that healthcare management has a dual logic: a market and a utility one. The paradox or the limitation comes from the fact that there is a single reimbursement model. Doctor and healthcare manager, Tim Ferris, VP for Population Health at Partners Healthcare US (Harvard i-lab, 2014), highlights that is not uncommon that in order for healthcare providers to provide specific services, they shift costs from other areas (ibid.). This situation, at least in the US, may change for the accountable

care organisations (ACO). There is an increased tendency towards sharing risks, not only within ACOs, but in healthcare everywhere, even in insurance.

Girard (Harvard i-lab, 2014), doctor and President of Steward Health Care Network (US), gives an equation for deriving the most value: value being understood as quality divided by price times volume. This equation is in direct contradiction to the logic of a doctor, who is trained to focus on and do everything for one patient at a time, rather than a community or society as a whole.

> *But ultimately, only the real patient counts, and only the real patient is worthy of our full attention. (Bob Wachter, doctor and professor, opinion leader) (Wachter, 2015, p. 277)*

Dr. Girard also considers that significant savings could be derived from the management of the chronically ill patients, ambulatory treatments, but also from remote consultations. But because not all good ideas are reimbursed, managers have to consider how to extract the maximum value given the constraints, including taking irrational measures (i.e. bringing people in the hospital instead of having a remote consultation). Managers are more risk averse and so medical devices or technologies used or recommended by a healthcare provider often need approval from management (ibid.).

6.3.3. THE CITIZEN LOGIC

This logic reflects that people choose based on personal values, with a sense of belonging to larger groups (Alford & Friedland, 1985; Dunn & Jones, 2010; Windrum & García-Goñi, 2008).

Digital health brings forth the citizen logic as challenger to the incumbent medical profession and state logics, dominant in the traditional healthcare setting (Christensen et al., 2009). In previous healthcare studies, this logic has been implied by other logics, the care logic (Dunn & Jones, 2010) or the community logic (Waldorff et al., 2013). Overtime, with the introduction of the market logic in healthcare, the patient transformed from a passive recipient of care to a consumer of health (Christensen et al., 2009; IMS Institute, 2015). Such transformation was mainly led by political discourses of incumbent actors

of healthcare (Nigam & Ocasio, 2009), less by patients themselves. However, patients advocate groups can be tracked back a long time, associated with the civil rights movement, as shown in the previous chapter. One of the first patient advocate groups was founded in the UK in 1974, The Association of Parents of Vaccine Damaged Children (Harlow & Rawlings, 2013).

Patients are essentially people and, despite the dramatic effect an illness may cast over their lives, illness remains only one aspect of their often-complicated lives. The medical act and treatment are not filtered by strong rationality, but get entangled in their systems of believes, lifestyle, idiosyncrasies and trust.

> *Their first thought is hair loss, what about my children... my sexuality... Is my husband still going to love me, how is my body going to transform? And when they hear from the healthcare professionals that they might have a fever, they are like "Ah, fever! I get fever, you know... that's easy to deal with" and they don't realise that there is a different consequence of this fever under chemotherapy. And so, sometimes, you need to take care of what patients want to know in order that they can hear what they need to know. (Colleen Young, communications, opinion leader)*

Trust is one of the causes of non-adherence to treatment and, possibly, a way to improve adherence is through education and technology.

> *And I think that even the choice of words matters: there is compliance and then even adherence is a bit better than compliance... and then participation is better than adherence. Compliance I think it's not something that sets the right tone. Adherence is still... you are kind of adhering to what they say. Whereas participation recognises what a patient does and the factors in their life that have an impact. That's a much better model, it works much better and forward-looking organisations look at how to achieve that. It's great for the outcome for the patient and I think that the care team quite enjoys that. But there is a different approach than the status quo in a lot of places. (David Chase, entrepreneur, opinion leader)*
>
> *Actually being a patient though isn't just about me the patient, it is about finding a doctor then building a relationship like the one that I have with my transplant team and specially with the guy who is at*

> *the top of the tree my transplant surgeon Anil Vaidya. (…) You see this whole journey is like no other (…). They become your second family, the one you literally have trusted with your life, they know you like no one else, even your mum and dad can do. Going right back to that walk to theatre, holding hands with my wife Anil would have been the only other person who could truly have known how scared we were and how that walk could have been the last time we held hands. (Michael Seres, patient entrepreneur, article on personal blog, 2013)*

Consumerism, later on patient empowerment or engagement, is very much part of the political agenda for a long time. Until recently, this engagement was realised through patient groups, associations or nongovernmental organisations (NGOs). Over the past few years, patient engagement took a hands-on approach. For instance, in the 2009 case of the swine flu, patients were encouraged to self diagnose by the NHS. A major cultural shift caused by the evolution in information technology is the redefinition of the patient role.

> *By encouraging layfolk to be overly dependent on doctors we have all too often inadvertently disempowered the populace in health matters, turning potentially powerful, knowledgeable, health responsible citizens into ignorant, fearful, isolated clients of professionalized health care. The rise of consumer health informatics and online self-help provides the perfect remedy this situation. (Tom Ferguson, doctor) (Ferguson, 1996)*
>
> *Self care is an under-utilized resource. […] This is not just about a change in service provision, but about a cultural change, allowing patients to be partners in their care, letting them decide what support they need, when they need it and how. (UK Department of Health report, 2006)*

The engagement of the citizen, as opposed to being simply a recipient of welfare, spurs from the citizen's rights, "the power to engage in the economic struggle and made it possible to deny him social protection on the ground that he was equipped with the means to protect himself" (Marshall 1964 in Alford & Friedland 1992, p. 155).

The idea that patients are consumers is not much agreed by the medical community. I only mention here a few arguments offered by an online article

on Kevin.MD, by doctor Shirie Leng (2015): they are accessing services under a state of vulnerability, sometimes with no prior notice or planning; they don't choose to buy services, rather are forced into this by circumstances; usually patients are not paying directly; they are not buying a product that a consumer would expect to derive positive returns; and, not last, what patients find satisfactory does not correlate with the quality of care provided.

Since 2004, European Commission (EC) made clear that health consumers are also healthy citizens, not only patients (European Commission, 2004). This conception has roots in the dominant welfare state doctrine that still dominates healthcare in Europe. Similarly, in the US, the insured people are also healthy people.

> *Etymologically, a patient is a person who suffers. Medical dictionaries also consider patients to be people registered with a doctor, irrelevant of their sufferings. Therefore, national health systems (i.e. the UK NHS) may conceive all citizens as patients by birth alone. (Macnaughtan, 2015a)*

In both cases, even if in different manners, both healthy people and people affected by an illness (patients) are recognized as stakeholders. Less so are the carers, although "[t]he demand for health services is determined in part by the patient and in part by the family/social group to which patients belong" (Windrum & García-Goñi, 2008, p. 654).

> *Thirty percent of U.S. adults help a loved one with personal needs (...) Caregivers are significantly more likely than other internet users to say that their last search for health information was on behalf of someone else. (PEW report) (Fox & Brenner, 2012)*

Their importance as healthcare stakeholders is relatively recent - for instance, the UK Whole System Demonstrator (WSD, 2008 – 2011), the biggest randomized controlled trial in telehealth (which involved remote patient monitoring), recognized carers as key stakeholders, along with patients.

> *"There are examples where patients' carers and family members were involved in drawing up and 'owning' the care plan" (WSD report) (Giordano, Clark, & Goodwin, 2011, p. 8).*

Therefore, I consider carriers of this challenger logic patients (if there is illness), carers and people, generally. Perhaps, it is important to stress again that citizens also engage in political activism and social movements, where occasionally, relatively powerless actors come to "mobilize and organize fields" (Fligstein & McAdam, 2011, p. 1).

6.3.4. The market logic

This logic is guided by efforts to increase shareholders' value through considering opportunity costs, potential returns, and competitive edge (Gawer & Phillips, 2013; Scott et al., 2000; Thornton, 2002). In this sense, technology is evaluated based on opportunity cost and market potential. Carriers of the market logic are intrinsically less risk averse and more likely to propose disruptive solutions to healthcare (Christensen et al., 2009).

> *Now I think there's this fourth revolution building on the third, which is the digital revolution, this diffusion of technologies that are not well defined. And the interesting thing about the fourth revolution is that it is a little digital and a little physical. It's about all these aspects of our humanity that are being transformed. Amazing changes in technology! (John Nosta, digital health evangelist, opinion leader)*

Although the market logic is part of the healthcare constellations of logics, it does not manifest as freely as in other contexts, due to the other powerful logics (state and medical profession).

> *At the same time, because I was deeply rooted in healthcare, and trained in really rigorous research, I recognised that some of what people were discussing or hoping for was a little bit naive. Aspiration was to apply the tech to make healthcare better, but there was a lot of naivety about how complex human physiology is, how complex healthcare is. (David Shaywitz, doctor entrepreneur, opinion leader)*

Scott et al. (2000) showed how the era of state involvement, with the logic of equity, caused intense fragmentation, which allowed subsequently the managerial and market logics to enter. In this sense, managers "appear to have been the beneficiaries, not the agents, of the deinstitutionalization" (ibid., p. 328).

The main stakeholders carrying this logic are most of the market players, with some hybrid representatives. Of these, the CDHT producers (apps, wearables, insideables, platform producers) will be treated in the chapters to come. There are other numerous players in this arena: medical devices companies, consultancy companies, traditional ICT and health IT providers (EHR and EMR), technology integrators, (big) data integrators, other health related service providers (i.e. non-physicians care providers), pharmaceutical companies or academic institutions. The list may not be complete, but it is relevant at the time of data collection. Most such stakeholders embrace predominantly the market logic (except pharma and medical devices, which have more hybridity due to their proximity to healthcare and strong regulatory constraints), but this becomes more blended, the closer they get to the healthcare field.

6.3.4.1 Pharmaceutical and medical device companies

These stakeholders operate under tremendous fragmentation and, similarly to healthcare stakeholders, they are under the influence of several logics coexisting, although the market logic remains dominant. They do have strong regulations, therefore the state logic applies, they produce directly and often exclusively for the healthcare professionals, therefore there are elements from medical professional logic, and they do operate under the science regime, and so there is science logic.

6.3.4.2 Consultancy companies

Consultancies have the role to apply experience from adjacent fields (in this case, digitalization of other types of businesses), to disseminate and create best practices, to fill in expertise gaps, manage implementation and organisational change. Bessant and Rush (1995) identify a number of roles that consultants fulfil for technological change, and they identified multiple “bridging activities”.

User needs	Bridging activity	Supply side
Technology	Articulation of specific needs Selection of appropriate options	Sources of technology
Skills and human resources	Identification of needs Selection Training and development	Labour market Training resources
Financial support	Investment appraisal Making a business case	Sources of finance – venture capital, banks, government, etc.
Business and innovation strategy	Identification and development Communication and implementation	Environmental signals – threats, opportunities, etc.
Knowledge about new technology	Education information and communication Locating key sources of new knowledge Building linkages with the external knowledge system	Examples of best practice Emerging knowledge base
Implementation	Project management Managing external resources Training and skill development Organisational development	Specialist resources

Table 11. Intermediary roles of consultants (Bessant & Rush, 1995, p. 101)

Consultants have a mediating role and, however less visible, they play an important role in the maturation of a field. Consultancies, even though driven mainly by the market logic, drive hybridisation of institutional logics between fields through their exposure to different institutional contexts.

6.3.4.3 Infrastructure providers

They are mobile networks, telephone and data providers, even broadcasters. The infrastructure could be considered a barrier and an opportunity. With the infrastructure providers offering better and faster services and continuously covering more areas, the communication infrastructure becomes increasingly an opportunity. Infrastructure providers have the role of almost literally building the foundation for digital health. The communications industry is fundamental for the digital economy and it is one of the main facilitators of convergence of services. Although concerns with privacy of health data might lead to a hybridisation or plurality with state and citizen logics, as it will be shown in the next chapter, presently these providers are conducting their businesses based on the market logic, with focus on service diversification and exploitation of already existing distribution channels. Data collected by these providers may become an important revenue stream either by directly exploiting it or selling it forward.

6.3.4.4. ICT technology producers

Similar to the infrastructure providers above, ICT producers have a vested interest in promoting their products and so the more uptake of digital

technology in healthcare, new market leads open. Recently, many of the ICT providers offer cloud data services and therefore their logic might eventually combine with state and citizen logics, similar to the case of infrastructure providers. Most of them evolved to offer platforms and nurture their own ecosystems. Additionally, some become distributors for digital solutions (i.e. apps stores).

6.3.4.5. Non-physician providers

Examples could be other agencies (telehealth, social care services), professionals (nurses, assistants to doctors, wellness coaches), independent professionals (optometrists, mental health or physical therapists) who participate in care. Depending on goals and expertise, their logics will be possibly the most eclectic as the dust settles in digital health. They may work in teams with a doctor or independently. In the US, these roles increased by 11% since 2008 (Weldon, 2014), possibly due to the recent changes in the US healthcare policies, which set the grounds for new incentives and organisational forms (i.e. Accountable Care Organisation - ACO). In ACOs, the continuum of care is to be rewarded throughout the system formed by different organisations (hospitals, primary care or social care organisations, NGOs). The main incentives (shared savings) are placed on the system performance related to the population served (Tim Ferris, Partners Healthcare, iLab, 2014).

6.3.4.6. Integrators

Digital technologies are "configurational technologies" (Fleck, 1994, p. 243), meaning that in order to be successful in their local implementation, there is a need of general technical knowledge (that healthcare providers may not possess) and local practical understanding. Integrators could fill in this space and therefore, their logic would end up hybridising the medical profession and a market logics.

Sometimes, system integrators create platforms. "Industry platforms are products, services or technologies that are developed by one or several firms, and serve as foundations upon which other firms can build complementary

products, services or technologies." (Gawer, 2011) Platforms (i.e. Microsoft, Intel, Apple, Google, Facebook…) offer a bundle of core components that can become technical standards, based on which other producers can create or build their own products (Baldwin & Woodard, 2009). Service integrators often address solutions, rather than insular pieces of technologies. Consequently, they are important players in the maturation of the market, because of their role to accommodate multiple logics.

6.3.4.7. Distributors

These could be medical device distributors, websites, app stores, ICT providers and others. In the case of the medical device distributors, given their proximity and generally long term relationship to the healthcare field, the logic is a blend of market, medical profession and state logics, in the favour of market logic. For instance, many of the Phillips, GE or Monica Healthcare devices are generally distributed through big medical distributor channels.

In digital health, distributors are mainly online retailers or apps stores and these are driven by the market logic, with very little customisation to any particular field, therefore they are governed by the market logic.

6.3.5. SCIENCE LOGIC

This logic is concerned with advancing knowledge and is guided by "communalism, individualism, desinterestedness, originality, skepticism" (David, 2004, p. 573). As an institution, science is subject to penetration from the market logic of production and consumption (articles, books, discoveries and technologies) and from the state logic for access to resources (Alford & Friedland, 1985; David, 2004).

As David (2004) suggests, there should be a difference between the republic of science and the republic of technology. The last one is "devoted to maximizing wealth stocks corresponding to the current and future flows of economic rents, and so requires the control of knowledge through secrecy or exclusive possession" (ibid., p. 576). Herein, I consider technology as an enabler of institutional change (Christensen et al., 2009; Petrakaki et al., 2012). The main stakeholders of this logic are traditionally the academic and research

organisations, which have the goal to create and disseminate knowledge, mostly as a public good.

In healthcare, the logic of science "focuses on knowledge of diseases built through research and innovative treatments" (Dunn & Jones, 2010, p. 116). Historically, science has been a main driver of medical professionalisation, as well as professional fragmentation.

> *Most research being done to date, is primarily done for the sake of research, secondarily for the sake of healthcare, and thirdly, if at all, for the sake of individual patients. This is a result of the very complex weave that makes up the current research process. And I am not saying that good or even great research cannot come from the current research process. (Sara Riggare, patient researcher, opinion leader) (Riggare, 2016)*

Academic and research organisations mix the logic of science, with market and state logics (Thornton & Ocasio, 1999), in the favour of science. However, now they are demanded to confront and accommodate citizen logic, as shown by the quotation above. Many of the traditional healthcare stakeholders are to various degrees engaged with the logic of science (pharma, medical device manufacturers, consultancies). That would also become the case with digital health players, overtime.

> *The idea of scrutinizing an idea, of questioning its clinical validity, of looking at its real data to support its use, I think will, well out of necessity, come to the forefront. And with that might come some scepticism. (John Nosta, digital health evangelist, opinion leader)*

Apart from often being dependent on funding from the state, researchers are incentivised to produce private endeavours of economic value. Aside from the engineering dream the digital health represents (digestible sensors, machine2machine intelligence, artificial intelligence, nanochips...), such science organisations have a vested interest in the potential of big data for research, funding and IP exploitation.

There is a difference between European academic institutions and the US ones (Goldfarb & Henrekson, 2003), in the sense that in Europe there are top down

policies that do not always make it easy for universities to commercialise scientific knowledge, whilst in the US the "institutional setting characterized by competition between universities for research funds and research personnel, which in turn has led to significant academic freedoms to interact with industry, including significant involvement in new firms" (ibid.: 639). Recent initiatives (for instance, in the UK or Australia) look to foster a closer interaction with the industry. Most recently, in Europe, an increasing number of grants require statements for economic, social and academic impact, or require academia-industry collaboration. Regardless of how the funds are flowing, it will become obvious in the following chapter that digital health developments are legitimised and encouraged by current trends and by academic work.

6.5. Conclusions

This chapter fulfils the first part of the second phase of this research - the analysis of the institutional context of the emerging digital health, by identifying the institutional logics at play and their main representatives. Institutional logics are understood as ideal types, and stakeholders carry them in more or less ideal forms (Scott, 2008; Thornton et al., 2012). Based on my analysis, five institutional logics coexist in the digital health field: state, medical profession, citizen, market and science. Stakeholders have been identified through their field level interactions (Scott, 2008), and are relevant at the time of data collection, as they may change with the evolution of the field (ibid.). Digital health introduces the citizen logic as a challenger logic to the incumbent medical profession and state logics, dominant in the traditional healthcare setting (Christensen et al., 2009). In previous healthcare studies, this logic has been implied by other logics, the care logic (Dunn & Jones, 2010) or the community logic (Waldorff et al., 2013). The other four logics are described in detail, alongside their historical evolution. The next chapter moves into presenting the evolution of this emergent field.

CHAPTER 7. DIGITAL HEALTH EMERGENCE

7.1. INTRODUCTION

This is the third chapter situated at the field level of analysis. Here[4], I explore the digital health field emergence, as a process. I reveal its institutional complexity via stakeholders' interactions, driven by hybridisation, conflict and ambivalence. These interactions allow me to determine the institutionalisation stage. Given that the field emergence has not been previously investigated by other studies while it happens, only through retrospective lenses, I aim to provide a better and more vivid understanding of institutionalisation, particularly relevant for a fragmented field, with high complexity. Having established the precursors of the institutional change in chapter 5 and the ideal types of the institutional logics and their main carriers in chapter 6, in this chapter I analyse the digital health's evolution from 2007 to February 2016.

7.2. CONTEXT AND TRIGGERS OF THE DIGITAL HEALTH EMERGENCE

Digital technologies contributed to the change in the rules of competition across industries (Ilinitch et al., 1996). The ICT industry itself changed dramatically from the introduction of personal computer and the rise of platforms and ecosystems (Gawer & Phillips, 2013; Mulligan, 2011; Jacobides et al., 2018). "This shift fundamentally altered the organizing principles of the industry: it changed how competition happened, as well as how innovation happened. […] The locus of competition also changed, as much innovation became focused on components and around the definition of 'open standards'" (Gawer & Phillips, 2013, p. 1041).

It is beyond the scope of this research to assess, predict or advocate the impact of digital technologies over the future of medicine or healthcare; what is

[4] This chapter builds upon the conference paper: "Plurality of institutional logics in digital healthcare: The rise of the hybrid patient" (Macnaughtan, Patriotta, Pinnington, & Raman, 2015), as explained in chapter 1. The analysis is enriched with data collected afterwards and expanded in depth and enlarged given that there are fewer limitations on its length.

important for this research is that they potentially pave the way to significant institutional changes.

> *"We have learnt that, despite considerable investment, industry [n.b. ICT] does not yet have the capability to apply itself to health as it has done to most other industries; there is no effective global market and still no common solutions. Everything remains bound up with existing interests, politics, resources and essentially insular thinking" (EHTEL 2009: 12).*

Healthcare and ICT have a long history, as presented in chapter 5. However, since 2007, there were several factors that instigated a revived interest in using digital technology for health. The launch of the iPhone (2007) was a game changer not only for digital health, but also for other industries. Other smartphones and tablets soon followed the iPhone, and so the personal mini computer, truly mobile, proliferated. Prices drop rapidly and allow for an accelerated adoption worldwide.

Mobile, sensing and affordable technology was not the only factor that led to the emergence of digital health; there were also economic, politic and even social factors. The economic downturn (2008) or the demographics showing that population lives longer with chronic diseases translated in overwhelmed governments facing the ever-rising cost of healthcare. Governments became interested to stimulate new areas of economic growth and to identify areas for reducing costs.

Healthcare has been a major political ground for decades. Regulators often interfered in healthcare in various ways, like reimbursement or measures that locked in technologies (Christensen et al., 2009) in a very expensive world. In the case of digital health, regulators are lagging behind, and seem torn between the urgency of cost containment and the maintenance of an over-reaching control (Macnaughtan, 2014).

The more resources went towards innovation, the smarter, more affordable technology became. Given the diminishing return of investment on the stock market following the 2008 economic crisis, venture capitalists and angel investors looked for new opportunities for higher returns, and therefore

significant capital went towards early ventures. "[I]nnovation is occurring in more venues, not just governmental and industrial research labs but increasingly at technology companies, startups, small-team academic labs and by creative entrepreneurs and other individuals" (Swan, 2009, p. 493). This aspect itself is currently debated across the spectrum of life (Frellick, 2015; Ioannidis, 2015; Waters, 2015) and social sciences (Pearce & Raman, 2014), not only in relation to healthcare (Waring, 2015).

7.3. STAGES OF FIELD EMERGENCE

Based on my analysis, I identify three distinctive periods (ingenuous, legitimation and mobilisation) for the evolution of digital health to the time data collection ended (early 2016). I show how entrance of new players influence the institutionalisation processes, how logics have facilitative or degenerative effects on each other and how stakeholders, primarily those carrying the incumbent and challenger logics, develop ambivalent responses to institutional complexity.

7.3.1. THE INGENUOUS AGE (2007 -2009)

This is the time when developments in digital technologies challenge the status quo (Christensen et al., 2009; Fligstein & McAdam, 2011) and create a wave of awareness for several stakeholders of their potential to enable change in healthcare.

The interest for using mobile technologies in health is often fostered at this stage by states' commitment. In developed countries, such commitment is due to the need to identify areas of economic growth, the rising costs of healthcare, and the population demographic changes that additionally increase the financial burden on healthcare systems. In January 2008, the European Union (EU) launched the Lead Market Initiative and digital health was identified as one of the most promising markets for economic growth. Similarly, in the US, the Health Information Technology for Economic and Clinical Health Act (2009) sets a stimulating agenda for this field.

A number of telehealth pilot studies are launched across the world, focused mainly on long-term conditions (LTC) management and aiming to produce

proof of economic and clinical benefits. Evidence dominates the acceptance of new technologies, treatments and practices in medicine. Under the influence of the managed care logic, requirements for evidence was extended from clinical to economic benefits too.

> *You are not going to get paid for anything unless you can prove that you can save them money... In the world we're moving into, more than ever, if you can't justify the cost benefits, then you will fail. (James Sweeney, CEO of CardioNet) (mobihealthnews, 2009)*

This hybridisation process between the state, market and medical profession logics appeals to healthcare managers. The amalgamation of clinical and economic benefits may also represent a conflict with both citizen and medical profession logics. It may be a rhetoric that payers and state promote to continue to silence professional expertise by "taming complexity with numbers" (Pearce & Raman, 2014, p. 389) or by obscuring certain clinical and ethical issues. For instance, patients "may find the obligation of self-surveillance overwhelming, forcing them to confront their illness, engage in routine actions they would rather avoid" (Lupton, 2013, p. 261) or they may simply trick the system, if it does not live up to their expectations (Nicolini, 2007).

States most often position the transfer of the medical gaze from hospital to home as an encouragement of consumerism and of patient choice, and thus it attempts to stimulate in people the hybridisation of the medical profession and the citizen logics. But they also present patients to doctors and healthcare managers as additional resources, and thus it tries to enforce the hybridisation of the medical profession and the market logics upon healthcare actors. This stance is arguably a reflection of the increasingly neoliberal state agendas (Ayo, 2012). "They position lay people as ready and willing to actively engage in their own healthcare and promote their own health, in the attempt to shift the burden of such responsibilities from the state to the individual" (Lupton, 2013, p. 266). Such cultural change is mainly demanded from doctors (conflict) and is presented to patients as a benefit.

> *This is not just about a change in service provision, but about a cultural change, allowing patients to be partners in their care, letting*

them decide what support they need, when they need it and how. (UK Department of Health, 2006).

This is the period when it becomes evident that patients do not look for advice from doctors only, there are digital tools like symptoms checkers, patient networks (i.e. PatientsLikeMe, WellSphere), medical resources (WebMed, NHS library) and several other gadgets (later on called wearables) that allow them to self monitor (FitBit, ActiHealth) or self manage (Trixie Tracker, Keas, Google Health or Microsoft HealthVault) – for a comprehensive list of available solutions during this period, see Swan (2009). It is the time when patients, enabled by digital technologies, do engage with their own health, hybridising with the medical profession logic.

Patient voices begin to be heard not only through NGOs or patients associations, but also through the voice of individual patients. Dave deBronkart, ePatient Dave, becomes a well-known activist for patient's rights to take part in medical decisions and to own their personal health data (PHD). Regina Holliday turns into a patient advocate after she became a widow in 2009. Two years later, she initiates an entire movement, The Walking Gallery (Holliday, 2011), which continues to grow to this day. At this stage, citizens mainly oppose the medical profession logic and mobilise via the internet.

The world was talking about patients' rights and data access. This was caused in part by paint and social media. If using social media could get our message out to the world think of what could happen if the medical establishment and empowered patients embraced it. (Regina Holliday, carer and artist) (Holliday, 2009)

Gone are the days when patients were passive recipients of care dispensed by healthcare providers in a one-sided "doctor knows best – and patients know nothing" model. Today engaged patients participate in their care, in an empowering partnership with nurses, physicians, staff and organizations who understand the new model. (Dave deBronkart, also known as ePatient Dave) (deBronkart, 2009b)

What would you say to policymakers who are discussing the implementation of a national health information infrastructure? Here's what I'd say: E-patients want access to tools and

information. Many will find what they need, many will not. You can help. - CTO US Department of Health, opinion leader, Susannah Fox (Fox, 2009)

Digital technologies allegedly change the patient from a "minimally-informed advice recipient to an active participant, instigating collaborator, information sharer, peer leader and self-tracker engaged in participative medicine; a transition is underway from paternalistic health care to partnership models" (Swan, 2009, p. 513). This denotes an ambivalence in citizens' response to the medical profession logic: on one hand they hybridise by accessing specialist information, on the other hand they attempt to change the existing practices where doctors render control over health data, diagnostic or treatment.

It started when I found PatientsLikeMe. You can produce a pdf that you can bring to your doctor. He found it interesting. So I started exploring more. (Sara Riggare, patient researcher, opinion leader)

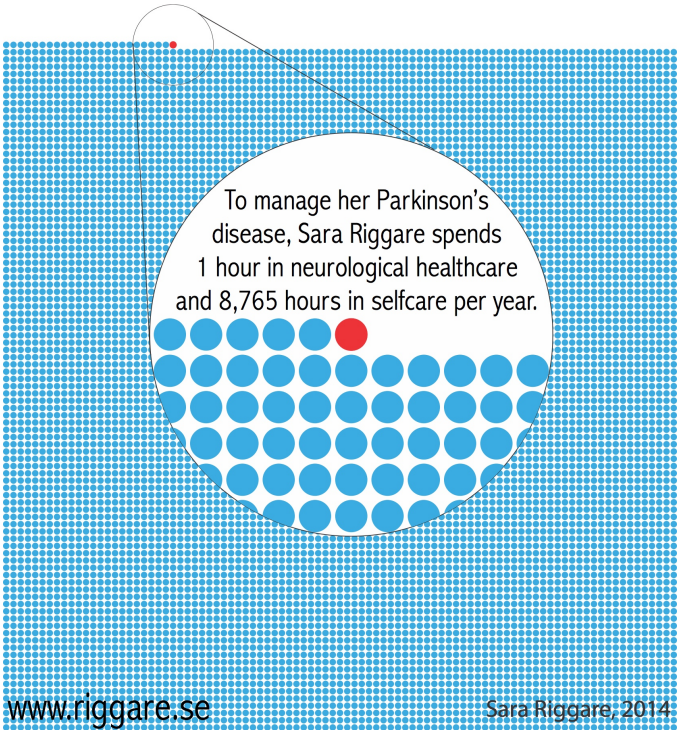

Fig. 26. Sara Riggare's representation of selfcare (2014).

We started to add not only what does the patient need to know, but also what does the patient want to know. And it's a significant shift there. (Colleen Young, communications, opinion leader)

Doctors are only invoked by the actions and rhetoric of other stakeholders, although there is some awareness of the potential impact digital technologies

may cast over the doctor - patient relationship. Hybridisation with the medical profession logic at field level is indicated by conferences like Health 2.0, Medicine 2.0 (2008), or associations like Society for Participatory Medicine (2009) cofounded in the US by patient Dave deBronkart and doctor Daniel Zev Sands. Even the names of these conferences are indicative of a paradigmatic change. There are scattered digital health companies founded by healthcare professionals directed to patients (i.e. Ieso Digital Health, UK, which is founded by two psychotherapists). At this stage, doctors strongly oppose the consumerisation of medical knowledge or the escape of the lab from its traditional setting.

In 2008, several consumer genetic testing companies were served by California's Public Health Department with a cease and desist letter, which appeared to have been stirred by the medical community. This shows that the regulators are not comfortable with the new world, the direct to consumer health services that aim at what traditionally used to be governed by medical professionals only. Although that particular measure taken by regulators was not successful, some of that battle is still continuing today (Herper, 2015).

> *We believe we are in compliance with California law and are continuing to operate in California at this time. Our testing is conducted in an independent CLIA-certified laboratory and we utilize the services of a California licensed physician. However, we would like to have continued discussions with the Department regarding the appropriate regulation of this unique industry. (23andMe in press) (Madrigal, 2008).*

The traditional ICT producers and service providers are encouraged by the incentives presented by states, the technological advancements (i.e. miniaturisation, sensors) and technological uptake from citizens. They attempt to organise in industry associations; Continua (2006) is credited for introducing patient remote monitoring in the reimbursement scheme in the US (Harbert, 2009; mobihealthnews, 2009).

The focus on patients as consumers, along with the increased availability of sensors for health self-tracking, opened the door for digital health.

> *Towards the middle of 2006 several start-ups began targeting healthcare using Web 2.0 technologies such as wikis, mash-ups, video, blogs, communities, and user-generated data. And to be fair Wondir which was sucked into the Revolution Health vortex started a now defunct blog called Health 2.0 in late 2005. In early November 2006 Matthew did a podcast with 3 Health 2.0 companies on THCB (n.b. acronym for the website The Healthcare Blog), and the community was beginning to emerge. ("History Health 2.0," n.d.)*

In 2007, a first of its kind industry event, the Health 2.0 (US) conference, gives this very young market a positive signal.

> *Indu and Matthew started kicking around the idea of a next steps on Health2.0 in January 2006 and after a few changes in team, partnerships and timing they created an advisory board, and talked about holding a conference. After discussions with a couple of original charter sponsors (thanks to Mike Haymaker at Cisco, and Daniel Palestrant at Sermo for taking the plunge) they committed to holding a conference on September 20, 2007 in San Francisco. That conference massively exceeded expectations, with nearly 500 attendees, and a hundred more on a wait list. ("History Health 2.0," n.d.)*

Adding to this, at the end of 2009, resources are on the rise for wireless sensing devices - i.e. Monica Healthcare, FitBit, WellAware – as shown by one of the first market reports in this field, called "Wireless Health: State of the Industry, released by MobiHealthNews (US), at the end of their first year of publishing online (mobihealthnews, 2009). With the introduction of smartphones, the number of consumer health apps rise rapidly.

> *From symptom navigators to chronic disease management tools; from medical reference guides to remote monitoring applications; from medication adherence apps to soothing relaxation applications. Chances are if you have thought of a potential health-related application, there's a version of it already in the iPhone App Store. (mobihealthnews, 2009)*

With their focus on consumers, digital health producers contribute to the escape of medicine (Lupton, 2013) from the confined space of specialist

knowledge. Therefore they come into conflict with the medical profession logic, despite the fact that they themselves hybridise with both citizen and medical profession logics, depending on their product/solution.

Pharmaceutical companies (pharma) remain, by large, not involved. Pharma is dominated by a constellation of logics and, at this stage, it just contemplates hybridising the market and science logics with the citizen logic.

> *So what we learned by that which I think it changed a lot of for the drug manufacturers. That having patients talk to one another helped with adherence rather than what they'd feared - people talking about side effects and therefore not taking them. (...) And sometime they would come on the conversations on the forums and talk about how difficult it was to manage their joint pain or whatever they were particularly experiencing. They were often giving tips to one another - maybe take pills in the evening rather then in the morning or vice-versa. And also give to each other signs of encouragement: "You're doing well. You're doing this for your daughter. You don't want not to use all of the ammunition that you have to fight this disease." I hate using battle metaphors, but you want to give everything that is in your power to save your life. And so they really encouraged people to stay on the drug. (Colleen Young, communications, opinion leader)*

Pharma seems to be most interested by exploring potential benefits from having instant access to generous pools of clinical trial participants. For instance, in May 2008, Novartis collaborated with PatientsLikeMe for recruiting patients for clinical trials and they have claimed that this reduced the study duration by several months (Swan, 2009).

Digital health has a quick, serendipitous start, with steady growth of digital health solutions. At the end of this period, some common themes surfaced: reimbursement, regulation, business models, evidence and patient as healthcare resource. The market and the state logics promulgated the citizen logic, for different reasons, nevertheless both contributing in their own right. The market fostered the independent, rebellious, sophisticated user, whilst the state fostered the resourceful, dignified, independent patient. Doctors remain a sounding board, their participation being subtle at best.

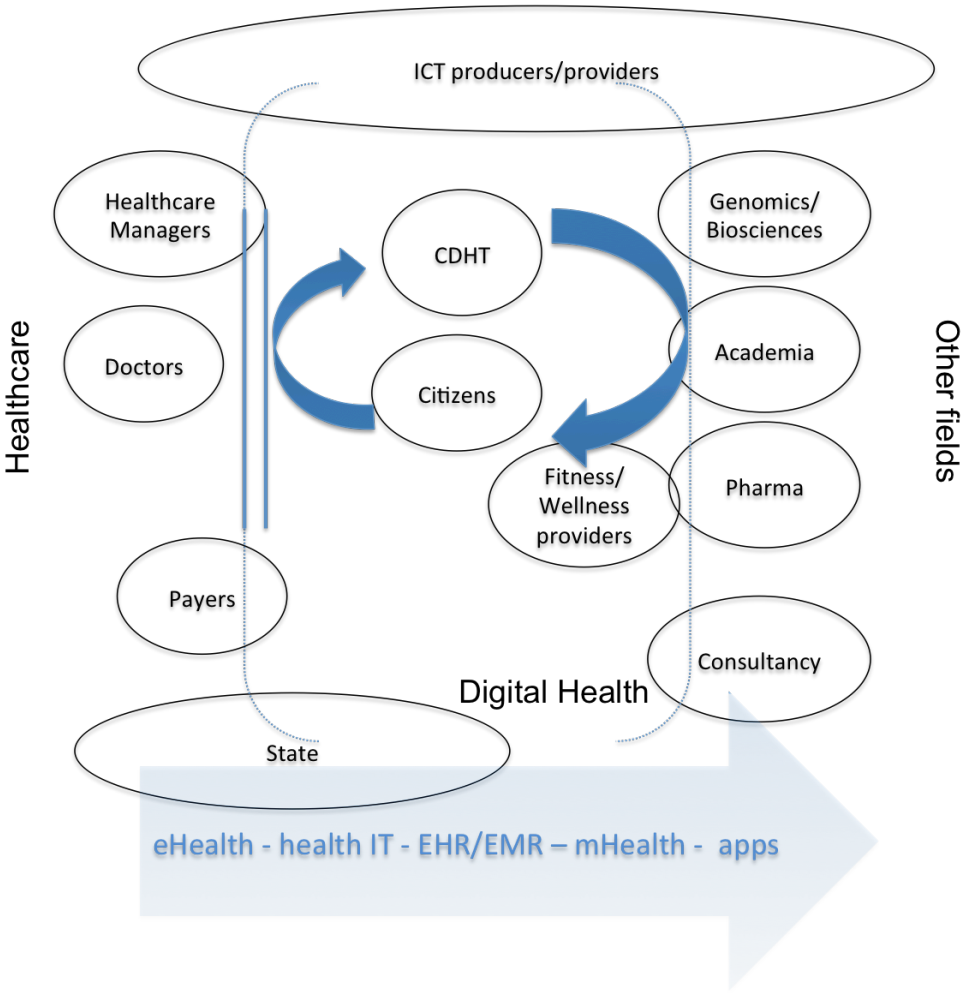

Fig. 27. Synthetic view of the stakeholders in the ingenious phase

Although most stakeholders become aware of the possible impact ICT may have on healthcare, only few fully engage, particularly those who could put health information at patients fingertips. State, technology producers and citizens are such examples. Conflicts between logics are mainly between state (including payers), citizen and market (technology producers) on one hand, and medical profession (primarily doctors, and, to a lesser degree, healthcare managers), on the other hand. Ambivalent or neutral positions are maintained by pharma, for instance.

7.3.2. The legitimation age (2010 -2012)

Terminology continues to change and morph in meanings. "Digital health" (Davis, 2015) becomes the favourite term, as opposed to mHealth or eHealth, although they all continue to be used. Digital health communities appear where professionals of various descents share ideas and connect. "The modern world

has created the "social movement," the "organization," and the idea that one can deploy networks to expand one's power. Reflexive social actors have picked up on these inventions and used them" (Fligstein & McAdam, 2011, p. 23). Opinion leaders have a significant role in establishing socio-political legitimacy and a social identity for challengers (Aldrich & Fiol, 1994; Fligstein & McAdam, 2011; Selznick, 1948). They also have the role to co-opt and find ways to reconcile certain aspects for the emerging field.

> *A real page-turner for me was a conference in Dubai, where all the major telecom companies in the world were present. Everyone was talking about mHealth, how huge it would become, and how many people would be using it, and thereby earning many billions of dollars. When it was my turn to deliver my keynote, I asked the audience 'How many patients are present here?'. Not one, it appeared. 'And are there any doctors?'. Yes, just one, a doctor of dentistry who, it appeared, had walked into the wrong conference-room by mistake" (Lucien Engelen, healthcare intrapreneur, opinion leader)*
>
> *I help people navigate health and technology. [...] And I contribute to debates around the world about how data, social media, and technology can be used to support health. (Susannah Fox, at that time, PEW Associated Director, opinion leader)*
>
> *A doctor follows [the] Heisenberg principle: he's always somewhere else. Patients are 24 hours waiting for two minutes of a doctor who comes in like Superman and goes out again. (...) We are the last generation who will know so little about our health. (Walter de Brouwer, entrepreneur, opinion leader)*

These are examples of justifications opinion leaders invoked, using skilfully paradoxes, personal drives, personal stories or invoke powerful emotions – like a patient waiting for a doctor that is never there when needed.

WALTER DE BROUWER

Entrepreneur and innovator, who looks to empower patients to "rewrite medicine" (2014)

- Co-founder and CEO at Scanadu
- A scholar and visionary, founder of Starlab and creator of "Deep Future" research

LUCIAN ENGELEN

"Disruptor" of healthcare through technology, in the name of the patient

- Director of REshape Innovation Center and Radboud University Medical Center
- Over half a million followers on LinkedIn

SUSANNAH FOX

Researcher in health and technology, dedicated to "help people navigate" both

- Her findings have influenced business decisions and inspired research
- She is currently with the Robert Wood Johnson Foundation, after 14 years of directing Pew Research's health portfolio.
- Susannah sits on the board of several patient centred organizations and of Stanford Medicine X.

JOHN NOSTA

Digital health philosopher and "thinker entrenched in the world of science, medicine and innovation"

- Founder of Nostalab, with the mission to "reimagine health and wellness"
- Strategic advisor for nuviun and member of the Google Healthcare Advisory Board
- Contributor for Bloomberg and Forbes

PAUL SONNIER

Catalyser

- Founder of the Digital Health group on LinkedIn (2009), 30,000 + members
- Story of Digital Health website
- The Digital Health Post (2014)
- Involved with the World Economic Forum in Digital Health matters and, as judge, with the XPRIZE Nokia Sensing XCHALLENGE

Fig. 28. Opinion leaders in the legitimation stage (Macnaughtan, 2015c)

Like in any young field, consultancy companies have the role to apply experience from adjacent fields (in this case, digitalisation of other industries) to disseminate and create best practices, to fill in expertise gaps, manage implementation and organisational change, the so called "bridging activities" (Bessant & Rush, 1995). In the previous years, there were only rare niche market reports (Parks and Associates, mobihealthnews). Now, major consultancy firms enter the game, but they do not play a major role in hybridising logics and practices. Pricewaterhouse Coopers (PwC) has been the most active ever since this period. The startups research2guidance (2009) and Rockhealth (2010) set themselves apart for producing in-depth market reports on digital health, particularly on funding and general trends.

The knowledge economy continues to challenge the information asymmetry paradigm that used to provide unilateral decision-making authority to doctors only.

THE DIFFERENCE BETWEEN PATIENTS AND CONSUMERS

	Patients	Consumers
Level of engagement in decisions about their treatments	Low: depend on physicians to make decisions on their behalf	High: depend on physician recommendation and personal verification
Level of awareness of treatment options and associated costs	Low: depend on physician opinion	High: depend on online tools and social media
Source of trust in providers they use	High: based on personal experiences and word-of-mouth	High: based on personal experiences and comparison shopping
Primary unmet needs	Access within a reason-able timeframe + personal attention	Value: access + service delivery + outcomes + cost
Unmet need from insurance plan sponsor	Large networks of providers to enhance access and convenience + manageable out-of-pocket costs	Narrow networks of high-performing (high-value) providers + predictable costs

Fig. 29. Patients versus consumers (Keckley, Coughlin, & Eselius, 2012, p. 73)

Patients become more empowered by gaining a seat at few healthcare conferences (Engelen, 2012), albeit most of them were new ones, designed to include patients - i.e. Doctors 2.0 & You (France), Stanford Medicine X (US), Medicine 2.0 Harvard. Lucien Engelen ignited the "patients included" in healthcare conferences movement in 2010 and, by the end of 2012, amongst the conferences listed in one of his LinkedIn posts (Engelen, 2013), only one was a medical conference as such, on Parkinson's disease.

Fig. 30. Patients Included logo by Lucien Engelen (2010)

Some patients become opinion leaders through their online communities and participation to patient included conferences like Tedx, Doctors 2.0 & You (France) and Stanford Medicine X (US) - amongst them, Brittany Jones, Hugo Campos, Michael Seres or Sarah Kucharski. The growing online patient communities and blogs bring forth the idea of "peer-to-peer" healthcare (Fox, 2011a) - people connect with each other, share other types of information than those exchanged with doctors and have other types of support from their peers (Fox, 2011a; Hartzler & Pratt, 2011; Swan, 2009). The growing number of online patients (also called e-patients or patient experts) and communities continue to reinforce the citizen logic. Some of the issues claimed by patients were:

> *Data ownership, connectivity, low cost. But one thing is for sure. In this world of low cost connectivity, in which we live today, we all here should find it unacceptable for data to bypass the patient. (...) We all have the right to our health information, it's a matter of fairness, it's a matter of justice and it's a matter of patients' rights. (Hugo Campos TEDx Talks, 2011)*

Patients being disfranchised by current business models of medical device manufacturers. Medical device companies really look at doctors as their customers, not patients. Patients are really the recipients of the therapy, and for the most part, are just expected to trust that everything is going to be alright. (ibid.)

Online community/Peer-2-peer healthcare. Peer-to-peer healthcare acknowledges that patients and caregivers know things — about themselves, about each other, about treatments — and they want to share what they know to help other people. Technology helps to surface and organize that knowledge to make it useful for as many people as possible. (Susannah Fox, at that time, PEW Associated Director, opinion leader) (Fox, 2011b)

Participation. What patients can really contribute to the process of participatory medicine, so that healthcare isn't simply handed down from doctors, but it's something that patients participate in to help further their progress. (Sarah Kucharski, epatient) (BasilStrategies, Sarah Kucharski, 2012)

Crowdsource your health. People are contributing and participating in multiple ways. There are testimonies, art, poetry, suggestions, videos, performances. Many doctors have called in to propose their methodologies and technologies. I have had very interesting and profound discussions with people who are prepared to deal with very complex things every day of their lives. I've communicated with doctors who are perfectly open to the possibility of such a paradigm change for the word "cure". Artists, designers, activists, are giving me wonderful parts of "cure". Many "patients", "ex-patients", "relatives" and "friends" of "diseased people" are sharing their experiences, are opening discussions, are sharing the information I found on possible medical cures. (Salvatore Iaconesi, e-patient) (Lichty, 2012)

Despite self-monitoring or self-quantification being on the rise (Fox, 2012a; PwC, 2012) and despite research showing positive economic and clinical outcomes, there is much left to explore about how people experience these technologies. Critical voices are barely heard. "The subject produced through the use of m-health technologies is constructed as both an object of surveillance and persuasion, and as a responsible citizen who is willing and able to act on the health imperatives issuing forth from the technologies and to

present their body/self as open to continual measurement and assessment" (Lupton, 2012).

Digital health explodes with wearables, apps, and mobile devices (smartphones and tablets), whilst prices drop, making these technologies more affordable.

> *Our joy of experiencing and creating new technologies may just outpace our need for them, or direct us towards the most-fun-to-use technologies rather than the most necessary ones. (Sanjay Basu, doctor) (Schiff 2012)*

Similarly, there are concerns of inequalities, but PwC (2012) showed that there is a better adoption rate of mHealth technologies in developing countries, pointing out that need and lack of legacy systems may encourage adoption of novel ways to improve access to healthcare.

Business to consumer (B2C) models are emerging based on the assumption (hybridisation with citizen logic) that

> *...the reason why individuals have NOT engaged with their health is because they have NOT been provided with tools that are beautifully designed, addictive to use, revealing on one's health habits (a.k.a closing the feedback loop), and empowering. (Zussa, 2012)*
>
> *Another interesting trend: The price of consumer health apps continues to drop [...] making the average price for all consumer-facing health apps as of April 2012: $2.05. (Dolan, 2012)*

There is ambivalence, in the sense that digital health producers enable lay people to take upon themselves actions traditionally performed by doctors (they hybridise with medical profession and citizen logics in a manner that puts these two logics in conflict). For instance, Scanadu's mission is to bring the emergency room in people's home. They are making a device for consumers, which is easy to use outside the doctor's office and it can monitor body functions.

> *"Check your health as easily as your email." (Scanadu, 2010)*

The attention patients and lay people get from digital health producers evolves as ambivalence, but hybridisation with citizen logic is dominant and therefore

it gets stronger. It expands the health focus from patients to all citizens, from illness to health. The interest in empowering lay people through digital health is also signalled by industry competitions like Qualcomm Tricorder Prize and Nokia Sensing xChallenge, both launched in 2012. Funding becomes more available at seed and early stage investment levels and so many start-ups appear. In the US, whilst most healthcare related fields had a decrease in investments in 2012, digital health had 45% increase, mainly going towards wearables and patient engagement (Rockhealth, 2012a).

CDHT producers are joined by established ICT producers (i.e. Intel, Microsoft, Philips), who have the interest that the new market uses their products or standards (Garud et al., 2002). In 2012, most players are existing technology companies, not traditional health IT companies (Rockhealth, 2012b).

Despite the overall excitement with healthcare innovation, medical communities remain sceptical, at best.

> *Doctors resistance is likely to hold back some aspects of mHealth... still, most interviewees believe that doctors will be unable to resist – especially as payers join patients in demanding change. (PwC, 2012, p. 16)*

In "The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care", Eric Topol prophesies a "new medicine" that will render the "old medicine" obsolete. Old medicine is understood by the author similar to Voltaire: "Doctors prescribe medicine of which they know little, to cure diseases of which they know less, in human beings of which they know nothing" (Voltaire in Topol, p. XII). New medicine is the consequence of the "digitized human", the "consumers coming together to demand a new, individualized medicine will be the most powerful means of changing the future of health care" (E. Topol, 2012, p. 261). However, doctors' voices begin to be more exposed, even if only because of their resistance.

The Whole System Demonstrator (WSD), the biggest randomized control trial (RCT) in telehealth in the world (at the time of writing), did not even manage to convince in its home country, the UK. Most importantly, technologies used were outpaced by the time the results were published in 2011. However, it

proved that there are economic and clinical benefits from remote monitoring implementation at scale. Although most RCT studies at this point have a double focus on the economic and clinical outcomes continue, they are not at the forefront of the digital health adoption debate anymore. The propensity for specialist doctors to be more opened to embracing innovation than primary care doctors has also been remarked by previous studies (Dunn & Jones, 2010; Scott et al., 2000), contradicting Christensen et al.'s assumption (2009) that innovation will take on from the periphery of healthcare. This becomes more and more obvious with the evolution of digital health, where adoption by the healthcare establishment started from specialised areas. However, states try to convince mainly primary care doctors to uptake digital solutions, possibly because they have the role of system gatekeepers or because they often have to manage chronic diseases, where most of the healthcare costs go. States' focus remains costs, access or prevention.

Academia plays a major role during this period. By becoming actively involved, it confers the field the much-needed social legitimacy. This is the time when the research potential of PHD becomes evident and the term "Big Data" enters healthcare. Academic organisations are attracted by the digital health field mainly for access to funding and industry partnerships, or for access to data for science.

> *Patient Reported Outcomes. "Although observational studies using unblinded data are not a substitute for double-blind randomized control trials, this study reached the same conclusion as subsequent randomized trials, suggesting that data reported by patients over the internet may be useful for accelerating clinical discovery and evaluating the effectiveness of drugs already in use" (Wicks, Vaughan, Massagli, & Heywood, 2011).*
>
> *Remote interventions/Lifestyle changes. "The review provides a framework for the development of a science of Internet-based interventions, and our findings provide a rationale for investing in more intensive theory-based interventions that incorporate multiple behaviour change techniques and modes of delivery." (Webb, Joseph, Yardley, & Michie, 2010)*

> *Big Data. "For example, my post last June about IBM Watson's foray into medicine generated a spirited debate in the comments about what source material Watson would be fed and what other models might emerge to take advantage of health care data. Strata Rx 2012 featured multiple speakers on data & analytics, as did the Wired Health Conference: Living By Numbers." (Fox, 2012b)*

New academic organisations appear, and interestingly, abandon to some extent the established focus on evidence and randomised control trials (Pearce & Raman, 2014). "Metrics, targets and star ratings clouded the picture. […] The task changed in 2010, when the National Institute for Health Research called for studies on organisational culture, the role of the patient, the costs and financial implications of patient safety and the boundaries between elements in the whole system" (Waring, 2015).

The academic community hybridises with both market and citizen logics, and so it gives digital health further legitimacy, as an authority stakeholder. A few academic programs in digital health appear, i.e. Institute of Digital Healthcare, University of Warwick, UK (2010) or CATCH, Univ. of Sheffield, UK (2012). Because of the science focus, academia creates a bridge to the medical profession logic, albeit in ambivalent terms. In an emerging field, "researchers and organizations linking universities and commercial activities are engaged in practices that fit neither the logics of "basic" or "applied" research" (Morrill, 2006, p. 7). Academic organisations add to the overall socio-political legitimacy (Patriotta et al., 2011; Raman & Mohr, 2014), in conjunction with the state, ICT and CDHT producers and citizens.

The state remains one of the drivers of digital adoption at the level of healthcare providers. In the UK, there are investments towards researching new care models, such as telehealth, and, in the US, the Accountable Care Act (ACA, 2010) incentivises providers to innovate and collaborate across sectors.

> *I think when the Affordable Care Act was passed in the US, it was really the catalyst for it. There were other things - the economy pushing people to cut costs. By the time ACA was passed, the tech caught up with the idea. (Lisa Suennen, investor, opinion leader)*

States begin to experience difficulties in balancing opportunities and challenges (governance, privacy, safety) brought in by digital health. The Federal Drug Administration (FDA) publishes some draft guidance in 2011, and the EU publishes guidance for medical software (2012). Most other countries do not have any policies or follow the guidance issued by the US and the EU (PwC, 2013). The EU continues to invest in programs to foster interoperability, PHD exchange and adoption of digital health across member countries (European Commission, 2012).

The lack of clear reimbursement models for digital solutions represents an obstacle for adoption by the medical community. However, given the claims of savings, some payers are willing to adopt them, for instance the NHS (UK). There are differences between the private and public insurers (PwC, 2012), but it is reasonable to assume that both want value for money, rather than only cost reductions. Based on a PwC report (ibid.), payers are more likely to encourage patients to self-monitor (40%) than doctors (25%). Payers seem to be overall supportive to the promises of digital health, so they are becoming a supporter of the citizen logic and oppose the medical profession logic.

> *Payers are likely to shift even closer to the patient position because they will bear most of the economic consequences if healthcare systems fail to reform. (PwC, 2012, p. 14)*

During this period, the digital health field continues to grow and expand its boundaries, letting in or even bringing in new stakeholders. Institutionalisation processes are more intense, with ambivalent responses from carriers of the state, market and citizen logics. The conflict between medical profession and citizen logics continues. Digital health consolidates its socio-political legitimacy, particularly because of the involvement of academic organisations, but also because of more neutral players (other ICT providers, consultancies) that form a critical mass. This stimulates and mediates the hybridisation between the science, market and medical profession logics.

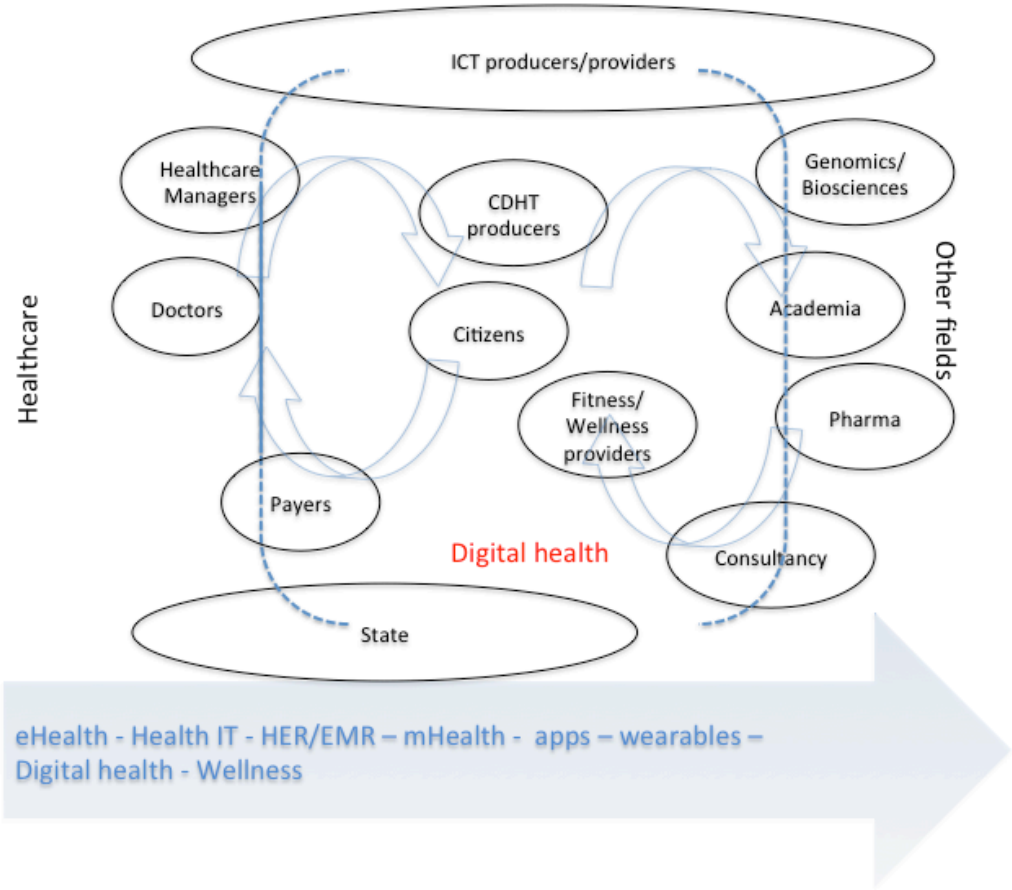

Fig. 31. Synthetic view of the stakeholders in the legitimation phase

At the end of this period, there is a rise of a health citizen, consumer and stakeholder. Debates are multiplied and diversified: doctors' resistance versus patient empowerment, peer-2-peer healthcare, quantified self, data protection and potential, infrastructure, interoperability, to governance, regulation and business models (including reimbursement).

7.3.3. The mobilisation age (2013-2016)

This stage could also be called 'democratisation' (Beverungen et al., 2015; Selznick, 1951), because it reflects the levelling of forces in the digital health field. 'Democratisation' is primarily used in the context of digital technologies to signify affordability and access. In healthcare, the term denotes on one hand the escape of medical knowledge, of the body and the lab from the traditional realm of the healthcare field, to become more accessible and controllable by lay people; on the other hand it refers to the availability and affordability of technology, which allows for innovation to come from unconventional

channels. Not to forget the social side of the digital technology – the sharing economy.

> *[T]his collective intelligence of this type of group is fundamentally superior to that of a traditional position based organisation. I think it's both the emotional and the cognitive drive that creates a reality that is unstoppable. (John Nosta, digital health evangelist, opinion leader)*

At this stage, most stakeholders (PwC, 2015) enter the field, recognize each other as co-participants, establish relationships or build barriers, co-opt and negotiate openly.

State's uncertainties perpetuate, with difficulties to balance the medical profession and market logics. However, the state faces increased pressure from digital technology makers who organise and lobby. In the US, the FDA keeps changing the guidelines. For instance, in 2015, before data collection ended, the FDA exempted wellness applications from regulatory oversight. Alongside the FDA, other departments get involved, the National Coordinator for Health Information Technology (ONC), the Federal Communications Commission (FCC), the Health and Human Services (HHS) and the Centre for Medicare and Medicaid Services (CMS). The EU only gets to launch a public consultation on mHealth as late as in 2014.

> *The eHealth Action Plan 2012-2020 indicated that the rise of mHealth is blurring the distinction between the traditional provision of clinical care and self-administration of care and wellbeing; and that different actors were seeking clarity on their roles and responsibilities in the value chain of mobile health. (European Commission, 2014b, p. 10)*

Such hesitation from the state generates uncertainty, confusion and resistance from most stakeholders: ICT and CDHT producers, patients, doctors or healthcare managers. It seems that neither the state's actions, nor inactions are satisfactory (Macnaughtan, 2014; research2guidance, 2014). More critical voices claim that the state is not going to enforce real change (ambivalence) in healthcare, due to its own bureaucratic structures and lobby groups.

> *Technology can – and will help – but all too often it's a tactical overlay to try and patch the flawed system we're living with today. (Dan Munro, Forbes healthcare contributor, opinion leader) (Munro, 2013)*
>
> *The technology part is easy. We know how to make this work, but we lack the societal will to make it happen. The government can do much to push the system along, but device manufacturers, technology companies and hospitals need to do the rest. (Anna McCollister-Slipp, patient and judge on Qualcomm Tricorder XPRIZE) (McCollister-Slipp, 2014)*

Despite such turmoil, the use of digital health solutions continues to take off.

> *Most medical treatments have been designed for the "average patient." As a result of this "one-size-fits-all-approach," treatments can be very successful for some patients but not for others. This is changing with the emergence of precision medicine, an innovative approach to disease prevention and treatment that takes into account individual differences in people's genes, environments, and lifestyles. (Office of the Press Secretary, 2015)*
>
> *Some commentators have focused only on diagnostic tissue testing, but with advances in Genomic testing, big-data collation and linkage between large data-pools such as the NHS, the UK is in a prime position to exploit a strong scientific base and leadership in this nascent market by creating the newest Catapult centre. (Lewis, 2015)*
>
> *DeSalvo [at the time ONC Director, then assistant secretary to DoH] appears to be listening ("We're taking a step back", she told me), but voluntarily shrinking one's own bureaucracy and power has never been among our government's core competencies. (Bob Wachter, doctor and professor, opinion leader) (Wachter, 2015, p. 217)*
>
> *HHS Chief Technology Officer Susannah Fox[5] first told FedScoop in June 2015 of her ambitions to drive medical innovation in the hacker and maker movement — a phenomenon created by the re-emergence of do-it-yourself inventors and physically handy manufacturers*

[5] Susannah Fox was quoted before in this thesis as Assistant Director at PEW Research Centre, based on her role at that time.

> *using technological advances like 3-D printers and cheap microcomputers. (Mitchell, 2016)*

With the explosion of solutions and PHD volume, ethics and privacy come more and more to the forefront. Doctors are being one main stakeholder who is wary about these aspects, as being the first line in protecting patient privacy; and the state is expected to react, as ultimate guarantor of citizen rights.

> *The justification of the means by the end may sound good in theory, but I'm concerned about who may get hurt along the way. (...) I'm grateful for the thoughtful voices in digital health, who are willing to hold up their hands to balance the bright and shiny with the responsibility to put it to use within optimal ethical frameworks in which it can do the most good. (Sue Montgomery, nurse, opinion leader) (Montgomery, 2015)*

Doctors and healthcare managers are now in a state of limbo, in between evidence based and personalised approaches, between efforts to increase patients adherence to treatment and offering them choice, between the best outcomes for populations and the best outcomes for individual patients, between what they know and what patients want.

> *Like most systems — politics, weather, nutrition — these polarized extremes, autocratic paternalism versus loosey-goosey patient autonomy, simply lead to degradation of relationships and societal frameworks. (Cardin, 2015)*
>
> *Most of the time people with good ideas come in (...) but they have so little understanding of the context of healthcare that they don't understand all the reasons of why it's not going to be successful. (Tim Ferris, doctor and manager, Senior Vice President of Population Health Management at Partners HealthCare) (Harvard i-lab, 2014)*
>
> *These doc-entrepreneurs have waded into the most challenging patient populations – the so-called Hot Spotters – and become population health heroes. (David Chase, entrepreneur, opinion leader) (Chase, 2016)*
>
> *If the key to improved healthcare is better knowledge of individuals, and if we have better tools for this, where is the breakout success of applied data science in healthcare – a company whose success is tied*

not to selling the promise of individualized care and improving health, but who has demonstrably and reproducibly used this strategy to deliver better real-world outcomes, in a fashion persuasive enough to convince to someone to pay for it? (David Shaywitz, doctor entrepreneur, opinion leader)

[On other obstacles for digital health] Behaviour - making it part of regular business processes. Now people are asking for extra money to do digital health, while I think it should come out of regular improvement. (Lucien Engelen, healthcare intrapreneur, opinion leader)

But where is the integration and the motivation for healthcare providers to take part in these conversations in a way that is beneficial to their work? And we may have technologies out-there saying that 'you can invite your care providers and you'd have better access to them' and they're pretty much failing on that promise. We haven't understood the motivations well enough or there isn't the payment structure in place that participation can be rewarded to the carers. (Colleen Young, communications, opinion leader)

Payers are also more willing to consider and reimburse novel solutions, especially in the US, following the Obamacare. New, innovative health insurers appear - Oscar is one of them, born at the end of 2012, and considered to be "[a] post-Obamacare health insurer in New York has big-name backers, a tech pedigree, and an eye for data" (Ungerleider, 2014).

At this stage, there is an increasing digital health uptake from the medical community, so there is more hybridisation with both market and citizen logics. There are even healthcare providers who have app stores (NHS, Cleveland Clinic, Partners Healthcare). In the UK, there is guidance issued by the Royal College of Physicians for medical apps (Comstock, 2015b). Several healthcare providers (NHS, Cleveland Clinic, Mayo Clinic) have created innovation executive roles or departments to facilitate digital transformation. Sometimes they hire experts from ICT, showing intense hybridisation with the market logic. But, there are still on-going unresolved issues between doctors and other participants in the emergent digital health field.

Digital health producers continue to grow at a fast pace. Investments keep growing year after year and so the number of deals - 2014 almost matches the combined funding from the previous three years, and funding in 2015 surpasses that of 2014. There are mergers and acquisitions (sign of market validation and beginning of coagulation).

> *2015 was another year of big numbers for digital health—the year closed out with over $4.5B in funding flooding into the space, a sizable increase in the number of later stage rounds, and 187 M&A deals. (Wang, King, Perman, & Tecco, 2016)*

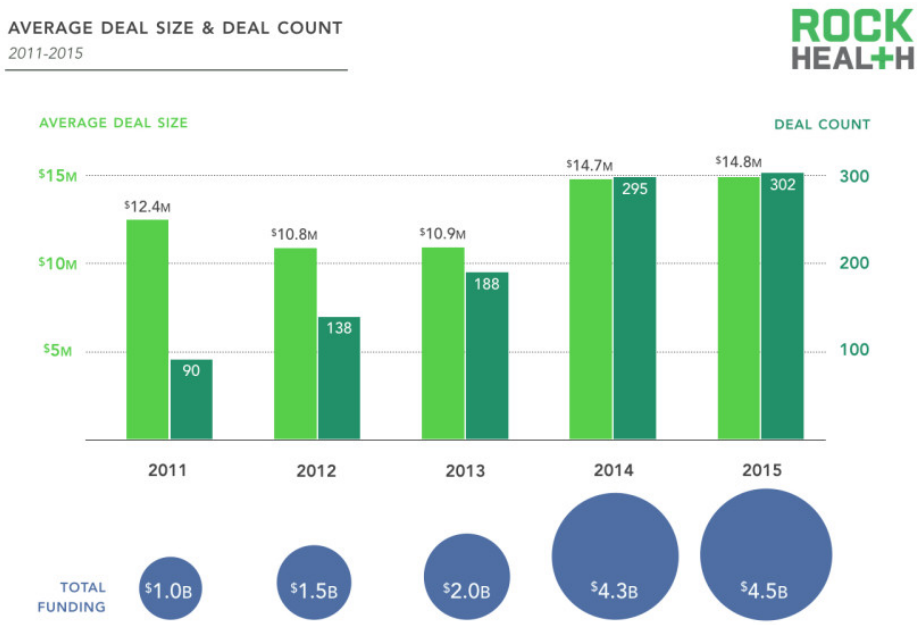

Fig. 32. Funding 2011 – 2015 based on RockHealth (Wang et al., 2016)

In 2013, Scanadu runs the most successful crowdfunding campaign of a digital health company (Wikipedia, 2015), proving the faith the market and the citizens place on digital health. This also sends a strong signal that innovation in healthcare is not innovation as usual and it hints to the democratisation of the space.

> *[T]his crowdfunding where you say "Come and we will build", you know the reverse of this [n.b. of developing a product first and then put it on the market]. Plus, at the same time, you are building it - you are building it with a community and also crowdsourcing the legal*

aspects of this community, and the usability aspects… I think that's one of the biggest new trends of building medical devices now… (Walter de Brouwer, entrepreneur, opinion leader)

I believe it in many ways digital health is defined by the collaborative experience. It's no longer about control - where the doctor has 100% control or the pharmaceutical industry has 100% of control around the messaging for a particular drug product or service. Today control is replaced by collaboration. (John Nosta, digital health evangelist, opinion leader)

Research2guidance (2014) finds that 36% of the app developers entered the market in 2013 and the first quarter of 2014. The same report shows that there are solutions developed by medical specialists (20%) and highlights even a category of app developers, 'helpers' (32%), with the primary intention to help others (ibid.), demonstrating strong hybridisation with citizen logic. Market logic is found to hybridise with both challenger (citizen) and incumbent (medical profession) logics, and hence its carriers are prone to ambivalence.

Because it's not what you do, it's not how you do it, it's why you do it. You see this all the time in digital health. People come up with new ways of measuring blood glucose or a wearable to measure some wellness aspect. We know how they do it - leverage technology to support some aspect of health. But WHY they do it… the centre of our human brain. And human brain is not about function, is about emotion. The nonverbal drive - because you want to change the world, because you want to save a life, because you want to have a better life with your child. (John Nosta, digital health evangelist, opinion leader)

In this day and age, where the explosion of apps, etc., if you don't walk in the shoes of the patient, that is going to be using your technology, you're gonna fail. You're gonna absolutely fail! (Michael Seres, patient entrepreneur, opinion leader)

The hybridisation process between the market and medical profession logics is also reflected in hiring practices, co-founding structures or organisational governance. An increasing number of digital health companies have doctors on advisory boards. Similarly, hybridisation is revealed by the time and money CDHT producers (i.e. Monica Healthcare, SmartInhaler, Wellframe) put into

offering their technologies to healthcare or academic organisations for research, in the effort to legitimise their products and obtain contextual information for perfecting them. More companies present mission-orientated founders' stories. Such founders could be clinicians (Alivecor, Ieso Digital Health), caregivers (i.e. Scanadu, myTomorrows) and even patients (i.e. 11health, mySugr, Sleepio) or other technology or life science specialists (i.e. Theranos, 23andMe).

> *I would not be in this business if I did not have unrealistic expectations of what this company can do in society. (Anne Wojcicki, biologist entrepreneur)*
>
> *When my father had no more treatment options and was dying of lung cancer, I could have given him access to promising unapproved therapies because I worked in the biotech industry. When he passed away I realized how unfair it was that only I had that option. That's why I founded myTomorrows. (Ronald Brus, doctor and carer)*

Deborah Kilpatrick, CEO at Evidation Health, says during the Innovation Summit at Stanford Medicine X (2015) that there are no digital health specialists and so we see a dance between data and clinical specialists, which leads to the redefinition of outcomes. Such remark shows how digital health develops as distinctive field, which requires distinctive capabilities.

Apple continues to disrupt. It launches the Apple Watch and the HealthKit development platform in 2014, but most notably, it creates the Apple Research Kit (2015).

> *It's really incredible... in the first 24 hours of research kit we've had 11,000 people sign up for a study in cardiovascular disease through Stanford University's app. And, to put that in perspective-- Stanford has told us that it would have taken normally 50 medical centers an entire year to sign up that many participants. (Tim Cook, Apple CEO)*

Only a few days after, Apple announces an ethical approval from an independent board required for scientists willing to use the Research Kit for research (hybridisation with medical profession logic).

> *As researchers become comfortable with the idea of running a trial exclusively through an app, studies might become riskier. If that*

happens, developers will likely have to make some changes — changes that may include coming up with more secure ways of keeping minors from participating in these trials, for instance. (Duhaime-Ross, 2015)

Similarly, Theranos (US) becomes a disruptor by 'democratising' the lab (hybridisation with citizen logic). It brings lab testing close to patients, with convenient (via Walgreens), cheap, independent of insurance, pain free blood tests, patient online access and control over test results. Theranos is perceived to defy the traditional peer review process of scientific discovery, by taking discovery out of the academic reach (conflict with science and medical profession logics) and protecting it through secrecy (market logic) (Loria, 2015). Its board of directors looks more like a state department than a company's board. Theranos follows all regulatory requirements, but it is not shy to push for political change (Office of Arizona Governor, 2015), joining other companies, for instance 23andMe, and more recently Walgreens or MDlive. Theranos though is shattered by a scandal over regulatory and clinical robustness. At the end of data collection, debates were on-going. This is a fulsome example of ambivalence in an emerging, fragmented field, as well of the vulnerability new organisations have.

Now everyone is like "Oh, it's all going to hell! All overrated! Look at Theranos… ". I think now, in contrast, people are getting overly negative. And instead of saying "Well, you tried to be disruptive, and look at how it's not worked out", you think that people were foolishly naive to try. (David Shaywitz, doctor entrepreneur, opinion leader)

The idea of scrutinizing an idea of questioning its clinical validity, of looking at its real data to support its use, I think it will, well out of necessity, come to the forefront. And with that might come some scepticism. I think that companies like Theranos have hurt and helped the digital health space. Digital health space because it may have directly impacted venture capital, engaging in some ideas that may not be completely, fully baked, it may mean investors may not to be happy to take the risk. It failed up digital health by a lack of transparency and failure to rise above the scrutiny. (John Nosta, digital health evangelist, opinion leader)

> *I find both very interesting, and some discouraging, especially the Theranos one. So much money has gone into it and it was just a balloon. I think there is something there, but the media hype makes you unable to see it. No one will ever know because that company will never come back I think. (Sara Riggare, patient researcher, opinion leader)*

There is perhaps more maturity in how technology is evaluated and various shortcomings become exposed and discussed.

> *There will be more focus on evidence and proof of value. Federal government fined Luminosity a few days ago... I don't think regulatory wise is going to become such a big burden. I think there is some good to the regulation, that things function as they say. The biggest issue is going to be too many companies and too little evidence. And the ones who can't prove it are not going to make it. (Lisa Suennen, investor, opinion leader)*

However, CDHT companies begin to expand on their solutions. There is still a significant amount of experimentation, serendipity and business model morphing.

> *I spoke to her [n.b. one of Empatica's co-founders] at the ethics conference last summer, and I think one of the things they are doing: extending applications of existing technologies. (...) With Empatica - a device to help with communications, one of her students took it home over the Christmas break because her brother was autistic and wanted to work with him. And she was monitoring the data in the lab and she saw this tremendous spike in his brother's data at one point. A few minutes later... her brother has a seizure. And so they found that they could anticipate when these seizures happen. (Sue Montgomery, nurse, opinion leader)*

The enthusiasm for wearables is apparently curved (Mark Sullivan, 2015). There are perceptions that digital health looks to empower the super-healthy, less a person who suffers from an illness.

> *A fitness tracker could be programmed to encourage more activity up to a point, and then warn the user to slow down as the step count grew too high. But the marketing campaign for that type of product*

would discourage sales growth. (...) When people develop technology for patients, they often don't even consult with a single patient. (Carly Medosch, patient)

Despite such concerns, Rock Health releases in 2015 a report on consumers' attitudes towards digital health, which shows that wearables occupy the majority of the landscape and that there is actually a spike in adoption by people with health problems.

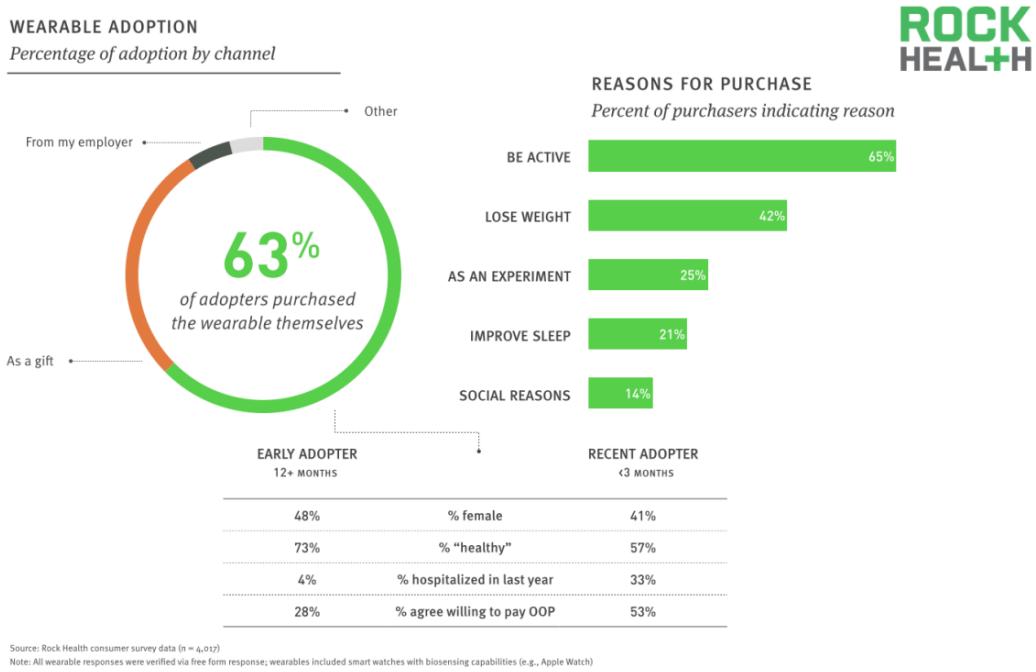

Fig. 33. Rock Health data on wearables adoption (Gandhi & Wang, 2015)

Although health apps download rates are increasing, so are the uninstall ones (research2guidance, 2014), and engagement remains modest (Ayogo, 2015; Dias, 2014; Fox, n.d.; Pennic, 2015; Salber, 2015). This becomes a major preoccupation for CDHT producers, as user engagement represents part of the market validation of the product. Nonetheless, the market is learning fast given the estimated 160000+ health apps on the major app stores in 2015 (IMS Institute, 2015).

There are more than twice as many health apps as there were in 2013, but whether those apps are better tools for doctors and patients is a mixed bag: while apps today are more likely than two years ago to connect to another device or wearable and more likely to connect to

social media, they are no more likely to connect to provider systems or to have more than one function, according to a new report from IMS Health. (Comstock, 2015c)

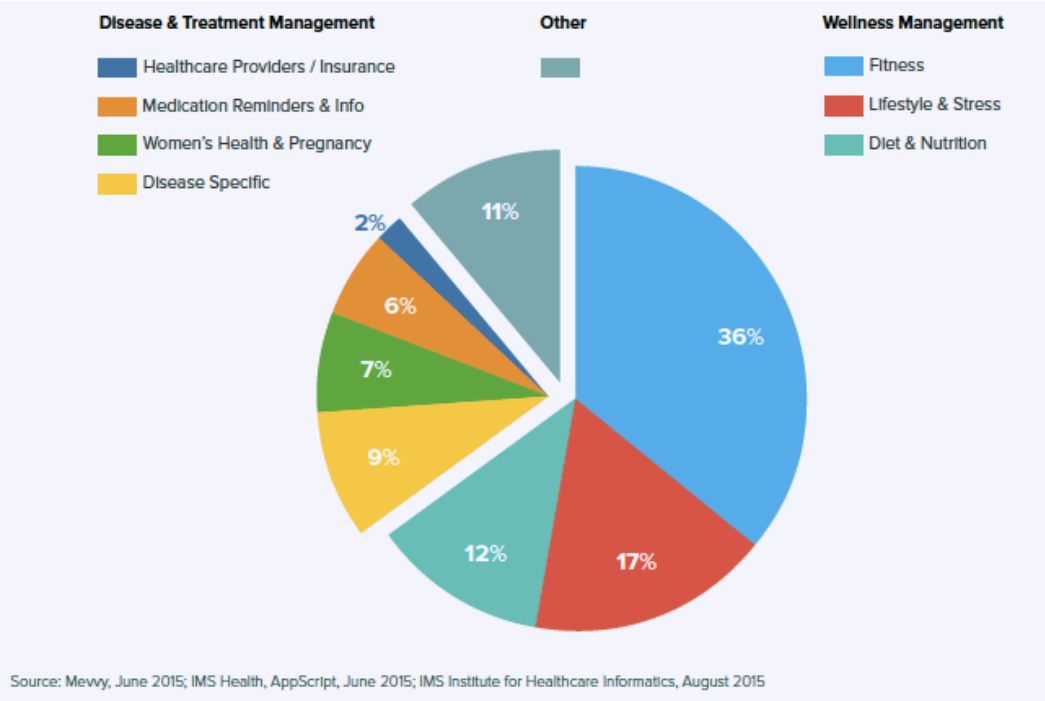

Fig. 34. Apps segmentation in 2015 (IMS Institute, 2015, p. 4)

Many connectors, integrators, and data analytics companies who mitigate various aspects of adoption, integration, security, and interoperability enter the field. Such intermediary services (i.e. Validic) appear to have the highest revenues (Research2guidance, 2014), proving the need for filling in information and skill asymmetries across fields – i.e. healthcare and digital health, pharma and patients, or CDHT and patients. Such multifaceted hybridisation points forge crossovers, new practices, new boundaries, and therefore reflect the on-going process of institutionalisation in the nascent digital health field.

Overall, there is a light segmentation of the market, although categories remain fluid. Such categories may be: wearables/insideables, artificial intelligence, telemedicine, consumer engagement, health tracking, analytics and big data, payer or hospital administration, EHR, gamification and virtual reality.

I think we are already seeing that: there are enterprise-focused technologies (employer, insurer, government, provider), there are

> *patient and consumer focused solutions and there are different verticals - administrative focus, clinical focus. (Lisa Suennen, investor, opinion leader)*

During this age, the most significant entrance is made by pharma. A report claims that patients consider pharma companies "responsible" to engage with them (Accenture, 2014). A similar message came across during the Patient Opinion Leaders and Pharma session (at Doctors 2.0 & You, Paris 2015). "Responsible" being the right choice of words or not, the fact remains that pharma looks to engage with patients via CDHT, and therefore to hybridise with the citizen logic. Dr. Wolfgang Renz, Corporate Vice President, Boehringer Ingelheim, says that pharma gets the idea that wellness, preventive medicine, and mobile health are the future, but their regulatory regime is so strict that the industry did not yet find a formula (plenary talk mHealth Summit, Berlin 2014). Neil Jordan, Worldwide Director of Microsoft Health, considers that pharma is the game changer in digital health (plenary talk DHL, Dubai 2015). With the release of the Apple Research Kit, 2015 seems to bring a new wave of enthusiasm in the pharma industry. Some pharma companies branch out and start investing in digital health (i.e. Bayer's Grants4Apps), as a 'beyond the pill' approach (Jain, 2015). Other promising avenues for pharma mediated by CDHT are personalised medicine, genomics and lifestyle (Accenture, 2014; Gerber, 2015; Jain, 2015; Merrill Thompson, 2015; Validic, 2015; Xavier, 2015).

> *That said, there are a lot of efforts underway to address medication adherence, from Boehringer Ingelheim and others' pilots with AdhereTech, to Novartis' work with Proteus Digital Health, to Johnson and Johnson's huge, unbranded Care4Today mobile platform. (…) "And the intent is to show that the drug plus the digital solution is more efficacious than the drug itself, and the competing drug. I think it's that kind of success that will prove to the industry this is no longer a science experiment, this is something that can be a game changer". (Comstock, 2015a)*

The academic world continues to explore (with ambivalence) new digitally mediated avenues: patient engagement, service redesign, genomics, personalised medicine and so on. There is a push for using PHD for the "public

good" (RWJF, 2015; University of California, 2014). It has been shown that in times of crisis (emergence is similar to institutional crisis because it is a contested space), different actors have to negotiate over different definitions of the "common good" (Patriotta et al., 2011). Opinions are divided on the need for privacy and PHD use for scientific advancement (Heubl & Saafeld, 2014). "In some contexts, digital users are the willing generators of personal data; in others they are the objects of imposed data surveillance. Programs for eliciting and responding to these data are proliferating within government and commercial environments" (Lupton, 2014c, p. 8). In this context, a new business opportunity appears: health data banks for citizens to allow them to own, control and share their health data (Our Data Mutual in UK, healthbank in Switzerland, or datacoup in US, Cancer Moonshot initiative in the US). When debating the PHD worth, ownership and control, there is increased ambivalence between citizen, market, science and medical profession logics. This type of debate proves that digital health is still emerging, with no clear rules of the game or ownership (Fligstein, 2002).

> *While you might dismiss this as a publicity stunt, I was struck by the comments of the company's founder and CEO, Charles Dunlop, who has been diagnosed with advanced prostate cancer, according to Times, and is keen to share rather than hoard or sell Ambry's data because, in his words, "I don't want to wait an extra day." (David Shaywitz, doctor entrepreneur, opinion leader) (Shaywitz, 2016)*

Atul Butte, professor at University of San Diego, considers that we got so far in the democratisation of science and technology, the transformation runs so deep, that we should expect to see biotech garage startups soon (Atul, 2015).

Citizens mobilise and their voices are getting louder, more empowered.

> *Patients and caregivers need to bravely step forward again and again to talk about the problems in the healthcare system. (Regina Holliday, carer, opinion leader) (Holliday, 2015, p. xx)*
>
> *Social change and technical change are hard. But people's lives are at stake, and that's something worth doing hard things to improve. We can do it; they can do it. (...) Plan for action, and bring friends. It will*

> *affect them, too. (Dave deBronkart, epatient, opinion leader) (deBronkart, 2015)*
>
> *For those of us with chronic disease, a digital health revolution is the best chance we have. We need it to succeed. We're desperate for innovation that works. We have experienced tremendous developments and intuitively grasp the potential, but when we peruse the app store and download a few, their usefulness rates as "meh" at best. (McCollister-Slipp, 2014)*

Patients are for the first time recognized by a medical journal, The British Medical Journal, as legitimate stakeholders.

> *"The BMJ's patient partnership strategy, launched in 2014, introduced innovative internal editorial changes aimed at making patient partnership integral to the way the journal works and thinks. We did this because we see partnering with patients, their carers, community support networks, and the public as an ethical imperative essential to improving the quality, safety, value, and sustainability of health systems." (The BMJ, n.d.)*

The role of the patient is now more and more theorised. There are now patient advocates/opinion leaders (i.e. Regina Holiday, Dave deBronkart, Michael Seres, Britt Johnson), patient experts (usually the ones who are suffering from a chronic condition), patient researchers (i.e. Emily Kramer-Golinkoff or Sara Riggare), patient entrepreneurs (patients who design solutions based on their personal experience with the disease – i.e. Michael Seres). The conversation around the patient role moves from patient engagement to empowerment, to participation and even to leadership.

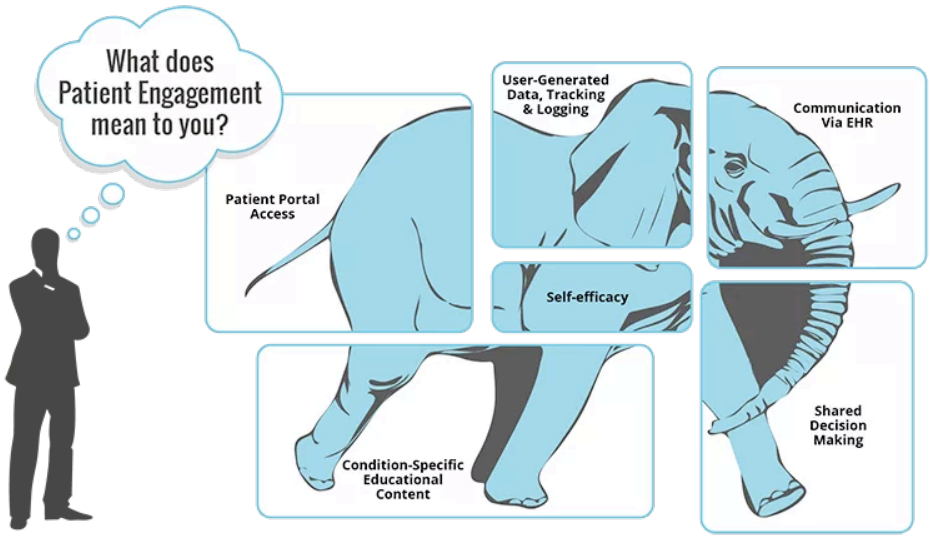

Fig. 35. Patient engagement represented by a CDHT producer (Ayogo, 2015)

Learning to take emotion out of a decision is hard. It is especially hard when you are building a technology based on your own personal experience. Every day I strive to make our technology the best it can possibly be. (Michael Seres, patient entrepreneur, opinion leader) (Seres, 2015b)

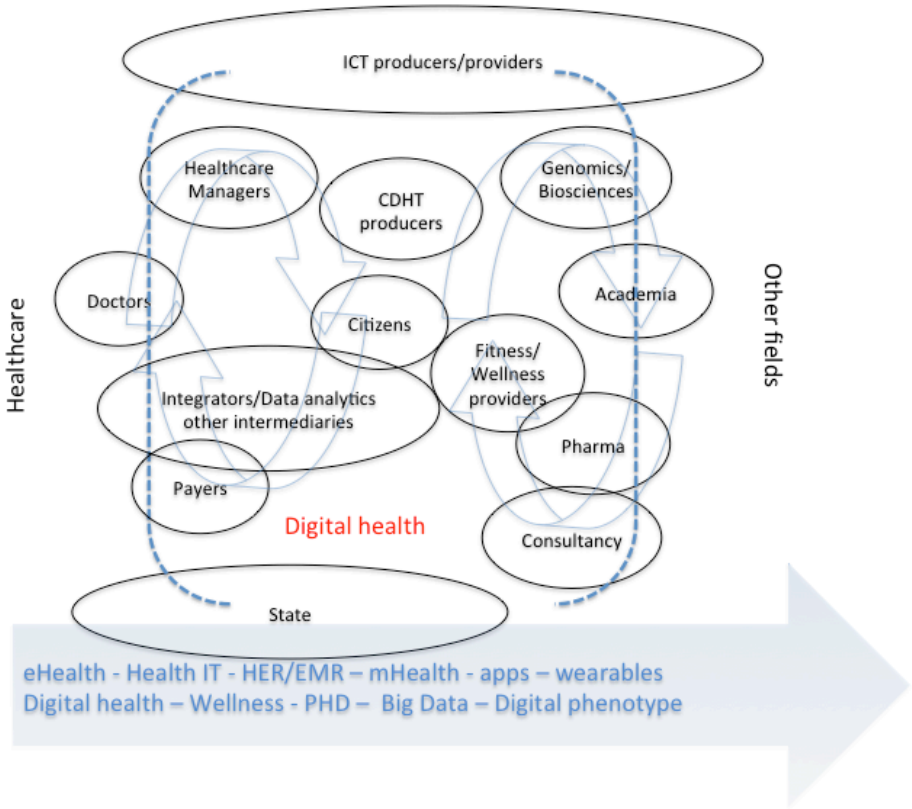

Fig. 36. Synthetic view of stakeholders in the mobilisation phase

During mobilisation, by the time data collection ended, digital health gets crowded, not only with apps, wearables, insideables, but with new players (pharma, integrators, intermediaries). The language diversifies, with some terms becoming prevalent and new ones appearing: wearables, insideables, apps, expert patient, gamification, health 2.0 or Big (Health) Data. This period marks the beginning of some digital health differentiation: based on focus (wellness, health), type of information collected or offered (monitoring, disease management, education), users (wellness users, patients or doctors) and finally by type of interaction (consultation, diagnostic, disease management, education or administration). It is important to bear in mind that these new categories are in flux, as reflected for instance in market reports like those produced by Rock Health. This means that the field is still evolving and revolving, in pockets of negotiations. I call this *granularity* of the field, when categories and relationships are still in flux, and evolve in fluid, morphing ecosystems.

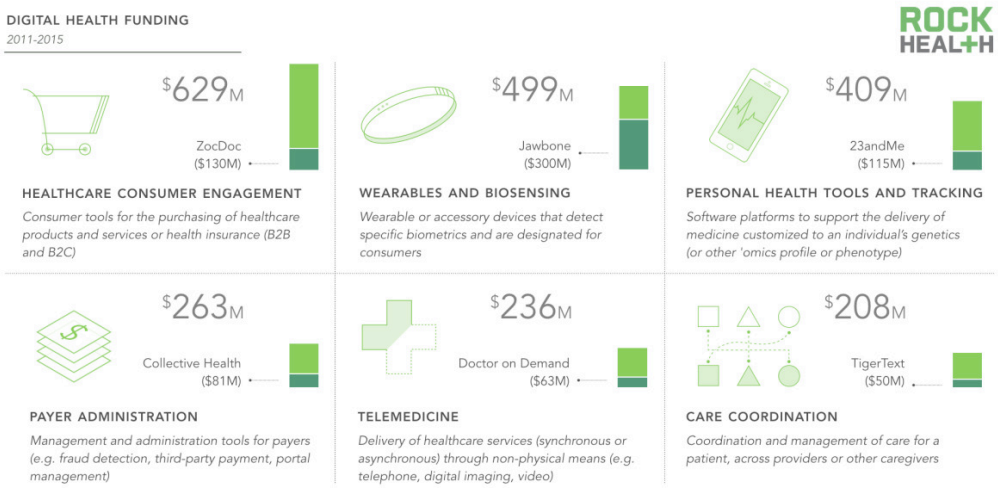

Fig. 37. Type of market segmentation (incomplete) (Wang et al., 2016)

Debates over the role of each stakeholder are on-going, showing the institutional complexity, the unfinished institutionalisation, and the power struggles in this field. An excellent example is offered by the "Twitter firestorm" caused by Mark Cuban, a US businessman, who on April 1, 2015 wrote three tweets that caused intense debates:

1) If you can afford to have your blood tested for everything available, do it quarterly so you have a baseline of your own personal health

2) create your own personal health profile and history.It will help you and create a base of knowledge for your children,their children, etc

3) a big failing of medicine = we wait till we are sick to have our blood tested and compare the results to "comparable demographics (Mark Cuban, business man)

The intense social media turmoil over the next 48 hours was documented by Dan Munro, who concluded:

> *Simply saying we shouldn't do something because we don't know the value – and there is risk – seems to be an especially weak argument at the same time as trying to engage people more directly in their health and well being. Mark knows this personally and just pre–empted what he's already seeing in the market. We may not elect to participate in the experiment – but that doesn't mean the experiment itself doesn't have value – or that it shouldn't be recommended for those who can afford it by someone who's actually doing it. The technology has arrived. Patients will decide what works best for them and we should let them.*

7.4. DIGITAL HEALTH, A MELTING POT OF POSSIBILITIES AND ISSUES

In this chapter, I show how digital health interstitial emergence takes place with the gradual involvement of stakeholders. Their engagement with innovation opens up the digital health space, by tackling discontinuities in the healthcare system, expanding the understanding of healthcare from illness to disease and connecting stakeholders in ways that were not possible before.

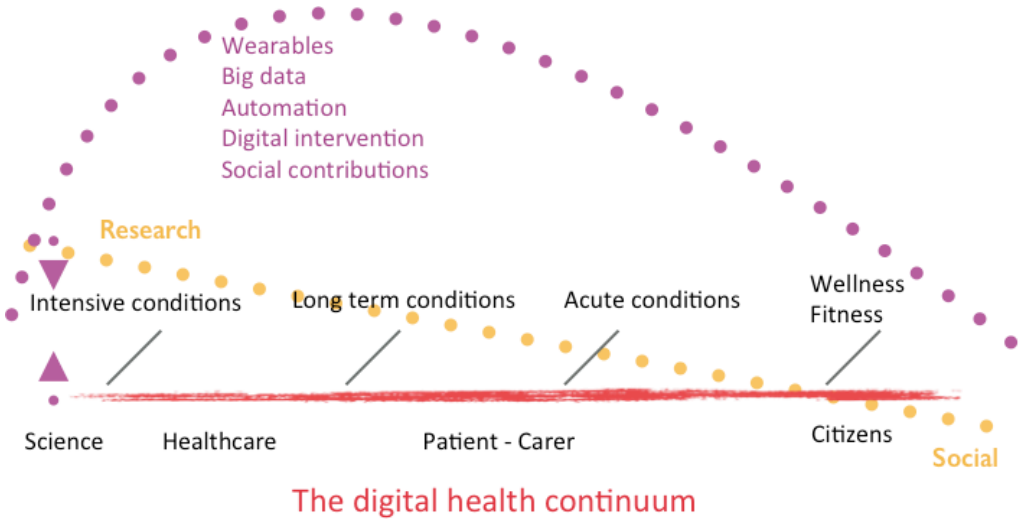

Fig. 38. The digital health continuum

The diagram above intends to present intuitively how digital solutions impact across the spectrum, from the social side to healthcare and science. All players have their specific inputs into the field expansion and institutional evolution. For instance, on the social side, we have examples from patient forums/groups to patient networks, and even to citizens donating via crowdfunding. Moreover, there are citizens contributing to medical science too – Cancer Research UK develops games where lay people could help scientist fight cancer.

> *Play to Cure: Genes in Space is Cancer Research UK's second Citizen Science project – last October the charity launched Cell Slider TM in partnership with the Citizen Science Alliance, which reduced the time it would take for researchers to analyse a subset of archived breast cancer samples from 18 months to just three months – with more than 200,000 people classifying almost 2 million cancer images. The aim is to help Cancer Research UK scientists with their research to better understand breast cancer risk and response to treatment. (Cancer Research UK, 2014)*

Without the digital intermediation, such mass contributions from people to science would have not been possible. The orange dotted line shows how the social side and the science converge towards healthcare, barriers being eroded over time. Similarly, the conversation shifted from healthcare being focused on illness only, to prevention and enhancing health. However, the closer an innovation came to illness, the heightened pressure to comply with incumbent

logics (medical profession, state and science). The purple dotted line represents how new connections are made across the spectrum via digital solutions and devices.

These new interactions challenge the traditional power relationships and thus lead to a continuous morphing of all roles, pushing the citizen to the forefront. Solutions like those above developed by Cancer Research UK allow people to contribute to science. There are also other examples of solutions where stakeholders outside the traditional healthcare field contribute to the demise of status quo (Scanadu's crowd funding campaign for instance, 23andMe and Theranos getting involved in changing legislation and working with regulators). Such diversified participation gives the sense that digital health develops similarly to a social movement.

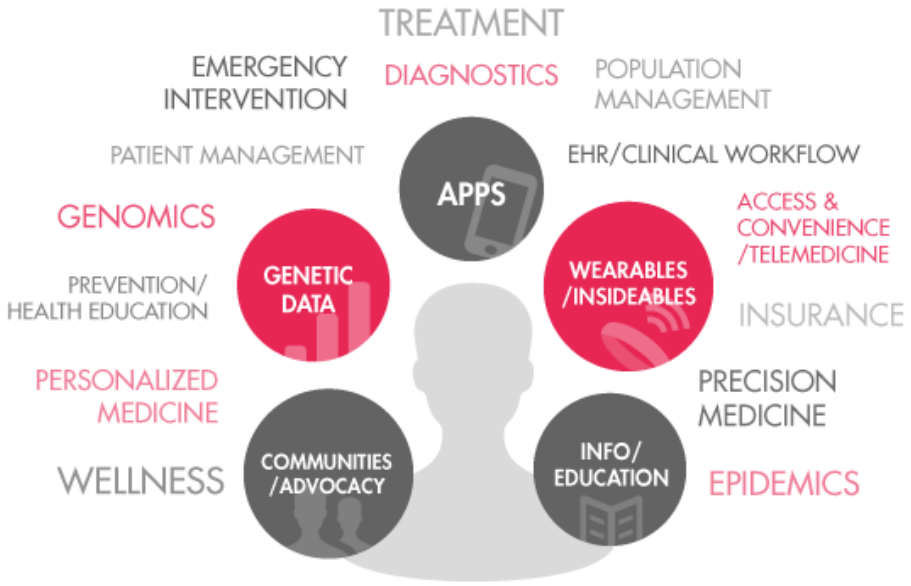

Fig. 39. Digital health's inflated agenda - citizen centred representation (Macnaughtan, 2015c)

The figure above shows how all these innovations brought to the fore a multitude of opportunities that have at centre a new patient or health aware citizen. However, various challenges accompany these opportunities, from new roles and practices, to adoption, to evidence or regulation.

During this phase, the terms "democratisation" and "uberisation" of healthcare are very much used and even if they would fade over time, they have a great bearing on the sense making and sense giving at the field level. They are metaphors for misalignments and desired realignments between the digital technologies and healthcare fields. They also indicate the increasing influence of the market logic. Democratisation reflects primarily the change in the balance of power, with the increased influence of the citizen logic. Eric Topol writes a second book in 2014, as influential as the first one, *The Patient Will See You Now*, dedicated to precisely the role the patient and technology will disrupt healthcare at its core. He considers the proliferation of smartphones to be a moment similar to the Gutenberg one (E. J. Topol, 2015).

> *So we are seeing a magical time in human history that some people call Gutenberg moment, the printing press moment. I would argue that it's even bigger than that - it's not only one technological achievement, it's multiple technological, human and social achievements. (John Nosta, digital health evangelist, opinion leader)*
>
> *Just as the printing press democratized information, the medicalized smartphone will democratize health care. Anywhere you can get a mobile signal, you'll have new ways to practice data-driven medicine. Patients won't just be empowered; they'll be emancipated. (Eric Topol, doctor, opinion leader) (E. J. Topol, 2015)*
>
> *They [n.b. the smartphones] will perform blood tests, medical scans, and even parts of the physical examination. Topol calls this "bottom-up medicine", in which digitally empowered patients will truly take charge of their own health care. Just as smartphones and social networks powered the uprisings of the Arab Spring, in Topol's view they are now poised to bring democracy to medicine. (Jauhar, 2015)*

The democratisation of healthcare also means that innovation is now coming from unconventional routes, not only from clinical/research centres, pharma or medical device companies, but also from CDHT producers and even citizens. The implications are that basic roles, practices, business models and governance are being challenged. The state finds itself eventually not being able to grasp and cope with the pace of innovation. "Regulators seem to have difficulties in both identifying and clarifying the basic principles in which to ground these (de)regulations. There are a few themes which return obstinately

in regulatory debates: data, patient, disease and medical device" (Macnaughtan, 2014).

With the democratisation of healthcare, there is an increasing debate over the democratisation of medical education itself, a field that didn't change in over a century - from 3D models of the human body, collaborative learning, gamified information delivery systems and evaluation, to the potential of virtual and augmented reality. Stanford Medicine X launched in 2015 the first event on medical education.

> *Medicine X | Ed will focus on the future of medical education in the new Millennium, the role technology and networked intelligence might play in driving educational innovation, the new challenges facing health care education in the new Millennium, as well as the need to change the culture of medical education to be more patient-centered, participatory and patient-safety-focused. (Stanford Medicine X, 2015)*

The uberisation of healthcare points to the dream of a perfect market in healthcare, where demand will instantly match the need, for the right price and the right quality. This means that low cost medical providers will disrupt the expensive ones; that telemedicine, do-it-yourself and other models will disrupt what we know about doctor-patient, patient-payer, doctor-payer relationships. Uberisation also is also about connectivity and ubiquity and the unfinished character of digital technologies. Digital health opens doors for both new modi operandi and new connections to be made. Inherent to mobile, digital, sensing technologies are attributes like availability, universality, serendipity, affordability and immediacy. Digital technologies respond to and enable a highly "adaptive" generation (Sculley, 2014), with little regard for traditional ways of doing business, prescriptions and channels. Such behavioural and cultural propensities would eventually transfer to expectations from healthcare, as an essential part of an autonomous, mobile and connected life.

7.5. INSTITUTIONALISATION PROCESSES

Institutionalisation processes are both hybridisation and conflict, with increased prevalence of the former. The conflict unfolds initially as resistance from powerful incumbents (doctors) and almost ignorance from challengers (CDHT producers and citizens). The entrance of other players with more neutral stances towards the rival logics (consultancy companies, academic organisations) allows for increased hybridisation. This does not mean that conflict evaporates, but only that the interstitial space constantly opens up, forming a critical mass.

The ambivalent responses of most stakeholders denote the on-going negotiation and legitimation processes, as well as the heightened degree of ambiguity. The granularity of the field allows for the development of concurrent pockets of negotiations that represent proto-ecosystems (i.e. alliances, networks, research initiatives, hybrid organisations, industry associations). This granularity allows for ambivalence, without being a threat in itself for the field or incumbent organisations (Waldorff et al., 2013).

The multiplication of players and institutional logics erodes the incumbent logics (state and medical profession) and facilitates the rise of the citizen challenger logic. This makes the digital health emergence resemble a citizen rights movement (Fligstein & McAdam, 2011). And last, access to resources plays a significant part in the interstitial emergence of the field, from the creation of a bandwagon effect, to the co-optation of incumbents (doctors, pharma) via incentives and penalties (from payers and regulators) or prospects of alternative resources (investors, crowd-funding, academic centres, new market opportunities). Digital health is possibly one great example of disruptive innovation, as Schumpeter envisions it, because it causes a paradigmatic change. Not only the technology evolved, but…

> *[t]he combination of passive (sensor mediated) observation and proactive life-style strategies for disease suppression can define a new era of health and wellness. (John Nosta, digital health evangelist, opinion leader, (Nosta, 2013)*

7.6. THE DIGITAL HEALTH FIELD EMERGENCE

I show how digital health emerges through three phases, by the time data collection ended, the ingenious, the legitimation and mobilisation stages. The ingenious phase is characterized by genuine experimentation, serendipity, opportunity recognition and by the fact that initially the interstitial emergence goes unnoticed by some incumbents (i.e. healthcare, pharma). Mobilisation engages a critical mass of stakeholders and brings in alternative practices, which cause intense institutional negotiations. My findings introduce a stage between the ingenious and mobilisation stage – legitimation, as a stepping-stone between the two. In digital health's case, political legitimacy was conferred from the outset by state commitment and citizen uptake, during the ingenuous phase. Social legitimacy is co-constructed through the initial interaction of stakeholders and, more importantly, through *legitimising* (academia) and mediating actors (consultancies, other intermediaries) who are capable to co-opt more resistant stakeholders (herein doctors and pharma).

At the time I finished the field research, digital health was still in its mobilisation stage, with most stakeholders being active in the field. During mobilisation, there is certain *granularity* in the emergent field. This is different from segmentation, which takes place only when there is significant decrease in uncertainty and ambiguity that allows stakeholders to organise on various levels and around value propositions. This degree of clarity was not attained by digital health by the time my research ended. However, the granularity of the field, means that there are proto-ecosystems, where stakeholders try, experiment and negotiate various aspects of certain innovations (Jacobides et al., 2018), without threatening field survival.

It is beyond my research to foresee the future of digital health - if this field is going to get to stabilisation, how it's going to be segmented, if it's going to be absorbed by adjacent fields… It is clear though this is a space where healthcare related innovation comes from untraditional places as well – digital consumer technology producers, patients, and citizens, at large. To this end though, many others in this rising field share Lisa Suennen's observation:

I am not sure that digital health should be a concept at all anymore, or ever. In no other industry we talk about the technology driving that industry separate from the industry itself. (Lisa Suennen, investor, opinion leader)

7.7. THE HYBRID ROLE OF THE EMPOWERED PATIENT

Digital health brings forth a new hybrid role: the *empowered patient*. An empowered patient, who self-educates and manages their own health and wellbeing, challenges the traditional healthcare settings at its core: professional authority (Abbot, 1988; Nicolini, 2006; Petrakaki et al., 2012). In this way, this role is a proto-institution, the epitome of the citizen logic in digital health.

	Old Patient	**New Patient**
Doctor encounter	Illness	Illness, wellness or neither (DIY, peer 2 peer, CDHT)
Control over interactions	Doctor	Convenience
	Discontinuous	Continuous, via data streams
Focus of attention	Symptoms	In addition, self-generated data
Validation of diagnostic	Lab tests	Over the counter tests, self quantification
	Doctor expertise	Doctors, peers, crowd wisdom, automated analysis/processes
	Physiological measurements by doctors	Self-generated data
Treatment	Doctor	Patient choice Peers, alternative references
Control over treatment	Treatment adherence	Patient participation
		Transparency
Support and education	Doctor and other non-doctor medical personnel	Peers, internet sources
Outcome	Cure illness	Personal satisfaction/values Cure illness, improve health or wellness
	Clinical outcomes	Patient reported outcomes and satisfaction

Table 12. Towards the empowered patient/citizen

Between the view of an empowered patient who quantifies themself, self manages, even diagnoses, provides knowledge advancements and the view of the vulnerable patient (Lupton, 2013, 2014d) who faces illness, confronts with

specialist data, needs support from doctors and even the state, there is still a large gap, where the concept of "loosey-goosey patient autonomy" (Cardin, 2015) reigns, for which even digital health does not offer a solution yet. I name this a hybrid role, because it brings together the vulnerability of a person, with the right to choose, the ability to choose (Seres, 2013b, 2013c) and the combined ability and desire to self quantify, self manage or even self diagnose. The conflict between the citizen and the medical profession logics may present in many ways. To mention a few: patients may expect to have total control over PHD, patients may not consider doctors as the only source for medical advice, or patients may expect to be partners in their diagnosis and treatment.

Doctors, who used to rely on statistical evidence for groups of patients, are now under pressure to take more precise, personalized approaches. How would all these changes impact healthcare providers, insurance or pharma companies in the long run is difficult to predict. It may create new roles - health data specialists, health coaches, health management and wellness providers - or completely new lines of business and research; time will tell.

7.8. Conclusions

This chapter reveals the evolution of the emergent digital health field and so it provides context for the analysis at organisational level. Changes in the institutional space are marked by intense processes of hybridisation and conflict, which eventually allow for the citizen logic to strengthen. The evolution by the time data collection ended goes through three main stages: ingenious, legitimation and mobilisation phases. During the last phase, the digital health space expands, opens up to many stakeholders, blurs boundaries, allows for unconventional paths to innovation in healthcare and challenges the existing power relationships, practices and even regulations. All these processes are possible due to the granularity of the field during mobilisation. I highlight the emerging role of the empowered patient/citizen as being central to the field institutionalisation as a whole and to the institutional work at organisational level, as it will become clear in the next chapter.

CHAPTER 8. ORGANIZATIONS IN DIGITAL HEALTH COMPLEXITY

8.1. INTRODUCTION

In this chapter, I analyse how three organisations undertake institutional work to navigate the complexity of the digital health emergent field. My findings indicate that there are several conditions that influence organisational responses to complexity: the position in the field, the plurality and ambiguity of the field, the represented future and the identity project. The position in the field determines the co-optation of key stakeholders to allow organisations to build competencies, access resources, gain legitimacy and build a market. Such co-optation processes allow for the hybridisation of logics. The institutional pluralism and ambiguity of the field present both challenges and opportunities for organisations. Organisations show flexibility and adaptability and become true institutional agents. And not last, organisations will respond differently to complexity depending on the represented future and their identity project. Social skills and leadership prove to have material consequences in organisational development in a new world.

8.2. BRIEF OVERVIEW OF THE ORGANISATIONS

Before proceeding, it is useful provide a brief refresh on the three companies: Mira Rehab, YouLife and 11 Health.

Mira Rehab is developing exergames, clinically based video games that incorporate exercises and movements with game interaction. To that end, they integrate sensors, at the time of study Microsoft Kinect, to support clinical physiotherapy. It all started when four Romanian master level students (business, engineering and IT) decided to join a student competition and they ended up amongst the ten finalist teams of the international competition Microsoft Imagine Cup, 2011. Following an invitation by HealthBox, a London digital health accelerator, to participate in their programme, they founded the company in 2012. Mira Rehab has been operating ever since in

both the UK and Romania. It is relevant to mention that at the time of founding, the company had a minimal viable product (MVP). They had investments from two angels in Romania, followed by HealthBox. Products were sold mainly in UK and Romania, with commercial interest from other countries in Europe, mainly via a B2B model, although a B2C model was not dismissed, just not actively pursued as a line of business at the time of the study.

YouLife is a company founded in the UK, which provided corporate client solutions for assessing personal health risks. Over the years, they have developed specific questionnaires, based on national clinical guidelines for specific health risks (chronic diseases, cancer), and also offered an overall score. Some of these were developed in collaboration with universities in the UK. In 2014, the board decided to pivot into digital and change from a business to business (B2B) to a business to consumer (B2C) model. YouLife had produced digital products previously for corporate clients: a website with specific access for management and personnel and an app (OtherLife). Despite that, they considered that the transformation of the company needed to be separated from its previous endeavours, as a radical change. Therefore, they have started a completely new product and business model, here named NewLife. The company self funded the development by diverting revenue from the legacy business. The NewLife app went live in 2015, via app stores, as a B2C model.

11 Health is a company based in the UK, founded in 2013. In 2015, it started operations in the US as well. The company produces a device, containing a sensor, which is attached to a stoma bag and, via an app, it supports the condition management for patients, and later for medical professionals. Michael Seres, the founder, came up with the idea following his own experience as a patient using a stoma. An angel investor invested in the company initially and so it was funded in in 2013, having a prototype ready, with a B2C model, followed later by B2B and B2B2C models.

8.3. TAMING LIMINALITY

As part of a new emerging field, organisations are peripheral to the adjacent fields, in this case to healthcare, academia, other digital technologies fields, amongst others. I have shown in chapter 7 how the liminal field of digital health expands from fundamental science and research to the consumer digital technologies, and how different logics have greater relevance on organisations depending on their position on the continuum. The figure below shows where on the digital health continuum each organisation is situated, based on the solution offered. 11 Health is the closest one to healthcare, offering a solution initially designed for patients living with chronic conditions who have a stoma bag attached and are hospitalised during the process of their medical condition. Mira Rehab is also close to healthcare, because it's initially designed for patients who need physical recovery, but are not necessarily hospitalised during the management of their medical condition. YouLife, with its NewLife offering, situates closer to the consumer digital market. It offers a health risk assessment and it's not meant to diagnose or treat a medical condition.

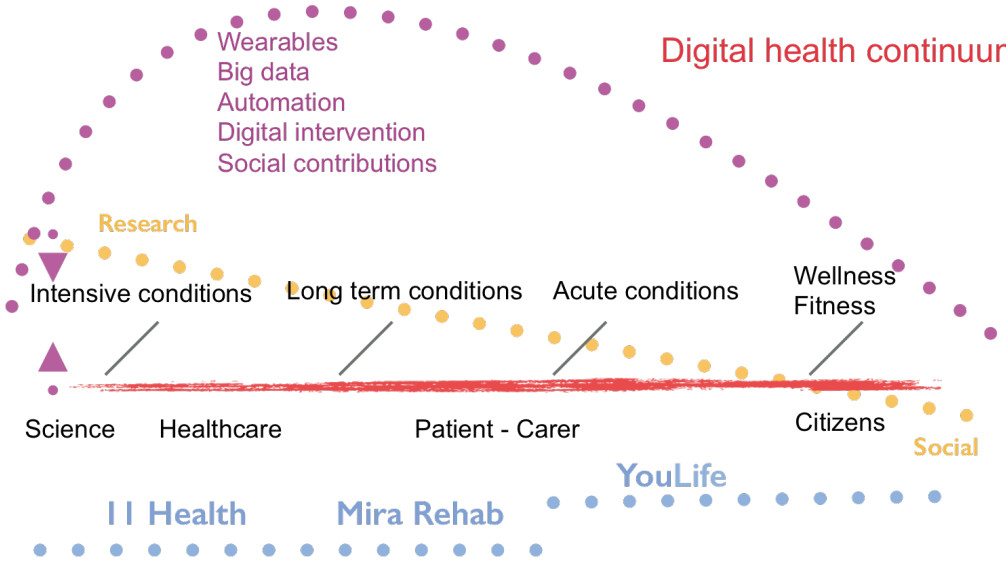

Fig. 40. 11 Health, Mira Rehab and YouLife on the digital health continuum

Their position determines their orientation and interaction with other stakeholders. This position is not static; it is subject to evolution, given the emergent nature of the field and the novelty of the ventures. All three companies, since their inception and even at short interview intervals (a few months), showed a realignment of their product and/or strategy. For instance,

11 Health evolved from a product designed for patients only to having more products for other stakeholders. At the end of 2015, they were launching an app for hospital staff – doctors and nurses. The app designed for patients also got an enhancement by getting integrated with the Apple Watch (a wearable).

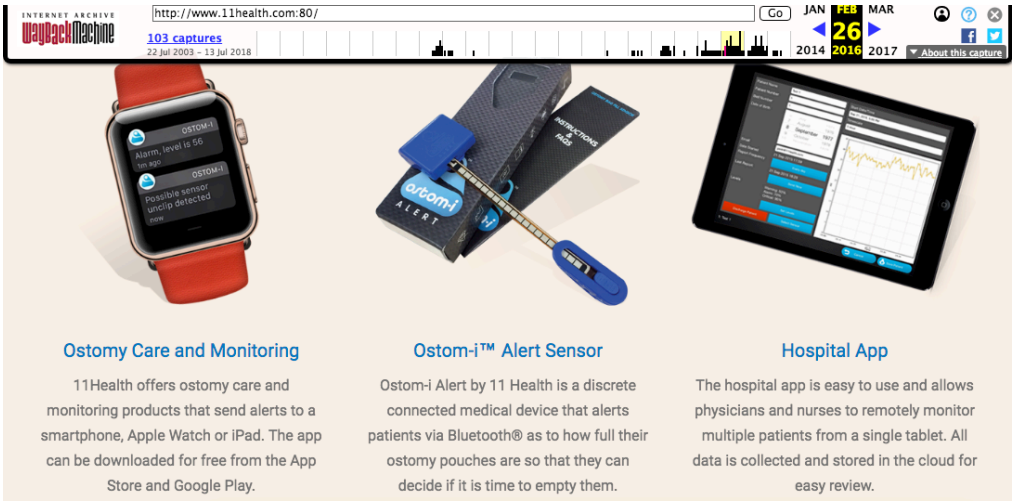

Fig. 41. 11 Health product offering at the beginning of 2016

Mira Rehab, following an SBRI grant, began developing their product to accommodate specific needs for the aging population, i.e. cognitive improvements and fall prevention. This became a new business segment, closer to a consumer model.

Most companies recognised their main stakeholders, including the regulator. With one exception, 11 Health, none of them got directly involved with regulators, aside from complying with the rules they recognised as being applicable to them. Mira Rehab and 11 Health had the CE mark for their patient facing technologies, and 11 Health also had FDA approval.

In 11 Health's case, Michael Seres had previous interactions with regulators as a consequence of his active presence online as a patient.

> *My big breakthrough came on the World Inflammatory Bowel Disease day, in May 2012. I was invited to speak in Brussels, at the European Parliament. Flights were booked and then I caught an infection. (...) So we agreed to do a Skype live link to the European Parliament, except the nurses came in and told me I need to swallow a radioactive egg to see how my stomach was emptying. So, from the*

> *depths of some CT scanner, we did a Skype link to Brussels. If only they would have actually known where I was and what I was doing, it could have been interesting, but they didn't. (Michael Seres, CEO, founder 11 Health) (Seres, 2013a)*

Michael Seres maintained his involvement with regulators in the UK in different capacities. For instance, he was collaborating with NICE to bring in patients for evaluating technologies. His company was also working with regulators to find ways to prescribe and reimburse digital products inside the NHS. This type of involvement is representative for the type of work early ventures in an emergent field have to undertake and that requires additional resource which are already scarce (Aldrich & Fiol, 1994). This kind of work would benefit the entire field, in time. To that end, Michael's double capacity, founder and patient advocate, turns him into an entrepreneur beyond his organisation - an institutional entrepreneur.

Mira Rehab worked within the existing regulatory constraints and did not engage directly in specific actions aimed at regulators. However, the significant SBRI grants in the UK not only gave them legitimacy, but also informed the state agency on the value of their products. YouLife, on the other hand, did not engage with regulation further than considering the broad requirements for handling personal data in the digital space. It may be that it did not see itself as a healthcare company and therefore did not make any formal moves in that direction. However, they had to comply with certain regulations in relation to data privacy for the healthcare sector, as they found out in France, more than in the UK. Therefore, their business representative in France was a strong advocate for a role designed to make sure that compliance related to data is ensured for every region.

> *Data is far more then this; it's all the legal compliance. (…) To me it would be the key knowledge within the company. (…) If we intend to use this free app as trigger to sell (…), we have to be aware of possible issues that may be local. Only if we understand where the limits are, we can move forward. (B. F., business development, YouLife).*

In respect to other stakeholders, all organisations engaged for two main reasons: product development and legitimacy. Mira Rehab recognised itself as

agnostic of healthcare. Despite the fact that the first product layout was to support patients to undergo physical therapy at home, their main, longstanding efforts were to engage with clinicians. The advice they recognised as most significant and often encountered even before they formed the company, was that they needed clinical input. Consequently, they looked to engage with doctors and physiotherapists from the very beginning. They needed the clinical knowledge, as they considered that they only put a digital layer over a specific medical practice, as Cosmin Mihaiu (co-founder Mira Rehab) expressed it. To that end, they established connections with medical professionals before they founded the company, in Romania at first. Then, they brought in very early on an advisor, Bibhas Roy, consultant orthopaedic surgeon, with whom they maintained a long lasting working relationship. They also ran significant research with the University of Manchaster, UK. On the side, they continued to work with orthopaedists, neurologists and physiotherapists in Romania. However, they had a significant role in developing the product, even in matters that were apparently more pertaining to the clinical side.

> *We were reading on the internet and then we were going to a medical specialist and we were asking if it's ok that movement. (Andrei Dascalu, co-founder Mira Rehab)*

Interviews inside Mira Rehab reveal how much regard they have for healthcare professionals' input and how much this helped improve their product. They also show appreciation of how open-minded medical professionals were towards them, even though they were "only IT" people, with no medical background. They recognise that their product is co-created with their external collaborators with medical background.

As for the patient perspective, the product was actually built around the idea that Cosmin Mihaiu had, based upon his own experience as a patient. Cosmin, in his TED talk at the beginning of 2015, tells his own story and explains the purpose of the company.

> *When I was growing up, I really liked playing hide-and-seek a lot. One time, though, I thought climbing a tree would lead to a great hiding spot, but I fell and broke my arm. I actually started first grade with a big cast all over my torso. It was taken off six weeks later, but*

> *even then, I couldn't extend my elbow, and I had to do physical therapy to flex and extend it, 100 times per day, seven days per week. I barely did it, because I found it boring and painful, and as a result, it took me another six weeks to get better. (Cosmin Mihaiu, co-founder Mira Rehab, 2015)*

In Mira Rehab's case, the involvement with the patient was also mediated by a foundation set up in Romania, called Un zâmbet cu Mira (A Smile with Mira). This foundation offered physiotherapy to children, particularly children with difficulties in accessing that type of medical care.

Their involvement with medical professionals drove their further involvement with patients and carers. On the blog section of their website, there are singular case studies that reflect some very profound interactions.

> *Trying to quantify Timi's progress after 2-3 months of using MIRA and Kinesiotherapy is certainly not easy. (...) Beyond this, whether playing as Izzy the Bee trying to pick up flowers or The Submarine searching for treasures, Timea has improved her ability to focus and her willpower. "She's like a CD, you just have to burn files on it, day after day, with patience and confidence", says her mother while tying Timi's shoes. (Teodora-Gabriela Fleseru, MD, Paediatric Resident, 1st Paediatric Clinic, Cluj-Napoca and Silaghi Ciprian, Kinesiotherapist at A smile with MIRA, Cluj-Napoca) (Fleseru, 2016)*

With their focus on clinical evidence, they recognised early on the relevance of interacting with the academia. So much so, that Alina Călin started very early on to manage the scientific side of the business, and they proved to be successful in securing several research and combined research and development grants. The interaction with the clinical and academic world, also offered Mira Rehab the legitimacy needed for investors, and healthcare at large, based on all four co-founders accounts. They turned their business model around from an initial B2C to a B2B model, as explained by Andrei Dascalu (co-founder Mira Rehab), in terms of strategic priorities: obtain validation by prestigious institutions, try to transform them into sales contracts and home recovery became last. They considered that the ground work with clinicians and academia would establish them as trustworthy all around, as well as keeping transparent communications via their website and social media. In

2015, they have launched the blog side of their website in order to maintain an on-going presence online and to offer more insights into what they were doing and what their company was about.

11 Health, being founded by a long-term patient, came into being with a deep understanding of both being a patient and having that specific medical condition. Michael Seres had been a patient since he was 12 years old. Before even thinking of a company, he started a blog online, "Being Patient isn't Easy", which, amongst others, documents a large part of his experience as an adult patient. In that way, he was involved on social media with patients, doctors and general public too.

> *Most of you here today that use social media, you'll recognize this social media stage. I used about six out of nine of these tools to communicate with patience, healthcare professionals, family and friends around the world. (Michael Seres, CEO, founder 11 Health) (Seres, 2013a)*

In this way, the company involved a priori both with patients and medical personnel.

> *It was from experiences in the hospital bed. It was from bags that leaked, it was from watching nurses. (…) I would time how long it took them to come in, empty the bag, measure it, put it on a flow balance chart and put it back again, and it was quite a lengthy process for them and also difficult process for them… It's not just about me; it's about them managing it. And it was that that I had a lot of time in hospital to think: 'You know what? It got to be another way.' (Michael Seres, CEO, founder 11 Health) (Seres, 2015a)*

From the outset, their product was designed for patients and the involvement with them was and remained intense. In respect to the healthcare professionals and providers, formal relationships came in much later and it was a lengthy, and in parts, frustrating process. Michael Seres maintained a continuous connection with his bowel transplant surgeon, Anil Vaidya, who joined the advisory board. A formal collaboration with a medical organisation came only in 2015, with Stanford University Hospital. This collaboration was also relevant for developing the app for the in-hospital use by medical

professionals. 2015 was also the year when the company started to attend more medical conferences in relevant specialties. Similar to Mira Rehab, the company started with a B2C model, to come to the realisation that it was difficult to grow that way only, and so a B2B and a B2B2C model came about.

> *[M]ainly through social media and word of mouth at the moment. We have not yet reached a big enough market share in the hospitals for it to filter down from the doctors to the patient. (…) The idea is that the grassroots know about the device, and then the doctors know about it, and the two come together. (Michael Seres, CEO, founder 11 Health)*

Given that the UK was found to be not well suited for either B2C or B2B2C model at that time, the B2B and B2B2C model was mainly pursued in the US, where the first dedicated sales person was employed. In the UK, all developments proved to be lengthy and resource consuming.

> *Because we had a landscape that says people don't pay for anything yet. The NHS pays for everything. (…) We lost an investor in the business because he didn't believe the NHS would adopt technology quickly enough. So we lost investment and ironically, the other investors that invested in the business discounted the UK market. (Michael Seres, CEO, founder 11 Health)*

Healthcare professionals were needed to reach out to more customers, as distribution channels. But, more importantly, the product development itself got to a stage where the medical input was important.

> *"We can definitely do it, technology wise, the question is 'it is beneficial to doctors and patients to be able to measure that?' Or is it worth the time to do that versus the value of having that." (A. C., technical lead, 11 Health)*

11 Health had intense interactions with patients, healthcare professionals, regulators and investors, and also with the IT world, as it was one of the core competencies that needed the most development inside the company. Therefore, following the VC investment, significant resources went towards growing the technical capabilities of the organisation.

YouLife focused on engaging with customers, as this was the core objective of the pivoting – moving away from the corporate clients (B2B) towards

consumers (B2C). Engaging consumers proved to be challenging. Their position in the field of digital health was on the consumer side, which was the most crowded segment. Acknowledging that, the search for potential partners who could bring in large numbers of users began and it lasted to the end of my data collection period. YouLife engaged in discussions with diverse potential partners on the consumer market, from different sectors (i.e. digital technology producers, insurance). The constant searching was also due to the fact that there was no agreement over the utility of the product. Should it be a platform and build an ecosystem or a "village" as V. D. (customer lead) called it? Or a plug in, something that can be added to other apps or digital products? Several scenarios were analysed concurrently at this stage. In the end, the "village" won. That meant the company was to develop strategic partnerships with other companies for monetisation. Given that the process of going to the market proved to be a source of disappointment, in the sense that the app did not take off either as downloads or engagement, despite having a significant mobile platform distribution partner, the attraction of potential commercial partners proved to be difficult too. The app could not prove on two relevant uptake/success indicators, downloads and engagement. Those were indicative for showing market value and potential and so for closing partnership deals.

> *["Village" strategy] If we can work with the right partner apps and device manufacturers to build that ecosystem, I think that's really powerful, so they will be able to actually understand what the risks are. (I. D., business development, YouLife)*

> *["Village" strategy] By doing this with multiple partners, I suddenly got a huge distribution network that I couldn't possibly achieve on my own. So we just do what we do well, and we integrate with best partners, and we cross-fertilize with data and with consumers. (M. B., co-founder YouLife)*

> *["Plug in" strategy] When you register in a website, occasionally you get that image that you have to type in a code to prove that you are a human being, not a computer, and if you look at that it says 'powered by such and such'. Look, that's what we need NewLife to be. We need people to just accept that when you talk about your health as a*

number, you talk about NewLife. (J. K., technical development, YouLife)

A board decision was made late 2015 for the "village", and so the product ended having the health assessment at the core, a conversation part and a suggestion part where consumers would find products for health and wellness deemed relevant for them. The conversation part was intended to drive engagement, as the health score was not calling for much interaction. People would try it and then not engage or uninstall the app. The conversation was meant to be an automated health/wellness coach that would assist people in choosing goals and would guide them on how to achieve them. The conversation engine had as ultimate goal behavioral change, considered at that time the Holy Grail of prevention. The topic of behavioral change was debated intensively at the field level, also in the context of treatment adherence and chronic diseases (for instance, type 2 diabetes).

Although the focus remained the consumer, no proactive action (focus group, questionnaire, user experience) was taken in that direction, despite the realisation that it was not easy to get easily their interest in engaging with a health risk app. In addition, there was the discoverability problem on a market that had tens of thousands of wellness and fitness apps. With the user – app experience, the company made an attempt to analyse recordings of app usage, but it did not render much insights, based on company's respondents. Moreover, an internal resource with previous experience in another company in engaging people online in health matters was not given a voice. A strategic decision was made to bring in a new competence in digital, meaning hiring a person with a proven record in designing successful digital consumer products.

There was one stakeholder that YouLife engaged constantly, the academia. It was based on an early realisation, prior to the NewLife app, that academia brings value in terms of trust, product development and resources. They engaged with academia for clinical validation of questionnaires, for working on the conversation part and for insights on the business model.

[A university] provided some validation for one of our algorithms, which is really, really good. It's good for PR and it's good for

establishing our point in the marketplace. We had a business student who presented his project based on what partners we could work with. (...) So there are advantages for them working with businesses. And it's beneficial to companies like ours who want good expertise in some ways that are often cheaper, because there is the reciprocal thing. (M. R., finance YouLife)

The advisory board shows the tight connection with academia and the content of the website's blog contains mainly articles about scientific facts on wellness. Also, one of the team members, the clinical lead, was well promoted online.

Although the "clinical" and "health" terms came up a lot in conversations as well as on online and promotional materials, and the company was aiming to make an impact on people's health, there were no direct connections shown and made with the healthcare world. However, the potential benefits towards healthcare systems were acknowledged.

I think there's a lot of noise made around m-health, the fact that you have it on you all the time, it's easier, it's easily accessible, it's actually pretty cheap, relatively, and there's a lot of work that can be done in the preventative space to impact the services at the end of it, the NHS. (I. D., business development, YouLife)

All companies had scarce resources (time, money, knowledge), therefore all had to make choices, prioritise stakeholder involvement to build core competencies and forge a market for their products. Nonetheless, all stakeholder interactions are a source of valuable learning.

Even if we would have gotten funding in the first year Mira appeared, I don't think we would have been capable to manage the money. Second, we have learned a lot over time, from many people, and how to spend and what would be more beneficial, to respect our strategy. (Andrei Dascalu, co-founder Mira Rehab)

Legitimacy is an on-going preoccupation for all, shown not only by engaging with experts and academia, but also by co-opting them on advisory boards. Mira Rehab even sets up its governance structure to have a dedicated lead for science (Alina Călin, co-founder). This shows how important building trust and

legitimacy is felt by new ventures, as previous studies have also shown (Navis & Glynn, 2011; Santos & Eisenhardt, 2009; Suchman, 1995).

All three companies prioritise stakeholders that are deemed to bring the highest value for forging the market, bridging the expertise gap, or for creating legitimacy. For 11 Health and Mira Rehab, the regulatory compliance confers legitimacy too. All three companies co-opt legitimising actors in their advisory boards from academia, healthcare or digital health. Another way to indirectly get endorsed by legitimising actors is to associate with institutions like medical or patient associations and prestigious organisations. Similar to previous research, legitimacy is indeed perceived as a core resource by young ventures, particularly in a new field. Other modalities to build legitimacy are: displaying achievements and awards, providing organization history – show persistence (both Mira Rehab and 11 Health), having a blog to provide information, educate, tell stories, build a market, show endorsement (by publishing articles written by stakeholders or influential names in the field) and provide evidence.

Fig. 42. Additional source of legitimacy for Mira Rehab – A Smile with Mira NGO in Romania, set up early 2015 (picture from personal archive, Interface conference, Canada)

All organisations are very preoccupied to establish trust and legitimacy. "The role of trust is central to all social transactions (ranging from marriage to international affairs) where there is ignorance or uncertainty about actions and outcomes. (…) Trust is a critical first-level determinant of the success of founding entrepreneurs because, by definition, there is an absence of information and evidence regarding their new activity" (Aldrich & Fiol, 1994, p. 650).

In summary, the more long-term relationships were, the more symbiotic, and therefore the more hybridising. Such relationships develop mainly where the expertise gap was larger, as shown by Mira Rehab and 11 Health. Andrei Cantea (co-founder Mira Rehab) considers their medical collaborators as part of the team and acknowledges their contributions to the product development. Both Alina Călin (co-founder) and Priya Maloni (consultant business development) look into continuously improving their connections in the field, find avenues to expose and foster research. Both organisations show how collaboration is driving understanding and understanding is driving hybridisation of logics (Nicolini, 2009; Prout, 1996; Van de Ven & Gardu, 1993).

8.4. TAMING CONTRADICTIONS

In an emerging field, there are multiple logics vying for dominance, and ambiguity does not give many clues as to how the institutional arrangement is going to unfold. In this section, I present how all three organisations deal with these two aspects that create contradictions - plurality of logics and ambiguity.

8.4.1. PLURALITY

All the organisations are CDHT producers and therefore they may connect multiple stakeholders. My analysis shows that predominantly they did not choose to overtly confront incumbent stakeholders, or the most powerful ones in adjacent fields - in this case, medical professionals and regulators. Their main mechanism is co-optation and it is driven by genuine business needs, like knowledge and competencies gaps and market development, not by ideology.

The engagement with various stakeholders generates significant learning and opportunity detection. Most companies went through several iterations of their business model. To support this, I give the example of 11 Health who first featured patients on their website, then briefly stated that it is a patient led technology company, to finally position itself as a connected device company for healthcare, and three major beneficiaries (users) were given equal representation. This reflects the learning from interactions with stakeholders and from the evolution of the field itself.

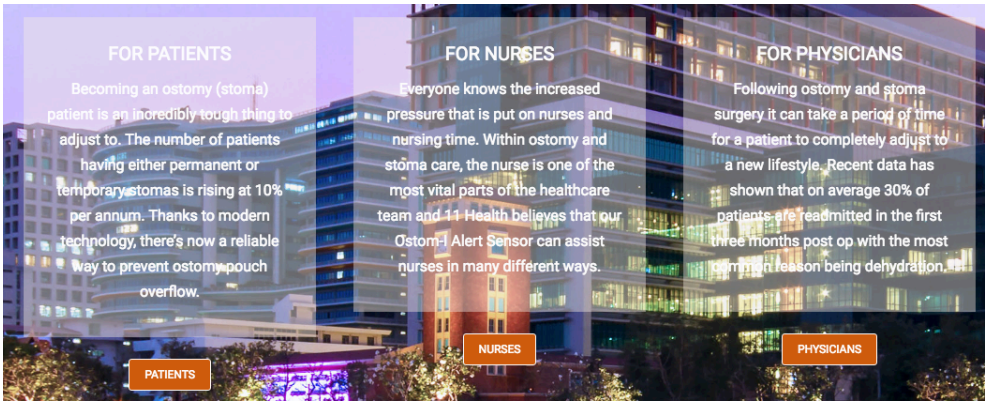

Fig. 43. 11 Health's landing page with three user categories (beginning of 2016)

Similarly, Mira Rehab was initially presenting patients the value of exercising at home, to end up presenting its value propositions to more user categories: healthcare professionals/providers, patients and payers.

Fig. 44. Mira Rehab Opportunity page with three beneficiaries (beginning of 2016)

In that sense, both organisations end up being positioned similarly to medical device companies. YouLife only addressed the consumer in their communications or inside the app and maintained throughout its positioning as a consumer digital health solution.

Regardless of how they communicated, all organisations, through the virtues of the intangible character of their digital solutions, were able to both compartmentalise and hybridise logics. Compartmentalisation is realised by having different categories of users having their own "entry" – interface, log in, even their own application (11 Health or Mira Rehab). In this way, all stakeholders are "safe", do not feel threaten and they can pace themselves in what they want to do. Additionally, their feedback and involvement is valued and encouraged. In the same time, all user categories are informed on the needs and practices of the others and even play a role in designing practices. Consequently, companies take on the function to centralise, prioritise, design, accommodate these needs, acting as an institutional broker.

YouLife did not get to that level of morphing by the time my data collection ended, when the NewLife app was only consumer facing. When discussing partnerships and how data is going to be accessed and by whom, there were contradictory ideas inside the organisation. What remained certain was that they intended to co-opt other players. However, the consumer app was itself compartmentalised, so the consumer would choose the level of engagement, as well as if wanting to engage with other types of users. The consumer had access to the health assessment core, the conversation part and the partners' part where products were recommended.

> *We are using the data, but we're not going to sell that data to any odd person. It's there to benefit you, and the products we will be introducing will be there for a specific reason, to benefit you, to prove your health, not just a blanket product or a blanket service because we make money out of it. It's to make sure that it impacts your health, that it improves your health. That's really important. (I. D., business development, YouLife)*

In the case of YouLife, the user/consumer was not that much in control, had no input in the creation of the product, it was not co-opted. Given the little involvement the main stakeholder had in the product development, YouLife is most similar to direct to consumer digital technology market.

> *It's the same with the pharma - they want the data. Microsoft wants the data, because probably they're better able to market products and*

services to the end user. I don't think they would ever want to be viewed as a health company, but they would probably rather be viewed as a health ecosystem, with preferred partners that focus on the best areas and various areas. So I don't think they have ever announced themselves as a health company, more as a... I don't know what the right word is... it's the ecosystem I think they're trying to build. . (I. D., business development, YouLife)

For the hybridisation process, I provided examples of co-creation in the previous section on Mira Rehab and 11 Health. I have highlighted mostly how they worked towards co-opting external stakeholders. But the exchanges were mutual. Healthcare professionals got fresh insights and contributions too. There were physiological parameters that they were not able to measure before, or, at least, not that accurately, efficiently and continuously.

We were reading on the internet and then we were going to a medical specialist and we were asking if it's ok that movement. (...) Because if we would have asked ten physiotherapists what is good for something specific, it wouldn't have been very constructive from the beginning, because there are different opinions between specialists. The best way was to ask them: is this movement ok for this problem?" (Andrei Dascalu, co-founder Mira Rehab)

Because it is a very innovative technology in the marketplace, and myself being in front of the most important surgeons and hospitals in the world for the past several months... the level of interest is something I've never seen before. (K. P., US business lead, 11 Health)

Digital technologies allow CDHT companies to be more things to different people, to accommodate multiple identities (Jacobides et al., 2018; Kraatz & Block, 2008; Selznick, 1984). The hybridisation also happens because the CDHT producers act as brokers between logics. For instance, the "patient engagement" idea has less push back from healthcare professionals if it proves to lead to better health outcomes or that healthcare has a scientific benefit (i.e. "we can follow what a patient does based on some parameters that could not have been monitored before" – Alina Călin, co-founder Mira Rehab). Hybridisation is facilitated by the congruent aims between logics (Pache & Santos, 2010). When logics are instantiated, when the situation is contained,

understood, evaluated, and when healthcare professionals have a say, an "empowered patient" becomes a desirable notion or at least a neutral one. Similarities to other digital ecosystem (Jacobides et al., 2018) can be drawn, in the sense that CDHT producers design solutions that accommodate different roles in such a way that each role derives more value through the new practice, that surpasses the cost of the relative changes from their previous roles or practices.

8.4.2. AMBIGUITY

An emergent field is a liminal space, suspended somehow in time, between the old and the new. This situation makes organisations permanently scan the environment. Apart from keeping an eye on the state/regulator (Aldrich & Fiol, 1994), payers and healthcare, they keep scanning broadly for technology trajectories (Akrich, 1992; Gawer & Phillips, 2013; Geels, 2005; Rip & Schot, 2002).

YouLife looks at how digital platforms are evolving (i.e. Apple, Samsung, Microsoft), but it's reserved on committing to certain technological paths, out of fear of betting on the wrong one. Similarly, the technical lead of 11 Health was not taken by the Apple Watch (a wearable) for instance, but the company eventually integrated with it. Mira Rehab is also scanning, but, on the contrary, they are confident that the proprietary modular architecture allows integration with a variety of sensors and technologies and therefore they show fewer concerns about what platform or technology would eventually win. Their product is flexible by design. Aside the problem of committing technologically too early, there is the question of efficiency in allocating resources (as stated by technology leads inside all organisations), at a particular development phase.

In terms of competition, 11 Health did not identify a competitor, although it had the expectation that other companies would enter the area. YouLife identified competitors and they were monitoring them. In Mira Rehab's case, there were several companies that approached physiotherapy through games in various ways. They were not only watching their competitors, but also got in touch with several. Moreover, they shared news related to competitors on

social media, as a way to foster a market (Andrei Dascalu, co-founder) and contribute to the "cognitive legitimacy" (Aldrich & Fiol, 1994) of their niche.

> *Competitors... every month a few more. Competition validates the market. There is no dominant one. I am happy when I am told our product is better. (Cosmin Mihaiu, co-founder Mira Rehab)*

There is a lot of learning happening at all levels: individual, organisation, or the field itself.

> *There's a lot of people out there who say they're health experts, people who say they're digital experts, bit actually some of them don't even know how to spell the word digital and I'm not being mean about it, but they are no experts in digital health. (M. B., co-founder YouLife)*

The ambiguity makes organisations more focused on the future than on the past, and therefore less tributary to an institutional iron cage. The representation of the future (Akrich, 1992; Gawer & Phillips, 2013; Geels, 2005) becomes the most important determinant of organisational action.

> *I believe that all new technologies can apply to healthcare (Cosmin Mihaiu, co-founder Mira Rehab)*
>
> *I think in time we will get more digital interventions; we will get using more and more things. I think technology will allow us to do so much more, but I think we are still a long way away from the practical use on the ground everywhere, at the moment. (Michael Seres, CEO, founder 11 Health)*
>
> *And if we can work with the right partner apps and device manufacturers to build that ecosystem, I think that's really powerful, so they will be able to actually understand what the risks are. And if they have risks, put them in contact with the right services to help them reduce those risks. (I. D., business development, YouLife)*

As shown in the section on taming liminality, YouLife, did not engage with healthcare. But they were aware that if they could prove that consumers would adopt their app, then healthcare would become interested in it.

> *If I can get the efficacy and show I can do that, this business will be of immense value because you've got something that the NHS has been trying to get to for years and years. How do you encourage*

consumers to take control of their own health and to improve their overall health? (M. B., co-founder YouLife)

The quote above also informs on the "conflict" between medical profession, state and citizen logics. The involvement with the healthcare field was not as much avoided, as it was temporised. At this stage, it was deemed not to be efficient to engage with without evidence of people engagement. This is also an example of a judgement over the evolution of the field and its stakeholders.

Another call from the future, in respect to technology, is interoperability or integration. Therefore, some concerns are related to committing too early (Rip & Schot, 2002; Van de Ven & Gardu, 1993) on a technological path (11 Health and YouLife). However, all companies are aware of their need to integrate in time with other solutions and technologies. 11 Health integrated their hospital app with Epic, one of the main EHR providers in the US, and their patient app with the Apple Watch. This is moving towards the vision of the continuum of care that the digital health promises.

Institutional constraints are sometime better understood in hindsight.

Even if it would have got funding from the beginning and we were very good, I still believe we wouldn't have succeeded, because the market, in my opinion, was not ready for such technologies. (Andrei Dascalu, co-founder Mira Rehab)

The statement above shows the relevance of understanding the emergence phase when looking at an organisation in its context. During mobilisation, the legitimacy of such solutions is established enough. The next two quotes, also add to the understanding of the difference between the stages of field emergence - first is about the ingenious phase and the second one is about the mobilisation phase:

[2013] I then realised that I needed some money in order to take a very basic prototype and turn it into a proper device so I went to look for an investor to put in a bit of money and through recommendations of recommendations I, in the end, presented it to a gentleman called Adam Blooms who agreed to invest in the business and he gave me the first bit of money to take the prototype and see whether we could

build a proper device. He was the first investor. (Michael Seres, CEO, founder 11 Health)

[End of 2015] It's disruptive innovation in the marketplace, there is nothing like it, so I think there is a high level of support inside and outside and a lot of excitement as well because it addresses a need that simply cannot be addressed right now. (K. P., US business lead, 11 Health)

Given their focus on the potential of technologies and their vision of the future social arrangements, all these organisations, through their value propositions, are in fact promoting "proto-institutions".

8.5. BRAVE NEW WORLD

It follows that, in a way, all these "fools" (Aldrich & Fiol, 1994) are institutional entrepreneurs. One of the dimensions they guided themselves by through the tremendous complexity of this emerging field is the identity project of the organisation. I am pointing here to agency and its projective quality (J. Battilana & D'Aunno, 2009). As I've shown above, all organisations are guiding themselves based on scenarios or scripts of the future, therefore they have an identity project. Their identities are becoming, not following existing recipes. Consequently, each organization represents a proto-institution in its own right, and, if successful, it will fulfill their desired identity. For instance, Mira Rehab's dream is to make their platform available to as many patients as possible, so they can recover in a fun way, in the comfort of their homes and with the safety of being overseen or guided by a healthcare professional. At the time my data collection ended, they were launching the home version of their solution integrated with the hospital version. Their identity project is that Mira Rehab allows fun recovery at home, but it is not there yet, it is on its journey. This is relevant, because their projected identity guides their actions.

The future script embedded in technology is based on the innovator's view of the stakeholders and is pointing to envisioned value/risk, practices and it "assumes that morality, technology, science, and economy will evolve in particular ways" (Akrich, 1992, p. 208). There is value infused in the way the organisations project themselves in the future, with an ideal identity – their

own identity project. And not only value, there is emotion. As Voronov and Vince (2012) show, cognition is simply not enough for action. In conditions of ambiguity, grounding actions on hard facts is impossible; therefore emotions are an important determinant for action.

YouLife considers itself as being part of the consumer empowerment future. Mira Rehab is dedicated to make physiotherapy more fun, as "games are essential for anything" (Cosmin Mihaiu, co-founder Mira Rehab) and at home. "At the heart of it [n.b. 11 Health], it is a device trying to improve the lives of patients" (Michael Seres, CEO, founder 11 Health).

8.5.1 Distinctiveness matters

As trapped in between worlds, organisations attach their identities to digital health, as being the umbrella for digital innovation in health IT. Even if at times digital health may be a blurry, inconvenient term (contestation in the field, for instance, Theranos case mentioned in chapter 7), it remains a distinctive category that not only offers a sense of belonging, but also gives an advantage in relation to certain stakeholders (i.e. initially investors, academia and state agencies offering grants). Similar to findings of another research in categorisation, new fields and access to funding, having a distinctive category proves to be a competitive advantage (Navis & Glynn, 2011).

However, their attachment to digital health is not overt. Organisations do not label themselves as digital health companies on their websites or communications, particularly Mira Rehab and 11 Health, which are closer to healthcare; perhaps to avoid potential institutional logics conflict. However, as time passes, the 'digital health' label becomes a positive differentiator from the legacy, traditional health IT producers, inside the healthcare field itself. As I have shown in chapter 5, before 2007, the healthcare and IT fields had a long history, mainly dominated by disillusionment.

> *If you have something that's digitally sound and something that's new, people typically will embrace that, more so than something that's been around for a while, something that's not necessarily you know, run through a digital platform. (K. P., US business lead, 11 Health)*

"Digital platform" term in the quote above points to the legacy health IT systems, not any digital platform.

However, all organisations are careful in how they adhere to new emerging categories. I have given the example of 11 Health, which settled at some point for being a "connected device" company - not a medical device one (too much legacy, powerful incumbents), not a digital health one (too vague and contrary), not a patient led one (too radical, alienating from incumbent players). Mira Rehab designs games for recovery, but it does not position itself as a gamification or serious games company, terms very much used in the realm of digital health.

> *I am a big fan of gamification as a principle. I believe it is a necessity to transform a boring process in a more interesting one and is a very good thing. On the other hand I find it overused, it's applied to anything. I find serious games a wrong definition. It seems you need serious because games would point to something that it's not essential. From my point of view, games are essential to everything. (Cosmin Mihaiu, co-founder Mira Rehab)*
>
> *Yes, we do build serious games, but it's more than games. Because we have a platform that does more than that, in the sense that we can follow what a patient does based on some parameters that could not have been monitored before. It is something very new for the medical professionals. And so it is a medical device. (Alina Călin, co-founder Mira Rehab)*

The versatility in attaching different categories in different occasions relates to the concept of "social skills". Entrepreneurs need soft skills to navigate complexity and give meaning (Fligstein, 2001). "Actors' conceptions of themselves are highly shaped by their interactions with others. When interacting, actors try to create a positive sense of self by engaging in producing meaning for themselves and others" (ibid. p. 112).

Another way to generate meaning for both the organisation and others is through stories (Maclean, Harvey, & Chia, 2012; Patriotta et al., 2011; Zilber, 2009). Stories allow for contradictions to evolve and dissolve, for conflict and hybridisation to unfold at the same time. And what else would institutional

work be but a "creative" approach to contradictions (Hargrave & Van de Ven, 2009)? Stories are also vehicles to connect to higher orders or values (Patriotta et al., 2011; Weick, Sutcliffe, & Obstfeld, 2005). Cosmin Mihaiu's (co-founder Mira Rehab) TED talk had over 1 million views at the time of data collection. Such outreach could not have been achieved any other way, given their limited resources. What made Cosmin's talk so impactful was that it had a great narrative. Although Mira Rehab did not intend to generate this type of content, that TED talk continues to serve them well. However, they have started publishing individual case studies, stories of using their technologies.

11 Health also has a great narrative. In this case, Michael Seres' advocacy work made his story known to large online communities before the company was founded. On their website, there are videos with Michael's story, as well as company's story. They also have a milestones page where one can trace the company's evolution. Moreover, on the blog and social media channels, patient stories are also promoted. YouLife, on the other hand, has a video that shows a healthy lifestyle, not differentiating itself from traditional marketing materials in consumer fields, pharma or insurance, for instance. On their blog, there are articles that promote healthy lifestyle, providing scientific, clinically valid information, but no narratives.

Aside from patients, carers, citizens, scientists and healthcare professionals, all three companies recognized digital health producers at large as stakeholders. All technical leads were aware of the wearables and other evolutions in this area. But most importantly, all organisations were participating and scanning for events in digital health. Such events represented platforms to showcase, learn from others in this field, network, find investments and other opportunities (see also chapter 7).

8.5.2 Leadership matters

Each company provides significant insights in the role leadership plays in the context of high institutional complexity.

YouLife, as I explained in the previous sections of this chapter, had more difficulties setting a vision or a strategic path. There was a perceived

disjunction at its high-level management structure. Most respondents identified W. M., the person responsible for innovation until the end of 2015, as being the creative mastermind and the force behind the company's transformation. Most of them described him in flattering terms, on the line of "he is the creative genius; incredibly inspiring" (M. R., finance YouLife). All information I gathered about him was secondary, as he became unavailable to interview due to internal developments in the organisation.

> *He's the madman in our office. He's so innovative; he couldn't care less whether we make money out of it. In his eyes, it's an idea. He wants to impact health, he wants to improve people's health, that's it. Now, obviously, it's a business and we do have to make money somehow, but he would like to be in the position of a kind of a Steve Jobs, to have the little room downstairs in the bunker that just has a team thinking of the next big thing. Maybe we'll get there, I don't know... M. B. needs to be in that kind of space as well, but our CEO will only be there once we are probably in a better place financially. Because we need to prove the model, we need to get it monetised, we need to work out what works and what doesn't and we'll do it pretty quickly, I'm confident. (I. D., business development, YouLife)*

Despite the value (creativity, inspiration) the team saw in him, there was a board decision that led to W. M. only having a vague advisory role to the board of directors; he was not to interact with the team going forward. This created a low morale throughout the company. The picture below is a representation during an interview that is trying to show that the product development will be affected without having an important driver, creativity.

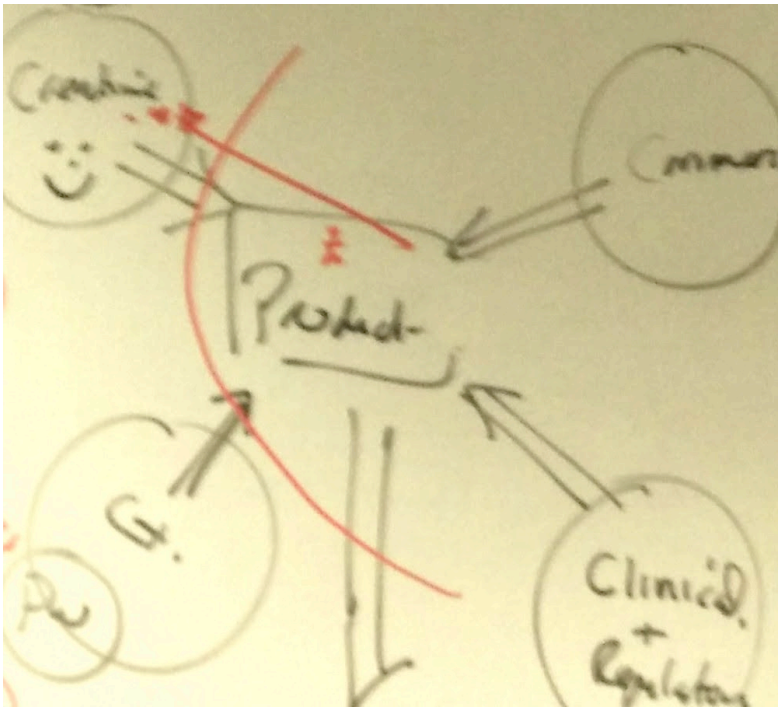

Fig. 45. Leadership as creativity (V. D., customer focus, YouLife)

Only a few respondents seemed to settle with this board decision, for instance M. R. from finance: "we are at the stage where we understand these ideas", but most of the team felt this was a significant drawback.

> *I think W. M. would still want to be here right now. (...) We are already missing W.M. (V. D., customer focus, YouLife)*
>
> *If we moved from getting people healthier into insurance, then I should know that. (J. K., technical development, YouLife)*

Adding to W. M.'s departure, there was an increased sense of lack of communication with the top management, and amongst the team members. Several employees did not feel valued or felt that the direction of the company was decided at top level and it did not filter down. Some members even experienced a loss of purpose, as they considered their mission was moving away from doing "good" by people - making them healthier. They felt that this strategic decision was not serving well that mission, as they understood it when the company had decided to pivot.

It is relevant that the company was trying to pivot from the world of employer benefits and insurance with the identity project of becoming a consumer focused organisation with the purpose to make people healthier. The initial

vision was to go for the consumer engagement, consumer health education and prevention, away from its legacy. In this case, it seems that the founding logic, the legacy or the "iron cage" won, or at least it won that phase of the battle. The return to the founding logic (market logic) had innovative elements, but further away from the citizen logic than the initial vision was. If that was just another morphing or if that return to the legacy logic was permanent, it was impossible to assess at the time data collection ended. Alternatively, if that was a leadership failure, it might as well have been the case.

In contrast, Mira Rehab and 11 Health offer two interesting examples of leadership. Mira Rehab is a case of shared leadership, as I name it. Although Cosmin Mihaiu (co-founder) was the CEO and became very popular due to his TED talk, he always circled back to the team of co-founders when discussing his role or the company. So much so that I felt appropriate to leave the CEO part aside when referring to him in this research too, as it would have given a sense of extra authority when they all proved and affirmed that it was shared. Each co-founder talked in the same terms, very consistently, about the other founders: how they were each responsible for a side of the business, although helping each other, how each was "pushing" (Andrei Dascalu, co-founder) for their own part, despite any personal discomfort with their roles at times. This transformation of the team was much influenced (based on their accounts) by the early interaction with a mentor who remained in their advisory board, Jake Arnold–Forster. I find this an interesting case of collective/shared leadership, not documented in literature, to my knowledge. In terms of identity, they kept the sense of a technology team who placed a digital veil on an arid part of healthcare to make it fun and engaging, and so to have better health outcomes for patients, whilst contributing to science.

As highlighted by previous authors (Kraatz, 2009, 2009; Kraatz & Block, 2008), and most notably theoreticised by Selznick (1984), subtle substances of leadership transform both the organisation, providing it with a "self", and the leader.

> *We can say that we are doing 'Un zâmbet cu Mira' [n.b. an NGO] because we are helping others. But in the end, for us, for myself, as I*

> *do not do anything else on the side, for me is... I don't know... a lifestyle. And if Mira succeeds, I can say I succeeded too. I cannot be hypocritical and say the financial side does not motivate me. On the other hand, when we take part at the testing of the product, and when we see... there are also children with various problems... it's super motivating when you see their joy. (Andrei Dascalu, co-founder Mira Rehab)*

11 Health is an example of entitativity (Campbell, 1958) or of a company that becomes an institution in its own right (Kraatz & Block, 2008; Selznick, 1984). 11 Health embodies the citizen logic of digital health expressed best by the role of the empowered patient.

> *He does have the two roles: he is the advocate on one side, and an entrepreneur. But he also got to run a company and I think he's still trying to maintain that balance. I think it's a tremendous load on his part, like travelling schedule and demanding hours, but I think I can't see that really changing because he's always been that driven. (D. B., communications 11 Health)*

Michael himself is holding more roles and one identity and this may be challenging at times, requiring a permanent balancing act (Kraatz, 2009; Selznick, 1984).

> *I'm very conscious of not wanting to impose my patient voice on consumers so I come across as someone that is just trying to sell people that I engage with on a daily basis. I really don't want to be seen as someone that is just using my voice to purely benefit my company. There is a line, which I try not to cross, and so my personal voice is about trying to raise the role of the patient, trying to promote patients as innovators, and within that I talk about the business. But the business also has to have its own social media presence. So there is a fine line. (Michael Seres, CEO, founder 11 Health)*

Although deeply rooted in humanistic values, like helping people to lead better lives, 11 Health maintains a balance that allows it to be multiple things to multiple entities. In other words, it can contain multiple logics (Kraatz & Block, 2008). It is a receptacle of identities, whilst fostering a new collective frame. And those identities do not come into conflict, they hybridise by the

very hybrid nature of their receptacle. In this case, Michael is recognised both inside and outside the company as the "expert" and the business driver. It embodies the role of the empowered patient, and therefore, for the field at large, he is a connotative leader (Kraatz, 2009); "both an agent of institutionalisation and a defender and steward of the living social entity that ultimately emerged from this perspective" (ibid., p. 62).

> *I tend to just look at what needs to be done right now; Michael is a visionary. (A. C., technical lead, 11 Health)*
>
> *People like Michael are leading the way. That's what makes it really exciting. This is the first time I've ever been a CEO and a CEO is so connected with the product and the vision. (D. B., communications 11 Health)*
>
> *It's not about going on to be a businessman. It's a real solution to a real problem that can help you or other patients. And it's your inbuilt passion and your drive that gets you through. Business just comes later. (Michael Seres, CEO and founder 11 Health)*

Leadership proves to be a significant factor for organisations' success. Additionally, their identity projects, even if failing as businesses, contribute to the field institutionalisation, its structure and its governance (Aldrich & Fiol, 1994; Fligstein, 2001; Kraatz & Block, 2008).

In a sense, Mira Rehab represents a less mature form of statesmanship (Selznick, 1984), of the type of leadership that builds institutions, even though its leaders are not necessarily as aware of the process. Perhaps, in time.

If I connect what I have shown on organisations and their search for legitimacy and, more than that, trust (via symbolic actions as well, like stories), with the findings on leadership, this collective case study shows the importance of leadership for building trust inside and outside the organisation. Trust is a concept that links all levels: personal, organisational and the field level, and is a basis for exchanges in condition of ambiguity. And so, the "social process of gaining legitimacy is shaped by the interpersonal processes of achieving trust in the organizing process" (Aldrich & Fiol, 1994, p. 650). It follows that leadership is indeed a major resource in a complex institutional context for a

new organisation, and for an emergent field as well, as leaders become agents of institutionalisation (Kraatz, 2009; Kraatz & Block, 2008; Selznick, 1984).

8.6. Conclusions

New organisations facing extreme institutional complexity are influenced in their engagements with stakeholders by their position in the field. Their motivation resides mainly on closing the knowledge and competencies gap and obtaining legitimacy, in other words to access basic resources. They also prioritise engagements, as they operate under serious resource constraints. At an early stage of company formation, relationships with stakeholders are often mediated by mechanisms of co-optation that lead to co-creation. Co-creation facilitates significant hybridisation processes.

In an emergent field, institutional work is less tributary to the "iron cage" and more orientated by scenarios of the future and perceived opportunities. Additionally, in a pluralistic environment, digital technologies concurrently support the compartmentalisation of various logics, as well as their hybridisation. Not last, leadership is instrumental for organisations, being in itself a strategic resource. Organisations with strong leadership become institutionalisation agents that contribute to the emerging structure and governance of the new field. Such examples offer insights on the "bottom up" institutionalisation, as opposed to the "iron cage" dominant perspective.

CHAPTER 9. DISCUSSIONS AND CONCLUSIONS

9.1. INTRODUCTION

My research fosters the understanding of institutional complexity in conditions of pluralism and high ambiguity. It employs a theoretical framework based on institutional logics and institutional work, and, empirically, it unfolds as a multi-level, multi-case inductive inquiry set in an emergent field. In this chapter, I summarise the main findings, I present the theoretical implications for the institutional theory and I revisit the theoretical model presented in chapter 3. I also reflect on wider implications and offer practical insights. The chapter ends with general reflections on my research and future directions of study.

9.2. SUMMARY OF FINDINGS

The main contributions are related to the emergence process of a field (a phenomena that was only studied retrospectively or it was theoretically inferred) and institutionalisation processes in conditions of high complexity, given by a pluralistic, fragmented and ambiguous field. The institutionalisation processes were analysed both at field level and at organisational level. The institutional work undertaken by organisation informs on the bottom up institutionalisation.

9.2.1. FIELD EMERGENCE

9.2.1.1. Institutional context of adjacent fields

My analysis starts with the historical presentation of the main institutional fields that influence the interstitial emergence of the digital health – the ICT and the healthcare fields. This analytical stage is a prerequisite for the understanding of field emergence, because it shows how changes in the two fields made it favourable for digital health to emerge. In healthcare, I show how the role of the state supported, at different times, both the professionalisation and the demise of the medical professional authority, or

how it played a role in the dissemination of certain medical technologies (vaccines, for instance). The state also tried to push for the adoption of health IT in many countries (i.e. Germany, UK, Australia, US), but these efforts were less successful (see chapter 5 for more history). Furthermore, I show how the state logic itself underwent significant transformations, from the welfare to the neoliberal doctrine. Such changes brought about significant shifts in the healthcare field fragmentation and, most importantly, in its governance: the emergence of managed care approach or the rise of consumerism. This historical part also highlights unintended consequences, for instance the increase in healthcare agency bureaucracy (i.e. the NHS). The state facilitated the transition from a healthcare field where professional authority was dominant to one under a managed care approach, and last to one fostering a self-management approach. Therefore, the brief healthcare history has merits beyond these contributions, as it highlights the role of technology in the field's institutional transformation.

The digital technology field also went through significant transformations of governance and rules of the game. Over the past three decades, there were important changes regarding the locus of innovation and rules of competition. Digital technologies, given their open character and the fact that they are completed by the user's input, became increasingly democratised. And so platforms and ecosystems came about and users become more powerful in determining technological trajectories. Digital technologies made space for new forms of organising the social and economic life, social media being also indicative for this phenomenon. Not last, the digital technologies field went through an intense process of convergence (Mulligan, 2011; Jacobides et al., 2018), which accelerated their expansion as well as innovation.

The histories of the two fields also bring forth contrasts between them. For instance, digital technologies field is a rapidly changing environment, where innovation is worthy in its own right, and it has high user centricity. On the other hand, healthcare is a fragmented field, with discontinuities and tensions between stakeholders, where change happens slowly and technology takes a long time to be adopted. For instance, the cochlear implant took 39 years to become marketable, but a close loop insulin system developed by a patient and

her partner as an open source DIY device became worldwide spread within the type 1-diabetes online communities in a few years only. This is an example of the speed innovation disseminates in the digital world when there is a well-defined need, even if it is health related.

9.2.1.2. Stages of emergence

Morrill (2006) depicts three stages of emergence: innovation, mobilisation and structuration, each being dependent on the previous stage's success. Innovation is characterised by experimentation and opportunity and the interstitial emergence goes generally undisturbed by incumbents. Mobilisation engages a critical mass of supporters and, finally, structuration presents legitimated alternative practices. My findings refine this model entirely and introduce a new stage - *legitimation*, and bring theoretical insights into interstitial emergence and institutionalisation.

In the ingenuous phase (similar to innovation phase), most active stakeholders are coming together voluntarily based on shared interests or unsatisfied needs. Initially, the main stakeholders are the digital health producers, the state and citizens. Therefore, the inherent characteristics of the consumer digital technologies field are dominant, such as fluidity, experimentation and serendipity (Santos & Eisenhardt, 2009). My findings suggest that such characteristics take the field genuinely beyond the market logic, towards the ludic aspect of technology and invention, where innovation is gratifying in its own right. It is possible that the ludic and serendipity aspects are characteristic to emergence around technical innovations. Morrill (2006) theorised the model of emergence in the context of new practices in the dispute resolution area, close to the legal field. Moreover, it may be that these aspects are specific in the digital age, because, as I have shown in previous chapters, digital technologies changed the locus of innovation and the rules of competition.

For the ingenious phase to complete successfully, a significant mass (Morrill, 2006) along with promising solutions or resources have to form primarily via facilitative (hybridisation) institutional processes. This phase confers cognitive legitimacy (Aldrich & Fiol, 1994), it makes the field visible and this attracts

stakeholders capable to confer socio-political legitimacy (ibid.) during the next phase - the *legitimation* phase. My research indicates that only after socio-political legitimacy is established, the mobilisation phase is possible. Socio-political legitimacy means that a new idea, practice, innovation is considered appropriate and possible (ibid.). In digital health's case, political legitimacy was conferred from the outset by state commitments and citizen uptake, during the ingenuous phase. However, socio-political legitimacy is co-constructed through the initial interaction of stakeholders and, more importantly, through *legitimising* (academia, researchers, medical professionals) and mediating (consultancies, other intermediaries) actors, who are capable to co-opt more resistant stakeholders (herein, doctors and pharma). I highlight the legitimation phase as a stepping-stone for mobilisation. It is possible that this phase is specific to field emergence close to adjacent fields that are fragmented and have some degree of centralisation, because of the existence of multiple and often powerful stakeholders. Morrill's model was developed for the emergence of a field closed to a more centralised one and the actors involved had previous established authority. What was contested was a new practice only. In contrast, in digital health, due to its proximity to a semi-centralised fragmented field – healthcare, contestations ran deep: from actors to practices and higher societal values. Therefore, legitimation was easier to reveal as a phase in its own right, as it required the co-optation of more diverse stakeholders and it lasted a longer period of time.

Mobilisation is the most contested phase of field emergence. There is democratisation (Beverungen et al., 2015; Selznick, 1951), because most stakeholders have to face a range of possible alternative identities and futures (Aldrich & Fiol, 1994; Fligstein & McAdam, 2011), due to the ambiguity of rules and governance. Consequently, the incumbents' power, if not contested, is significantly diminished. This is when the role of socially skilled actors (Fligstein, 2001) is most important, i.e. opinion leaders, social and moral entrepreneurs. They have the capacity to induce cooperation and frame the future linking to higher order of values - "better future", "common good". They give sense via stories, theorisation and the use of distinctive categories. Interestingly, opinion leaders, or influencers, play a bigger role at the

beginning because they are capable to depict a possible attractive future, make compelling arguments on the merits of change (connect to higher order of values) and promote stories that allow for contradictions to settle. The leadership role of the entrepreneurs at field level becomes relevant later on - almost as in adventure stories, with heroes and sometimes antiheroes (i.e. Elizabeth Holmes of Theranos). They often legitimise their endeavours by connecting to higher orders – for instance, research2guidance even named a category of innovators as "helpers" (2014). Furthermore, leading entrepreneurs inspire action by offering much-needed lessons and recipes for other entrepreneurs or for aspiring ones.

When I finished the field research, digital health was still in its mobilisation stage, when most stakeholders had entered the field. During mobilisation, there is field *granularity*. I introduce this term to differentiate from segmentation, which happens only when there is a significant decrease in ambiguity and stakeholders can organise around well-defined categories of products and value propositions. Such a degree of clarity was not attained by digital health when I data collection ended. The granularity of the field allows for fluidity and no hard fixings. Granularity means that there are concurrent pockets of negotiations between various stakeholders, *proto-ecosystems* (i.e. alliances, networks, research initiatives, hybrid organisations, industry associations). Most importantly, this granularity allows for both conflict and action/innovation to happen (Waldorff et al., 2013), it is not a threat for the field's survival and coagulation. In such proto-ecosystems, different stakeholders come together to negotiate or test the materialisation of a value proposition (Jacobides et al., 2018).

Finally, based on existing theorisation (Morrill, 2006), if the nascent field survives the intense contestations of the mobilisation phase, there is stabilisation (similar to Morrill's structuration) - a new institutional order settles in. I call this stage stabilisation, because structuration efforts begin during mobilisation. Stabilisation is reached when there is less ambiguity and a structure is better defined, with easily identifiable roles, practices and rules of the game.

9.2.2. INSTITUTIONALISATION IN COMPLEXITY

9.2.2.1. Plurality of logics

Chapter 6 identifies the institutional logics and their carriers as presented in digital health by the time data collection ended: medical profession, state, market, citizen and science logics. Medical profession logic means that their representatives have access to a body of knowledge, are licensed to employ it and have autonomy in their decisions (Abbot, 1988; Leicht & Fennell, 2008; Scott, 2008). State logic is focused on collective welfare through rationalisation and uniformity (Alford & Friedland, 1992; Scott, 2008). Despite the rise of the neoliberal doctrine (Swyngedouw, 2005), healthcare remains an area where the state continues to manifest in its welfare capacity. The market logic is guided by the need to increase shareholders value through the consideration of opportunity costs, potential returns and competitive edge (Gawer & Phillips, 2013; Scott et al., 2000; Thornton, 2002). The citizen logic refers to the fact that people choose based on personal values, with a sense of belonging to larger groups (Alford & Friedland, 1985; Dunn & Jones, 2010; Windrum & García-Goñi, 2008). I choose the term "citizen" to reflect that "when exercising one's autonomy and freedom, it is expected that the responsible citizen will allow his or her lifestyle to be guided under the auspices of knowledgeable experts and normative prescriptions of what it means to be healthy" (Ayo, 2012, p. 104). Science logic is focused on advancements of knowledge and is guided by "communalism, individualism, desinterestedness, originality, skepticism" (David, 2004; Dunn & Jones, 2010).

In the next table, I present a synthetic view of the institutional logics acting in digital health and some of their representative stakeholders.

Institutional Logics	Medical Profession	State	Market	Citizen	Science
Representative carriers	Doctors Other healthcare professionals	Payer Regulatory bodies	Healthcare Managers Pharma Medical devices Distributors ICT & health IT providers	Patient Carer Wellness aware people … Citizens	Doctors Academic institutions Researchers
Contents	License to use certain knowledge, autonomy in decisions	Collective welfare, consensus, rationalization, uniformity, distribution, coordination	Opportunity cost, potential returns, market share	Values, with sense of belonging to larger groups	Communalism, individualism, desinterestedness, originality, skepticism (David, 2004)
Focus of attention	Individual illness	Health of nations or populations	Cost/Benefit	Personal wellbeing (wealth, health and/or wellness)	Knowledge advancement
Basis of authority	Professional/ Information asymmetry	Vote	Market share	Right to wellbeing	Evidence/ Information asymmetry
Legitimacy	Licensing/ Professional affiliations	Legal and bureaucratic hierarchy	Certification Standards Brand	Pursue of self interest	Affiliations Publications
Basis of obligation	Defeat illness (science and care)	Constituencies	Shareholder value Contracts	Personal values	Contribution to knowledge
Structure of authority	Professional networks	Hierarchy Bureaucracy	Volatile and changing (provider and user)	Personal networks	Networks
Strategy	Build personal reputation	Build consensus Increase overall welfare	Increase share	Maximize personal wellbeing	Build personal reputation
Innovation	Diagnosis Treatment	Social (re)design	Desirability Usability Functionalities	Self management Creativity Knowledge	Pure science to technology (or IP)
Logic of investment	Better health outcomes	Political capital	Market return	Personal wellbeing	Knowledge as public good
Coordination mechanisms	Standard bodies Protocols Professional peers Affiliations	Regulations Incentives	Certificates Standards Associations	Affiliations to interest groups, communities or family	Affiliations Publications Professional peers

Table 13. Digital health institutional logics as ideal types and representative stakeholders

The merits of this endeavour are threefold. First, it accounts for all institutional logics at play, which is most relevant when studying an area that is both new and understudied (Greenwood et al., 2011). Second, the content of the healthcare logics is assumed in most studies and not well explained. This is often the case for the stage logic, for instance. However, the state logic suffered significant transformations over time and therefore its logic shouldn't be taken for granted by researchers. In addition, the market logic has its own specificity in the digital technologies context, where competition and innovation have a different meanging. My research also defines the science

logic in the context of healthcare, for the first time. Third, I bring forth a new emergent logic that was not identified and theoreticised before, the citizen logic.

9.2.2.2. Institutionalisation in emergence

My findings at the field level show that in the early stage of a field, the ingenious phase, there is intense hybridisation mainly because stakeholders enter voluntarily. Over the next stages, hybridisation, conflict and ambivalence manifest concurrently. I define *ambivalence* as the process of simultaneous conflict and hybridisation and it is the most common institutionalisation process amongst digital health stakeholders. Ambivalence is present because of the uncertainty and ambiguity of the field emergence, and because there are unsettled tensions between the incumbent logics (market, state and medical profession logics) in the healthcare field. Not last, due to the high ambiguity, there is a significant orientation to possible scenarios of the future, and ambivalence manifests also as a consequence of the conflict between the past, the present and the future.

The organisational level analysis shows that organisations engage with stakeholders mainly to close the knowledge and competency gaps, to gain resources and to nurture the market. It becomes clear that due to intense learning processes, there is intense hybridisation to the far end of co-creation at organisational level. Conflicts are avoided by new organisations either by delaying engagement with powerful stakeholders, by using categories skilfully or by compartmentalisation of solutions and value propositions.

State actions or lack of prove to have significant influence both at field and organisational levels. I find that the citizen institutional logic is the beneficiary of existing conflicts inside the healthcare field, where more logics reside in an "uneasy truce" (Reay & Hinings, 2005). This institutional outcome is similar to how the managerial logic came into ascendance (Scott et al., 2000) at a previous time.

A new role, the empowered patient, is representative for the increase in power of the citizen logic in the emergent field. It represents a proto-institution

(Zietsma & McKnight, 2009) and it is being negotiated intensively in the digital health. Previous studies similarly show how technology redefines roles in healthcare and may causes redistribution of power between actors (Barley, 1986; Nicolini, 2006).

9.2.2.3. The hybrid role of the empowered patient

The idea of patients having more choice in their health has been recurrent in political discourses (Scott et al., 2000) during the past decades. What changed now is that digital technologies, an exogenous factor for healthcare (Pache & Santos, 2010; Scott, 2008), offer the means for patients to engage in ways that were not previously possible.

The state, the CDHT producers and academic representatives form a critical and *significant* mass, with facilitative effect on the rise of the citizen logic. This effect is both intentional and unintentional. For instance, the CDHT producers encourage patients/citizens to self-quantify by designing attractive products. They do not mean to undermine doctors' authority, at least not always and not in the first place. Additionally, they realise the value of health data – big data, but so do the citizens who begin to demand control over PHD, creating a conflict. The state wants to enforce patient self-management, but it does not foresee that eventually this self-management would generate a conflict precisely with the empowered patient it helps create. There is "bounded intentionality" (Thornton et al., 2012, p. 80) of stakeholders, which lie paradoxically on rational constraints, like "social identity, goals, cognitive limitation" (ibid.). "Where a formal authority has been accustomed to the assumption that its constituents respond to it as individuals, there may be a rude awakening when organizations of those constituents on a non-governmental basis creates nuclei of power which are able effectively to demand a sharing of power" (Selznick, 1948, p. 35).

Lately, one of the common debates is about patients' health literacy, as pointer to the information asymmetry between doctors and patients. CDHT solutions may pose as mediator for this expertise gap, as shown by two of the organisation case studies (Mira Rehab and 11 Health) and partially by the YouLife case study. When the empowered patient is instantiated, there is less

conflict with the medical profession logic, as the apparent conflict is not over the goals (often better health outcomes or increased efficiency). In this way, the change in incumbent practices has a higher benefit than the cost of change. Consequently, organisations act intentionally or not as institutional brokers for and promoters of the empowered patient.

The organisational level shows how the citizen logic is advanced not necessarily as opposed to the incumbent logic of the medical profession, but by providing the means to patients/citizens to get more control over their own health. Both field and organisational levels reveal how the citizen logic is the beneficiary of the unsettled contestations between the incumbent logics in the healthcare field: state, market and medical profession logics.

9.2.2.4. Institutional work at organisational level

My research shows that during the mobilisation stage of the institutional emergence, organisations mostly engage with stakeholders in their field proximity to close the competence and knowledge gap, access resources and nurture a new market. These interactions are dominantly mediated by hybridisation and compartmentalisation of logics. This situation may be due to the fact that organisations in my study were not backed by powerful organisations, they were relatively new and operating under scarce resources, that they did not pursue conflict between logics. The main mechanisms were collaborative to the far end of co-creation. Case studies show that legitimacy and trust are perceived as important resources and much internal and external institutional work is directed towards building them. In a highly complex environment, trust is the main exchange currency.

Organisations compartmentalise for different stakeholders, but they also create and mediate interactions, acting as institutionalisation agents between logics. Both compartmentalisation and hybridisation were best supported by the digital technologies intrinsic characteristics that allow deploying concurrently multiple interfaces, levels of interactions, customisations, as well as by their unfinished character, meaning that on-going readjustments or additions can be managed. In terms of engaging with the state logic, organisations closer to

healthcare, a regulated fragmented field, are more prone to getting involved with state agencies.

Another commonality, albeit specific to most digital technology companies (Jacobides et al., 2018), is the morphing of products and business models. Moreover, organisations end up running concurrent business models, sometimes monetising from other stakeholders than the main beneficiaries (i.e. payers versus patients). "Firms identify what drives value to users (B2C), but do not always charge the users for it; often they charge other clients (B2B), who are willing to fund a venture to acquire its client information or access, or to show that they are affiliated with value-adding services (B2B2C)" (ibid., p. 2264).

The three case studies show that amidst plurality and ambiguity, firms orientate mainly based on the scenarios of the future, rather than the pre-existing institutional arrangements. All organisations remained true to their founding logics, albeit the founding logic suffered intense transformations in its enactment. This shows the importance of the founders' logic in the early stage of a new venture. Orientation based on scenarios of the future is reflected in their projective, ideal identities, which are the main determinant for action. In itself, building an ideal identity represents an important form of institutional work.

9.3. THEORETICAL CONTRIBUTIONS TOWARDS THE INSTITUTIONAL THEORY

9.3.1. FIELD EMERGENCE AND INSTITUTIONALISATION

Building on previous research, the field level study enriches the theoretical understanding of field emergence and institutionalisation. The figure below synthesises my model for field emergence, with four phases: ingenious, legitimation, mobilisation and stabilisation, showing the dominant institutionalisation processes during each phase. For stabilisation, I present possible and alternative outcomes. The model assumes that all stages are necessary for emergence to be successful, although returns to previous stages

are possible. The arrow indicates that this model can explain institutional crisis in mature fields as well.

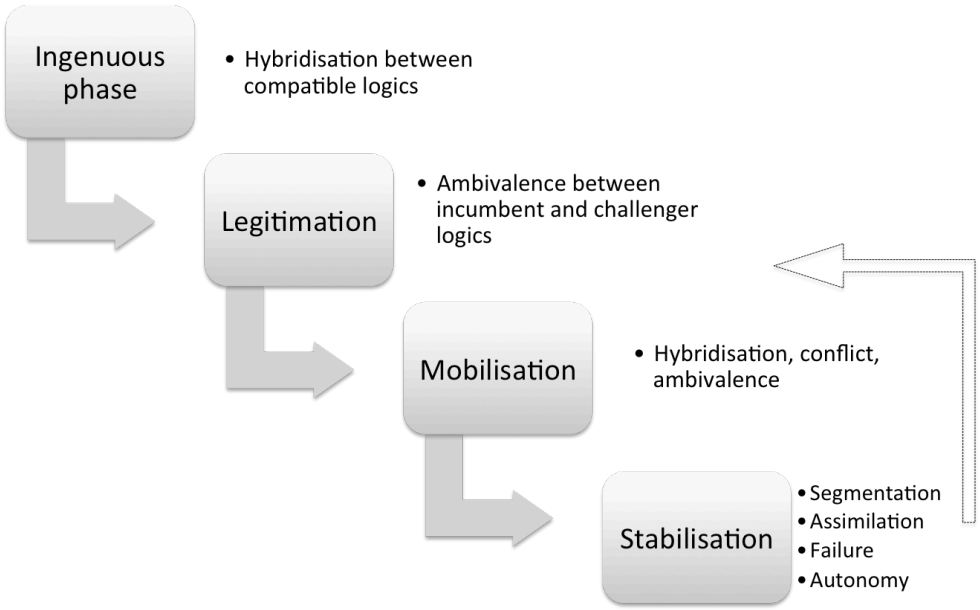

Fig. 46. A new model for field emergence and institutionalisation processes

Although in this case the field did not reach the maturity phase, stabilisation, I gathered significant insights to refine the model of emergence adding to existing theorisations. Compared to Morrill's emergence model, I define an additional phase, *legitimation*. I show the relevance of the *legitimising* actors, individuals (opinion leaders and social entrepreneurs) or organisations (healthcare, academia). This phase indicates that for mobilisation to happen, it is not enough to have only a critical mass (Morrill, 2006), but a *significant* mass, which confers socio-political legitimacy. This phase shows how digital health emergence resembles a social movement, by promoting the citizen logic amongst powerful incumbents. The role of opinion leaders is to connect the past to a possible future, link to higher order of values, connect to a common good and a good cause and promote stories to alleviate contradictions. Several entrepreneurs grow beyond their organisations to become social entrepreneurs, who have significant impact for the coagulation and the institutional configuration of the field. They provide templates for action, encourage risk taking, offer proof of change, generate new practices and knowledge and provide compelling stories.

During mobilisation there is a certain *granularity*, which allows for negotiations and conflicts to continue (Purdy & Gray, 2009; Waldorff et al., 2013), without endangering the survival of the field. Finally, stabilisation happens only when roles, practices and rules of the game are easier to identify; hence ambiguity decreases significantly. Stabilisation means the survival of the field, with its own new field logic or a constellation of logics (Goodrick & Reay, 2011). If stabilisation fails (Aldrich & Fiol, 1994; Gray, Purdy, & Ansari, 2015), several scenarios are possible: the field is cannibalised by adjacent ones, gets segmented and partially assimilated to one or a few fields, or is segmented into several niche fields. Stabilisation may reverse to mobilisation, if certain events forcefully influence its course (exogenous or endogenous triggers). These iterations between stabilisation and mobilisation could explain mature field crisis, when a field has to regain its stability or face extinction. Nonetheless, the longer the field survives, the more likely it is to produce changes in adjacent fields. For instance, Apple's introduction of the Research Kit caused a rapid shift in rethinking how clinical trials could be run, impacting pharma.

The digital health case shows that interstitial emergence is not a mere response to "a real or perceived institutional failure" (Morrill, 2006, p. 2) in nearby fields, as suggested by previous studies (Morrill, 2006; Purdy & Gray, 2009). It is mainly a response to perceived opportunities - resources and technologies (Gurses & Ozcan, 2014). An interstice may appear as a result of endogenous factors in adjacent fields, for instance institutional failures or practical problems (Fligstein, 2002; Morrill, 2006). In this case, healthcare has its own institutional failures generated by internal fragmentation and institutional constellation of logics (Goodrick & Reay, 2011; Reay & Hinings, 2009; Scott et al., 2000): for instance, the conflict between "care" and "science" (Dunn & Jones, 2010), or failure to "care" about health, not just illness. Practical problems of healthcare could be cost inefficiencies, incapacity to treat all illness, transparency, access and so on. This research shows how digital health appears at first to address wellness and illness via patient education, or "care" via peer networks. It then evolves towards "do it yourself" healthcare and eventually expands to the far end of medicine, even offering new ways to find

cures via Big Data, algorithms or citizen science (Candido do Reis et al., 2015). Additionally, this case does not support the theoretical assumption that challengers, in order to have impact, have to offer a view "premised on what exists and how goods are already delivered" (Fligstein & McAdam, 2011, p. 18). Digital health is based precisely on what may be missing and new delivery channels.

9.3.2. INSTITUTIONALISATION ALL THE WAY

The field level shows that during field emergence, there is great complexity because of ambiguity, lack of integration, high number of stakeholders and institutional logics, new roles and practices or organisational forms (Aldrich & Fiol, 1994; Julie Battilana & Dorado, 2010; Fligstein & McAdam, 2011; Purdy & Gray, 2009). This study supports previous findings that high specificity of institutional logics creates a complex institutional arena (Greenwood et al., 2011; Thornton et al., 2012). Therefore less prescriptive logics tend to hybridise at a higher pace, for instance market, science and citizen logics. Vocabulary, attention and justifications accumulate and change from one stage to the other (Nigam & Ocasio, 2009; Thornton et al., 2012), due to the gradual assimilation of stakeholders and the experimentation with technologies and new practices. At first, an emerging field attracts stakeholders who carry more similarities between their logics (Greenwood et al., 2011). This allows for mutually facilitative effects (Waldorff et al., 2013) and contribute to the cognitive legitimacy of the field. The more stakeholders step in, conflicts appear and debates become more intense (i.e. over interoperability, safety, validity, privacy, evidence or ownership), but so does engagement.

The organisational level analysis offers valuable insights on the institutional work that organisations undertake. It shows how organisations represent proto-institutions (Zietsma & McKnight, 2009), in the sense that they bring an identity project and orientate themselves based on future scenarios. They also adhere to distinctive categories and form connections in the emergent field, contributing to its coagulation. They act as knowledge and competency generators who contribute to the field maturation. Both field and organisational levels showed how medical professionals, patients and entrepreneurs enabled

by digital technologies were not only changing practices, but were co-creating new practices. Additionally, they create new organisational and technological structures that generate new conceptions of control and governance.

Due to the digital technology unfinished character, organisations are able to compartmentalise for various stakeholders, in a way that allows them to develop new practices and identify common goals. In this way, organisations become institutional brokers. They mediate hybridisation processes between stakeholders, even if there is a significant knowledge and expertise gap between them (patients and doctors, for instance). Part of their institutional work is also building trust and legitimacy for themselves, but in doing so they contribute to the entire field's cognitive and socio-political legitimacy. The diagram on the next page shows how institutionalisation processes intensify and how field emergence is also a bottom up process.

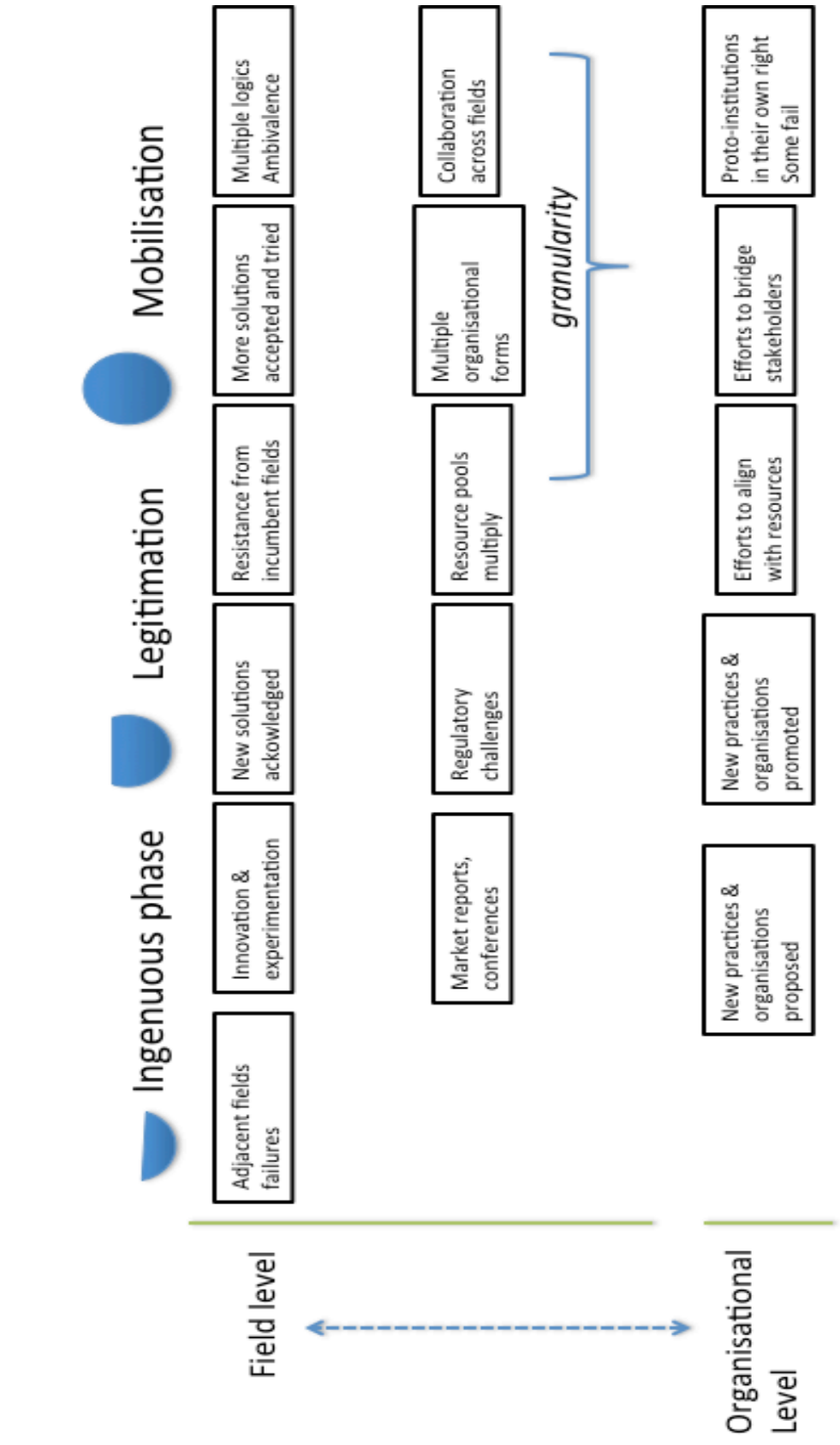

Fig. 47. Institutionalisation all the way

Organisations represent institutional agents to the point where they can become "institutions in their own right" (Kraatz & Block, 2008). One of the organisations in my research, 11 Health, represents a Selznickian institution, in the sense that it not only becomes a receptacle for multiple identities, but develops an organisational "self" (Kraatz & Block, 2008; Selznick, 1984). This means that it becomes infused with value, humanistic value (ibid.). Its founder in fact represents the empowered patient at its best, capable to find solutions to improve patients lives, engages in political actions and maintains his own and his company's integrity (Greenwood et al., 2011; Kraatz, 2009; Kraatz & Block, 2008; Selznick, 1984). In relation to this, both the field and organisational levels of analysis bring forth the importance of trust and leadership (Aldrich & Fiol, 1994; Fligstein, 2001; Kraatz, 2009; Kraatz & Block, 2008) for the institutionalisation and institutional work in complexity. Leadership builds internal capabilities for the organisation to hold multiple identities and act as institutional agent. A leader makes sense and gives sense in a world of uncertainty. A leader also projects an identity that is tributary to the future, not to the ambiguity of the present or the legacy of the past. In that sense, the creativity trait, however subtly manifested, is important for the organisation survival: it supports the creation of new values and meanings for multiple stakeholders and finds competitive edges by new approaches.

Organisations find it difficult to respond to diverse and often competing demands, therefore, they need "something" to hold them together and help them navigate the change. For a new organisation, leadership is not only a condition for success, but for its survival in a forever changing landscape, due to its ability to build trust. Trust links all levels, personal, organisational and the field levels, and is the main basis of exchange in conditions of high complexity. Leaders enable organisations to build strong strategies, co-opt partners and raise resources from often sceptical and inexperienced sources.

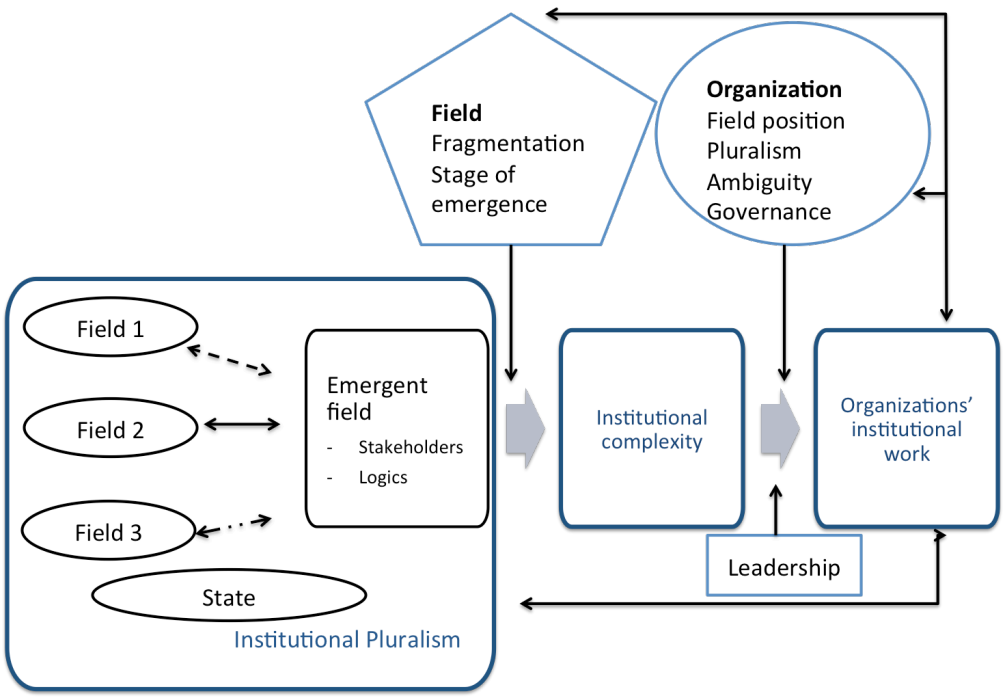

Fig. 48. Institutionalisation in complex environments

The figure above enhances the theoretical framework that guided and was validated by this research to reflect the importance of leadership all the way - for the field and organisational survival. Leadership is hardly noticed when things go well or when there is a stable and predictable environment. However, this is not the case of digital health that proposes new modus operandi, new scientific avenues, and new roles for stakeholders involved: doctors, patients, citizens, pharma, technology companies, insurers, investors or regulators.

This research shows that institutionalisation of a new field is also a bottom-up process (Selznick, 1984) and how less powerful actors, particularly in conditions of high institutional complexity, can cause massive change (Greenwood et al., 2011; Kraatz, 2009; Kraatz & Block, 2008; Santos & Eisenhardt, 2009; Selznick, 1984).

9.3.3. FURTHER IMPLICATIONS

My research adds to previous work showing that institutional logics do not rely on cognitivism solely (Friedland, 2013; Patriotta et al., 2011; Thornton et al., 2012) and joins the calls for researchers to consider more prominently the role of values, emotions and materiality in institutionalisation.

"Institutional logics all bind value, practice, and object. Institutional logics are, one might say, practical forms of value rationality" (Friedland, 2013, p. 36). Therefore, altering any of these cause further consequences on the institutional arrangements. Different debates use varied justifications (Boltanski & Thévenot, 2006; Friedland, 2013; Patriotta et al., 2011) in the attempt to reach common understanding over a common good (i.e. patient safety, privacy, rights). Such changes in debate framings is explained by individuals being able to simultaneously access and combine different orders of worth (Patriotta et al., 2011) or value rationales, grounded in "myriad moments of located passion" (Friedland, 2013, p. 44). This research shows the impact of leadership at field and organisational levels, because one of its main functions is to rise above uncertainties and debates and present a better future by association with higher order values.

"Ideals are called ideals for a reason" (Kraatz & Block, 2008, p. 262) and the fact that they are not perfectly reflected in the real world, does not mean they have no practical implications. They can drive collaboration to the far end of co-creation, as shown in this research. Institutional logics maintain a subtle connection between practices and values, not as simple cognitive deductions, but as simultaneous value attachments, which maintain them humbly in the realm of social possibilities (Friedland, 2013). This conception may well explain the "foolishness" of entrepreneurs in emergent fields, "for they are navigating, at best, in an institutional vacuum of indifferent munificence and, at worst, in a hostile environment impervious to individual action" (Aldrich & Fiol, 1994, p. 645).

> *And if I had to start a company and fail a thousand times and start it over again and fail, I would do that. And so when I realized that, then it was about doing whatever it takes to make this a reality. Because*

it's a change that can happen and has to happen in our world! (Elizabeth Holmes, founder Theranos) (Computer Society, 2014)

The rise of the empowered patient may be considered in the broader context of a socio-political evolution towards "governance-beyond-the-state" (Swyngedouw, 2005, p. 1991), a consequence of the interaction between a neoliberal state, digital innovation and citizens. The capacity of new roles and identities to survive depends upon a successful negotiation of a new conception of control (Fligstein & McAdam, 2011). In order for a new conception of control for doctor – patient/citizen to emerge, many aspects have to be negotiated and possibly renegotiated, as "[n]o value sphere can justify the ultimate value upon which it depends. Each depends on an intellectual sacrifice" (Friedland, 2013, p. 31).

Voronov and Vince (2012) show that emotions are very relevant for institutional work and propose a fantasmatic frame, alongside a cognitive one. Such frame is connected to the power concept, as it is constantly driven by desires, tested against reality and orientated towards future. As stated before in this thesis, the sense giving process is future orientated and concerned with influencing the environment (Gioia & Chittipeddi, 1991). My research shows that such a fantasmatic frame (i.e. ideal identity or future script) is indeed infused with emotions, but it is mostly value orientated, rather than power. Consequently, it is relevant to consider emotions, values and representation of the future when researching emerging institutional fields, given their high degree of uncertainty and ambiguity that require institutional work. In this way, I am echoing other scholars like Friedland (2013), Kraatz and Block (2008) Kraatz (2009) and Voronov and Vince (2012) in arguing that values and emotions are most relevant for understanding institutional processes and institutional work at all levels of analysis.

Digital technologies are complex artefacts that challenge the separation between the organisation and its environment (Gawer & Phillips, 2013; Nicolini, 2007; Orlikowski, 2010; Petrakaki et al., 2012). They bring change via democratisation of specialist knowledge, alternative channels for action and information through peer-to-peer communications, and therefore they challenge temporary, spatial, ownership and governance conventions.

In the light of the increasing acknowledgement of materiality in institutional logics research (Gawer & Phillips, 2013; Morrill, 2006; Thornton et al., 2012), I add a few remarks on collaborative digital health technologies as enablers and mediators for institutional complexity and change. The encounter of healthcare and ICT has been dominated by managerial approaches (Macnaughtan, 2015b; Scott et al., 2000) until 2007, with the evolution of smart, affordable, mobile and sensing consumer devices. I show that CDHT solutions open up space and mediate the negotiation and renegotiations of roles, practices, ownership and governance, by revealing existing tensions or presenting new avenues. Additionally, digital health opens up space for broader participation in health innovation, which in return, stimulates further technical and institutional innovation.

Innovation is a constant aim for technology producers as it drives both the competitive edge and higher returns. It has been theorised that technology has its own logic (David, 2004) driven by rationales of economic returns, therefore secrecy is important. However, the digital technologies changed this paradigm with its evolution towards platforms and ecosystems (Mulligan, 2011; Gawer & Phillips, 2013; Jacobides et al., 2018). Additionally, change is intrinsic to the digital technologies field, given their very unfinished character. As previous research showed, change manifests rather as a constant in the digital technologies field, rather than an institutional moment or crisis (Rindova & Kotha, 2001; Santos & Eisenhardt, 2009; Gawer & Phillips, 2013). In that sense, digital technologies may have their own institutional logic, where change is a core value and therefore an institutional constant. This may be fruitful to consider by further research.

9.4. PRACTICAL CONTRIBUTIONS

9.4.1. REGULATION, MEDICAL PROFESSION AND INNOVATION

Regulations can foster innovation (Fligstein, 2002; Mazzucato, 2013), lock it in (Christensen et al., 2009) or hinder it simply due to lack of understanding of all contingencies (Macnaughtan, 2014). Contrary to existing theorisation (Aldrich & Fiol, 1994; Fligstein, 2002), this study shows how early or lack of regulatory intervention does not necessarily stabilise an emergent field, but it may open it further to contestation. Decision makers and regulators may want to consider other ways to fuel innovation and channel change, like creating spaces for experimentations (Rip & Schot, 2002) and opening space for innovation (Fox, 2017), where various stakeholders can meet, try new practices, roles and technologies.

As discussed in chapter 6, regulation is required to watch over the development of the healthcare and digital technologies innovation trajectory. However, the digital economy calls for a smarter, more adaptable regulatory approach in healthcare as well. Over the past decades, governments tried to enforce adoption of IT solutions in health, and despite significant resources, no transformative progress was made. Causes are complex and beyond the scope of this research, although they are touched upon in chapter 5. But one of these causes was the medical professionals' resistance. This in itself is a complex phenomenon, however studies show that healthcare is driven by technology. The paradox is that doctors' resistance resides mainly to solutions that are designed from a managed care perspective, rather than from a science or care perspectives.

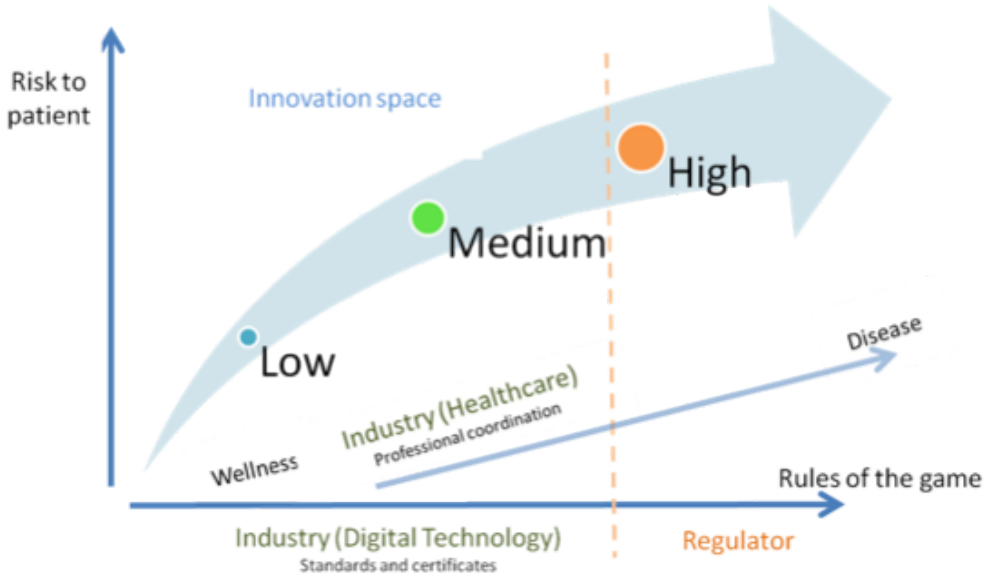

Fig. 49. Alternative regulatory design (with deregulation of healthcare) (Macnaughtan, 2014)

Therefore, my research shows that the return to the medical professional expertise is most powerful to stimulate adoption of innovation. In that sense, deregulation in some areas may be considered. Through the diagram above, I offer a potential model for healthcare deregulation based on patient risk to allow for adoption of innovation, by relying more on sector coordination governed by the healthcare professional authority. "Perhaps the time for (de)regulation inside healthcare itself has arrived, to let innovation tackle a wide range of problems in different, creative and - why not - cheaper ways" (ibid.).

However, setting the rules of the game, like interoperability, privacy and ownership of data, should remain the primary concern of the regulators. By following the advise on deregulation of practice and expertise and regulation of the rules of the game, regulators would embrace more the characteristics of an "entrepreneurial state" (Mazzucato, 2013). Excellent examples of leadership for unlocking the creative potential of the digital health and healthcare are offered recently by two former executives in the US Department of Health, Karen DeSalvo (ONC Director, then DoH assistant secretary) and Susannah Fox (CTO in DoH). NHS, via the app library, for instance, is another example of an entrepreneurial regulator. "Doctors and hospitals, regulators, and policy makers need to convert to this religion [...]. The fact that cost-lowering,

accessibility-enhancing disruptive enablers can address only the simplest of problems at the outset is indeed a gospel of good news" (Christensen et al., 2009, p. xlviii).

Another call for regulators, medical professionals and academia is the need to reinvent medical innovation to stimulate interaction with technology and entrepreneurship. Adoption of innovation inside healthcare calls for intrapreneurial skills at the very least, as my research indicates. In order for innovation to disseminate systemically, there is a need to shift the culture for medical profession to stimulate creativity and entrepreneurship as well.

9.4.2. Entrepreneurs and investors

Several practical implications can be drawn for new organisations, particularly for building internal capabilities. One recommendation is to keep the communications opened inside the organisation. As simple as it may seem, in young organisations, with limited resources, it was shown that there was a lack of communication. This is important because it allows for learning to disseminate, it fosters competencies, it keeps focus and it allows individual team members to adapt, assimilate or contribute to vision and strategy.

A second recommendation is towards allowing job ownership to emerge. In this research, only one company demonstrated this fully (Mira Rehab), and this proved to unlock creativity, lateral thinking, and better coordination inside and outside the organisation.

All organisational cases showed that values are important, as well as leadership and identity. Conflict at top level creates disengagement. However, having a good cause has material effects on the evolution of a company. A good cause offers a sense of purpose to organisational members and stimulates learning and creativity. For outsiders, it projects a sense of integrity and creates good will. My research indicates that leadership is an essential indicator of organisational survival and success in a complex institutional environment, where trust becomes the main basis of transactions. Additionally, creativity as leadership trait indicates that such organisations are more adaptive and capable to attract co-optation from powerful stakeholders. A recent "poll of fifteen

hundred CEOs identified creativity as the number-one "leadership competency" of the future" (Dyer, Gregersen, & Christensen, 2009, p. 1), in the fast changing digital economy.

Young organisations in digital health, having scarce resources and a complex environment to navigate, have to establish strong collaborations to access expertise, and in doing so to maximise their resources. My research shows that co-creation of new to the world digital solutions alongside the end-users is the most strategically meaningful and resourceful mechanism. It also opens space for learning and even fosters the market itself. In a multi-stakeholder context, organisations have to offer clear value propositions to each and communicate clearly and efficiently with each category. In order to that, different vocabularies may apply. Similarly, in a context where technology happens fast, and demand is evolving and shifting, it is important to coordinate and integrate with other solutions, integrate in an ecosystem or build one.

Not last, I have shown that legitimacy has material consequences on organisational survival and access to resources. Amongst modalities to obtain legitimacy in digital health, I mention:

- Association with credible actors – via partnership (academia or healthcare organisations) or co-optation in advisory boards, association with opinion leaders
- Proof of persistence – via a detailed history of the organisation, founding stories
- Stories - as a way to transition from status quo to the future
- Build trust – founder stories, display of achievements
- Good cause articulation
- Meaningful value propositions for all significant stakeholders
- Scientific or economic evidence communicated for a broad audience
- Strategic social media engagement

Through this study, I show that organisations act mostly serendipitously. Drawing maps of stakeholders and potential ones, along with how value can be generated from engaging with them, may better orientate and help new

organisations to build strategies, value propositions and concurrent business models in a complex institutional context. As this research demonstrates, most organisations changed their products and business models significantly, as learning and interactions with stakeholders intensify.

The next table is mapping YouLife's stakeholders, as developed during data collection. The green colour marks existing congruence in goals, yellow marks ambivalence (on-going negotiations or uncertainties) and the lack of colour shows untapped territories or no identify overlap. At the bottom, there are several indicators to take into account when engaging with particular stakeholders. Decisions to engage with stakeholders should depend and be phased on such indicators, the particularities of the solution offered and resources available. For instance, Mira Rehab considered that its solution needs intense expert input from medical professionals, and therefore their efforts went initially towards building strong partnerships within medical communities relevant to their products: at the beginning orthopaedists and physiotherapists, followed by neurologists. In time, they learned that clinical connections offered them also a competitive market advantage - access to resources and distribution channels. Therefore, they prioritised the engagement with this stakeholder (doctors) and the deployment of the B2B model, and delayed the B2C and B2B2C models.

Stakeholders	Public Health	Health Providers	Research, Univ…	Foundations	Wearables	Retail	Insurer/ Payer	Employer	Mobile Operator/ Producers	Gamification	Welness & fitness
Health Literacy											
Population Health Risk		ACOs, GPs…		Advocacy groups, foundations with research branches							
Engagement in Physical Activities											
Self Tracking											
Data											
Acquisition cost	High and long term	High and long term ACOs, perhaps	Low	Medium	High	Medium	Medium	Medium	Medium	Medium	Low
Return	N/A	N/A	High	High	High	N/A	Medium	Medium	High	High	High
Access to market Ecosystem	N/A	Medium	High	Medium	High	N/A	Medium	Medium	High	High	High
Benefits vs. acquisition time	Long term	Medium	Short	Short	Short	Medium/ Long	Medium	Short/Medium	Short	Short	Short
Monetization					Yes	Yes	Yes	Yes	Yes	Yes	Yes

Table 14. Sample stakeholder map for YouLife

In the digital economy, the main beneficiaries do not always represent the main revenue stream (Jacobides et al., 2018). And this is most often the case in digital health, too. It is therefore important for young ventures to have a stakeholder plan (see also fig. 14), not only a business plan. Consequently, a good practice may be drawing roadmaps for stakeholder evolution to guide and prioritise product development and business models, to maximise resources and legitimacy. Given scarcity of resources and a fast changing environment, this is a fine line to walk for many, indeed.

The most important practical insight of this research for CDHT producers, investors and other stakeholders is that in digital health an organisation needs four licenses to succeed.

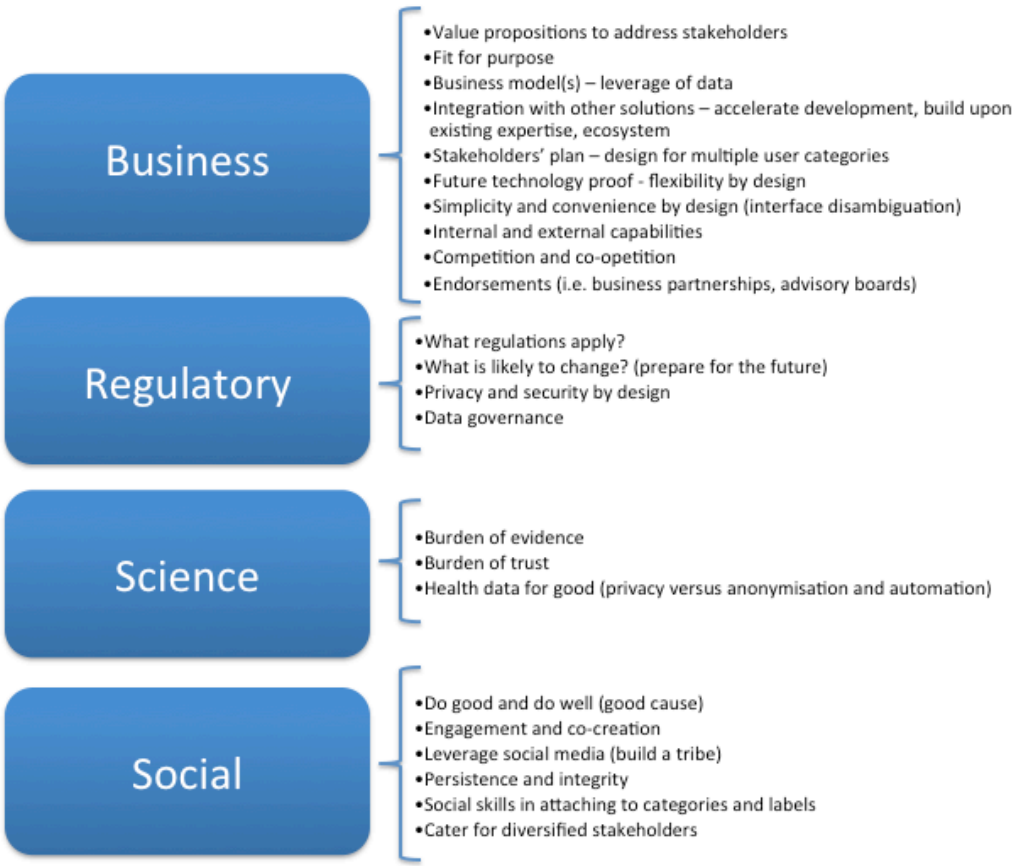

Fig. 50. Four licences to succeed in digital health

The figure above proposes an evaluation model for digital health innovations and a high level guidance on how to assess and respond to these four pillars. The business licence takes into account the constant changes and complexities of a fragmented field where there are multiple stakeholders. Provided resources

are limited, organisations have to prioritise and phase their product and business development. The regulatory licence relates to the fact that digital health is subject to regulations (laws and regulations) and professional (codes and standards) scrutiny. Science relates to professional authority and more broadly to building trust and confidence for a new product and a new organisation. The social licence becomes more relevant in the digital economy, where people connect and disconnect simultaneously and rapidly, where word travels fast and unmerciful. Social engagement is also a way to maximise resource, for instance via crowd funding and crowd wisdom, or via increasing impact and building a bandwagon adoption. It also facilitates co-creation, engagement and brand attachment.

However, the weight of each licence is dependent on the position of the organisation on the digital health continuum. For instance, YouLife found the market logic to be most accommodating, so it had less attention for regulations that apply in healthcare. However, it did not deploy successfully for engaging efficiently with their target audience. However, 11 Health is an example of successfully getting to the point where it was satisfying all four licences.

Not last, young organisations in digital health benefit from the capacity to articulate their development in terms of product and business model over time, in a compelling mode both internally and externally. Roadmaps for development and stakeholders engagement ensure just that, and by that, they can attempt to satisfy all licences above over time and corresponding to their solution on the digital health continuum.

9.5. Reflections and future direction of research

My research makes several and complex contributions to the institutional theory in the realm of institutional complexity, field emergence and institutionalisation. In its complexity also reside some of its limitations, in the sense that it may have been better suited for a team of researchers to undertake, due to the volume and richness of data.

In respect to the field level analysis, the main limitation is inherent to single case studies; therefore further explorations of emergent fields are needed. For

instance, the legitimation phase may be specific to interstitial emergence adjacent to fragmented fields (Fligstein & McAdam, 2011). To further research agenda, I suggest that studies of the evolving roles of digital health stakeholders may render not only practical insights, but also theoretical ones on how conceptions of controls and governance (Fligstein & McAdam, 2011; Gawer & Phillips, 2013; Swyngedouw, 2005) may change in the digital world. Additionally, building on this study, further explorations of the digital health field will advance insights in field emergence, particularly because digital health is still far from stabilisation.

At the organisational level, due to the diversity of solutions in the field, further research may look at organisations that are more similar to allow for finer contributions on specific areas. My research did not focus on the relevance leadership has for new organisations in institutional complexity. However, it proves that leadership has material effects on organisational survival and success. Therefore, I concur to the existing opinions (Kraatz, 2009; Kraatz & Block, 2008) that this is an area of research that could produce interesting theoretical insights, as the cases of "shared leadership" or the "entitativity" an organisation has reached under a connotative leader that were revealed by my research.

Not last, digital technologies allow for new forms of organising the social and economic life (Gawer & Phillips, 2013; Jacobides et al., 2018). Their impact on institutionalisation has been explored but they deserve further understanding (Gawer & Phillips, 2013; Rindova & Kotha, 2001; Santos & Eisenhardt, 2009). It would perhaps be of theoretical and empirical interest to explore digital technologies as an institutional logic in its own right, as has been suggested before that technology and science logics are different (David, 2004). Digital technologies may have change as a core value and constant rather than an institutional disruptor as conceptualised until today. Considering digital technologies as an institutional logic in its own right may render interesting insights of the digital econony.

9.6. Concluding remarks

“The future has arrived — it’s just not evenly distributed yet" (attributed to William Gibson)

I used this quote in one of my first articles about digital health - a quote that is invoked in the digital health space very often. Digital technologies connect and disconnect us in various ways, at a very fast pace. They remain a significant driver of social, economic and scientific change. Much research in this field is needed to keep pace, understand, let alone control these changes. There is tremendous opportunity in digital health, as it is indeed built upon intangible value substances.

REFERENCES

Abbot, A. (1988). *The System of Professions*. Chicago: University of Chicago Press.

Accenture. (2014). *Great Expectations: Why Pharma Companies Can't Ignore Patient Services 2014*. Retrieved Jan. 2015, from Accenture website: http://www.accenture.com/SiteCollectionDocuments/PDF/Accenture-Great-Expectations-Why-Pharma-Companies-Cant-Ignore-Patient-Services-Survey.pdf

Akrich, M. (1992). The De-Scription of Technical Objects. In Wiebe E Bijker and John Law (Eds.), *Shaping technology/building society: studies in sociotechnical change.* Cambridge: MIT Press

Aldrich, H. E., & Fiol, C. M. (1994). Fools Rush in? The Institutional Context of Industry Creation. *The Academy of Management Review*, *19*(4), 645–670. https://doi.org/10.2307/258740

Alford, R. R., & Friedland, R. (1985). *Powers of Theory: Capitalism, the State, and Democracy* (6th ed.). Cambridge University Press.

Atul, B. (2015). *UCSF's Atul Butte on the future of big data and the potential for "garage biotech."* Retrieved Jan. 2016, from https://www.youtube.com/watch?v=pY5_KSMlAUQ&t=36s

Ayo, N. (2012). Understanding health promotion in a neoliberal climate and the making of health conscious citizens. *Critical Public Health*, *22*(1), 99–105. https://doi.org/10.1080/09581596.2010.520692

Ayogo. (2015). Patient Engagement Definition: What Does it Mean to You?. Retrieved March 2016, from Ayogo website: http://ayogo.com/blog/patient-engagement-definition/

Baldwin, C. Y., & Woodard, C. J. (2009). The Architecture of Platforms: A Unified View. In Annabelle Gawer (Ed.), *Platforms, Markets and Innovation.*. Cheltenham, U.K. and Northampton, MA: Edward Elgar Publishing.

Barley, S. R. (1986). Technology as an Occasion for Structuring: Evidence from Observations of CT Scanners and the Social Order of Radiology Departments. *Administrative Science Quarterly*, *31*(1), 78–108. https://doi.org/10.2307/2392767

Barley, S. R. (2008). Coalface Institutionalism. In Royston Greenwood, Christine Oliver, Roy Suddaby & Kerstin Sahlin (Eds.), The SAGE Handbook of Organizational Institutionalism (491–518). London, UK: SAGE Publications Ltd.

Barley, S. R., & Tolbert, P. S. (1997). Institutionalization and Structuration: Studying the Links between Action and Institution. *Organization Studies*, *18*(1), 93–117. https://doi.org/10.1177/017084069701800106

Basil Strategies. (2012). *Interview with Sarah Kucharski -- Doctors 2.0 & You*. Retrieved Nov. 2015, from https://www.youtube.com/watch?v=3JPO9Qq1AFU

Bates, J. (2014). The strategic importance of information policy for the contemporary neoliberal state: The case of Open Government Data in the United Kingdom. *Government Information Quarterly*, *31*(3), 388–395. https://doi.org/10.1016/j.giq.2014.02.009

Battilana, J., & D'Aunno, T. (2009). *Institutional Work and the Paradox of Embedded Agency*. In B. Leca, R. Suddaby, & T. B. Lawrence (Eds.), *Institutional Work: Actors and Agency in Institutional Studies of Organizations* (31-58). Cambridge, U.K.: Cambridge University Press

Battilana, Julie, & Dorado, S. (2010). Building Sustainable Hybrid Organizations: The Case of Commercial Microfinance Organizations. *Academy of Management Journal*, *53*(6), 1419–1440. https://doi.org/10.5465/AMJ.2010.57318391

Beach, D. (2010). Neoliberal Restructuring in Education and Health Professions in Europe Questions of Global Class and Gender. *Current Sociology*, *58*(4), 551–569. https://doi.org/10.1177/0011392110367998

Beckert, J. (1999). Agency, Entrepreneurs, and Institutional Change. The Role of Strategic Choice and Institutionalized Practices in Organizations. *Organization Studies*, *20*(5), 777–799. https://doi.org/10.1177/0170840699205004

Bessant, J., & Rush, H. (1995). Building bridges for innovation: the role of consultants in technology transfer. *Research Policy*, *24*(1), 97–114. https://doi.org/10.1016/0048-7333(93)00751-E

Beverungen, A., Böhm, S., & Land, C. (2015). Free Labour, Social Media, Management: Challenging Marxist. *Organization Studies*, *36*(4), 473–489. https://doi.org/10.1177/0170840614561568

Boltanski, L., & Thévenot, L. (2006). *On Justification: Economies of Worth*. Princeton, NJ: Princeton University Press.

Bort, J. (2015). Thanks to Apple, 11,000 people signed up for a heart disease study in one day. Retrieved March 2015, from Business Insider website: http://uk.businessinsider.com/apple-makes-heart-disease-study-go-nuts-2015-3

Boulos, M. N., Wheeler, S., Tavares, C., & Jones, R. (2011). How smartphones are changing the face of mobile and participatory healthcare: an overview, with example from eCAALYX. *BioMedical Engineering OnLine*, *10*(1), 24. https://doi.org/10.1186/1475-925X-10-24

Bowen, G. A. (2008). Naturalistic inquiry and the saturation concept: a research note. *Qualitative Research*, *8*(1), 137–152. https://doi.org/10.1177/1468794107085301

Brown, R. E. (2006). Myth of symmetry: Public relations as cultural styles. *Public Relations Review*, *32*(3), 206–212. https://doi.org/10.1016/j.pubrev.2006.05.022

Campbell, D. T. (1958). Common fate, similarity, and other indices of the status of aggregates of persons as social entities. *Behavioral Science*, *3*(1), 14–25. https://doi.org/10.1002/bs.3830030103

Cancer Research UK. (2014). Cancer Research UK launches 'spaceship' smartphone game to seek cancer cures. Retrieved March 2015, from Cancer Research UK website: https://www.cancerresearchuk.org/about-us/cancer-news/press-release/2014-02-04-cancer-research-uk-launches-spaceship-smartphone-game-to-seek-cancer-cures

Candido do Reis, F. J., Lynn, S., Ali, H. R., Eccles, D., Hanby, A., Provenzano, E., … Pharoah, P. D. P. (2015). Crowdsourcing the General Public for Large Scale Molecular Pathology Studies in Cancer. *EBioMedicine*. https://doi.org/10.1016/j.ebiom.2015.05.009

Cardin, T. (2015). Powerless in the setting of patient autonomy? Try maternalism. Retrieved May 2015, from KevinMD.com website: http://www.kevinmd.com/blog/2015/05/powerless-in-the-setting-of-patient-autonomy-try-maternalism.html

Chase, D. (2016). Large Companies Ally To Target Healthcare Problem Already Solved By Smaller Companies. Retrieved Nov. 2016, from Forbes website: http://www.forbes.com/sites/davechase/2016/02/05/large-companies-form-alliance-to-study-problem-already-solved-by-smaller-companies/

Cheek, J. (2008). Healthism: A New Conservatism? *Qualitative Health Research*, *18*(7), 974–982. https://doi.org/10.1177/1049732308320444

CHM Revolutionaries. (2014). *Theranos Founder & CEO Elizabeth Holmes in Conversation with Michael Krasny*. Retrieved Jan. 2015, from https://www.youtube.com/watch?v=UKY3scPIMd8&feature=youtube_gdata_player

Christensen, C. M., Grossman, J. H., & Hwang, J. (2009). *The Innovator's Prescription: A Disruptive Solution for Health Care*. New York: McGraw-Hill.

COCIR. (2010). COCIR telemedecine toolkit. For a better deployment and use of telehealth. Retrieved Aug. 2012, from http://www.cocir.org/uploads/documents/-903-cocir_telemedicine_toolkit_march_2010.pdf.

COCIR. (2011). COCIR eHealth toolkit for an accelerated deployment and better use of eHealth. Retrieved Aug. 2012, from http://www.cocir.org/uploads/documents/eHealth%20Toolkit%20LINK2.pdf.

European Commission. (2015). Health care and long-term care. Retrieved Jan. 2016, from http://ec.europa.eu/economy_finance/structural_reforms/ageing/health_care/index_en.htm

Comstock, J. (2015a). In-Depth: Pharma steps up digital health efforts. Retrieved Nov. 2016, from MobiHealthNews website:

http://www.mobihealthnews.com/39778/in-depth-pharma-steps-up-digital-health-efforts

Comstock, J. (2015b). UK's Royal College of Physicians lays out guidelines for medical apps | mobihealthnews. Retrieved May 2015, from http://mobihealthnews.com/43278/uks-royal-college-of-physicians-lays-out-guidelines-for-medical-apps/

Comstock, J. (2015c). IMS: 1 in 10 health apps connects to a device, 1 in 50 connects to healthcare providers | MobiHealthNews. Retrieved Oct. 2015, from http://mobihealthnews.com/46863/ims-1-in-10-health-apps-connects-to-a-device-1-in-50-connects-to-healthcare-providers/

Crawford, R. (1980). Healthism and the Medicalization of Everyday Life. *International Journal of Health Services*, *10*(3), 365–388. https://doi.org/10.2190/3H2H-3XJN-3KAY-G9NY

Currie, W. L., & Guah, M. W. (2007). Conflicting institutional logics: a national programme for IT in the organisational field of healthcare. *Journal of Information Technology*, *22*(3), 235–247. https://doi.org/10.1057/palgrave.jit.2000102

David, P. A. (2004). Understanding the emergence of 'open science' institutions: functionalist economics in historical context. *Industrial and Corporate Change*, *13*(4), 571–589. https://doi.org/10.1093/icc/dth023

Davies, A., & Newman, S. (2011). *Evaluating telecare and telehealth interventions. WSDAN briefing paper.* Retrieved Jan. 2012, from King's Fund website: https://www.kingsfund.org.uk/sites/default/files/Evaluating-telecare-telehealth-interventions-Feb2011.pdf

Davis, S. (2013). 2014 Essays: The Role of the Smartphone in Digital Health. Retrieved Apr. 2015, from Bionicly website: http://bionicly.com/2014-essays-the-role-of-the-smartphone-in-digital-health/

Davis, S. (2015). The Smartphone Is The Platform For The Digital Health Stack. Retrieved Apr. 2015, from Bionicly website: http://bionicly.com/digital-health-stack/

deBronkart, D. (2009a). e-Patient Dave. Retrieved Apr. 2015, from http://www.epatientdave.com/

deBronkart, D. (2009b). Ushering in the Era of the Participating Patient. Retrieved Oct. 2016, from e-Patient Dave website: http://www.epatientdave.com/2009/08/26/the-participating-patient/

deBronkart, D. (2015). "No MU without ME": join the campaign to fight health data hiding | e-Patients.net. Retrieved May 2015, from http://e-patients.net/archives/2015/04/no-mu-without-me-join-the-campaign-to-fight-health-data-hiding.html

Deephouse, D. L., & Suchman, M. (2008). Legitimacy in Organizational Institutionalism. In Royston Greenwood, Christine Oliver, Roy Suddaby & Kerstin Sahlin (Eds.), *The SAGE Handbook of*

Organizational Institutionalism (pp. 49–77). London: SAGE Publications Ltd. https://doi.org/10.4135/9781849200387

Della Mea, V. (2001). What is e-Health (2): The death of telemedicine? *Journal of Medical Internet Research*, *3*(2), e22. https://doi.org/10.2196/jmir.3.2.e22

Dias, J. (2014). Is the Phrase "Patient Engagement" Overused?. Retrieved Nov. 2014, from HIT consultant website: http://hitconsultant.net/2014/04/21/is-the-phrase-patient-engagement-overused/

DiMaggio, P. J., & Powell, W. W. (1983). The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields. *American Sociological Review*, *48*(2), 147–160. https://doi.org/10.2307/2095101

Djellal, F., & Gallouj, F. (2005). Mapping innovation dynamics in hospitals. *Research Policy*, *34*(6), 817–835. https://doi.org/10.1016/j.respol.2005.04.007

Dolan, B. (2012). Just launched: Our 2012 Consumer Health Apps Report | mobihealthnews. Retrieved Apr. 2015, from http://mobihealthnews.com/17925/

Drucker, Peter. F. (1994). *Innovation and entrepreneurship: Practice and principles.* (6th ed.). Oxford: Butterworth-Heinemann.

Duhaime-Ross, A. (2015). Apple makes ethics board approval mandatory for all medical research apps. Retrieved Apr. 2015, from The Verge website: http://www.theverge.com/2015/4/29/8513367/apple-research-kit-ethics-board-mandatory-clinical-trial

Dunn, M. B., & Jones, C. (2010). Institutional Logics and Institutional Pluralism: The Contestation of Care and Science Logics in Medical Education, 1967–2005. *Administrative Science Quarterly*, *55*(1), 114–149. https://doi.org/10.2189/asqu.2010.55.1.114

Dyer, J. H., Gregersen, H., & Christensen, C. M. (2009). The Innovator's DNA. *Harvard Business Review*, (December 2009). Retrieved from https://hbr.org/2009/12/the-innovators-dna

European Commission. (2014). EC launches Green Paper consultation into mHealth. 1. Retrieved Sept. 2014, from https://ec.europa.eu/digital-single-market/en/public-consultation-green-paper-mobile-health

Eisenhardt, K. M., & Graebner, M. E. (2007). Theory Building From Cases: Opportunities And Challenges. *Academy of Management Journal*, *50*(1), 25–32. https://doi.org/10.5465/AMJ.2007.24160888

Engelen, L. (2012). No-Show patients on conferences : Patients Included™. Retrieved May 2015, from Gras groeit niet door er aan te trekken ! website: https://lucienengelen.wordpress.com/2012/02/15/no-show-patients-on-conferences/

Engelen, L. (2013). (2) No-Show patients on conferences : Patients Included™. Retrieved July 2018, from LinkedIn Pulse website:

https://www.linkedin.com/pulse/20130326140319-19886490-no-show-patients-on-conferences-patients-included/

Engelen, L. (2015). What's a Hospital Without Beds? Much Better. Retrieved March 2015, from LinkedIn Pulse website: https://www.linkedin.com/pulse/come-out-bed-move-lucien-engelen

European Commission (2004). *eHealth action plan 2004 2010*. Retrieved Sept. 2014, from http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52004DC0356

European Commission. (2012). *eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century*. Retrieved Sept. 2014, from ec.europa.eu//digital-agenda/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century

European Commission. (2014a). mHealth, what is it? - Infographic. Retrieved Nov. 2014, from Digital Agenda for Europe website: ec.europa.eu//digital-agenda/en/news/mhealth-what-it-infographic

European Commission. (2014b). *Green Paper on mobile health ("mHealth")*. Retrieved Jan. 2015, from file:///C:/Users/psxlm/Downloads/GreenPaperonmobilehealth%20(6).pdf

European Parliament, & European Council. (2011). *DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare*. Retrieved Jan. 2014, from http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF

Ferguson, T. (1996). *Health Online: How to Find Health Information, Support Groups and Self-help Communities in Cyberspace*. Reading, Mass: Da Capo Press Inc.

Fleck, J. (1994). Learning by trying: the implementation of configurational technology. *Research Policy*, *23*(6), 637–652. https://doi.org/10.1016/0048-7333(94)90014-0

Fleseru, A. (2016). Case study on a 14 years old girl with a very rare condition: Congenital Disorder of Glycosylation. Retrieved July 2018, from MIRA Blog website: http://blog.mirarehab.com/2016/02/23/case-study-on-a-14-years-old-girl-with-a-very-rare-condition-congenital-disorder-of-glycosylation/

Fligstein, N. (2001). Social Skill and the Theory of Fields. *Sociological Theory*, *19*(2), 105–125. https://doi.org/10.1111/0735-2751.00132

Fligstein, N. (2002). Markets as Politics: A Political-Cultural Approach to Market Institutions. In N. W. Biggart (Ed.), *Readings in Economic Sociology* (pp. 197–218). Blackwell Publishers Ltd.

Fligstein, N., & McAdam, D. (2011). Toward a General Theory of Strategic Action Fields*. *Sociological Theory*, *29*(1), 1–26. https://doi.org/10.1111/j.1467-9558.2010.01385.x

Fox, S. (2009). Health IT Policy: E-patients want access-. Retrieved Oct. 2016, from Susannah Fox website: http://susannahfox.com/2009/09/17/health-it-policy-e-patients-want-access/

Fox, S. (2011a). Peer-to-peer Health Care. Retrieved Apr. 2015, from Pew Research Center's Internet & American Life Project website: http://www.pewinternet.org/2011/02/28/peer-to-peer-health-care-2/

Fox, S. (2011b). Mind the Gap: Peer-to-peer Healthcare. Retrieved Oct. 2016, from Pew Research Center: Internet, Science & Tech website: http://www.pewinternet.org/2011/08/02/mind-the-gap-peer-to-peer-healthcare/

Fox, S. (2012a). What's the future for self-tracking? Retrieved Oct. 2016, from Pew Research Center: Internet, Science & Tech website: http://www.pewinternet.org/2012/09/28/whats-the-future-for-self-tracking/

Fox, S. (2012b). Thinking critically about Big Data and health care. Retrieved Oct. 2016, from Susannah Fox website: http://susannahfox.com/2012/12/30/thinking-critically-about-big-data-and-health-care/

Fox, S. (2017). Creating space for innovation. Retrieved July 2018, from Susannah Fox website: https://susannahfox.com/2017/10/08/creating-space-for-innovation/

Fox, S. (2012). The e is for engagement. Retrieved Apr. 2015, from Pew Research Center's Internet & American Life Project website: http://www.pewinternet.org/2012/10/29/the-e-is-for-engagement-2/

Fox, S., & Brenner, J. (2012). Family Caregivers Online. Retrieved July 2018, from Pew Research Center: Internet, Science & Tech website: http://www.pewinternet.org/2012/07/12/family-caregivers-online/

Frellick, M. (2015). Research Claims Are Skirting the Peer Review Process. Retrieved May 2015, from www.medscape.com website: http://www.medscape.com/viewarticle/840267

Friedland, R. (2013). God, Love, and Other Good Reasons for Practice: Thinking Through Institutional Logics. In Michael Lounsbury and Eva Boxenbaum (Eds), *Research in the Sociology of Organizations*: *Vol. 39*. *Institutional Logics in Action, Part A* (pp. 25–50).

Friedland, R., & Alford, R. R. (1991). Bringing Society Back In: Symbols, Practices, and Institutional Contradictions. In W. W. Powell & P. DiMaggio (Eds.), *The new institutionalism in organizational analysis* (pp. 232–263). Chicago, IL: University of Chicago Press.

Friedland, R., Mohr, J. W., Roose, H., & Gardinali, P. (2014). The institutional logics of love: measuring intimate life. *Theory and Society*, *43*(3–4), 333–370. https://doi.org/10.1007/s11186-014-9223-6

Gandhi, M., & Wang, T. (2015). Digital Health Consumer Adoption: 2015. Retrieved Oct. 2015, from Rock Health website: https://rockhealth.com/reports/digital-health-consumer-adoption-2015/

Garud, R., Jain, S., & Kumaraswamy, A. (2002). Institutional Entrepreneurship in the Sponsorship of Common Technological Standards: The Case of Sun Microsystems and Java. *Academy of Management Journal*, *45*(1), 196–214. https://doi.org/10.2307/3069292

Garud, R., Jain, S., & Tuertscher, P. (2008). Incomplete by Design and Designing for Incompleteness. *Organization Studies*, *29*(3), 351–371. https://doi.org/10.1177/0170840607088018

Gawer, A. (2011). What Managers Need to Know about Platforms. *The European Business Review*. Retrieved June 2015, from http://www.europeanbusinessreview.com/managers-platforms/

Gawer, A., & Phillips, N. (2013). Institutional Work as Logics Shift: The Case of Intel's Transformation to Platform Leader. *Organization Studies*, *34*(8), 1035–1071. https://doi.org/10.1177/0170840613492071

Geels, F. W. (2005). *Technological transitions and system innovations : a co-evolutionary and socio-technical analysis*. Cheltenham, UK : Edward Elgar Publishing

Gerber, Z. (2015). What Can Pharma Learn From J&J and Sanofi About Reaching Millennials? | PM360. Retrieved Oct. 2015, from http://www.pm360online.com/what-can-pharma-learn-from-jj-and-sanofi-about-reaching-millennials/

Getmyhealthdata. (2015). Electronic Health Info Petition [Noncommercial]. Retrieved May 2015, from http://getmyhealthdata.org/

Gioia, D. A., & Chittipeddi, K. (1991). Sensemaking and sensegiving in strategic change initiation. *Strategic Management Journal*, *12*(6), 433–448. https://doi.org/10.1002/smj.4250120604

Gioia, D. A., Corley, K. G., & Hamilton, A. L. (2012a). Seeking Qualitative Rigor in Inductive Research: Notes on the Gioia Methodology. *Organizational Research Methods*, 1094428112452151. https://doi.org/10.1177/1094428112452151

Gioia, D. A., Corley, K. G., & Hamilton, A. L. (2012b). Seeking Qualitative Rigor in Inductive Research Notes on the Gioia Methodology. *Organizational Research Methods*, *16*(1), 15–31. https://doi.org/10.1177/1094428112452151

Giordano, R., Clark, M., & Goodwin, N. (2011). Perspectives on telehealth and telecare. Retrieved April 2015, from The King's Fund website: http://www.kingsfund.org.uk/publications/articles/perspectives-telehealth-and-telecare

Glynn, M. A., & Lounsbury, M. (2005). From the Critics' Corner: Logic Blending, Discursive Change and Authenticity in a Cultural Production System*. *Journal of Management Studies*, *42*(5), 1031–1055. https://doi.org/10.1111/j.1467-6486.2005.00531.x

Goetz, T. (2008). Attention, California Health Dept.: My DNA Is My Data. Retrieved May 2015, from WIRED website: http://www.wired.com/2008/06/attention-calif/

Goldfarb, B., & Henrekson, M. (2003). Bottom-up versus top-down policies towards the commercialization of university intellectual property. *Research Policy*, *32*(4), 639–658. https://doi.org/10.1016/S0048-7333(02)00034-3

Goodrick, E., & Reay, T. (2011). Constellations of Institutional Logics Changes in the Professional Work of Pharmacists. *Work and Occupations*, *38*(3), 372–416. https://doi.org/10.1177/0730888411406824

Goodrick, E., & Salancik, G. R. (1996). Organizational discretion in responding to institutional practices: Hospitals and cesarean births. *Administrative Science Quarterly*, *41*, 1–28.

Gray, B., Purdy, J. M., & Ansari, S. (2015). From Interactions to Institutions: Microprocesses of Framing and Mechanisms for the Structuring of Institutional Fields. *Academy of Management Review*, *40*(1), 115–143. https://doi.org/10.5465/amr.2013.0299

Greenwood, R. C., Magan Diaz, A., Xiao Li, S., & Lorente, J. C. (2010). The Multiplicity of Institutional Logics and the Heterogeneity of Organizational Responses. *Organization Science*, *21*, 521–539.

Greenwood, R., Raynard, M., Kodeih, F., Micelotta, E. R., & Lounsbury, M. (2011). Institutional Complexity and Organizational Responses. *Academy of Management Annals*, *5*(1), 317–371. https://doi.org/10.1080/19416520.2011.590299

Gulati, R., & Higgins, M. C. (2003). Which ties matter when? the contingent effects of interorganizational partnerships on IPO success. *Strategic Management Journal*, *24*(2), 127–144. https://doi.org/10.1002/smj.287

Gurses, K., & Ozcan, P. (2014). Entrepreneurship in Regulated Markets: Framing Contests and Collective Action to Introduce Pay TV in the US. *Academy of Management Journal*, amj.2013.0775. https://doi.org/10.5465/amj.2013.0775

Harbert, T. (2009). Healthcare reform gives health-monitoring electronics a new diagnosis. Retrieved April 2015, from EDN website: http://www.edn.com/electronics-blogs/other/4313018/Healthcare-reform-gives-health-monitoring-electronics-a-new-diagnosis

Hargadon, A. B., & Douglas, Y. (2001). When Innovations Meet Institutions: Edison and the Design of the Electric Light. *Administrative Science Quarterly*, *46*(3), 476–501. https://doi.org/10.2307/3094872

Hargrave, T. J., & Van de Ven, A. H. (2009). Institutional work as the creative embrace of contradiction. In B. Leca, R. Suddaby, & T. B. Lawrence (Eds.), *Institutional Work: Actors and Agency in Institutional Studies of Organizations* (120–140). Cambridge, U.K.: Cambridge University Press

Harlow, C., & Rawlings, R. (2013). *Pressure Through Law*. London: Routledge.

Hartzler, A., & Pratt, W. (2011). Managing the Personal Side of Health: How Patient Expertise Differs from the Expertise of Clinicians. *J Med Internet Res*, *13*(3), e62. https://doi.org/10.2196/jmir.1728

Harvard i-lab. (2014). *Opportunities & Challenges: Digital Health and Health System Collaborations*. Retrieved Dec. 2014, from https://www.youtube.com/watch?v=mFP2ioCDdjs

Haveman, H. A., & Rao, H. (1997). Structuring a Theory of Moral Sentiments: Institutional and Organizational Coevolution in the Early Thrift Industry. *American Journal of Sociology*, (102), 1606–1651.

Healthstartup. (2014). The Ultimate Guide To The World's Digital Health Ecosystem » HealthStartup. Retrieved May 2014, from http://www.healthstartup.eu/the-ultimate-health-startup-resources-guide/

Herper, M. (2015). What 23andMe's FDA Approval Means For The Future Of Genomics. Retrieved May 2015, from Forbes website: http://www.forbes.com/sites/matthewherper/2015/02/20/what-23andmes-fda-approval-means-for-the-future-of-genomics/

Heubl, B., & Saafeld, N. (2014). Jump off the privacy train: your data will make us all healthier! Retrieved May 2015, from nuviun website: http://nuviun.com/content/jump-off-the-privacy-train-your-data-will-make-us-all-healthier

Hirsch, P. (2008). Been there, Done that, Moving On: Reflections on Institutional Theory's Continuing Evolution. In Royston Greenwood, Christine Oliver, Roy Suddaby & Kerstin Sahlin (Eds.), *The SAGE Handbook of Organizational Institutionalism* (783–789). London: SAGE Publications Ltd.

Hirsch, P., & Lungeanu, R. (2012). Between Endogenous Logics: Deinstitutionalization of Mortgage Lending as Carnival, Not Tsunami. *National Convention of the Academy of Management, Boston, MA*.

Hirsch, P. M., & Bermiss, Y. S. (2009). Institutional "dirty" work: preserving institutions through strategic decoupling. In B. Leca, R. Suddaby, & T. B. Lawrence (Eds.), *Actors and Agency in Institutional Studies of Organizations* (262–283). https://doi.org/10.1017/CBO9780511596605.010

Hirsch, P. M., & Wohlgezogen, F. (2009). Negotiating Actor-Environment Relations: A Framework for Comparative Research. in Brayden G King, Teppo Felin, David A. Whetten (Eds.), *Studying Differences between Organizations: Comparative Approaches to Organizational Research* (Research in the Sociology of Organizations, Volume 26) (153–182). Emerald Group Publishing Limited.

History Health 2.0. (n.d.). Retrieved July 2018, from Health 2.0 website: https://health2con.com/about-2/

Holliday, R. (2009). Thoughts on Medicine and Social Media. Retrieved Apr. 2015, from Regina Holliday's Medical Advocacy Blog website: http://reginaholliday.blogspot.co.uk/search?updated-min=2009-01-

01T00:00:00-08:00&updated-max=2010-01-01T00:00:00-08:00&max-results=39

Holliday, R. (2011). Regina Holliday's Medical Advocacy Blog: The Walking Gallery. Retrieved Apr. 2015, from http://reginaholliday.blogspot.co.uk/2011/04/walking-gallery.html

Holliday, R. (2015). *The Writing on the Wall*. CreateSpace Independent Publishing Platform.

Ilinitch, A. Y., D'Aveni, R. A., & Lewin, A. Y. (1996). New Organizational Forms and Strategies for Managing in Hypercompetitive Environments. *Organization Science*, *7*(3).

IMS Institute. (2015). *Patient Adoption of mHealth: Use, Evidence and Remaining Barriers to Mainstream Acceptance*. Retrieved Dec. 2015, from http://www.imshealth.com/portal/site/imshealth/menuitem.c76283e8bf81e98f53c753c71ad8c22a/?vgnextoid=0b96ccb4c3402410VgnVCM10000076192ca2RCRD

Ioannidis, J. A. (2015). Stealth research: Is biomedical innovation happening outside the peer-reviewed literature? *JAMA*, *313*(7), 663–664. https://doi.org/10.1001/jama.2014.17662

Istepanian, R., Laxminarayan, S., & Pattichis, C. S. (Eds.). (2006). *M-Health: Emerging Mobile Health Systems*. New York, U.S.A.: Springer-Verlag

Jacobides, M. G., Cennamo, C., & Gawer, A. (2018). Towards a theory of ecosystems. *Strategic Management Journal*, *39*(8), 2255-2276. https://doi.org/10.1002/smj.2904

Jain, S. H. (2015). How Pharma Can Offer More than Pills. Retrieved July, 2015, from Harvard Business Review website: https://hbr.org/2015/07/how-pharma-can-offer-more-than-pills

Jauhar, S. (2015). 'The Patient Will See You Now,' by Eric Topol. *The New York Times*. Retrieved Nov. 2015, from http://www.nytimes.com/2015/02/15/books/review/the-patient-will-see-you-now-by-eric-topol.html

Jay, J. (2013). Navigating Paradox as a Mechanism of Change and Innovation in Hybrid Organizations. *Academy of Management Journal*, *56*(1), 137–159. https://doi.org/10.5465/amj.2010.0772

Jennett, P. A., Affleck Hall, L., Hailey, D., Ohinmaa, A., Anderson, C., Thomas, R., … Scott, R. E. (2003). The socio-economic impact of telehealth: a systematic review. *Journal of Telemedicine and Telecare*, *9*(6), 311–320. https://doi.org/10.1258/135763303771005207

Jonah Comstock. (2015). Harvard doctors argue the digital phenotype will change healthcare | mobihealthnews. Retrieved May 2015, from http://mobihealthnews.com/43327/harvard-doctors-argue-the-digital-phenotype-will-change-healthcare/

Jones, C., Boxenbaum, E., & Anthony, C. (2013). The Immateriality of Material Practices in Institutional Logics. In M. Lounsbury & E.

Boxenbaum (Eds.), *Institutional Logics in Action, Part A*: *Vol. 39 Part A* (pp. 51–75). Emerald Group Publishing Limited.

Jorge Juan Garcia F. at Doctors 2.0 & You Paris. (2013). Retrieved June 2015, from https://www.youtube.com/watch?v=UKY3scPIMd8&feature=youtube_gdata_player

Katila, R., Rosenberger, J. D., & Eisenhardt, K. M. (2008). Swimming with Sharks: Technology Ventures, Defense Mechanisms and Corporate Relationships. *Administrative Science Quarterly*, *53*(2), 295–332. https://doi.org/10.2189/asqu.53.2.295

Keckley, P., Coughlin, S., & Eselius, L. (2012). Consumerism in Health Care. *Deloitte Review*, (11), 70–83.

King's Fund. (2013). An alternative guide to the new NHS in England. Retrieved May 2015, from The King's Fund website: http://www.kingsfund.org.uk/projects/nhs-65/alternative-guide-new-nhs-england

Klepper, S., & Graddy, E. (1990). The Evolution of New Industries and the Determinants of Market Structure. *The RAND Journal of Economics*, *21*(1), 27–44. https://doi.org/10.2307/2555491

Kocher, B., & Roberts, B. (2014). Why So Many New Tech Companies Are Getting into Health Care. Retrieved Dec. 2014, from Harvard Business Review website: https://hbr.org/2014/12/why-so-many-tech-companies-are-getting-into-health-care

Kraatz, M. S. (2009). Leadership as institutional work: a bridge to the other side. In B. Leca, R. Suddaby, & T. B. Lawrence (Eds.), *Institutional Work: Actors and Agency in Institutional Studies of Organizations* (59-91). Cambridge, U.K.: Cambridge University Press

Kraatz, M. S., & Block, E. S. (2008). Organizational Implications of Institutional Pluralism. In Royston Greenwood, Christine Oliver, Roy Suddaby & Kerstin Sahlin (Eds.), *The SAGE Handbook of Organizational Institutionalism* (243–275). London: SAGE Publications Ltd.

Kunze, E. (2015). Google Is Working On Magnetic Nanoparticles To Detect Cancer Cells. Retrieved May 2015, from WT VOX - Wearables And IoT website: https://wtvox.com/2015/02/google-is-working-on-magnetic-nanoparticles-to-detect-cancer-cells/

Lamont, M., & Molnár, V. (2002). The Study of Boundaries Across the Social Sciences. Annual Review of Sociology, 28(1), 167-195.

Lawrence, T. B., Suddaby, R., & Leca, B. (2009). Introduction: theorizing and studying institutional work. In B. Leca, R. Suddaby & T. B. Lawrence (Eds.), *Institutional Work: Actors and Agency in Institutional Studies of Organizations* (1-27). Cambridge University Press.

Lawrence, T., Suddaby, R., & Leca, B. (2011). Institutional Work: Refocusing Institutional Studies of Organization. *Journal of Management Inquiry*, *20*(1), 52–58. https://doi.org/10.1177/1056492610387222

Lebret, H. (2018). Are Biotechnology Startups Different? *ArXiv:1805.12108 [q-Fin]*. Retrieved Jan. 2019, from http://arxiv.org/abs/1805.12108

Leicht, K. T., & Fennell, M. L. (2008). Institutionalism and the Professions. In Royston Greenwood, Christine Oliver, Roy Suddaby & Kerstin Sahlin (Eds.), *The SAGE Handbook of Organizational Institutionalism* (431–448). London: SAGE Publications Ltd.

Lewis, M. (2015). UK moves ahead with Precision Medicine Catapult. Retrieved May 2015, from mobile digital health website: https://mobiledigitalhealth.wordpress.com/2015/02/23/uk-moves-ahead-with-precision-medicine-catapult/

Lichty, P. (2012). La Cura: An Open Source Cure. An interview with Salvatore Iaconesi | www.furtherfield.org. Retrieved Oct. 2016, from http://www.furtherfield.org/features/interviews/la-cura-open-source-cure-interview-salvatore-iaconesi

Lim, S. Y., & Anderson, E. G. (2016). Institutional Barriers Against Innovation Diffusion: From the Perspective of Digital Health Startups. *2016 49th Hawaii International Conference on System Sciences (HICSS)*, 3328–3337. https://doi.org/10.1109/HICSS.2016.415

Loria, K. (2015). Scientists are skeptical about the secret blood test that has made Elizabeth Holmes a billionaire. Retrieved Apr. 2015, from Business Insider website: http://uk.businessinsider.com/science-of-elizabeth-holmes-theranos-2015-4

Lott, T. F., Blazey, M. E., & West, M. G. (1992). Patient participation in health care: an underused resource. *The Nursing Clinics of North America*, *27*(1), 61–76.

Lupton, D. (2012). M-health and health promotion: The digital cyborg and surveillance society. *Social Theory & Health*, *10*(3), 229–244. https://doi.org/10.1057/sth.2012.6

Lupton, D. (2013). The digitally engaged patient: Self-monitoring and self-care in the digital health era. *Social Theory & Health*, *11*(3), 256–270. https://doi.org/10.1057/sth.2013.10

Lupton, D. (2014a). Apps as Artefacts: Towards a Critical Perspective on Mobile Health and Medical Apps. *Societies*, *4*(4), 606–622. https://doi.org/10.3390/soc4040606

Lupton, D. (2014b). Critical Perspectives on Digital Health Technologies. *Sociology Compass*, *8*(12), 1344–1359. https://doi.org/10.1111/soc4.12226

Lupton, D. (2014c). Health promotion in the digital era: a critical commentary. *Health Promotion International*, 30(1), 174-183. https://doi.org/10.1093/heapro/dau091

Lupton, D. (2014d). The commodification of patient opinion: the digital patient experience economy in the age of big data. *Sociology of Health & Illness*, *36*(6), 856–869. https://doi.org/10.1111/1467-9566.12109

Maclean, M., Harvey, C., & Chia, R. (2012). Sensemaking, storytelling and the legitimization of elite business careers. *Human Relations*, *65*(1), 17–40. https://doi.org/10.1177/0018726711425616

Macnaughtan, L. (2014). What Have the Regulators Ever Done for Us? [Commercial]. Retrieved Dec. 2014, from nuviun website: http://nuviun.com/content/blog/what-have-the-regulators-ever-done-for-us

Macnaughtan, L. (2015a). You, Me and Digital Health. Retrieved Jan. 2016, from nuviun.com website: http://nuviun.com/content/you-me-and-digital-health

Macnaughtan, L. (2015b). The Curious Case of Digital Health. Retrieved June 2015, from http://nuviun.com/content/the-curious-case-of-digital-health

Macnaughtan, L. (2015c). All Eyes on Digital Health. Retrieved June 2015, from http://nuviun.com/content/all-eyes-on-digital-health

Macnaughtan, L. (2016). Digital Health – Game on - MIRA Blog. Retrieved May 2016, from http://blog.mirarehab.com/2016/04/26/digital-health-game-on/

Macnaughtan, L., Patriotta, G., Pinnington, L., & Sujatha Raman. (2015). *Plurality of institutional logics in digital healthcare: The rise of the hybrid patient*. Presented at the 31st EGOS Colloquium, Athens, Greece. https://doi.org/10.13140/RG.2.1.2859.3127/1

Madrigal, A. (2008). 23andMe to California: We're Not Ceasing or Desisting. Retrieved May 2015, from WIRED website: http://www.wired.com/2008/06/23andme-were-no/

Mark Sullivan. (2015). 30 days later, I'm returning my Apple Watch (full review) | VentureBeat | Gadgets. Retrieved May 2015, from http://venturebeat.com/2015/05/15/30-days-later-im-returning-my-apple-watch-full-review/

Mazzucato, M. (2013). *The Entrepreneurial State: Debunking Public Vs. Private Sector Myths*. Anthem Press.

McCollister-Slipp, A. (2014). The Grim Reality of Digital Health Today. Retrieved Nov. 2014, from Huffington Post website: http://www.huffingtonpost.com/x-prize-foundation/the-grim-reality-of-digit_b_5984580.html

Medicines and Healthcare Products Regulatory Agency. (2014). Medical devices: software applications (apps) - Publications - GOV.UK. Retrieved May 2015, from https://www.gov.uk/government/publications/medical-devices-software-applications-apps

Merrill Thompson, B. (2015). In-Depth: Anticipating FDA Regulation of Pharmaceutical Apps. Retrieved March 2015, from mobihealthnews website: http://mobihealthnews.com/40917/in-depth-anticipating-fda-regulation-of-pharmaceutical-apps/

Meyer, J. W., & Rowan, B. (1977). Institutional organizations: formal structure as myth and ceremony. *American Journal of Sociology*, (83), 340–363.

Miles, M. B., & Huberman, M. A. (1994). *Qualitative data analysis: An expanded sourcebook (2nd ed.)*. Thousand Oaks, CA, US: Sage Publications, Inc.

Mitchell, B. (2016). Maker movement at center of HHS' innovative strategy. Retrieved Nov. 2016, from FedScoop website: http://fedscoop.com/hhs-cements-maker-movement-as-a-cornerstone-of-its-innovative-strategy

mobihealthnews. (2009). *WIRELESS HEALTH: STATE OF THE INDUSTRY 2009 Year End Report*. Retrieved Jan. 2016, from http://mobihealthnews.com/wp-content/Reports/2009StateoftheIndustry.pdf

mobihealthnews. (2012). 75 FDA Regulated Mobile Medical Apps | mobihealthnews. Retrieved May 2015, from http://mobihealthnews.com/research/75-fda-regulated-mobile-medical-apps/comment-page-1/

Montgomery, S. (2015). Digital Health's Growing Conundrum: The Ethics of Everything. Retrieved Nov. 2016, from http://innovatemedtec.com/content/digital-healths-growing-conundrum-the-ethics-of-everything

Morrill, C. (2006). *Institutional change through interstitial emergence: The growth of alternative dispute resolution in American law, 1965–1995*. Retrieved from http://webuser.bus.umich.edu/organizations/smo/protected/resources/morrill.pdf

Mulligan, C. (2011). *The Communications Industries in the Era of Convergence*. London: Routledge.

Munro, D. (2013,). The Big Disruption That Isn't Happening In Healthcare - Forbes. Retrieved May 2015, from Forbes website: http://www.forbes.com/sites/danmunro/2013/09/06/the-big-disruption-that-isnt-happening-in-healthcare/

Navis, C., & Glynn, M. A. (2011). Legitimate Distinctiveness and The Entrepreneurial Identity: Influence on Investor Judgments of New Venture Plausibility. *Academy of Management Review*, *36*(3), 479–499.

Nettleton, S. (2004). The Emergence of E-Scaped Medicine? *Sociology*, *38*(4), 661–679. https://doi.org/10.1177/0038038504045857

Ng, I. C. L., & Smith, L. A. (2012). An Integrative Framework of Value. In *Review of Marketing Research*: *Vol. 9*. *Special Issue ? Toward a Better Understanding of the Role of Value in Markets and Marketing* (Vol. 9, pp. 207–243). https://doi.org/10.1108/S1548-6435(2012)0000009011

Nicolini, D. (2006). The work to make telemedicine work: A social and articulative view. *Social Science & Medicine*, *62*(11), 2754–2767. https://doi.org/10.1016/j.socscimed.2005.11.001

Nicolini, D. (2007). Stretching out and expanding work practices in time and space: The case of telemedicine. *Human Relations*, *60*(6), 889–920. https://doi.org/10.1177/0018726707080080

Nicolini, D. (2009). Medical Innovation as a Process of Translation: a Case from the Field of Telemedicine. *British Journal of Management*, *21*(4), 1011–1026. https://doi.org/10.1111/j.1467-8551.2008.00627.x

Nigam, A., & Ocasio, W. (2009). Event Attention, Environmental Sensemaking, and Change in Institutional Logics: An Inductive Analysis of the Effects of Public Attention to Clinton's Health Care Reform Initiative. *Organization Science*, *21*(4), 823–841. https://doi.org/10.1287/orsc.1090.0490

Nosta, J. (2013). The Asymptotic Shift From Disease To Prevention--Thoughts For Digital Health. Retrieved Oct. 2015, from Forbes website: http://www.forbes.com/sites/johnnosta/2013/12/12/the-asymptotic-shift-from-disease-to-prevention-thoughts-for-digital-health/

Oborn, E., Barrett, M., & Racko, G. (2013). Knowledge translation in healthcare: Incorporating theories of learning and knowledge from the management literature. *Journal of Health Organization and Management*, *27*(4), 412–431. https://doi.org/10.1108/JHOM-01-2012-0004

Office of Arizona Governor. (2015). Governor Doug Ducey Signs Legislation Reducing Barriers to Efficient, Cost-Effective Health Care. Retrieved May 2015, from http://azgovernor.gov/governor/news/governor-doug-ducey-signs-legislation-reducing-barriers-efficient-cost-effective

Office of the Press Secretary. (2015). FACT SHEET: President Obama's Precision Medicine Initiative [Gov]. Retrieved May 2015, from The White House website: https://www.whitehouse.gov/node/319876

Orlikowski, W. J. (2010). Technology and organization: Contingency all the way down. In N. Phillips, G. Sewell, & D. Griffiths (Eds.), *Technology and Organization: Essays in Honour of Joan Woodward* (239–246). Emerald Group Publishing Limited

Ozcan, P., & Eisenhardt, K. M. (2009). Origin of Alliance Portfolios: Entrepreneurs, Network Strategies, and Firm Performance. *The Academy of Management Journal*, *52*(2), 246–279.

Pache, A.-C., & Santos, F. (2010). When Worlds Collide: The Internal Dynamics of Organizational Responses to Conflicting Institutional Demands. *Academy of Management Review*, *35*(3), 455–476. https://doi.org/10.5465/AMR.2010.51142368

Patriotta, G., Gond, J.-P., & Schultz, F. (2011). Maintaining Legitimacy: Controversies, Orders of Worth, and Public Justifications. *Journal of Management Studies*, *48*(8), 1804–1836. https://doi.org/10.1111/j.1467-6486.2010.00990.x

Pearce, W., & Raman, S. (2014). The new randomised controlled trials (RCT) movement in public policy: challenges of epistemic governance. *Policy Sciences*, *47*(4), 387–402. https://doi.org/10.1007/s11077-014-9208-3

Pennic, J. (2015). 46% of Clinicians Believe mHealth Apps Will Improve Patient Engagement. Retrieved April 7, 2015, from

http://hitconsultant.net/2015/03/19/clinicians-mhealth-apps-patient-engagement/

Petrakaki, D., Barber, N., & Waring, J. (2012). The possibilities of technology in shaping healthcare professionals: (Re/De-)Professionalisation of pharmacists in England. *Social Science & Medicine*, *75*(2), 429–437. https://doi.org/10.1016/j.socscimed.2012.03.033

Pfeffer, J., & Salanick, G. R. (2003). *The External Control of Organizations: A Resource Dependence Perspective*. Retrieved from http://www.sup.org/books/title/?id=5889

Phillips, R., Henderson, J., Andor, L., & Hulme, D. (2006). Usurping Social Policy: Neoliberalism and Economic Governance in Hungary*. *Journal of Social Policy*, *35*(4), 585–606. https://doi.org/10.1017/S0047279406000092

Pouthier, V., Steele, C. W. J., & Ocasio, W. (2013). From Agents to Principles: The Changing Relationship between Hospitalist Identity and Logics of Health care. In M. Lounsbury & E. Boxenbaum (Eds.), *Institutional Logics in Action: Part A* (203–241). Emerald Group Publishing Limited

Prout, A. (1996). Actor-network theory, technology and medical sociology: an illustrative analysis of the metered dose inhaler. *Sociology of Health & Illness*, *18*(2), 198–219. https://doi.org/10.1111/1467-9566.ep10934726

Purdy, J. M., & Gray, B. (2009). Conflicting Logics, Mechanisms of Diffusion, and Multilevel Dynamics in Emerging Institutional Fields. *Academy of Management Journal*, *52*(2), 355–380. https://doi.org/10.5465/AMJ.2009.37308255

PwC. (2012). *Emerging mHealth: Paths for growth*. Retrieved Jan. 2014, from http://www.pwc.com/gx/en/healthcare/mhealth/assets/pwc-emerging-mhealth-full.pdf

PwC. (2013). *How supportive is the regulatory framework for mobile health applications?* (1–4). Retrieved Jan. 2014, from http://www.pwc.ch/user_content/editor/files/publ_health/pwc_mhealth_insights_january13_e.pdf

PwC. (2015). *Global health's new entrants: Meeting the world's consumer*. Retrieved Jan. 2016, from http://www.pwc.com/us/en/health-industries/healthcare-new-entrants/assets/pwc-global-new-entrant.pdf

Raman, S., & Mohr, A. (2014). A Social Licence for Science: Capturing the Public or Co-Constructing Research? *Social Epistemology*, *28*(3–4), 258–276. https://doi.org/10.1080/02691728.2014.922642

Rao, H., Morrill, C., & Zald, M. N. (2000). Power Plays: How Social Movements and Collective Action Create New Organizational Forms. *Research in Organizational Behavior*, *22*, 237–281. https://doi.org/10.1016/S0191-3085(00)22007-8

Reay, T., & Hinings, C. R. (2009). Managing the Rivalry of Competing Institutional Logics. *Organization Studies*, *30*(6), 629–652. https://doi.org/10.1177/0170840609104803

Reay, T., & Hinings, C. R. (Bob). (2005). The Recomposition of an Organizational Field: Health Care in Alberta. *Organization Studies*, *26*(3), 351–384. https://doi.org/10.1177/0170840605050872

research2guidance. (2012). 3rd mHealth Expert Survey. Retrieved Jan 2013 from research2guidance website: https://research2guidance.com/r2g/3rd-mHealth-Expert-Survey.pdf

research2guidance. (2014). *Mhealth app developer economics*. Retrieved Jan. 2015, from research2guidance website: http://mhealtheconomics.com/mhealth-developer-economics-report/

research2guidance. (2014). *mHealth App Developer Economics 2014 Study*. Retrieved Jan. 2015, from http://www.slideshare.net/research2guidance/research2guidance-mhealth-app-developer-economics-2014-study-slideshareresearch2guidance-m-health-app-developer-economics-slideshare

Riggare, S. (2016). FOR WHOSE SAKE IS RESEARCH DONE — REALLY? Retrieved Oct. 2016, from LinkedIn Pulse website: https://www.linkedin.com/pulse/whose-sake-research-done-really-sara-riggare

Rindova, V. P., & Kotha, S. (2001). Continuous "Morphing": Competing Through Dynamic Capabilities, Form, and Function. *Academy of Management Journal*, *44*(6), 1263–1280. https://doi.org/10.2307/3069400

Rip, A., & Schot, J. W. (2002). Identifying Loci for Influencing the Dynamics of Technological Development. In K. H. Soerensen & R. Williams (Eds.), *Shaping Technology. Guiding Policy; concepts Spaces and Tools* (158–176).

Ritvala, T., & Kleymann, B. (2012). Scientists as Midwives to Cluster Emergence: An Institutional Work Framework. *Industry and Innovation*, *19*(6), 477–497. https://doi.org/10.1080/13662716.2012.718875

Robinson, J. C. (2001). The end of managed care. *JAMA*, *285*(20), 2622–2628.

Rockhealth. (2012a). *2012 Digital Health Funding*. Retrieved Jan. 2013, from http://www.slideshare.net/RockHealth/2012-year-end-funding-report

Rockhealth. (2012b). *Rock Report: Business Models in Digital Health*. Retrieved Jan. 2013, from http://www.slideshare.net/RockHealth/rock-report-business-models-in-digital-health-by-rockhealth

Rudel, D., Fisk, M., & Roze, R. (2011). Definitions of Terms in Telehealth. *Journal of the Slovenian Medical Informatics Association*, *16*(1), 28–46.

RWJF. (2015). Data for Health: Learning What Works. Retrieved April 2015, from RWJF website: http://www.rwjf.org/en/library/research/2015/04/data-for-health-initiative.html

Salber, P. (2015). What is Patient Engagement? Depends on Who You Are -. Retrieved June 2015, from The Doctor Weighs In website: http://thedoctorweighsin.com/patient-engagement-depends-on-who-you-are/

Santos, F. M., & Eisenhardt, K. M. (2005). Organizational Boundaries and Theories of Organization. *Organization Science*, *16*(5), 491–508. https://doi.org/10.1287/orsc.1050.0152

Santos, F. M., & Eisenhardt, K. M. (2009). Constructing Markets and Shaping Boundaries: Entrepreneurial Power in Nascent Fields. *Academy of Management Journal*, *52*(4), 643–671. https://doi.org/10.5465/AMJ.2009.43669892

Schreinemacher, M. H., Graafland, M., & Schijven, M. P. (2014). Google Glass in Surgery. *Surgical Innovation*, *21*(6), 651–652. https://doi.org/10.1177/1553350614546006

Schumpeter, J. A. (1950). Chapter VII: The Process of creative destruction. In *Capitalism, Socialism and Democracy* (3rd ed.). Retrieved from http://www.compilerpress.ca/Competitiveness/Anno/Anno%20Schumpeter%20CSD%20Ch.%20VII%20Creative%20Destruction.htm

Scott, W. R. (2008). *Institutions and Organizations: Ideas and Interests* (3rd ed.). Los Angeles: Sage Publications.

Scott, W. R., Ruef, M., Mendel, P. J., & Caronna, C. A. (2000). *Institutional Change and Healthcare Organizations: From professional dominance to managed care*. University of Chicago Press.

Sculley, J. (2014). *Moonshot!: Game-Changing Strategies to Build Billion-Dollar Businesses*. New York: Rosettabooks.

Selznick, P. (1948). Foundations of the Theory of Organization. *American Sociological Review*, *13*(1), 25–35. https://doi.org/10.2307/2086752

Selznick, P. (1951). Institutional Vulnerability in Mass Society. *American Journal of Sociology*, *56*(4), 320–331.

Selznick, P. (1984). *Leadership in Administration: A Sociological Interpretation*. University of California Press.

Seres, M. (2013a). *(18) e-Participation and the NHS: Michael Seres*. Retrieved June 2015, from https://www.youtube.com/watch?v=WQGmQccP7Ss

Seres, M. (2013b). PART 2 – Are Patients From Mars and Health Care Professionals from Venus? Retrieved May 2015, from http://beingapatient.blogspot.co.uk/2013/05/part-2-are-patients-from-mars-and.html

Seres, M. (2013c). Are Patients From Mars and Health Care Professionals from Venus? - Part 1. Retrieved May 2015, from Being a Patient isn't easy! website: http://beingapatient.blogspot.co.uk/2013/05/are-patients-from-mars-and-health-care.html

Seres, M. (2015a). *Healthcare Innovation spotlight: Michael Seres*. Retrieved Jan 2016, from https://www.youtube.com/watch?v=M9hMybMZ8S4

Seres, M. (2015b). What can you learn from a patient entrepreneur? Retrieved Nov. 2016, from MedCity News website: http://medcitynews.com/2015/10/patient-entrepreneur/

Shaywitz, D. (2016). As Ambry CEO Demonstrates, Patients Drive Data Sharing - Forbes. Retrieved March 2016, from Forbes website: http://www.forbes.com/sites/davidshaywitz/2016/03/08/as-ambry-ceo-demonstrates-patients-drive-data-sharing/#2d30a0ea2323

Sonnier, P. (2015a). Digital Health Startup Resources. Retrieved May 2015, from Story of Digital Health website: http://storyofdigitalhealth.com/startups/

Sonnier, P. (2015b). Events. Retrieved May 2015, from Story of Digital Health website: http://storyofdigitalhealth.com/events/

Spong, A. (2015). Patients Included: a global patients' charter. Retrieved March 2015, from STweM website: http://stwem.com/2015/03/06/patients-included-a-global-patients-charter-for-conferences/

Stake, R. E. (2005). Qualitative case studies. In N. K. Denzin & Y. S. Lincoln (Eds.), *The Sage handbook of qualitative research* (3rd ed.). Thousand Oaks, CA: SAGE Publications.

Stanford Medicine X. (2015). About Medicine X | Ed – Stanford Medicine X. Retrieved Nov. 2016, from http://medicinex.stanford.edu/about-medicine-x-ed/

Stinchcombe, A. L. (1965). *Social Structure and Organizations* (J. G. March, Ed.). In (pp. 142–193). Chicago: Rand McNally & Co.

Suchman, M. C. (1995). Managing Legitimacy: Strategic and Institutional Approaches. *The Academy of Management Review*, *20*(3), 571–610. https://doi.org/10.2307/258788

Sullivan, M. (2014). 58 tech companies ask Congress to codify health IT laws so innovators know what the rules are. Retrieved May 2015, from VentureBeat website: http://venturebeat.com/2014/10/07/58-tech-companies-ask-congress-to-codify-health-it-laws-so-innovators-know-what-the-rules-are/

Swan, M. (2009). Emerging Patient-Driven Health Care Models: An Examination of Health Social Networks, Consumer Personalized Medicine and Quantified Self-Tracking. *International Journal of Environmental Research and Public Health*, *6*(2), 492–525. https://doi.org/10.3390/ijerph6020492

Swann, J., P. (2003). *The Food and Drug Administration (FDA)*. New York: Nova Science Publishers.

Swirsky, E. S., Hoop, J. G., & Labott, S. (2014). Using Social Media in Research: New Ethics for a New Meme? *The American Journal of Bioethics : AJOB*, *14*(10), 60–61. https://doi.org/10.1080/15265161.2014.948302

Swyngedouw, E. (2005). Governance Innovation and the Citizen: The Janus Face of Governance-beyond-the-State. *Urban Studies*, *42*(11), 1991–2006. https://doi.org/10.1080/00420980500279869

TEDx Talks. (2011). *Fighting for the Right to Open his Heart Data: Hugo Campos at TEDxCambridge 2011*. Retrieved June 2013, from https://www.youtube.com/watch?v=oro19-l5M8k

The BMJ. (n.d.). Patient and public partnership | The BMJ. Retrieved July 2018, from https://www.bmj.com/campaign/patient-partnership

Thornton, P. H. (2002). The Rise of the Corporation in a Craft Industry: Conflict and Conformity in Institutional Logics. *The Academy of Management Journal*, *45*(1), 81–101. https://doi.org/10.2307/3069286

Thornton, P. H., & Ocasio, W. (1999). Institutional Logics and the Historical Contingency of Power in Organizations: Executive Succession in the Higher Education Publishing Industry, 1958-1990. *American Journal of Sociology*, *105*(3), 801–843. https://doi.org/10.1086/210361

Thornton, P. H., Ocasio, W., & Lounsbury, M. (2012). *The Institutional Logics Perspective: A New Approach to Culture, Structure, and Process*. Oxford University Press.

Topol, E. (2012). *Creative Destruction of Medicine* (First Trade Paper Edition, Revised and Expanded edition). New York: Basic Books.

Topol, E. J. (2015). The Future of Medicine Is in Your Smartphone. *Wall Street Journal*. Retrieved Jan. 2016 from http://www.wsj.com/articles/the-future-of-medicine-is-in-your-smartphone-1420828632

UK Department of Health. (2006). *Supporting people with long term conditions to self care – A guide to developing local strategies and good practice*. Retrieved Jan. 2013, from http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4130868.pdf

Ungerleider, N. (2014). Oscar Is A Health Insurance Startup For Digital Natives. Retrieved Nov. 2016, from Fast Company website: https://www.fastcompany.com/3026928/tech-forecast/oscar-is-a-health-insurance-startup-for-digital-natives

University of California, S. D. (2014). *Personal Data for the Public Good. New Opportunities to Enrich Understanding of Individual and Population Health* [Market]. Retrieved Jan. 2015 from Robert Wood Johnson Foundation website: http://www.rwjf.org/en/research-publications/find-rwjf-research/2014/03/personal-data-for-the-public-good.html

UNSW Engineers. (2015). 'Google Maps' for the body. Retrieved May 2015, from Engineering website: http://engineering.unsw.edu.au/emag/news/%E2%80%98google-maps%E2%80%99-body

Validic. (2015). Digital health revitalizes pharma, life sciences and biotech. Retrieved Oct. 2015, from MedCity News website: http://medcitynews.com/?sponsored_content=digital-health-revitalizes-pharma-life-sciences-and-biotech

Van de Ven, A. H., & Gardu, R. (1993). Innovation and Industry Development: The Case of cochlear Implants. *Research on Technological Innovation, Management and Policy*, 5, 1-46.

Wachter, R. (2015). *The Digital Doctor: Hope, Hype, and Harm at the Dawn of Medicine's Computer Age* (1 edition). New York: McGraw-Hill Education.

Wachter, R. M., & Goldman, L. (1996). The Emerging Role of "Hospitalists" in the American Health Care System. *New England Journal of Medicine*, *335*(7), 514–517. https://doi.org/10.1056/NEJM199608153350713

Waldorff, S. B., Reay, T., & Goodrick, E. (2013). A Tale of Two Countries: How Different Constellations of Logics Impact Action. In M. Lounsbury & E. Boxenbaum (Eds.), *Institutional Logics in Action, Part A*: *Vol. A* (pp. 99–129). Emerald Group Publishing Limited.

Walley, K. (2007). Coopetition: An Introduction to the Subject and an Agenda for Research. *International Studies of Management & Organization*, *37*(2), 11–31.

Wang, T., King, E., Perman, M., & Tecco, H. (2016). Digital Health Funding: 2015 Year in Review. Retrieved Nov. 2016, from Rock Health website: https://rockhealth.com/reports/digital-health-funding-2015-year-in-review/

Waring, J. (2015). No shit Sherlock science – why it's still worth it. Retrieved April 2015, from The Conversation website: http://theconversation.com/no-shit-sherlock-science-why-its-still-worth-it-40179

Waters, G. (2015). Yes, biomedical innovation is sticking out its proverbial tongue! Retrieved May 2015, from LinkedIn Pulse website: https://www.linkedin.com/pulse/yes-biomedical-innovation-sticking-out-its-proverbial-waters-ph-d-

Weaver, G. R., TreviÑo, L. K., & Cochran, P. L. (1999). Integrated and Decoupled Corporate Social Performance: Management Commitments, External Pressures, and Corporate Ethics Practices. *Academy of Management Journal*, *42*(5), 539–552. https://doi.org/10.5465/256975

Webb, T. L., Joseph, J., Yardley, L., & Michie, S. (2010). Using the internet to promote health behavior change: a systematic review and meta-analysis of the impact of theoretical basis, use of behavior change techniques, and mode of delivery on efficacy. *Journal of Medical Internet Research*, *12*(1), e4. https://doi.org/10.2196/jmir.1376

Weick, K. E. (1988). Enacted sensemaking in crisis situations. *Journal of Management Studies*, *25*, 305–317.

Weick, K. E., Sutcliffe, K. M., & Obstfeld, D. (2005). Organizing and the Process of Sensemaking. *Organization Science*, *16*(4), 409–421. https://doi.org/10.1287/orsc.1050.0133

Wicks, P., Vaughan, T. E., Massagli, M. P., & Heywood, J. (2011). Accelerated clinical discovery using self-reported patient data collected online and a patient-matching algorithm. *Nature Biotechnology*, *29*(5), 411–414. https://doi.org/10.1038/nbt.1837

Wikipedia. (2015). List of highest funded crowdfunding projects. In *Wikipedia, the free encyclopedia*. Retrieved Dec. 2015, from http://en.wikipedia.org/w/index.php?title=List_of_highest_funded_crowdfunding_projects&oldid=661737690

Windrum, P., & García-Goñi, M. (2008). A neo-Schumpeterian model of health services innovation. *Research Policy*, *37*(4), 649–672. https://doi.org/10.1016/j.respol.2007.12.011

Windrum, P., García-Goñi, M., & Coad, H. (2016). The Impact of Patient-Centered versus Didactic Education Programs in Chronic Patients by Severity: The Case of Type 2 Diabetes Mellitus. *Value in Health: The Journal of the International Society for Pharmacoeconomics and Outcomes Research*, *19*(4), 353–362. https://doi.org/10.1016/j.jval.2016.01.014

Wooten, M., & Hoffman, A. J. (2008). Organizational Fields: Past, Present and Future. In R Greenwood, C. Oliver, R. Suddaby, & K. Sahlin (Eds.), *The Handbook of Organizational Institutionalism*. (129–149). Retrieved from http://dx.doi.org/10.4135/9781849200387

Wry, T., Lounsbury, M., & Jennings, P. D. (2014). Hybrid Vigor: Securing Venture Capital by Spanning Categories in Nanotechnology. *Academy of Management Journal*, *57*(5), 1309–1333. https://doi.org/10.5465/amj.2011.0588

Wry, Tyler, & Lounsbury, M. (2013). Contextualizing the categorical imperative: Category linkages, technology focus, and resource acquisition in nanotechnology entrepreneurship. *Journal of Business Venturing*, *28*(1), 117–133. https://doi.org/10.1016/j.jbusvent.2012.03.001

Xavier, P. (2015). L'avenir de la pharmacie ne dépend que d'elle-même. Retrieved June 2015, from La Tribune website: http://www.latribune.fr/opinions/tribunes/l-avenir-de-la-pharmacie-ne-depend-que-d-elle-meme-486261.html

Yin, R. K. (2009). *Case Study Research: Design and Methods* (4th ed.). In *Applied Social Research Methods*: *Vol. 5* (4th ed.). London: Sage Publications.

Zietsma, C., & McKnight, B. (2009). Building the Iron cage: Institutional creation work in the context of competing proto-institutions. In B. Leca, R. Suddaby, & T. B. Lawrence (Eds.), Institutional Work: Actors and Agency in Institutional Studies of Organizations (143-177). Cambridge: Cambridge University Press.

Zietsma, C. & Lawrence, T. B. (2010). Institutional Work in the Transformation of an Organizational Field: The Interplay of Boundary Work and Practice Work. *Administrative Science Quarterly*, *55*(2), 189–221. https://doi.org/10.2189/asqu.2010.55.2.189

Zilber, T. B. (2009). Institutional maintenance as narrative acts. In B. Leca, R. Suddaby & T. B. Lawrence (Eds.), *Institutional Work: Actors and Agency in Institutional Studies of Organizations* (pp. 205–235). Cambridge, U.K.: Cambridge University Press

Zussa, F. (2012). Digital Health Summit - OnDigitalHealth.com: In Healthcare, Consumer Tech doesn't mean a consumer business model. Retrieved May 2015, from Digital Health Summit website: http://digitalhealthsummit.com/news/in-healthcare-consumer-tech-doesn%E2%80%99t-mean-a-consumer-business-model/

APPENDIX A. OPINION LEADERS

The list below contains opinion leaders who were interviewed for this research. Note that others marked as opinion leaders were not interviewed, but recognised for their influence in the field.

Michael Seres has been identified as opinion leader, but his interviews were taken together with the ones on 11 Health. Similarly, John Nosta was a respondent for 11 Health, as he was part of the advisory board of the company. Interviews inside organisations also contained questions about the field, as explained in chapter 4, and shown in appendix B.

- **Michael Seres**, patient entrepreneur, 11 Health founder & CEO, UK
- **Denise Silber**, Doctors 2.0 & You founder, France
- **Sara Riggare**, patient researcher, PhD student in Selfcare for Parkinson's Disease at Health Informatics Centre, Karolinska Institute, Stockholm, Sweden
- **Lucien Engelen**, healthcare intrapreneur, founder of REshape Centre, Radboud University, The Netherlands
- **Colleen Young**, communications, Online Community Director, Mayo Clinic, US
- **John Nosta**, digital health evangelist, founder of NostaLab, Forbes contributor, amonst others, US
- **David Shaywitz**, doctor entrepreneur, DNAnexus Chief Medical Officer, Forbes contributor, US
- **Lisa Suennen**, investor, Managing Partner at Venture Valkyrie, US
- **Dave Chase**, entrepreneur, Health Rosetta Managing Partner, Forbes contributor, US
- **Sue Montgomery**, nurse, freelance healthcare writer and editor, US

APPENDIX B. SAMPLE INTERVIEW QUESTIONS

It is important to say that the interviews were semi-structured, therefore the questions were guiding and the conversations evolved more naturally.

Opinion leaders guiding questions

- When did you realise the potential of digital for healthcare?
- Why and how did you get involved with digital health?
- What is digital health, in your opinion?
- Is there anything that makes digital health be a separate arena from healthcare?
- Who are the stakeholders of digital health?
- How has the digital health evolved over time, in your opinion?
- What are opportunities/challenges?
- How do you think digital health will evolve or what changes will happen?
- What do you think is missing from the conversations surrounding digital health?

Organisation respondents guiding questions and the relevance of answers towards the organisation and the field, in recognising that institutional work develops both internally and externally.

Question	Level
What can you tell me about the competitive environment?	Both
How did it change over time and why?	Both
What would you say are the main risks and the main opportunities for your company?	Both
What do you find most challenging in this business/field? How do you address this?	Both
What do you think would change in this field?	Macro
What sources of information do you use? i.e. Journals, associations, follow other companies...	Both
What about partnerships?	Both
Or industry associations..?	Both
What is digital health?	Macro
Please tell me what you have you done before joining (founding) this company?	Meso
Please tell me about your company, since the beginning (or since you have joined the company)?	Meso
How has your company changed over time and what do you think has caused that change?	Meso
How have your product(s) changed over time?	Meso
Who do you think are the stakeholders of your products? Have they changed over time?	Meso
Who are your customers? Have your customers changed over time?	Meso
What would you say are the main risks and the main opportunities for your company?	Meso

Table 15. Guiding questions for interviews inside organisations

APPENDIX C. TERMINOLOGY CLARIFICATIONS

There are a number of terms for designating the use of technology in healthcare. The most common ones are telehealth, telecare, telemedicine, eHealth and remote patient monitoring. In the last decade though, more terms emerged: digital health, mHealth, personalized health systems, personalised medicine.

The table below presents a selection of terms existing and competing in digital health

Term	Definition	Source	Year
Telehealth	[...] the means by which technologies and related services at a distance are accessed by or provided for people and/or their carers at home or in the wider community, in order to facilitate their empowerment, assessment or the provision of care and/or support in relation to needs associated with their health (including clinical health) and wellbeing. Telehealth always involves and includes the service user or client. It includes remote patient management.	Telescope Rudel et al.	2011
	The term telehealth covers systems and services linking patients with care providers to assist in diagnosing, monitoring, management and empowerment of patients with long-term conditions (chronic patients). Telehealth solutions use devices (interactive audio, visual and data communication) to remotely collect and send data to a monitoring station for interpretation, to support therapy management programs and to improve patients' knowledge and behaviour.	COCIR Telemedicine Toolkit	2011
	Telehealth has been defined by the Department of Health as a service that 'uses equipment to monitor people's health in their own home… [monitoring] vital signs such as blood pressure, blood oxygen levels or weight'.	WSDAN	2011
	[...] as in remote vital signs monitoring. Vital signs of patients with long term conditions are measured daily by devices at home and the data sent to a monitoring centre for response by a nurse or doctor if they fall outside predetermined norms.	Telecare Aware	2012
Telecare	[…] from simple personal alarms (AKA pendant/panic/medical/social alarms, PERS, and so on) through to smart homes that focus on alerts for risk including, for example: falls; smoke; changes in daily activity patterns and 'wandering'. Telecare may also be used to confirm that someone is safe and to prompt them to take medication. The alert generates an appropriate response to the situation allowing someone to live more independently, and confidently, in their own home for longer.	Telecare Aware	2012
	The means by which technologies and related services at a distance are accessed by or provided for people and/or their carers at home or in the wider community, in order to facilitate empowerment or the provision of care and/or support in relation to needs associated with their health and well-being.	Telescope Rudel et al.	2011

Term	Definition	Source	Year
Telehealthcare	Telehealthcare is the convergence of telecare and telehealth to provide a technology-enabled and integrated approach to the delivery of effective, high quality health and care services. It can be used to describe a range of care options available remotely by telephone, mobile, broadband and videoconferencing	The Scottish Centre for Telehealth and Telecare	2012
Telemedicine	Telemedicine can be defined as the delivery of healthcare services through the use of Information and Communication Technologies (ICT) in a situation where the actors are not at the same location. The actors can either be two healthcare professionals (e.g. teleradiology, telesurgery) or a healthcare professional and a patient (e.g. telemonitoring of the chronically ill such as those with diabetes and heart conditions, telepsychiatry etc). Telemedicine includes all areas where medical or social data is being sent/exchanged between at least two remote locations, including both Caregiver-Patient/Citizen as well as Doctor to Doctor communication.	COCIR Telemedicine	2011
	The delivery of medical care at a distance by clinicians and other health care staff, via telecommunications technologies. Telemedicine will sometimes involve and include the service user / patient.	Telescope Rudel et al.	2012
	Telemedicine is the use of telecommunication and information technologies in order to provide clinical health care at a distance.	Wikipedia	2012
Remote Patient Monitoring/ Telemonitoring	Telemonitoring is the remote exchange of physiological data between a patient at home and medical staff at a hospital to assist in diagnosis and monitoring.	COCIR eHealth	2012
	Remote patient monitoring (RPM) is a technology to enable monitoring of patients outside of conventional clinical settings (e.g. in the home), which may increase access to care and decrease healthcare delivery costs.	Wikipedia	2012
Personal Health Systems	Personal Health Systems (PHS) assist in the provision of continuous, quality controlled, and personalised health services, including diagnosis, treatment, rehabilitation, disease prevention and lifestyle management, to empowered individuals regardless of location. PHS consist of: intelligent ambient and/or body devices (wearable, portable or implantable); intelligent processing of the acquired information; and active feedback from health professionals or directly from the devices to the individuals.	COCIR Telemedicine Toolkit	2011
Well-being	Quality of life characterised by satisfactory levels of health and welfare.	Telescope Rudel et al.	2011
	Well-being refers to positive and sustainable characteristics which enable individuals [and organisations] to thrive and flourish.	The Well-being Institute	N/A
Personalised Medicine	Personalized medicine is a medical model that proposes the customization of healthcare, with decisions and practices being tailored to the individual patient by use of genetic or other information.	Wikipedia	2012
	Personalized medicine is a young but rapidly advancing field of healthcare that is informed by each person's unique clinical, genetic, genomic, and environmental information. Because these factors are different for every person, the nature of diseases—including their onset, their course, and how they might respond to drugs or other interventions—is as individual as the people who have them.	U.S. net	2011

Table 16. Terminology

The Telecare Aware organisation considers that the separation between the 'telehealth' and 'telecare' is blurred and that eventually these terms will converge. "Although it is easy to predict that telecare and telehealth technologies will merge, and although the clients and patients they benefit are often one and the same individuals, we believe that it is still useful — at this stage of technological and linguistic evolution — to maintain a difference between the terms 'telecare' and 'telehealth'" (Hards, 2012).

'eHealth' and 'digital health' seem to be rather overarching terms that designate the use of IT and communication technologies in healthcare (COCIR (a), 2011). COCIR includes in the definition back end and front-end applications. For instance, image processing and storage application, data exchange protocols, interfaces between doctors - doctors, patients – doctors, patients – nurses etc. "[...] `e-health can be considered to be the health industry's equivalent of e-commerce`, and this could be one key for understanding the sense of e-health: just medical informatics and telematics on the shop shelves, a fashionable name for something already existing but otherwise difficult to sell" (Della Mea, 2001). Similarly, 'wireless healthcare' designates the use of wireless technologies and 'mHealth' refers to the use of the mobile technologies in healthcare.

The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) finds the following functions of eHealth (COCIR (a), 2011).

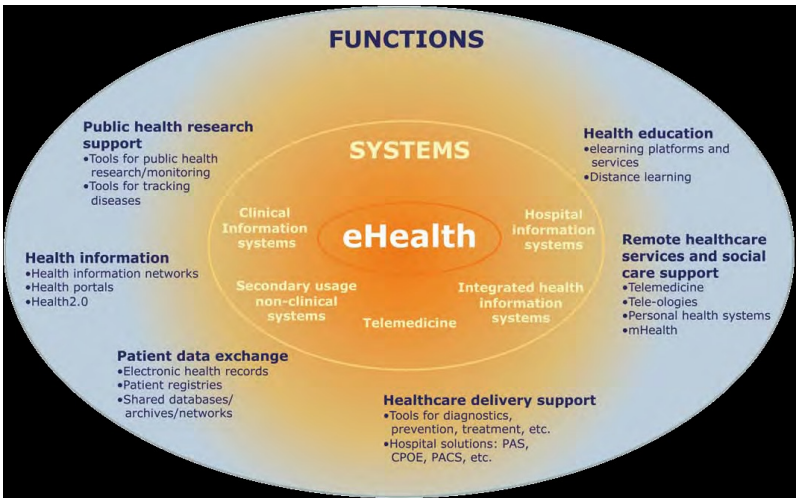

Fig. 51. Functions fulfilled by eHealth in the health sector (COCIR (a), 2011)

In 2011, in a paper produced by the Telescope (Telehealth Services Code of Practice for Europe) project (Rudel, Fisk, & Roze, 2011), a glossary of terms is presented, as the outcome of an intensive literature review effort. The focus of this document is to define telehealth, but it also presents a series of related terms and shows how they relate to each other.

Telehealth is described here as "the means by which technologies and related services at a distance are accessed by or provided for people and/or their carers at home or in the wider community, in order to facilitate their empowerment, assessment or the provision of care and/or support in relation to needs associated with their health (including clinical health) and wellbeing. Telehealth always involves and includes the service user or client. It includes remote patient management." (ibid., p. 32)

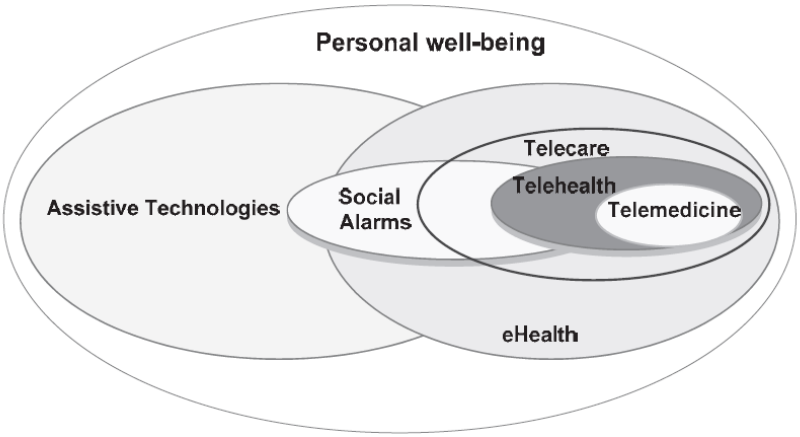

Fig. 52. Scope of telehealth by Telescope project (Rudel et al., 2011)

The important addition brought in by the Telescope project is the recognition of wellbeing as a field. "[...] it is recognised that health cannot be seen purely in clinical terms. Rather it is concerned with people's lives and people's homes – where services using telehealth technologies are provided by agencies; or, importantly, technologies are harnessed by individuals" (ibid., p. 34). In this report, telehealth includes telemedicine, because it concerns the clinical aspects only, the curative aspects of health. The World Health Organization (WHO) also acknowledges the separation between the clinical and non-clinical aspect of health related services, and, similarly, Telescope considers that telehealth can be delivered by non-healthcare agencies. This implies that telehealth can

be an independent domain, with its own professional codes, standards and service provisions.

In 2010, COCIR published the following understanding of telemedicine, as encompassing all areas in the figure below.

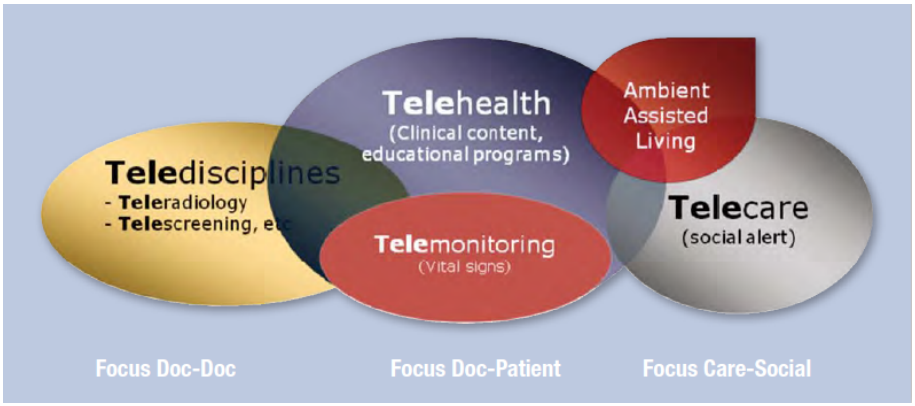

Fig. 53. Scope of telemedicine by COCIR (2010)

The merit of this representation is fact that it brings forth the connections between players.

In 2011, COCIR represented telemedicine in a bigger picture, including also mHealth as a standalone, but subsumed domain.

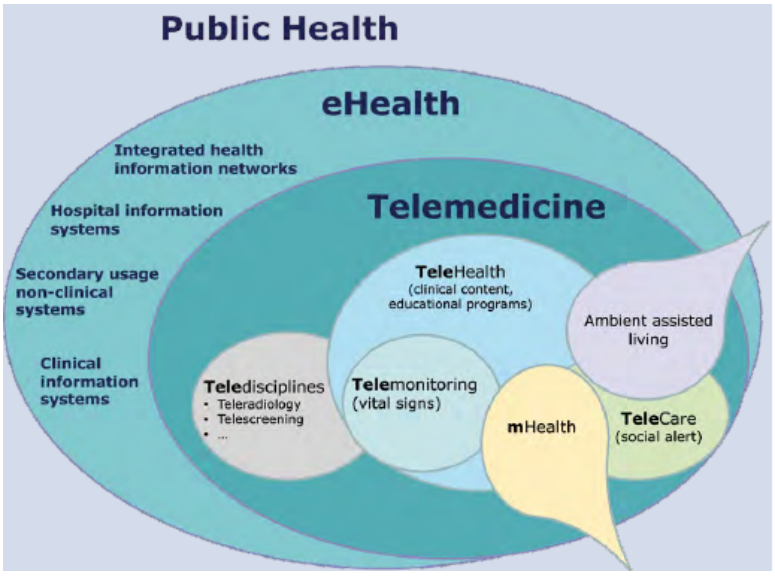

Fig. 54. Scope of telemedicine by COCIR (2011)

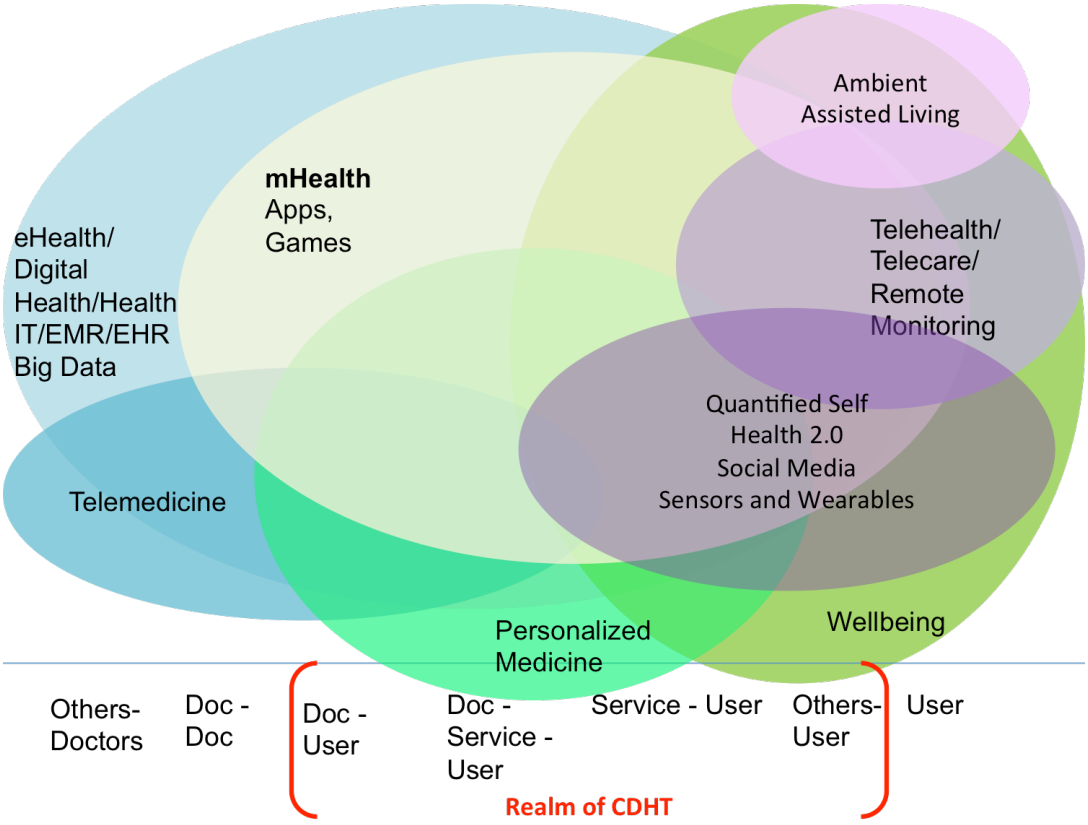

Fig. 55. Digital health and the scope of CDHT

Building on previous authors, in the figure above, I represent the digital health field and the CDHT, as subdomain, although the limits are more theoretical than practical. It is in agreement with the use of eHealth or digital health as overarching concepts. It shows that telemedicine implies clinical services, connecting doctors to doctors or doctors to patients. mHealth refers primarily to the delivery mode of the health and wellbeing, clinical or not, services. Well-being relates mainly to the social and individual aspects that help people "produce health", factors are under the individual's direct control - diet, exercise, and lifestyle. Education is also a very important factor for personal health outcomes (Windrum & García-Goñi, 2008; Windrum, García-Goñi, & Coad, 2016). Finally, 'telehealth' is encompassing many aspects of the health services, but the main differentiation is that it can and it should be delivered by telehealth services that may connect based on need to clinical services.

'User' could designate a patient, but not necessarily. It could be simply a person interested in their own well-being. 'Service' provider refers to what Telescope names agencies (Rudel et al., 2011). In my view, service providers

could be organisations affiliated or not to the healthcare sector. These new categories of health or health enhancing providers constitute primarily the concern of the regulators. 'Others' may designate actors like the payers, researchers, pharma... CDHT are concerned with digital solutions that connect various actors across digital health, not limited to the traditional healthcare players – healthcare professionals and providers and payers.

The figure above, in the interest of keeping it as simple as possible, did not include the emergent field of personalised medicine. This emergent field sees the potential of digital technologies in harnessing information on the environment and the person to help enhance its advances. It is also referred to as P4 Medicine, due to its stated guiding principles Personalised, Predictive, Preventive and Participatory (CEPMED, 2012).

I will close this terminology part, by offering an alternative view of digital health.

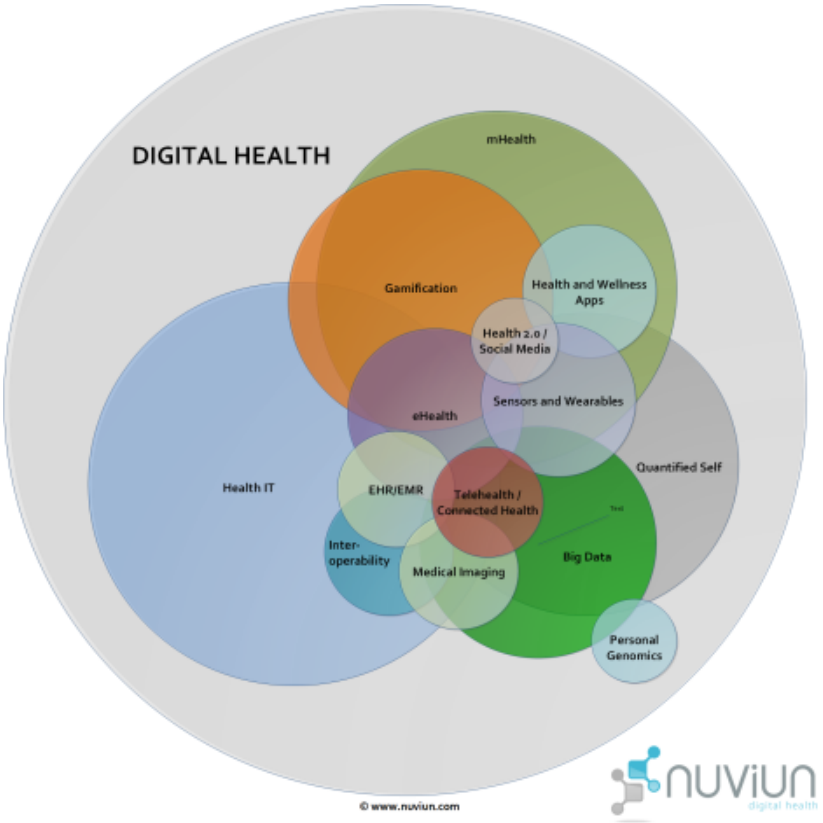

Fig. 56. Digital health landscape as viewed by nuviun (2014)

It is important to keep in mind that the terminology is changing still, including in respect to the meanings associated with the terms. The analysis above has relevance for the time data collection finished (2016).

APPENDIX D. DIGITAL HEALTH TIMELINE (2009 – EARLY 2016)

The timeline below gives some examples of developments in the field of digital health; it is not an exhaustive listing.

	2007 - 2009	2010 - 2012	2013 - 2016
Terminology	Health IT, eHealth, Wireless health, mHealth, telehealth, assistive technologies, telemedicine, remote monitoring, quantified self	Apps, wellness, wearables, digital health (Davis, 2015), Big Data	Insideables, precision medicine, personalised medicine, genomics, digital phenotype Personal Health Data (PHD) nuviun's digital health diagram (nuviun, 2014)
Technology	Existing EHR IT producers The Apple Store, 2008 The Android Market, 2009	Windows app store, 2010 Tablets, 2010 There is steady growth in wearables, apps, consumer health websites. Prices continue to drop. There were over 13 000 health apps in April 2012 on the Apple Store (Dolan, 2012) Dominant business models are business to business (B2B), but business to consumer (B2C) (Zussa, 2012)	EHR, apps and wearables continue to grow Beginning of convergence of wellness and health wearables and apps Apple Watch 2014 Microsoft Band 2014 Apple Research Kit 2015 Apple Research ethical approval required (Duhaime-Ross, 2015) Google enters into medical research (Kunze, 2015; UNSW Engineers, 2015) In October 2014, following the FDASIA Health IR report, 58 companies sent a letter to the US Congress clarity on who regulates what (Sullivan, 2014). Increasing number of apps specialised on chronic conditions: diabetes, obesity, congestive heart failure, chronic obstructive pulmonary disease. Patient education and fitness remain the largest categories of apps. (Research2guidance, 2014) Theranos (US) opens first labs in Arizona, US, 2013.
Investments	mobihealthnews report highlights increased venture capital investments (mobihealthnews, 2009)	Industry challenges (prize and prestige): Qualcomm tricorder xprize, 2012 Nokia Sensing xChallenge, 2014 Spread of incubators and accelerators: RockHealth (2010), Blueprint Health, The Ironyard, Health XL and	Multitude of accelerators, incubators, investment hubs for digital health (Healthstartup, 2014; Sonnier, 2015a) Government sponsored networks (Digital Catapult Centre, UK 2014) and testing grounds (United4Health, EU, 2014)

	2007 - 2009	2010 - 2012	2013 - 2016
		StartUp Health (2011), Healthbox and REshape Healthcubator (2012)	Dramatic rise of venture capitalist funding. Beginning of crowdfunding for health.
Market reports	Market reports on mHealth, wireless health or Digital Health by niche market research companies Research2guidance Parks and Associates mobihealthnews	Niche: RockHealth, 2010 Established consultancy firms: PwC 2012, Accenture 2011, Deloitte 2012 Market reports separate wellness and health apps Segmentation of health apps on: - types of users: patients, doctors - education or health management - monitoring	Both niche and most established consultancy and market research firms are providing regular updates on Digital Health, mHealth, wearables, apps…
Patient	ePatient Dave (deBronkart, 2009a) Society of Participatory Medicine, 2009, had as founders a doctor and a patient, Dave deBronkart (ePatient Dave)	Patient initiatives The Walking Gallery, Regina Holliday, 2011 Being a Patient isn't easy!, patient blog Michael Seres, 2011 Hugo Campos demands access to data generated by implants, 2011 Growing online communities of patients, "peer to peer" healthcare (Fox, 2011a) Journal of Participatory Medicine, 2010	The BMJ partners with patients, 2014 Petition collects signatures worldwide for patients' access to medical data (Getmyhealthdata, 2015) Patients Included: a global patients' charter (Spong, 2015) Social media campaign (deBronkart, 2015) for including patients in the Meaningful Use programme specifications, US, 2015
Medicine	23andMe began direct to consumer genetic testing in the US, November 2007.	Journal of Mobile Technology in Medicine, 2011 There is still little uptake on apps by the medical community (PwC, 2012). The Creative Destruction of Medicine (E. Topol, 2012) Eric Topol named the most influential doctor by Modern Healthcare magazine I 2012	Discoverability, evaluation and integration in clinical pathways in fitting new technologies in the clinical pathway (Editors, 2014; Harvard i-lab, 2014; Kocher & Roberts, 2014) 23andMe offers direct to consumer genetic testing in Canada and UK, 2014 Following the Personal Genome Project in US, there is a Personal Genome Project in the UK, "Liquid hospital" (*Jorge Juan Garcia F. at Doctors 2.0 & You Paris*, 2013) Digital phenotype (Jonah Comstock, 2015) CDHT for medical and pharmacology research (Bort, 2015; PwC, 2015) Google glass first live streamed surgery, 2013 (Schreinemacher, Graafland, & Schijven, 2014) Royal College of

	2007 - 2009	2010 - 2012	2013 - 2016
			Physicians issues guidance for apps, UK, 2015 First Theranos testing labs opened with Walgreens, US, 2013.
Academia	Evidence for economic and clinical benefits.	Awareness of Big Data for health, the many possibilities for research Terminology (COCIR, 2011; European Parliament & European Council, 2011; Rudel et al., 2011) Academic Programmes in Digital Health: Reshape Innovation Center, Radboud Univ., The Netherlands, 2010 Institute of Digital Healthcare, Univ. of Warwick, UK, 2010 CATCH, Univ. of Sheffield, UK, 2012	Big Data for Health Hospitals without beds (Engelen, 2015) More academic programs for digital health
State (regulators/payers)	In 2008, California regulators served cease-and-desist orders to Navigenics, 23andMe and other genetic companies. Following arguments, only months later, these companies received license to conduct business in California. Arguments: "My DNA Is My Data." (Goetz, 2008) Meaningful Use programme launched in 2009 in the US Multiple attempted deployments of Electronic Health Records (EHR or EMR) across Europe (UK, Germany) and other countries (Israel, Australia), which have generally not taken on. The Whole System Demonstrator (WSD) in the UK (2008 – 2010) was meant to be the biggest randomised control trial in telehealth and telemedicine, 2007 The European Union (EU) launches the Lead Market Initiative, where eHealth is identified as one of the most promising markets, 2008	First WSD results were published in 2011, pointing towards economic and health benefits. Overall, this initiative had little impact. Regulators continue to forge the adoption of digital technologies, particularly EHR systems eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century (European Commission, 2012) No reimbursement channels for CDHT Attention moves from evidence to interoperability, legacy systems, governance, accessibility, adoption… FDA releases first draft guidance on apps, 2011 By the end of 2012, there were 75 apps cleared by FDA (mobihealthnews, 2012) EU publishes guidelines for qualification and classification of stand alone software, 2012 Most other countries (outside the EU and the US) do not have specific regulations on mHealth, or they mimic the ones in the EU or US (PwC, 2013)	Continued focus on interoperability, privacy and data ownership FDA issues final guidance on mobile apps, US, 2013 FDASIA Health IT report points toward collaboration between FDA, and other governmental entities, possibly the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC), US, 2014 FDA announces its intend to exempt certain medical devices from premarket notification FDA issues another final guidance on mobile apps in order to have consistency with the guidance on medical devices, US, 2015 FDA announces a draft guidance: "General Wellness: Policy for Low Risk Devices", showing intention not to regulate such devices, US, 2015 Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS) publish certification criteria for health IT, US 2015 Guidelines on apps (Medicines and Healthcare

	2007 - 2009	2010 - 2012	2013 - 2016
			Products Regulatory Agency, 2014), UK EU launches a public consultation on mHealth, 2014. Summary report on the public consultation was published in January 2015, and these results are to be further discussed during eHealth Week, May 2015 Theranos pushes a bill in Arizona US to allow selling blood tests directly to consumers (Office of Arizona Governor, 2015)
Events	mHealth Summit, US, 2009, had initially 800 participants Medicine 2.0, first in Canada, then in various countries, 2008 Health 2.0, first in the US, then also in Europe, 2007	Patients included act (Engelen, 2012) Patient included conferences, examples Doctors 2.0 & You, France, 2011 Stanford Medicine X, US, 2012 Others: Digital Health Summit, US, 2011 Health Innovation Summit, US, 2010	Many events now related to Digital Health (Sonnier, 2015b) mHealth Summit Europe, 2014 Digital Health Live, UAE, 2015 Digital Health World Forum, UK, December 2015
Digital Health	mHealth Linkedin group founded by David Dohorty, 2008 Digital Health Linkedin group founded by Paul Sonnier, 2009		Digital Health UK LinkedIn group founded by Stephen Davis, 2013 Nuviun, standalone community platform for Digital Health, 2015

Table 17. Digital health timeline, to the beginning of 2016

APPENDIX E – DIGITAL HEALTH EVENTS ATTENDED

International Congress on Telehealth and Telecare	March 2012, The King's Fund, London, UK
Telehealth and Telecare in Scotland	May 2012, Edinburg, UK
Healthcare Efficiency Through Technology	October 2012, London, UK
mHealth Summit Europe	May 2014, Berlin, Germany
Digital Health Pit Shop Week	December 2014, London, UK
The Role of Psychology in Digital Health	March 2015, London, UK
Digital Health Live 2015	May 2015, Dubai, UAE
Doctors 2.0 & You	June, 2015, Paris, France
Stanford Medicine X	Sept. 2015, Stanford, US
Interface – Your Body**:** The Next Interface	Sept. 2015, Vancouver, Cana da
Digital Health World Forum	December 2015, London, UK

Table 18. Events attended during data collection

APPENDIX F. EXCERPT FROM JOHN NOSTA'S INTERVIEW, OPINION LEADER

What is digital health right now?

The convergence of technology and medicine: we look at it from a variety of perspectives. There is digital fitness, which is a traditional step counter or a digital tool that people use in the gym, there is digital health to advance some of these basic concepts into the area of health and wellness, and then digital medicine. So they probably are three discrete areas. For me digital health is about leveraging technology to prolong life, it's about longevity. So we see companies like Google Calico or Human Longevity that have a very specific pitch on life extension.

What would be the role of the state?

Government helps to put certain constraints on technological developments; sometimes for the better, sometimes for the worse. But in areas such as genomic research and artificial intelligence there may be a practical role for government to help organise some of these advances. The driverless car, as an example of technology, has to be put in the context of simple laws that govern driving.

Do you think this field took off with the smartphone?

I think that the smartphone is one of the pivotal aspects of digital health. It's the conduit through which information flows; it can travel. And the development of the smartphone and its processing power has enabled people to create what I call "care at a distance". So now we can measure and manage wellness using telemedicine, for people around the world, not only around the corner. So this smartphone is an important tool that is part of digital health. I believe that other aspects of digital health such as nanoparticles and nanotechnology. Nanoparticles mediate early cancer detection and are an

example of a very important area of digital health. Big Data's ability to show interesting correlations and trends is another area. A third area will be genomics; the rapid evolution and adoption of genomic analysis will be a very important part of the digital health movement. Those will make us think of the smartphone as an intrinsic or as a necessary connection. Often times we see things like telemedicine require the smartphone. Other advances in digital health such as nanotechnology, genomics and Big Data applications will not necessarily need the smartphone, but the cell phone, tablet, wireless communications can be linked to this in many ways. So, the interesting thing about the cell phone is it tells us that the 21st century really did not begin in the year 2000. I would argue that it began probably closer to the year 2015 or 2016. And one of the major steps along was the smartphone in 2007. So we are seeing a magical time in human history that some people call Gutenberg moment, the printing press moment. I would argue that it's even bigger than that - it's not only one technological achievement, it's multiple technological, human and social achievements.

When saying 'social', what are you thinking of?

It's not about social achievements, but about social issues that are coming together. For example, right now there is a tremendous sense of urgency to fix healthcare, whether it would be in the United States, regarding the extraordinary expense, whether it be around the world with people who have no access to care, pregnant moms in sub-Saharan Africa… There are pressing social issues and yet, in contrast to that we see, the emergence of the democratisation of health and as people stand up in a broader democratic voice - that they want the opportunity to own their healthcare data and manage their health and received care that they feel they're entitled to. Really, the only way many of those people will get care is through the technological innovations of digital health. So, what I say it's not just the printing press, it's not just technology, it's not just cloud storage capacity, it's not just your ability to have sensors that are small and inexpensive. That combined with other issues, such as social issues, come together in a very unique cauldron of innovation. That's why the point we live in now is truly an inflection point in history.

When it comes to challenges in digital health, is the US different from EU?

I'm not so sure I would say that they are different. The utility of the NHS as a provider of care is quite different than the United States'; it's a single-payer system. But they still see the application of technology to help people who can't get to the doctor, who have clinical conditions in and out of the hospital… So I believe there are two perspectives: one is the exoteric perspective and the other is the esoteric perspective. The exoteric, or practical real world aspects of digital health, certainly makes a difference - there's a difference in the payer, a difference in sociological acceptance of technology, a difference in the ageing population. The esoteric, conceptual ideas about saving lives, about leveraging technology in all those things, I believe are very, very similar.

I want to talk about very quickly - the electronics and information technology is one fundamental change in our in our industrial context.

There was water and steam, second one was the electrical power, creation of mass production and third electronics information technology. Now I think there's this fourth revolution building on the third, which is the digital revolution. And this diffusion of technologies that are not well defined. And the interesting thing about the fourth revolution is that it is a little digital and a little about physical. It's about all these aspects of our humanity that are being transformed; amazing changes in technology.

What do you think is missing from the conversation, if anything right now, from conversations surrounding digital health?

It's a tough question to discover what's missing. I think the discussion is robust. I believe that we will see probably a greater degree of clinical scrutiny. Ideas that are interesting may not pass the type of scrutiny that makes the mainstream, but the interesting thing here is that it does not make the idea bad. It just means that the idea has to be evolved a bit. I'll give you an example: remember the Apple personal assistant PDA, a personal device that you can write on and you could sync it to your computer by plugging it in. I was one of the early Apple products, it was like a phone, but there was no phone at that time and it failed. Failed not because technology did not support the idea and

people were just not ready for the idea. The idea of scrutinizing an idea of questioning its clinical validity, of looking at it real data to support its use, I think it will, well out of necessity, come to the forefront. And with that might come some scepticism. I think that companies like Theranos have hurt and helped the digital health space, because it may have directly impacted venture capital. Engaging in some ideas that may not be completely, fully baked, it may mean investors may not to be happy to take the risk. It failed up digital health by a lack of transparency and failure to rise above the scrutiny. I don't know if Theranos is successful or not, but when I look at the articles and the commentaries, it makes me frustrated and sad. We are all on the same digital health team. I love to see people succeed. You see a company like Theranos and you don’t even know what the problem is. They may emerge from this and be completely successful. But I don't know.

APPENDIX G. EXCERPT FROM MICHAEL SERES' INTERVIEW, OPINION LEADER, 11 HEALTH FOUNDER AND CEO

How did you kick it off the ground? Did you find somebody to finance anything?

At the very beginning, after I had built the prototype and started testing that on myself, I realised that I needed some money in order to take a very basic prototype and turn it into a proper device. So I went to look for an investor to put in a bit of money and through recommendations of recommendations I, in the end, presented it to a gentleman called Adam Blooms who agreed to invest in the business and he gave me the first bit of money to take the prototype and see whether we could build a proper device. He was the first investor.

And what year was that?

That was 2013.

And I guess you took it up from there. How many funding rounds did you have?

At the very beginning, we had a funding round literally for six months to see whether we could take the prototype and turn it into a proper device. During those six months, he realised that it is possible and there was market opportunity for the device. And then he invested more money, which allowed the business to basically go through proper development, proper mobile app development, as well and all the regulatory requirements for the adoption of the device. And that took us to January of 2015. And then in January 2015, we started raising a further round of funding from private individuals, to allow business to start scale up and invest in people and invest in infrastructure, and we have secured that when funding came in. And so now we are starting to scale up the business and then, at the end of this year, we will go for venture capital funding from the US.

And at the moment, you can commercialize the device in the US, is that correct? You have the FDA approval?

Correct. We can actually commercialize the device in the US and in the UK. The problem in the UK at the moment is that there is no mandate for prescribing technology. And, because our device is a consumer-driven device, the end user being a patient as opposed to the hospital system, we are waiting for the final go-ahead for our device to be adopted into the therapeutics, that it can be prescribed.

What about the European Union?

We can commercialize it. We are just having discussions now about distribution.

But is it OK to be sold in the European Union?

It is OK, yes.

And the distribution channels at the moment are direct to consumers?

Yes. So, we have two channels. One is direct to the hospitals where we're selling direct to the colorectal surgeons and nursing teams and then the on-going sales are direct to consumers.

For the hospitals are you going through distributers?

No, we're going directly.

And that's for the US mainly, at the moment?

Yes, that's right.

The way I see it, maybe I'm wrong, is somewhere close to a medical device, isn't it?

It's a class one medical device. So it's the lowest classification of medical device.

So it could also go through channels in Europe, through medical devices distributors and things like that.

Correct, absolutely.

Great, so I have a bit of history. And I saw you have a diverse background, you have worked in marketing, and you've also worked in the entertainment industry in a sense.

Yes.

And how did your experience pay off in the field?

I was very lucky; I worked with some major sporting brands and some major entertainment brands. (…) It gave me a structure and an understanding for process that I think has been invaluable.

And as well I guess in designing an app, to better understand user experience.

Yes, particularly with ZZZ we developed the first mobile game and so I had an understanding of user journey, user experience, what would turn people off, so we deliberately made our user journey very simple. We're not a gaming app, and therefore we don't have to have the most beautiful graphics or the most beautiful look of the buttons. But what was really important was that it was an easy journey for the patient to use, and so having a little bit of a background in that has helped enormously.

And combined I guess with your own experience as a patient.

Yes. I'm very conscious of very high drops of rates of apps from patients and I wanted to make sure that as a patient you really don't have to do very much, very often.

I do not know very much about the medical side of this but are there a lot of children who are going through this sort of problem? The vast majority of patients are children?

So 70% of the patients are adults and 30% are children or teenagers under the age of 21.

And do you have anything to facilitate this sort of patients? Like an app that will communicate to carers or that would be a bit educational for children, anything easy to customise for this sorts of patients?

At the moment, we just have one application targeted to everybody. We are very active on social media and used that as a vehicle to communicate what we're trying to do to the younger audience. We use Instagram a lot for imagery, we use Facebook and Twitter, and we're starting to look at Snapchat and other social media out there, as a way of engaging with the younger community. But at the moment, the device and the app is one size fits all.

Now that you talked about social media, how important do you think is social media for growing your business?

It's vital. It's absolutely vital. At the beginning, it was vital in understanding the market in the sense that it helped me to talk directly to patients, to learn whether there even were issues, whether other patients experienced the same problems that I had. I then was able to use it for market research - if there was a device would people would use it, would they want it, would it be paid for, what do they think is the right cost and so I could get all that information from social media. And now, it is the most vital way that I communicate with patients. Because I think what is vitally important in this business is that this is patient-led technology and patient-led innovation, so I am absolutely insistent that everything we do in a sense gets run by patients and social media will do that.

For instance, do you have any understanding, when you sell directly to consumers, do you think they come to you mainly through word of mouth?

Yes, mainly through social media and word of mouth at the moment. We have not yet reached a big enough market share in the hospitals for it to filter down from the doctors to the patient. At the moment, it's from the patients at the grassroots. (…) The idea is that the grassroots know about the device, and then the doctors know about it, and the two come together.

I know that you are a voice in the patient community, in the raising patient community. How much do you think that your role as patient goes back to growing a business in a sense?

I'm very conscious of not wanting to impose my patient voice on consumers so I come across as someone that is just trying to sell people that I engage with on a daily basis. I really don't want to be seen as someone that is just using my voice to purely benefit my company. There is a line, which I try not to cross, and so my personal voice is about trying to raise the role of the patient, trying to promote patients as innovators, and within that I talk about the business. But the business also has to have its own social media presence. So there is a fine line. I don't want people to think that I am using my personal following just for commercial gain. I really don't want that to come across.

I understand that you see it as an ethical issue, and you see your role as a patient leader in a way should be clearly delineated from your role as an entrepreneur?

Yes, it's really important to me that people don't feel that everything I'm doing is just so that I can earn some more money so I don't want to cross the line(…)

Do you think your company changed in its brief life? I mean, changed the orientation, in the way you communicate, in the design of the product? Do you think it changed a lot, or it followed a natural progression?

It has changed as more people have got involved, which is probably a natural progression. As the company grows, and we have more shareholders, and we have a chairman etc., you realise that people are actually very focused on their own personal gain, and I'm very clear to try and keep the company focused on improving the life of the patient. If we are keeping the focus on this, than the company is going to continue to make more money. The priority is 'What are we trying to do?' And that is a hard balance, as we grow.