University of Reading

UNFOLDING THE LEGITIMATION OF BREAKTHROUGH TECHNOLOGICAL INNOVATIONS:

A FRAMEWORK FOR ANALYSIS THROUGH THE LENSES OF TECHNOLOGICAL INNOVATION SYSTEMS

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Declaration

“I confirm that this is my own work and the use of all the material from other sources has been properly and fully acknowledged.”

Irene Talavera Fabra

Abstract

This thesis constitutes a pioneering effort to explore the mechanisms of innovation legitimation, a critical process in enabling movement of breakthrough innovations from the formative phase to a wider adoption. Guided by the importance of understanding why most breakthrough technological innovations fail to move beyond the formative phase of adoption and acquire critical mass on one hand, and the paucity of studies on the early phases of the innovation phenomena on the other, this research reviews the most relevant innovation theories and models in search of solid theoretical and analytical starting points to conduct the empirical study. Technological innovation systems (TISs) is selected as the most appropriate lens to explain the early phases of the innovation phenomena. Built on general system theory and co-evolutionary perspectives of innovation, TIS views technological innovation as a collective endeavour of actors, networks and institutions. Legitimation is identified in TIS literature as a critical process to move innovation from formative phases to wider diffusion. However, surprisingly, legitimation is largely under-researched in TIS literature.

Taking a critical realist perspective, this research explores TIS legitimation through qualitative research across two case studies for two different breakthrough technological innovations, in which document analysis and participant observation complements 33 semi-structured interviews with high profile experts.

This thesis' findings advance knowledge on how legitimation is built across different institutional contexts. The findings reveal the critical role of system builders along the legitimation process. The research identifies the extent of their transformative capacity when acting individually or in alliance with incumbent firms. Moreover, this thesis evidences the relevance of the pragmatic legitimacy dimension, largely ignored in TIS literature. In relation to this, this thesis partially supports the idea that societal problems and public debates contribute to legitimate breakthrough innovations, as research data suggests that adopters will additionally

perform pragmatic evaluations in search of appropriable benefits. Finally, this research discloses new relevant mechanisms for the legitimation of TISs, like the need to align the different organising visions in the TIS or the criticality to co-create knowledge.

The findings of this thesis have important implications for theory and practice. On the theoretical side, the research validates the principles of TIS for innovations outside the energy sector and it offers a set of propositions and a framework that contribute to unfold the mechanisms of innovation legitimation. Moreover, the framework and the developed propositions provide innovation practitioners with a practical tool to develop successful innovation strategies.

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Abbreviations

ANT	Actor-Network Theory
BTI	Breakthrough Technological Innovation
CAGR	Compound Annual Growth Rate
CD	Computational Dynamics Ltd
CFD	Computational Fluid Dynamics
CR	Critical realism
CHAM	Concentration Heat and Mass Transfer Ltd
DOI	Diffusion of Innovations
eHealth	Electronic Health
EU	European Union
ICT	Information Communication Technologies
NHS	National Health Service
LTS	Large Technological Systems
mHealth	Mobile Health
MLP	Multilevel perspective
NPD	New Product Development
SCOT	Social Construction of Technology
SI	Systems of Innovation
STS	Studies of Science, Technology and Society
TA	Technology assessment
TAM	Technology Acceptance Model
TIS	Technological Innovation System
WHO	World Health Organisation

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Chapter 1 - Introduction

1.1 Overview

This chapter introduces the thesis, which aims to explore the mechanisms that lead breakthrough technological innovations (BTIs) to successful diffusion trajectories. The chapter starts with a discussion of the research rationale, in which the theoretical and practical reasons that motivate the study, are discussed. After that, the research aim and proposed research questions are presented. The subsequent sections provide the reader with an overview of the research. These include a summary of the key contributions, main aspects of research methodology and an outline of the thesis structure.

1.2 Research rationale

Breakthrough technological innovations (BTIs) can be defined as radical or discontinuous innovations embodied by a technology that results in new market infrastructures (Garcia & Calantone, 2002). In contrast to incremental innovations, BTIs create new technological trajectories that transform the relationships between individuals, organisations and industries (Dosi, 1982; Anderson & Tushman, 1990). The diffusion of BTIs is by far more difficult than the diffusion of incremental innovations: whereas producers of incremental innovations benefit from existing structures and aligned institutions, producers of radical innovation need to deal not only with larger doses of change in the existing knowledge base, but also with the need to build up new structures as well as adapting, or possibly developing, new formal and informal institutions (Kukk et al., 2016).

BTIs play a critical role in macro and micro-economic success and are the main driver behind socio economic growth (Foster & Kaplan, 2011; Nelson & Winter, 2002). However, and despite of its importance, we are still far from understanding how and why many BTIs fail to fully diffuse (Chesbrough, 2006; Stevens & Burley, 1997; Norman & Verganti, 2014). Whereas the majority of innovation studies over the last 70 years have focused on explaining how innovations diffuse once they've acquired critical mass, less attention has been paid to examining the formative phase of the phenomenon, where, as illustrated in paths B and C in figure 1-1, the majority of BTIs fail to disperse extensively and either remain niche or disappear completely (Geroski, 2000; Rogers, 2003; Hekkert et al., 2011; Ghobadian et al., 2018).

Therefore, the rationale for this research emerges from important theoretical and practical motives aiming to identify the mechanisms that contribute to build successful diffusion trajectories (path A in figure 1-1). After examining main strands of innovation studies (see chapter 2 on literature review), this research takes technological innovation systems (TIS) (Carlsson & Stankiewicz, 1991; Hekkert et al., 2007; Bergek et al., 2008a), as the theoretical and analytical basis for the study of BTIs. Built on general system theory and co-evolutionary perspectives of innovation (Nelson, 1994; Nelson & Winter, 2002), TIS approach has attained over the last years increasing attention both in the policy arena and in social-science research (Markard et al., 2016). Consequently, this research seeks also to develop useful knowledge in the promising field of TIS.

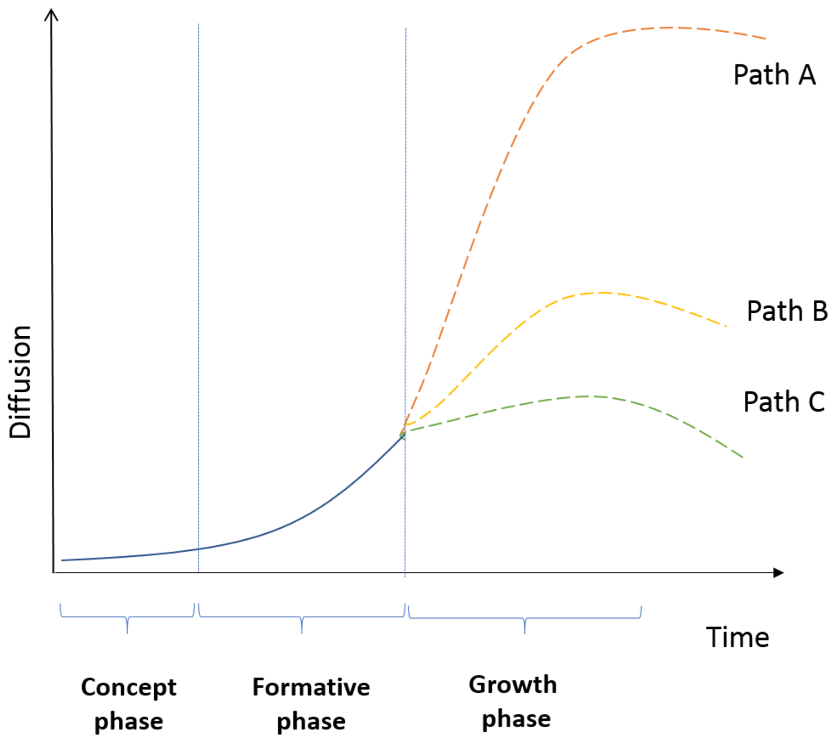

Figure 1-1 Figure 1 1 Phases of innovation diffusion. (Ghobadian et al., 2018)

1.3 Research aim and research questions

As outlined in the previous section, the overall aim of this research is to contribute to unfold the mechanisms that lead BTIs to successful diffusion trajectories (path A in figure 1-1). To accomplish such endeavour, this research takes systems of innovation, and in particular TIS (Carlsson & Stankiewicz, 1991; Hekkert et al., 2007; Bergek et al., 2008a), as the theoretical and analytical starting point for the analysis. TIS can be defined as the set of actors, networks and institutions that contribute to the overall function of developing and diffusing technological innovation (Bergek et al., 2008a). Therefore, in this research, TIS define the theoretical and analytical setting for the analysis of BTIs.

As discussed in section 2.6.3, TIS literature identifies legitimation as a critical process to move technological innovations (BTIs) from the formative phase to wider diffusion. Legitimation is defined as the process of acquiring social acceptance and compliance with the relevant actors and institutions such as norms, values, beliefs etc. (Bergek et al., 2008b). Legitimation is necessary to create demand and mobilise resources. It involves getting the new technology accepted as a desirable and realistic alternative to incumbent technology (Bergek et al., 2008b). In the words of Stinchcombe and March (1965), acquiring legitimation is a necessary condition to overcome the 'liability of newness'. However, despite its criticality, there is a lack of empirical research on how TISs acquire and build legitimacy (Bergek et al., 2008b; Bergek et al., 2015; Markard et al., 2016). In particular Kern (2015) suggests that TIS empirical research should look into the strategies developed by system builders to build legitimacy.

As a result of the above discussion, the overall aim of this research: unfolding the mechanisms that lead BTIs to successful diffusion trajectories, can be better accomplished by narrowing it down into a set of more specific questions around legitimation as a key process to move TIS from the formative to the growth phase (figure 1-1). These research questions, further discussed in section 2.7, are:

R.Q.1: how do and the extent to which system builders contribute to establishing legitimacy within a TIS?

R.Q.2: what are the principal mechanisms aiding the legitimation of a TIS?

R.Q.3: what are the key legitimation strategies capable of overcoming the 'liability of newness'?

1.4 Research contributions

This thesis makes contributions to theory, methodology and practice. The next three subsections provide a summary of the key contributions, which are further discussed and detailed in section 6.5.

1.4.1 Contribution to theory

The overall theoretical contribution of this thesis, is developing a set of propositions and a framework explaining TIS legitimation dynamics that can be incorporated into TIS literature.

Within the proposed framework, this research provides additional contributions to TIS legitimation, socio-technical transitions and theories of innovation and firms' competition.

A first theoretical contribution of this thesis relates to the contextual aspects of the legitimation process. This thesis evidences that legitimation is a process highly dependent on the external institutional contexts where the TIS needs to be accepted. Particularly, the framework presented in section 6.4, suggests that system builders will initially select institutional contexts where they perceive legitimation can be more readily attained. A second theoretical contribution of this thesis is the incorporation of pragmatic legitimacy into the TIS legitimation analysis. This research, extends the work of Suchman (1995) for the legitimation of new industries, by evidencing that system builders need to build legitimacy along 3 axes: pragmatic, moral and cognitive legitimacy. The pragmatic dimension of legitimation has been largely ignored by organisational and TIS studies (Aldrich & Fiol, 1994; Scott, 1995; Zimmerman & Zeitz, 2002; Markard et al., 2016). A consequence regarding the relevance of pragmatic legitimation, is that this research provides new insights on the influence of societal problems or public debates in the legitimation process. Scholars like Geels (2005a) propose that pressures at landscape level, like societal problems or public debates, act as triggers for technological change. Aligned to this, Markard et al. (2016) argues that problem agendas at the societal level contribute to build (or destroy) legitimation. As further developed in section 6.5.1, this thesis suggests that, although public debates and societal problem agendas contribute to mobilising resources and building moral legitimacy around certain TISs, this might become insufficient if relevant audiences (i.e. potential adopters) do not perceive appropriable benefits (pragmatic legitimation) in those technologies.

Another theoretical contribution is the identification of levers that contribute to building TIS legitimacy. As detailed in section 6.3, these include aspects like system builders' reputation, alignment of organising visions, contrasting expectations with evidence, or probably the most critical, the co-creation of knowledge.

Additionally, the results of this thesis partially question the *attackers' advantage* positions postulated by different theories of innovation and firms' competition (Anderson & Tushman, 1990; Chirstensen, 1997). Whereas these theories postulate the *creative* destruction of incumbent firms in the event of technological paradigm changes, this thesis finds that incumbent firms compete and collaborate with system builders and entrant firms during the formative phase of a TIS. They build on the knowledge developed by system builders, and mobilise their resources towards innovation trajectories that can better preserve their competitive advantage. As the research evidences, incumbents become critical for TIS legitimation in contexts with complex institutional structures.

1.4.2 Contribution to methodology

In addition to theoretical contributions, this research provides a set of methodological contributions pertaining to the operationalisation of different TIS analytical frameworks.

This study is one of the few that has operationalised TIS out of the field of sustainable technological transitions in the energy sector. Therefore, this research validates the principles of TIS for technologies outside the energy field.

The operationalisation of TIS frameworks has typically taken a meso level perspective focused in the analysis of the different TIS functions (Hekkert et al., 2007; Bergek et al., 2008a). However, more recent TIS studies have incorporated system builders as the centre of the TIS analysis (Hellsmark & Jacobsson, 2009; Hellsmark, 2010; Musiolik & Markard, 2011; Kukk et al., 2016). This research contributes to TIS methodologies by evidencing that TIS studies centred on system builders provide richer empirical results, particularly when looking at the dynamics surrounding different institutional contexts.

1.4.3 Contribution to practice

The results of this research are relevant to practitioners like policy makers, system builders and incumbent firms. The framework and its propositions can be valuable in the development of strategies and policy actions towards the successful diffusion of BTIs. As an example, the framework helps system builders to identify favourable contexts to legitimate BTIs. Moreover, this thesis provides a set of actions contributing to the development of pragmatic, moral and cognitive legitimacy. Chief among them is co-creation of knowledge. Additionally, this research provides insights on the factors that enhance the development of system builders' transformative capacity. As shown in figure 4-5 of section 4.3.3, organisational, institutional and leadership factors influence their ability to develop TISs.

Policy makers, on the other hand, can also benefit from the insights and results of this thesis. Their role is critical to mobilise resources and facilitate both the alignment of the different organising visions and the creation of collaborative spaces for knowledge development. The proposed framework helps them to identify and remedy frictions and misalignment along the different involved institutional contexts.

1.5 Research methodology

To accomplish the research's aim and questions discussed in section 1.3, this thesis conducted two case studies on two different breakthrough technological innovations (BTIs), as detailed in section 3.4.2. The first case study analyses a BTI named Computational Fluid Dynamics (CFD). CFD is a simulation technology developed by scientists that lead to the creation of a multibillion-dollar market and the transformation of a number of industries like the automotive industry (Hanna, 2015). The second case study analyses mobile Health (mHealth), a technological field that despite its great potential, hasn't yet been widely adopted due to a number of barriers (Labrique et al., 2013; WHO, 2016). Both case studies were carefully selected during the research design phase to represent two opposing poles with respect to innovation legitimation. As Eisenhardt (1989) recommends, the selection of contrasting case studies is an optimal strategy when the number of cases that can be studied is limited.

The case studies were conducted following a qualitative research approach with elite interviews of top experts and stakeholders as the main data source. To enhance data validity, as proposed by Yin (2003), interviews were triangulated with participant observation and document analysis. Moreover, as further discussed in section 3.7, other measures to enhance validity and reliability, like interview checks (Lincoln & Guba, 1985), were undertaken.

Research data was coded with N-Vivo 10 and thematic analysis was performed as described in section 3.6. As the result of the process, a set of propositions and a legitimation framework emerged, as discussed in sections 6.3 and 6.4 respectively.

The research takes a critical realist perspective (Bhaskar, 1989) that is consistent with both the underpinning theories and models used for the study, and the aim of the thesis. An in-depth discussion of the rationale for adopting a critical realist perspective is provided in section 3.2 and subsection 3.2.1.

1.6 Thesis structure

This thesis is structured as follows:

Chapter 2 offers a critical literature review on the main strands of innovation studies with the aim of identifying the best theoretical and analytical starting points for the analysis of BTIs. The chapter analyses Rogers' theory on Diffusion of Innovation (DOI), as well as different co-evolutionary innovation approaches like Studies of Science, Technology and Society (STS), Actor- Network Theory (ANT), Large Technological Systems (LTS), Multilevel Perspective (MLP) and Technological Innovation Systems (TIS). The last section of the chapter (section 2.7) provides a justification for the selection of TIS, as the most suitable theoretical and analytical starting point for the analysis of the formative phase of BTIs (see figure 1-1). Moreover, legitimation is identified as a critical and under-researched process during the formative phase. After that, the chapter finishes with a discussion on the identified gaps in TIS literature regarding legitimation and three research questions aimed at answering those gaps, and ultimately providing clarity on the mechanism leading to BTIs' successful diffusion trajectories.

Chapter 3 details the research methodology used in conducting the research. It discusses the philosophical considerations, the research approach and methods, the research context, the reliability and validity of data, the research ethics and the justification for the choice of research parameters like the selection of the case studies, the unit of analysis and the participants' profile. In addition, it provides the details regarding data collection and data analysis.

Chapters 4 and 5 analyse and discuss the two case studies in the thesis: the origins of Computational Fluid Dynamics, and mHealth technologies for diagnostics and chronic disease management, respectively. Data analysis is organised in four main areas of investigation and discussed in relation to relevant literature. As the result of the discussion of emergent themes, research findings are outlined.

The sixth and final chapter presents a summary of the research and a discussion of the attainment with respect to the research primary objective and the research questions. Following this, the chapter summarises the research findings and suggests a set of propositions that ground a framework attempting to explain the dynamics and strategies for the legitimation of TISs. The chapter continues with the research's contribution to theory, methodology and practice. The chapter ends by presenting the study's limitations and suggestions for future research.

1.7 Conclusions

This chapter has introduced the thesis by outlining the research rationale, aim and research questions. It has also provided an overview of the contributions made by this study to theory methodology and practice. The next chapter provides the reader with a review of the literature on different innovation strands with the aim of selecting the theoretical grounds for the study of BTIs.

Chapter 2 - Literature review

2.1 Introduction

As discussed in sections 1.2 and 1.3, despite its importance, there is a paucity of empirical research focusing on the early phases of innovation. Therefore, the aim of this literature review chapter is to identify, among the different strands of innovation studies, those that can better serve as a starting point to unfold the early dynamics of the innovation phenomena leading to innovation success or failure.

Classifying innovation literature is a complicated task. Innovation studies are characterised by a multiplicity of propositions that focus on different aspects of the phenomena, involve different levels of analysis and are grounded on different disciplinary literatures such as economics, organisational studies, entrepreneurship, marketing or sociology among others (Baregheh, Rowley & Sambrook, 2009; Crossan & Apaydin, 2010; Garcia & Calantone, 2002).

To accomplish the aim of the literature review, a narrative literature review approach was undertaken. As Bryman (2012) argues, a narrative literature review is the appropriate strategy when the review is a process of discovery in which the researcher cannot anticipate where it will take her. In contrast to systematic literature reviews, narrative literature reviews are wide-ranging in scope and less explicit about the criteria for inclusion and exclusion of studies. However, narrative reviews can incorporate practices from systematic reviews (Bryman, 2012). In this review, an exclusion criterion was applied to purely market perspectives or micro models entirely based on technology attributes[1]. The justification for the exclusion relies on the focus of the research on the early phases of BTIs. Moreover, as Bleda and del Rio (2013) contend, one of the few widely accepted premises of innovation research is that market factors are not the sole cause for BTI's failure, as internal dynamics in the environment where

[1] This includes for example New Product Development (NPD) and Technological Acceptance Model (TAM)

the innovation emerges can also block its development. The literature review process extended for more than a year. During this period, the researcher screened the most relevant journals and specialised books on innovation and technological change, and incorporated relevant publications into an EndNote database. Additionally, at the end of the review process, the researcher contacted via email and Researchgate three of the most cited scholars on Multilevel Perspective (MLP) and Technological Innovation Systems (TIS), who kindly answered her questions and provided additional references.

Consistently with the above discussion, this chapter provides the reader with an analytical and critical review of the most relevant models and theories that account for the early phases of the innovation process. The organisation of the chapter is as follows: section 2.2 analyses Rogers' Diffusion of Innovations (DOI) theory (Rogers, 1962; Rogers, 2003), as it is considered one of the most cited and used models in innovation studies. Section 2.3 analyses the grounds of evolutionary perspectives of innovation, where the phenomenon is analysed as the co-evolution of technology with society, firms, institutions etc. Section 2.4 focuses on Social Construction of Technology (SCOT) (Pinch & Bijker, 1987), Actor-Network Theory (ANT) (Callon & Latour, 1981), and Large Technological systems (Hughes, 1987), three theories based on the co-evolution of science, technology and society. Sections 2.5 and 2.6 analyse Multilevel Perspective (MLP) (Geels, 2005a) and Technological Innovation Systems (TIS) (Carlsson & Stankiewicz, 1991; Hekkert et al., 2007; Bergek et al., 2008a) respectively, two similar constructs grounded on the co-evolution of technology, firms and institutions. Finally, section 2.7 provides the reader with the conclusions and the justification for the theoretical and analytical starting points for the research. In addition, the gaps in the literature are discussed and three research questions are presented.

2.2 Diffusion of innovations

Innovation diffusion models have served as the primary tool to analyse technological innovation across different disciplines such as marketing, sociology, anthropology or economics (Hall, 2004; Meade & Islam, 2006; Rogers, 2003). Rogers' theory on diffusion of innovations (DOI) (1962) became the first general theory joining in a unified model the principles of different diffusion research traditions. Nowadays, Rogers' DOI is widely used within the innovation diffusion studies (Geroski, 2000; Rogers, 2003). Rogers (2004) estimates that in over 50 years of development of innovation diffusion theory, more than 5000 studies have been published in scholarly journals, with a rate of almost one study per working day in the first decade of this century. In the technological arena, Roger's theory has been extensively applied to many BTIs such as Internet, mobile technologies, online banking etc.(Gerrard & Barton Cunningham, 2003; Hsu, Lu & Hsu, 2007; Lee, 2004)

As figure 2-1 illustrates, innovation diffusion is characterised by a sigmoid function (S-curve) that plots how an innovation propagates over time. The steepness of the S-curve, called rate of adoption, is attributed to a number of different factors across the different innovation diffusion models [2] depending on the theoretical lenses and the unit of analysis.

The next two sections provide the reader with an in-depth critical analysis of Rogers' (2003) theory of diffusion of innovations (DOI), with a particular focus on how it accounts for the dynamics in the early stages of the innovation process.

2.2.1 Overview of Rogers' diffusion of innovations theory (DOI)

Rogers (2003, pp. 5-6) defines diffusion as: "*…the process in which an innovation is communicated through certain channels over time among the members of a social system […]*

[2] see reviews by Geroski (2000) and Meade and Islam (2006)

Diffusion is kind of a social change, defined as the process by which alteration occurs in the structure of a social system. When ideas are invented, diffused, adopted or rejected, leading to certain consequences, social change occurs…"

For Rogers (ibid), diffusion happens on a *heterophily* context in which adopters, individuals or organisations, differ in their disposition to accept the innovation. Those adopting it earlier (early adopters) act as change agents for the rest of the population. Therefore, critical mass, the point at which enough individuals have adopted the innovation that further diffusion becomes self-sustaining, is dominated by a communication process from early adopters to the rest of the social system (figure 2-1). As previously discussed, the focus of this research is on the early dynamics of the innovation phenomenon, or according to Rogers, on the dynamics before an innovation reaches (or not), enough critical mass to become self-sustaining.

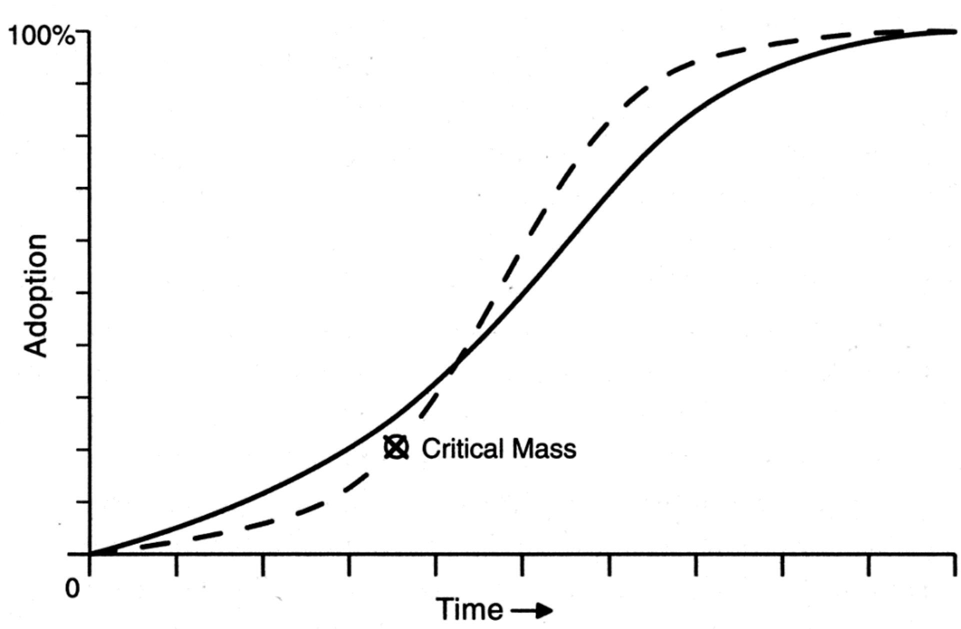

Figure 2-1 Critical mass in Rogers' DOI. (Rogers, 2003, p.344)

The decision to adopt or reject the innovation consists of five stages: (1) *knowledge*, when the potential adopter is exposed to the innovation and understands its functioning; *(2) persuasion*, when the adopter forms an attitude, favourable or unfavourable, towards the innovation; *(3) decision*, when the adopter engages in activities that lead to accept or reject the innovation; *(4) implementation*, when the adopter starts using the innovation; and *(5) confirmation*, when the adopter reinforces or reverses its decision.

Rogers states that the rate of adoption of an innovation depends on five main variables, as shown in figure 2-2. These variables are: *(i) perceived attributes of innovation, (ii) type of decision, (iii) communication channels, (iv) nature of the social system and (v) promotion efforts of the change agent.*

(i) The *perceived attributes of innovation* are the ones contributing most to the variance in the rate of adoption. Rogers establishes five perceived attributes of innovation: (1) *Relative advantage* is the degree to which an innovation is perceived as better than the idea it replaces. Advantage can be an economic or a social factor such as social prestige, satisfaction etc. (2) *Compatibility* is the degree to which an innovation is perceived as consistent with values, experiences and the needs of potential adopters. (3) *Complexity is* the degree to which an innovation is perceived as difficult to understand and use. (4) *Trialability* is the degree to which an innovation can be easily experimented and implemented. (5) *Observability* or the degree to which the results of an innovation are visible to others.

(ii) The *type of decision* also influences the rate of adoption. According to Rogers, collective decisions or decisions taken at an organisational lever take longer than individual decisions, particularly if the former are authority decisions and the latter optional. Therefore, optional decisions made by individuals are in general less complex and take less time than authority decisions made at an organisational level.

(iii) *Communication channels.* The type of communication channels employed to diffuse an innovation also have an influence on its rate of adoption. Rogers states that although mass media might be a satisfactory channel for less complex innovations, interpersonal channels to create awareness-knowledge, are often required to explain complex innovations or to reach late adopters. Consequently, if interpersonal channels are required, the rate of adoption is slowed.

(iv) *Nature of the social system.* Rogers defines a social system as: "a set of interrelated units that are engaged in joint problem solving to accomplish a common goal. The members or units of a social system may be individuals, informal groups, organisations, and/or subsystems." (Rogers, 2003,. p.24). According to Rogers, all members in the social system cooperate with the shared objective of solving a common problem. According to Rogers, the structures in the social system can facilitate or impede the diffusion of innovation in the system. The structures in the social system include formal and informal arrangements in the form of norms, beliefs, relationships and communication patterns between system members. As it will be discussed in sections 2.3 and 2.6, they are similar to the concept of formal and informal institutions (Bergek et al., 2008a). Despite the importance of the social system in the diffusion of innovations, Rogers acknowledges that compared to other aspects of diffusion research: "*there have been relatively few studies of how the social or communication structure of a system affects the diffusion and adoption of innovations in that system.*" (Rogers, 2003. p.25).

(v) *Extent of change agents' promotion efforts*. Finally, promotion efforts of the change agent also affect the rate of innovation adoption. According to Rogers, the relationship between the rate of adoption and the change agents' efforts, is not always linear and direct, as different stages of the innovation process provide greater payoffs than others. Rogers suggests that the greatest responses occur when opinion leaders are adopting, that is, in the early phases of the adoption process.

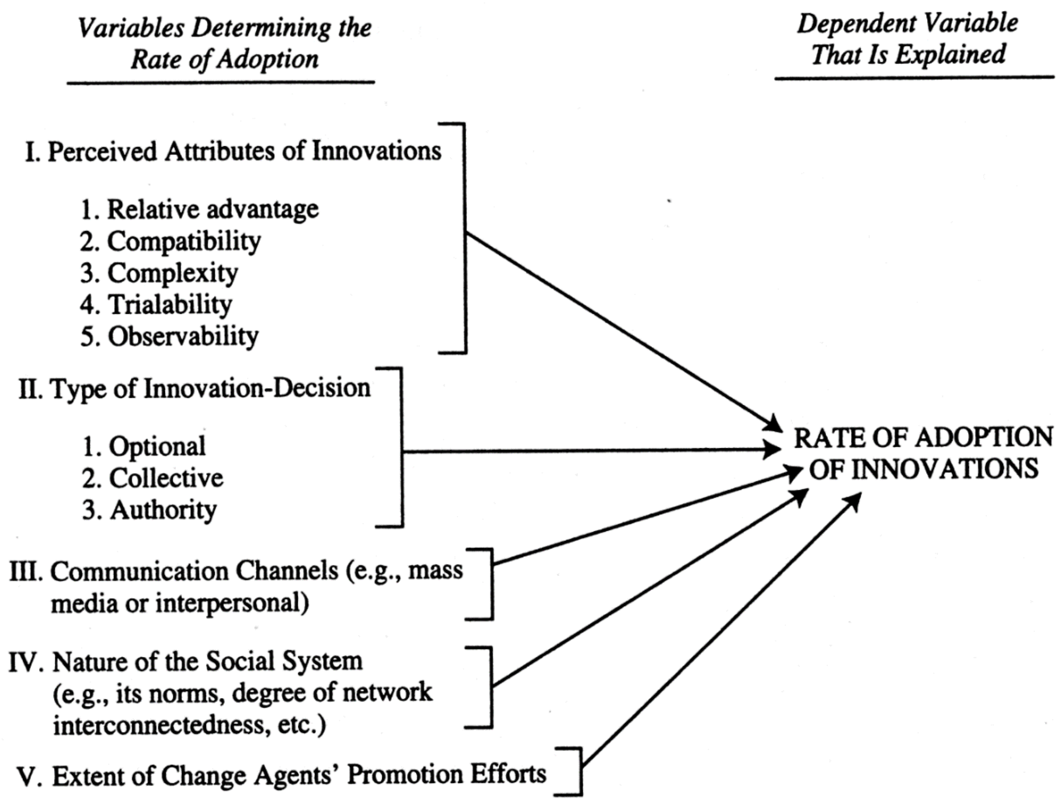

Figure 2-2 Rogers' DOI variables determining the rate of innovation adoption. (Rogers, 2003, p.222)

2.2.2 Criticisms to Rogers' diffusion of innovations theory

As previously discussed, Rogers' DOI is a seminal theory on innovation that has been applied to a large number of studies across different disciplines. According to Rogers (2003), major outcomes on Rogers' DOI studies relate to adopters' categorisation, opinion leadership, communication channels, decision process, perceived attributes and rate of adoption as represented in figure 2-2.

However, diffusion models seem to be insufficient to explain the dynamics of BTIs during the formative phases. As Rogers (2003) suggests, most of DOI studies focus on innovations once they've acquired critical mass. In this respect, Rogers reflects that future research should include the processes involved in shaping the innovation to its final form as:

"events and decisions occurring previous to this point have a considerable influence upon the diffusion process. The scope of future diffusion research should be broadened to include study of the entire process through which innovation is generated." (Rogers, 2003, p. 166).

In addition, and related to previous criticism, Rogers' DOI theory provides vague insights about the social systems that develop and adopt an innovation or about the social structures, in the form of formal and informal norms, that regulate those social systems. Rogers' DOI theory is guided by the assumption that the decisions triggering innovation diffusion, at individual or firm level, occur in a social system where the beliefs, values and interests of the majority of its members converge. Therefore, diffusion is mainly a communication process in which change agents and early adopters persuade other system members. Rogers defines this limitation as Pro-innovation bias: *"Pro-innovation bias is the implication in diffusion research that an innovation should be diffused and adopted by all members of a social system."* (Rogers, 2003, p. 106).

Rogers acknowledges that pro-innovation bias could be mitigated by studying the phenomenon beyond individual or firms' decisions and covering the process from its early R&D stages: *"One means of avoiding the pro-innovation bias might be to investigate the broader context of diffusion, such as the decision by a change agency to diffuse the innovation. A diffusion scholar might also study how the decision was made to begin R&D work to create the innovation, and how the innovation was shaped into its final form."* (Rogers, 2003, p. 114).
Finally, Rogers defends that further research on the influence of social systems and social structures should also be conducted. However, the scholar recognises that: "*it is a rather tricky business to untangle the effects of a system's structure on diffusion, independent from the effects of the characteristics of the individuals that make up the system.*" (Rogers, 2003, p.25).

Above discussed drawbacks suggest the need to further explore other theoretical approaches that look more in depth into the formative phases before BTIs acquire critical mass. Moreover, these new approaches should account on the influence of social systems and social structures, and to a certain extent, to better explore and reconcile agency and structure. Therefore, in the search of this, the next sections discuss co-evolutionary approaches to innovation.

2.3 Evolutionary approaches to innovation and technological change

As discussed in the previous section, the topic of this research requires perspectives that analyse innovation beyond a decision process of firms or individuals based on perceived technology attributes. Evolutionary perspectives of innovation and technological change analyse innovation as a change process in a wide network of actors and the institutions ruling them. Evolutionary theories have their grounding in evolutionary economics and studies of science, technology and society (STS) (Nelson, 1994; Nelson & Winter, 2002).

Evolutionary economics are founded in the work of Joseph Schumpeter and his *Theory of Economic Development* (Schumpeter, 1934). Schumpeter positioned individual entrepreneurship and technology innovation as the leading forces behind socio economic development. In his later work *Capitalism, Socialism and Democracy* (Schumpeter, 1962), capitalism is defined as a continuous evolutionary change driven by the creation of new markets, products, methods of production or new forms of industrial organisation that replace the existing ones. This form of progress is defined by Schumpeter as *Creative Destruction* (ibid). Based on Schumpeter's work, the studies of Nelson and Winter (1982) postulate that innovation is a collective social process where novelty is created in a process of selection among a variety of options. This process of variation, selection and creation, leads to technological trajectories (Dosi, 1982). In words of Dosi (1982) technological trajectories are the patterns in which organisations look for technological solutions to organisations' problems. Whereas incremental innovations progress along an existing technological trajectory, discontinuities and breakthrough innovations usually imply the emergence of new ones.

Evolutionary perspectives have grounded a wide range of theories, models and frameworks around innovation. For a broader appraisal of all of them, Geels (2005a) and Markard et al. (2012) provide excellent reviews. For the purpose of this research, this literature review will only focus on relevant models looking into technological change and the formative phases of innovation. As figure 2-3 shows, general evolutionary perspectives by Nelson and Winter (1977), Dosi (1982) or Freeman (1988) (left side of the figure) have led to different evolving constructs. The next sections examine those appearing in figure 2-3 as dotted-circled. In section 2.4, three different theories around Studies of Science, Technology and Society (STS) are examined. These include SCOT, ANT and LTS, all of them with a focus on the co-evolution of technology and society. On the other hand, Sections 2.5 and 2.6 analyse two similar and more recent constructs: Multilevel Perspective (MLP) and Technological Innovation Systems (TIS) respectively. As figure 2-3 shows, MLP takes input from STS studies and previous works on strategic niche management by Rip and Kemp (1998). TIS is based on previous studies on systems of innovation (Carlsson & Stankiewicz, 1991; Edquist, 1997) and Large Technological Systems by Hughes (1987). Both MLP and TIS, extend the analysis to the co-evolution of institutions and markets (Geels, 2005a) and are the most cited studies in the field of sustainable technological transitions (Markard et al., 2012).

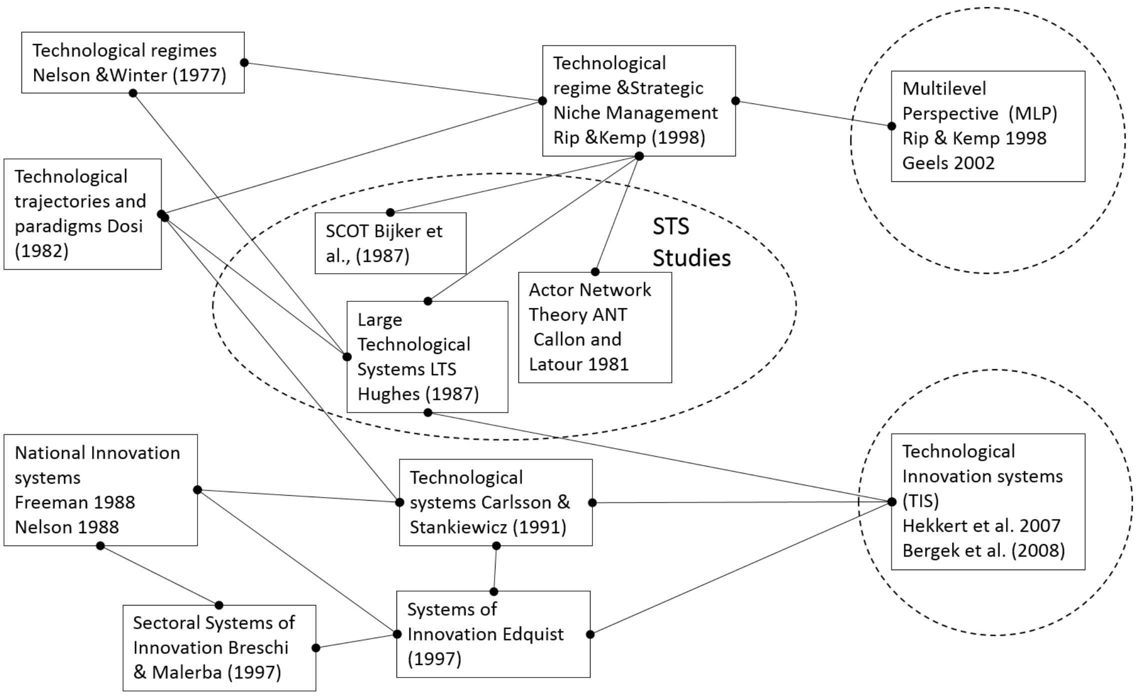

Figure 2-3 Research strands on innovation evolutionary approaches. (Adapted from Markard et al., 2012)

2.4 Studies of Science, Technology and Society (STS)

Societal factors play an important role in the early phases of the innovation process (Geels, 2005a). As a discipline, sociology is key to explain failed innovations (Mac Vaugh & Schiavone, 2010). The core of co-evolutionary studies of society and technology are the Studies of Science Technology and Society (STS). STS contemplate technological innovation as a phenomenon that fulfils a societal function like transportation, healthcare, supply of energy etc. (Geels, 2005a). This fulfilment is accomplished by socio-technical systems. As shown in figure 2-4. socio-technical systems, the central concept on STS studies, consist of a cluster of elements that include technology, regulations, user practices, markets, values, cultural meanings, infrastructure and maintenance and supply networks (Geels, 2005b). The basic idea on STS studies is that technology (artefacts) on one hand, and social functions (like regulation, user practices and markets or cultural meaning) on the other, fulfil societal needs. The notion of socio-technical systems was originally developed by Trist (1981) to study the relation of technology and individuals at the workplace and has later played a critical role in co-evolutionary models of innovation (Geels, 2005a; Bergek, 2008a).

This section analyses the most relevant models in STS studies (Geels, 2005a). The analysis focuses on the early phases of the innovation process. The analysed models are Social Construction of Technology (SCOT) (Pinch & Bijker, 1987; Bijker, 1997), Actor- Network Theory (ANT) (Callon & Latour, 1981; Latour, 1987, 2005; Law, 2009) and Large Technological Systems (LTS) (Hughes, 1987).

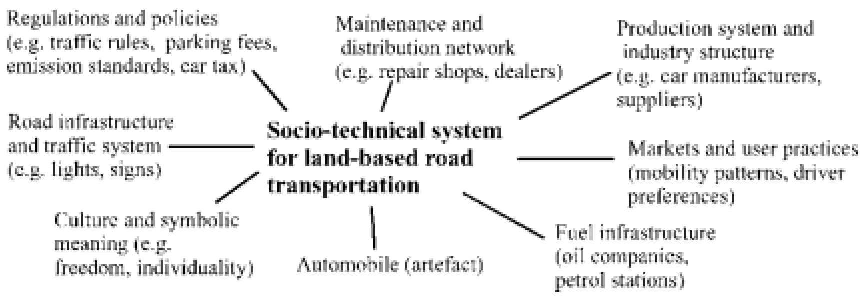

Figure 2-4 Socio Technical system for car transportation. (Geels, 2005b, p. 446)

2.4.1 Social Construction of Technology (SCOT)

Social construction of technology (SCOT) (Bijker, 1997; Pinch & Bijker, 1987), focuses on the role of relevant social groups to shape technology. In SCOT, the process of shaping technology is essentially a process of variation and selection of problems and solutions that translate, as a result, into new artefacts (Bijker, 1997). The dynamics can be explained through a conceptual framework of three components: *interpretive flexibility, relevant social groups* and *closure/stabilisation* (Bijker, 1997).

The first component, *interpretive flexibility,* suggests that artefacts do not emerge with a closed design. Technological artefacts present different designs that evolve over time until the final one is shaped by the negotiations of the involved social groups. The second component, *relevant social groups*, represents the different groups where all the members share the same set of meanings for a specific artefact. The development of the technology is then the process of negotiation between these different groups and their different meanings and views on the technology. As described in Bijker's study on the evolution of bicycle designs, different meanings of the artefact for the different social groups, such as social or gender status or working/non-working machine, created a diversity of prototypes and models in the 18thand 19th centuries. Finally, the third component, *closure and stabilisation,* represents the final stage where the artefact is accepted by all the relevant social groups and thus it presents its final layout.

Bijker (1997), adds the concept of *technological frame* to structure the interactions among actors within a social group. In the words of Bijker (1997): "*technological frame is not an individual's characteristic, nor a characteristic of systems or institutions; technological frames are located between actors, not in actors or above actors.*" (Bijker, 1997, p. 123). Technological frames incorporate as elements of interaction: goals, key problems, problem-solving strategies, requirements to be met by problem solutions, current theories, tacit knowledge, testing procedures, design methods and criteria. A technological frame is built up when the members in a relevant social group move in the same direction and constitute meaning for the technology through their alignment around the elements of their technological frame.

Bijker (1997) describes three different possible configurations attending to competing technological frames and relevant groups. The first configuration occurs when there is not a dominant group. Under this context innovation will flourish smoothly if sufficient resources are available. The second configuration occurs when there is a dominant group capable of enforcing the definition of problems and appropriate solutions. In this monopolistic situation, innovation is more likely to be conventional. Finally, the third configuration exposes two or more confronted groups with divergent technological frames. In this situation, the closure process can become erratic, and "arguments, criteria and considerations that are valid in one technological frame will not carry much weight in other frames." (Bijker, 1997, p. 279). External factors will play an important role in this configuration. The confrontation of social groups with differing technological frames can lead to an "amalgamation of vested interests" in which none of the social groups wins a total victory. As a consequence, innovations will be doubly conventional as they need to satisfy all relevant social groups.

According to Klein and Kleinman (2002), SCOT configurations represent rather descriptive and insufficient constructs to explain why innovations succeed or fail. Firstly, SCOT assumes that all relevant groups contribute to shape technology, neglecting power differences between relevant social groups: "*There are no actors or social groups that have special status. All relevant social groups contribute to the social construction of technology; all relevant artefacts contribute to the construction of social relations.*" (Bijker, 1997, p.288). Consequently, technological frames should be better developed to include the role of institutions that account for power: "*An adequate understanding of the limits of interpretive flexibility, stabilisation and closure requires attention to power asymmetry.*" (Klein & Kleinman, 2002, p. 35).

In summary, as it will be further discussed in section 2.4.4, the central criticism to SCOT relates to its myopia towards power and poor acknowledgment of the structures and institutions that contribute to develop or hamper innovation (Klein & Kleinman, 2002; Winner, 1993).

2.4.2 Actor- Network Theory (ANT)

Actor- Network theory (ANT) (Callon & Latour, 1981; Latour, 1987, 2005; Law, 2009) can be viewed as a subset of SCOT (Winner, 1993; Meyer, 2006). While in SCOT relevant social groups shape technology, ANT states that artefacts and humans are mutually and symmetrically shaped. In ANT stabilisation occurs through the linkages between actors and networks in a seamless web in which all human and non-human actors intervene at the same level to mutually shape the socio technical system. In the words of Law: *"the distinction between human and non-human is of little analytical importance."* (Law, 2009, p.147).

Law (2009) states that the Actor- Network approach is not a theory, but a toolkit that describes: *"…the enactment of materiality and discursively heterogeneous relations that produce and reshuffle all kind of actors including objects, subjects, human beings, machines, animals, nature, ideas, organisations, inequalities, scales and sizes and geographical arrangements…*" (Law, 2009).

In the early phases of a new technology, networks are constituted by a small number of elements and linkages. The innovation succeeds as long as networks enrol sufficient allied bodies and align their interests in a process of *enrolment* and *translation*. As a consequence, more linkages are created, leading to stabilised networks and *closure*. In ANT, closure results in *black-box* artefacts that are taken for granted and become irreversible. The irreversibility of an element in a network depends on the extent to which it is impossible to go back to a point where alternatives exist, and the extent to which the element shapes and determines future enrolments in the network (Callon, 1990).

ANT has been applied in many empirical studies: see Walsham (1997) for a recollection or more recent studies on technology adoption in sectors like healthcare (Greenhalgh et al.,2010; Bleakley, 2012), education (Fenwick et al., 2010) or urban research (Farías & Bender, 2012). However, ANT has been also subject to strong criticism. The focus of the main disapproval is the indistinctness between human and non-human actors (Alcadipani & Hassard, 2010). With this, power becomes an unresolved issue, as the social and technical spheres (human and non-human) account equally in the process of negotiation and translation.

Additionally, Miettinen (1999) stresses that in an innovation network the number of potential elements become unlimited and impossible to manage, as ANT does not provide the tools to select who are the relevant actors and linkages. Moreover, Geels (2005a) states that while the focus in ANT is on the micro level linkages that lead to enrolment and translation, it fails to explain how that is transformed into new structures at meso and macro level. ANT scholars incline to not separate the micro and macro level as: *"the same relational logics apply at any scale."* (Law, 2009, p. 147).

2.4.3 Large Technological Systems (LTS)

Large Technological Systems (LTS) (Hughes, 1987), describe a system or "seamless web" network of big complexity that contains different problem-solving components. Components of a LTS include technological artefacts, key actors, firms, knowledge and legislative artefacts like scientific articles and regulatory laws respectively etc. LTS studies look at how the linkages between all the socio-technical components of the LTS provide stability and ultimately "momentum" (Hughes, 1987). *System builders*, like Edison in the case of electricity systems, are heterogenous engineers that work not only in the development of technical artefacts. They also persuade potential adopters, transfer knowledge through texts, conferences etc., participate in the development of regulations, attract experts and capital into the system and develop initial markets. Through the activity of *system builders*, the components of a LTS are articulated and aligned through linkages at different levels: between firms, regulatory bodies, educational institutions etc. Once linkages are aligned and established, LTS acquire momentum. The higher the momentum, the more likely that a LTS will continue along its trajectory. Together with momentum, Hughes (1987), defines different phases for the emergence and development of LTS. These are: (i) invention, (ii) development, (iii) innovation, (iv) growth, competition and consolidation, and as previously described, (v) momentum.

Acquiring momentum, as discussed, is a consequence of the alignment of social and technical elements, which indicates that directionality in a LTS is aligned with the notion of technological regimes and trajectories postulated by evolutionary perspectives (Nelson & Winter, 1982; Dosi, 1982). According to Geels (2007, p.124), in LTS: *"trajectories are not only stabilised by beliefs but also by social and technical linkages, vested interests, regulations, infrastructures, and so on…".*

The central criticism around LTS is its lack of attention to radical innovations that substitute previous well-established technologies (Summerton, 1994; Geels, 2007). In other words, LTS does not account for technological replacement. Moreover, LTS is an agency oriented perspective focused on the linkages created by system builders. Although it accounts for the effect of regulation, vested interests etc. in the creation of linkages and ultimately, technological trajectories, LTS does not provide a framework to analyse breakthrough innovations at its infant state. All the empirical studies relate to historical radical innovations like the electrification of the United States (Hughes, 1987), the development of the first ballistic missile, the ARPANET (precursor of Internet) and the SAGE air radar system (Hughes, 1998).

A search on Google scholar suggests that over the last years, there hasn't been many LTS empirical studies. However, as shown in figure 2-3, its contribution on system builders is much present in the technological innovation systems (TIS) literature. These links are further analysed in section 2.6.

2.4.4 Criticisms to SCOT, ANT and LTS

As described in sections 2.4.1 to 2.4.3, SCOT, ANT or LTS present several limitations for the analysis of the early phases of breakthrough technological innovations. Although SCOT conceptualises the interaction between the elements of the socio-technical system through the concept of *technological frame*, its operationalisation is insufficient to explain the emergence of innovations beyond three descriptive configurations (Winner, 1993). As Klein and Kleinman (2002) suggest, the institutions accounting for power should be further developed and included in the technological frame. ANT, is also criticised for its myopia towards power structures (Alcadipani & Hassard, 2010), as well as its micro level focus that fails to explain the large amount of linkages in an innovation network (Geels, 2005a; Miettinen, 1999). LTS, as discussed in section 2.4.3, presents two main criticisms: the first is that it is unable to account for technology replacement (Summerton, 1994; Geels, 2007). Secondly, it doesn't provide satisfactory tools to analyse in a non-retrospective manner the linkages occurring during the formative phases of the phenomenon.

These criticisms, suggest that STS approaches to innovation such as SCOT, ANT or LTS require in addition, structural perspectives that embed the role of institutions and power. In the words of Winner:,*"…they regularly succeed in tracking a great deal of intense activity around technological developments of various kinds. They also show us the fascinating dynamics of conflict, disagreement, and consensus formation that surround some choices of great importance. But as they survey the evidence, they offer no judgment on what it all means, other than to notice that some technological projects succeed and others fail, that new forms of power arise and other forms decline..."* (Winner, 1993, p. 375).

The next two sections analyse Multilevel perspective (MLP) and Technological Innovation Systems (TIS), two similar constructs that incorporate structure and institutional perspectives into the socio-technical system approach.

2.5 Multilevel perspective (MLP)

2.5.1 MLP overview

Multi-level perspective (MLP) by Geels (2005a), is a mid-range theory grounded in the work of Rip and Kemp (1998) that integrates sociology, evolutionary economics, and innovation studies perspectives. MLP defines "system innovation" as the transition from one existing socio-technical system to a new one. In MLP, "system innovation" [3]is an innovation that produces not only a new product or process, but a whole new socio-technical system including: new productions systems, infrastructures, markets, user practices, regulation etc. (Geels, 2005a). In

[3] "System innovation" (Geels, 2005a) is equivalent to breakthrough or architectural innovations. It is important to distinguish "system innovation" from "systems of innovation". The latter, "systems of innovation" are theoretical constructs that include National systems of innovation or Technological innovation systems. They are discussed in section 2.6.

essence "system innovations" is comparable to the definition of BTI provided in section 1.1 (Garcia & Cantalone, 2002).

MLP distinguishes between three different levels of analysis to explain the transition between socio-technical systems: *niches, socio-technical regimes and landscape.* System innovations occur when niche technologies become new socio-technical regimes with the stimulus of favourable landscape conditions (figure 2-5).

Niches define the environment where radical innovations emerge. Due to their novelty and low initial performance, these innovations cannot compete in mainstream markets, and some initial protection is required. Niches occur in two overlapping phases: technological niches and market niches. In technological niches, protection to the emergent innovation is provided by public organisations or investment firms. In market niches, protection is provided by incipient market transactions that sustain the niche.

Regimes *(or* ***socio-technical regimes****)* define the coordination between the different groups of actors to define a web of rules, practices and standards that stabilise the system. Geels (2005a) defines five socio-technical regimes: technological, science, user/market, policy and socio-cultural. These regimes evolve dynamically and conform technological trajectories as defined by Dosi (1982): whereas socio-technical regimes are internally stabilised through incremental innovation along an existing technological trajectory, radical or system innovations, in contrast, create new technological trajectories by substituting the existing socio-technical system with a new one.

Landscape refers to the external circumstances that stimulate certain technical trajectories and not others. Landscape factors include aspects such as economic growth, political agendas, cultural and normative values, public debates, resource scarcities, wars, etc.

Geels (2005a), establishes a generic set of contexts that can favour the transition of socio-technical regimes. These are called *windows of opportunity* and include: internal problems or bottlenecks in the existing regime, negative externalities such as environmental impacts, change in user preferences not met by established technologies, strategic and competitive games between firms and availability of complementary technologies. These windows of opportunity facilitate the transformation of niches into new socio-technical regimes.

In MLP, the evolution of niches into new regimes, occurs as a gradual process of *niche accumulation*. In the beginning, niches start serving a functionality in the existing regime and from there, niches expand their capabilities to new application domains until they become the new socio-technical regimes. In a later work, Geels and Schot (2007), refine the concept of *trajectories of niche accumulation* and identify five prototypical transition pathways from niche to regime according to the variations in timing and nature of the multi-level interactions. The disruptiveness of the change will mainly depend on the pressure from the landscape level and the maturity of the niche innovations. These pathways, that can take place sequentially in the event of high and enduring landscape pressures, are: *reproduction, transformation, de-alignment and re-alignment, technological substitution and reconfiguration.*

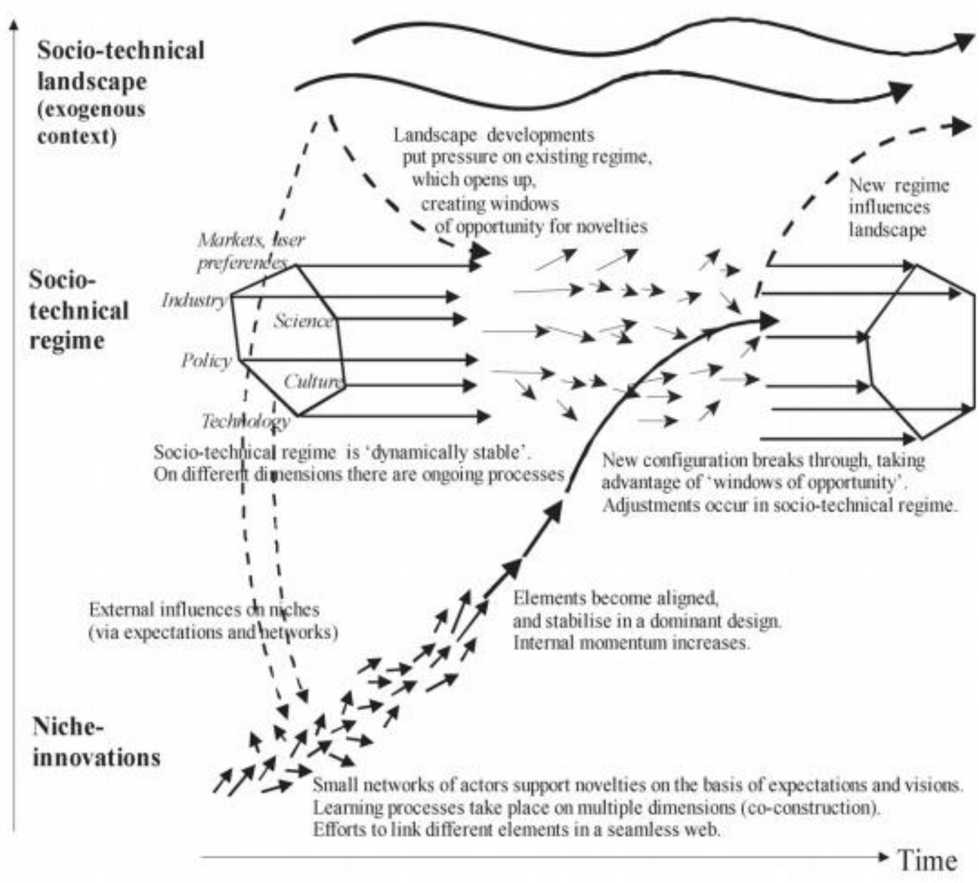

Figure 2-5 Overview of Multi-level perspective. (Geels & Schot, 2007, p. 401)

Reproduction: In absence of external landscape pressures (like public debates against the existing regimes, change in economic or political agendas etc.), regimes remain stable and radical niche innovations have little chance to succeed. In these contexts of non landscape pressures, incremental innovations will increase the performance of the existing socio-technical regime.

Transformation: Under moderate landscape pressure (see figure 2-5) at a moment when niche innovations are not yet mature, social actors in the regime will use their adaptive capacity to reorient development trajectories, changing the regime from inside through cumulative adjustments. Niche innovations will be embedded into the regime without disrupting it.

De-alignment and re-alignment: If landscape pressure is high and niche innovations are not sufficiently developed, the regime will be destabilised and the emergent niche innovations will co-evolve and compete for attention and resources until one becomes dominant and re-aligns the institutional framework of the new regime.

Technological substitution: If landscape pressure is high and niche innovations are sufficiently developed, they will likely breakthrough and replace the existing regime. This path assumes that regime actors will pay little attention to innovations developed by outsider actors.

Reconfiguration: In this context, niche innovations fit well in the existing regime and can be easily adopted. They are accepted as they improve performance and do not significantly transform the rules of the game in the regime. This pathway is similar to the *transformation* pathway, but in the *reconfiguration* case, the niche innovations although incremental in their origin can open up the space for future major reconfigurations in case of landscape pressure.

2.5.2 Criticisms to Multilevel perspective

MLP is subject to several criticisms (Genus & Coles, 2008; Smith et al., 2005; Markard & Truffer, 2008; Smith et al., 2010). These flaws can be summarised as:

(i) Use of historical case studies with lack of systematic methods for data analysis.

(ii) Overly functionalistic theory that neglects agency.

(iii) Poor definition and operationalisation of MLP regime concept. As a consequence, MLP hinders the dynamics inside a regime that result in different groups of actors maintaining incumbent technologies or enabling radical innovations.

(iv) Related to the previous criticism, power and politics at regime level not taken into account.

(v) Lack of functional distinctions between the levels. For example, distinction between nests of niches and sectoral level.

(vi) Focus on winning technologies.

(vii) Landscape pressures are insufficient to solely explain regime destabilisation or acceptance of radical technologies.

Geels (2011), responds to these criticisms and suggests that the main drawback on MLP relies on the definition and operationalisation of the concept of *regime*. As defined in section 2.1.5, a *regime* defines the coordination between the different groups of actors to define a web of rules, practices and standards that stabilise the system. However, as Geels (2011) contends: *"I agree with the critics that empirical studies sometimes use 'regime' as shorthand for 'system'[…] The reason is probably that these empirical studies tend to be interested more in the macro-patterns of transitions than in the micro-sociological dynamics of innovation acceptance. […] System then refers to tangible and measurable elements […] whereas regimes refer to intangible and underlying deep structures (such as engineering beliefs, heuristics, rules of thumb, routines, standardised ways of doing things, policy paradigms, visions, promises, social expectations and norms). So 'regime' is an interpretive analytical concept that invites the analyst to investigate what lies underneath the activities of actors.*" (Geels, 2011, p.31).

Consequently, as suggested by Smith et al. (2010), a better definition and operationalisation of regimes, should account for politics and power in order to understand how certain regimes and not others are accepted. "*How do entrenched regimes, upon which many of us are dependent, lose their economic and social legitimacy*?" (Smith et al., 2010, p. 446).

The next section analyses the systems of innovation strand, and in particular, technological innovation systems (TIS). TIS and MLP are closely related models in the study of innovation and technological change (Markard & Truffer, 2008). As previously quoted by Geels (2011), whereas regime (in MLP), is an interpretative analytical concept to define intangible structures, TIS provides more tangible analytical frameworks to assess the interactions between key actors, networks and the institutions (formal and informal) ruling them. They are further discussed in sections 2.6.1 and 2.6.2.

2.6 Systems of Innovation and Technological Innovation Systems (TIS)

Systems of innovation (SI) studies are built on general system theory and co-evolutionary perspectives of innovation (Nelson, 1982; Nelson & Winter, 2002). SI grounds on co-evolutionary approaches are discussed in section 2.3 and represented in figure 2-3. As in any system, systems of innovation (SI) consist of two main parts: (i) components and (ii) the relations among them. To function as a system, components need to form a coherent whole, fulfil a function and operate within delimited boundaries (Edquist, 2005).

Systems of innovation operate at 3 different levels of analysis: National or Regional (Nelson, 1988), Sectoral (Breschi & Malerba, 1997), and Technological (Carlsson & Stankiewicz ,1991; Hekkert, 2007; Bergek et al., 2008a). National, regional and sectoral systems of innovation look for comparable indicators between systems. These indicators might include: sources of production of innovation, public and private research efforts, quality of educational systems, collaborations between public and private research centres, venture capital availability etc. (Adams et al., 2013; Hekkert & Negro, 2009). Studies conducted at national, regional or sectoral level typically involve large numbers of actors, institutions and complex relations among them, making the dynamics of innovation and technological change difficult to map (Hekkert & Negro, 2009). By contrary, studies conducted at the technology level, particularly TIS, entail a more manageable number of actors, institutions and relationship complexity offering a reliable framework for the analysis of technological change dynamics (Bergek et al., 2008c; Hekkert & Negro, 2009).

As the overall focus of this research is to unfold the dynamics of the early phases of breakthrough technological innovations, the remainder of this section concentrates on the analysis of systems of innovation at technological level, that is, the analysis of technological innovation systems (TIS).

Technological Innovation Systems (TIS) can be defined as *the set of actors, networks and institutions that contribute to the overall function of developing and diffusing new products and processes* (Bergek et al., 2008a). A TIS can be part of a sectoral innovation system or involve different sectors. Also, it can be tied to a geographical dimension or be international. As previous innovation theories and models analysed in sections 2.4 and 2.5, TIS makes use of the socio-technical system concept, *"…we focus on technological innovation systems (TIS) …, i.e. socio-technical systems focused on the development, diffusion and use of a particular technology (in terms of knowledge, product or both) …"* (Bergek et al., 2008 a, p.408).

In a TIS, the interactions between components (actors, networks and institutions) are grouped under a set of sub processes named *functions*. Bergek et al.(2008a) define seven functions: *entrepreneurial experimentation, knowledge development, development of positive externalities, market formation, resource mobilisation, guidance on the direction of the search and legitimation.* The main purpose of the functions is to assess the performance of the TIS, its drivers and blocking mechanisms to set the basis for policy and strategic intervention (Bergek et al., 2008a; Hekkert et al., 2011).

As Hekkert et al. (2011) summarises: *"the structure presents insight in who is active in the system, the system functions present insight in what they are doing and whether this is sufficient to develop successful innovations."* (Hekkert et al., 2011, p. 4). The next subsection provides a detailed analysis of the structural components and functions of a TIS.

2.6.1 Structural components of a TIS

The structural components of a TIS are actors, networks and the institutions ruling them (Bergek et al., 2008a).

Actors are individuals, firms, and organisations that contribute to the development of the TIS. These can be universities, research institutes, public bodies, industrial associations, venture capitalists etc. Different TIS scholars (Hellsmark & Jacobsson, 2009; Musiolik et al., 2012; Kukk et al., 2016) have highlighted the relevance of *system builders* (Hughes, 1987) as a key subset of

TIS actors. As discussed in section 2.4.3, s*ystem builders* are critical agents in the development of breakthrough innovations (Hughes, 1987). In a TIS, system builders can be prime mover firms, entrepreneurs, organisations or any other actors interested in developing the conditions for them or for others to start companies or for the incumbents to develop new business opportunities (Hellsmark, 2010) As Kukk et al. (2016) argue, system builders take the role of institutional entrepreneurs and are able to shape institutions in the best interests of the technology. In highly institutionalised contexts or in the very early phases of the TIS, system building capabilities are most likely to be developed as a collective effort through networks (Musiolik et al., 2012).

Networks in a TIS are developed to deal with the non-market relations between actors, typically in the form of exchange of information, values and knowledge (Carlsson & Stankiewicz, 1991). As a differentiated structure to firms and markets, networks can be formal or informal. They might include standardisation or professional networks, public–private partnerships, industry-university links etc. Political and knowledge networks are important for the legitimation of a TIS during its formative phase: they act as advocacy coalitions to develop system building capabilities and to create a favourable environment for the TIS (Bergek et al., 2008b) . However, Hellsmark (2010) states that during the early phases of a TIS, different networks advocating for different technological trajectories might undermine the development of the TIS: " *…in a given TIS, there may be several advocacy coalitions, where each is typically associated with a specific technological trajectory. They consist of a range of actors with shared beliefs and compete to influence policy in line with these beliefs[…].However, the raging conflicts that characterise the early phase of a TIS typically undermine efforts to form advocacy coalitions and, therefore, the possibility of institutional alignment…*" (Hellsmark, 2010, p. 25).

Institutions include all the activities that rule the interactions between actors and networks. Institutions can be hard, like regulations controlled by juridical systems, or soft, like beliefs, values, norms and other cognitive rules controlled by social systems (Bergek et al., 2008b). As explained in other perspectives analysed in this chapter, see section 2.4.1 for SCOT (Bijker, 1997) or section 2.5 for Multilevel perspective (Geels, 2005a) , norms and cognitive rules influence the actions and decisions towards a specific closure process or trajectory. As North (1994, p.2) contends: "*Institutions are created by humans to structure human interaction in order to reduce uncertainty in pursuit of their goals (of those making the rules) in social, political and economic exchange. I define institutions as the formal rules (constitutions, statute and common law, regulations, etc.), the informal constraints (norms of behaviour, conventions, and internally imposed codes of conduct), and the enforcement characteristics of each.*"

The alignment between the new technologies, organisations and surrounding institutions is called ***institutional alignment***. Institutional alignment is key for TIS to acquire "momentum" (Hughes, 1987) and move from formative to growth phase (Bergek et al., 2008a; Hellsmark, 2010). However, the process of institutional alignment might result in complications for certain systems. As North (1994, p.361) contends, institutions are created: *"… to serve the interests of those with the bargaining power to create new rules…"* For example, mature and large technical systems (such as energy, healthcare or transportation) are dominated by a few large incumbent actors with considerable bargaining power. In these systems, institutional alignment results in a complex process dominated by uncertainty and conflicting interests between incumbent and entrant players (Hellsmark, 2010). Institutional alignment is tightly coupled with legitimation, a TIS function analysed in detailed in section 2.6.3.

2.6.2 Functions of a TIS

The functions of a TIS are a set of inter-related processes that measure the functioning and overall performance of the TIS: if the functions perform well, the TIS will successfully develop and in consequence, innovation will diffuse satisfactorily. Following on Bergek et al. (2008a) framework[4], TIS functions can be defined as: *entrepreneurial experimentation, knowledge development, development of positive externalities, market formation, resource mobilisation, influence on the direction of the search and legitimation.* Table 2- 1 provides a brief description of these functions.

Table 2-1 Functions in a TIS. Adapted from Bergek et al. (2008a)

TIS function	**What does it measure?**
Entrepreneurial experimentation	Trial and error activities that contribute to reducing uncertainty in the TIS and unfolding the learning process.
Knowledge development	Knowledge base and diffusion over time within the TIS. It distinguishes between different types of knowledge and different sources of knowledge.
Legitimation	The dynamics on how the TIS gains acceptance from all the relevant actors and stakeholders, in a context where competition from adversaries and incumbent TIS defenders, can lead to different manipulation strategies to legitimate the new TIS.
Market formation	It distinguishes three different phases in the formation of a new market: nursing markets, bridging markets and mass market (only if the TIS succeeds).

[4] See Bergek et al. (2008a, p. 426) for a comparison of TIS functions respect to other authors and analytical frameworks.

Resource mobilisation	The ability of the TIS to mobilise human and financial capital resources and complementary assets, such as complementary products or services, infrastructures etc.
Development of positive externalities	The collective dimension of the innovation and diffusion process. For instance, how investments by one firm can benefit others "free of charge", or how the development of a priori competing technologies can have a positive influence in the development of the TIS in focus. Examples: emergence of pooled labour markets, emergence of specialised intermediate providers, information flows and spill-overs.
Influence on the direction of search	The combination of incentives and pressures that actors have when deciding to enter a TIS (visions, expectations, belief in potential growth…), mechanisms in terms of competing technologies or business models, and external factors like demographic or economic debates.

Although the system nature of TIS might suggest that functions evolve as an orchestrated action, Bergek et al. (2008a) acknowledges that functions might emerge as unplanned and initial weak interactions, especially during the very early phases, when exogenous factors may dominate as the system components are still underdeveloped. As the TIS grows, the endogenous factors may gain strength, and strong interdependences between functions might be formed. Additionally, it can be expected that different actors might pursue different goals and have different conflicting interests in the development of a TIS. As Bergek et al. (2008a) suggest*: "Moreover, interaction between components may be unplanned and unintentional rather than deliberate even in a more developed innovation system. Using the notion of an 'overall function' does not imply that all actors in a particular system exist for the* *purpose of serving that function or are directed by that function. Actors do not necessarily share the same goal, and even if they do, they do not have to be working together consciously towards it (although some may be). Indeed, conflicts and tensions are part and parcel of the dynamics of innovation systems. Clearly, we do not see the system's components as directed or orchestrated by any specific actors." (Bergek et al. , 2008a, p. 408).*

To facilitate the analysis of a TIS and its complex dynamics and dependencies, its development can be divided into different phases. Bergek et al. (2008) suggest two differentiated periods: *formative* and *growth*. In the *formative* phase, the structures supporting the TIS, especially the technologies and markets, are rudimentary as the whole system is subject to a great deal of uncertainty. On the contrary, during the *growth* phase, the diffusion of selected technologies starts and markets move from nursing to bridging and ultimately mass markets (Bergek et al., 2008a). Hekkert et al. (2011) define, on the other hand, 5 phases in the development of a TIS: *pre-development, development, take-off, acceleration* and *saturation*. In the *pre-development* phase, prototypes are typically produced to evidence that technology works. Then, in the *development* phase, first commercial applications are sold. In the *take-off* phase, the technology diffuses on a larger extent, leading markets to the *acceleration* phase until *saturation* occurs, and diffusion is stabilised. Figure 2- 6 plots a diffusion S-curve along the different TIS phases defined by Bergek et al. (2008) and Hekkert et al. (2011) together with the critical TIS functions in each phase as stated by the scholars.

Hekkert et al. (2011) suggest that in the early phases of development of a TIS, knowledge development and entrepreneurial experimentation are the critical functions (figure2- 6). Knowledge development is central to the evolution of a TIS: in particular, how it is created and employed over time by the actors. In addition, entrepreneurial experimentation contributes to reduce uncertainty through trial and error efforts in demonstrations, pilots etc. The rest of the functions are also important in this phase as they can influence negatively or positively the entrepreneurial efforts. (Hekkert et al., 2011). For instance, *influence on the* *direction of the search* guides the visions and expectations of the actors on the potential of the technology and in the adoption of competing designs, new business models or different markets. However, if the visions of the actors are contested or they do not perceive a clear incentive in the innovation, the whole TIS can be blocked (Bergek et al., 2008a). Additionally, the development of positive externalities, in the form of complementarities offered even by a priori competing technologies, can play an important role in accelerating system growth (Bergek et al., 2008b). However, the take-off of the TIS or, in other words, the transition from the formative phase to the growth phase (see figure 2-6), won't succeed if the innovation is not legitimated (Bergek et al., 2008a; Bergek et al., 2008b; Hekkert et al., 2011). Legitimation, is therefore, the crucial TIS function to complete the formative phase of a TIS and move it to wider diffusion. The next section discusses in depth the insights of the legitimation function.

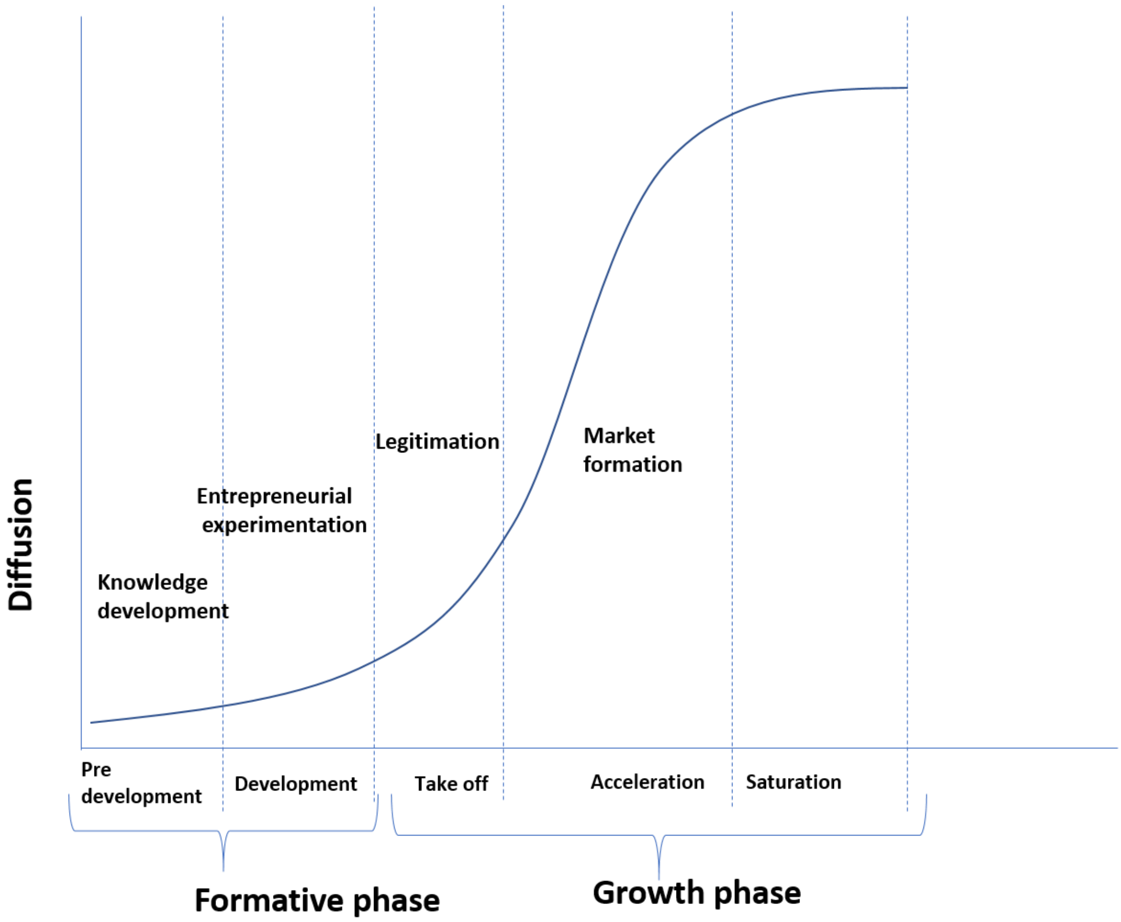

Figure 2-6 Critical functions in TIS development. Adapted from Bergek et al. (2008a) and Hekkert et al. (2011)

2.6.3 Legitimation, a critical function in the formative phases of TIS

Section 2.6.1 concluded highlighting the importance of institutional alignment for a TIS to gain momentum and succeed in its diffusion. Moreover, it was argued that institutional alignment is tightly coupled to the legitimation function. Section 2.6.2 presented the different functions of a TIS, and as shown in figure 2-6, it was argued that legitimation becomes a critical function for the take-off of an innovation (Hekkert et al., 2011), or as Bergek et al. (2008b) contend, critical to move the TIS from the formative to the growth phase. As the overall topic of this research is to unfold the early dynamics of BTIs leading to innovation success or failure, the rest of this section focuses on an in-depth analysis of the legitimation function.

Legitimation, is defined as the process of acquiring social acceptance and compliance with the relevant actors and institutions such as norms, values, beliefs etc. (Bergek et al., 2008b). As contended by Stinchcombe and March (1965), acquiring legitimation is a necessary condition to overcome the 'liability of newness'. TIS scholars argue that: "*legitimation involves getting the technology accepted as a desirable and realistic alternative to incumbent substitutes. In essence, legitimation then becomes 'the politics of shaping expectations and of defining desirability'* " (Bergek et al., 2008b, p. 581). In a TIS, legitimation is necessary to create demand and mobilise resources. Moreover, system builders gain political strength in the process of legitimating the TIS (ibid). However, surprisingly, despite the importance of legitimation, TIS empirical research has not paid much attention to study its underlying dynamics (Bergek et al., 2008b; Bergek et al., 2015; Markard et al., 2016).

Bergek et al. (2008b) suggest that technologies are typically legitimated by two different type of actions: (i) "expert" legitimation through technology assessments (TA), and (ii) "trust and familiarity" legitimation. Technology assessments (TA) are oriented to demonstrate through rational arguments the feasibility and performance of the technology. However, TAs are usually perceived as serving the political goals and interests of different groups of actors, and in consequence, they can create a negative effect among policy makers and investors (Bergek et al., 2008b). As an example, performance criteria and used methodologies are sometimes suspect of being adapted to promote certain technologies over others (ibid). Therefore, legitimation, beyond rational assessments, is required to build "trust and familiarity". Bergek et al. (2008b) state "trust and familiarity" is built as other TIS functions are strengthened (like knowledge development, entrepreneurial experimentation, or influence on the direction of search) and advocate networks and coalitions in "packs" of entrepreneurs are created. Through this, cumulative causation and virtuous cycles are created, leading to build the required legitimacy to transition the TIS from its formative phase to the growth phase (figure 2-6).

However, the arguments presented by Bergek et al. (2008b) as how in practice TIS acquire legitimacy are vague and suffer from a number of shortcomings. First, the existence of networks or advocate coalitions in favour of the TIS, does not necessarily imply a contribution to legitimation. As Hellsmark (2010) argues, other networks and advocate coalitions against the TIS can also be formed by TIS opponents. Second, the influence other functions on legitimation is not always explained. For example, although the dependency between legitimation and guidance on the direction of the search is recognised (Bergek et al., 2008b; Bergek et al., 2015), the mechanisms by which system builders and networks align visions and expectations of key actors, is still missing. Third, the influence of incumbent external institutional factors and structures (like predominant beliefs, values, regulation etc. across the different organisations, sectors or geographies where TISs needs to be legitimated) seems to be out of the TIS legitimation analysis. This aspect, the circumstances by which different external institutional settings enhance or hamper legitimation, is a criticism acknowledged by TIS scholars (Bergek et al., 2015). A more recent empirical study on TIS legitimation by Markard et al. (2016) suggests the influence of external factors like political agendas or societal debates in the legitimation of a TIS. However, none of the vast TIS research literature reviewed, tackles in depth the internal

TIS mechanisms that contribute to build legitimacy or the influence of the different external institutional settings where the innovation needs to be legitimated.

As Markard et al. (2016) contend: "*While legitimacy of organisations has received much attention in the literature (Deephouse & Suchman, 2008), comparably few scholars have looked into legitimacy at the level of an industry or technological field.*" (Markard, 2016, p.330). Organisational studies, as argued by Markard et al. (2016), have largely studied how firms and industries acquire, maintain or build legitimacy. Suchman (1995), states that as in the creation of new markets and industries, legitimation is a prerequisite in the development of new technological innovations. While in organisations legitimacy is typically attained by adhering to existing norms and practices (Zimmerman & Zeitz, 2002), BTIs usually come with new rules of the game. Suchman defines legitimacy as:" …a generalised 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).

Acquiring legitimacy involves alignment to a variety of institutional elements. Scholars classify legitimation according to different sources of legitimacy. As an example, Scott (1995) distinguishes between regulative, normative and cognitive legitimacy. Similarly, Aldrich and Fiol (1994) distinguish between socio-political regulative, socio- political normative and cognitive legitimacy. Zimmerman and Zeitz (2002), propose a framework around the three pillars of regulatory, normative and cognitive, and add a fourth dimension on industry legitimacy.

Suchman (1995), classifies legitimacy into three main types based on three differentiated behavioural dynamics: pragmatic, moral and cognitive. Pragmatic legitimacy relates to self-interest and it is obtained if there is an appropriable interest for the organisation. Moral legitimacy reflects a positive evaluation of the organisation and on whether its activities are desirable or 'the right thing to do'. Cognitive legitimacy reflects a dynamic in which organisations are legitimated because they provide routines, standards or models that are uncontestably taken for granted as they make the organisation meaningful and predictable.

Suchman (1995) suggests that legitimacy becomes more difficult to obtain, as one moves from the pragmatic to the moral to the cognitive. Aligned to this, Laïfi and Josserand (2016) found that cognitive legitimation represents the final stage, where the innovation is taken for granted and can be widely spread and diffused (Laïfi & Josserand, 2016).

Suchman's research on legitimacy has been largely cited in TIS studies (Bergek et al., 2008a; Bergek et al., 2008b; Hekket et al., 2011; Bergek et al., 2015; Markard et al., 2016). As Bergek et al. (2008b, p.581) contend: "*as (it) is widely acknowledged in previous research, legitimacy is a prerequisite for the formation of new industries and, we would add, new TIS.*" However, whether the dynamics to build legitimacy in organisations apply in the same fashion to BTIs, it is something that will have to be demonstrated by empirical research.

With the aim of identifying what type of actions can contribute to gain legitimacy, Suchman (1995) proposes three different strategies: (i) *conform* to existing institutions and audiences, (ii) *selection* of audiences that will support the new practices or (iii) *manipulation* of audiences and environments to create new legitimating beliefs. In addition to these three strategies, Zimmerman and Zeitz (2002) add a fourth one: *creation* of new institutional contexts that did not exist. Conforming to existing beliefs, norms and practices are the more convenient ways to gain legitimacy (Zimmerman & Zeitz, 2002), but paradoxically, some BTIs bring with them new rules of the game. As (Suchman, 1995, p. 591) argues: "*innovators who depart substantially from prior practice must often intervene pre-emptively in the cultural environment in order to develop bases of support specifically tailored to their distinctive needs.*" The strategy of selecting specific audiences where the innovation can be developed more easily presents some analogies to what in Multilevel perspective (section 2.5) referred to as niche management (Geels, 2005a; Rip & Kemp, 1998). Finally, manipulating audiences and creating new legitimating beliefs is the ideal of innovators, but might not be easily applicable if existing institutions have prevailed for a long time in the system (Hellsmark, 2010). As Tushman and Anderson (1990) postulated, discontinuities that destroy existing know-hows are more complex and take a long time to succeed. The different types of legitimation strategies postulated by Suchman (1995), if applied to BTIs and TIS, might suggest that audiences with different institutional settings will require different legitimation actions.

Following on the previous arguments, Suchman's (1995) postulations constitute an avenue to explore and deepen in the underlying mechanism of TIS legitimation.

The next section discusses the interplay of the TIS structural processes analysed in section 2.1.6 and the TIS functions analysed in section 2.6.2. The discussion puts a special focus on the legitimation function and the dynamics moving TIS from the formative phase to the growth phase (Bergek et al., 2008b).

2.6.4 TIS dynamics

TIS scholars have developed different analytical frameworks around TIS functions (Bergek et al., 2008a; Hekkert et al., 2007; Markard & Truffer, 2008; Jacbosson & Hellsmark, 2009). As discussed in the introduction of section 2.6, the purpose of these frameworks is to understand the evolution of TIS over time, to identify the pain points in the system, and ultimately, to provide guidance to policy makers. As analytical tools focused in the development and performance of TIS functions, TIS frameworks took originally a meso-level perspective. However, some researchers have more recently expressed their concern for the overlook of system builders' deliberate actions in the development of TIS. To amend this, different TIS studies have included in the analysis a more micro level perspective around the role of system builders (Hughes, 1987) in the development of innovation systems. Kukk et al., (2016) provide a comprehensive review of TIS studies accounting for the role of system builders in the development of TISs.

Hellsmark and Jacobsson (2009), for example, have developed a framework for TIS analysis that encompasses both the role of TIS system functions (Bergek et al., 2008a) and system builders. In a later refinement, Hellsmark (2010) operationalises the framework for the analysis of the formative phases of the TIS: that is, the main focus of this research. The rest of this section focuses on Hellsmark and Jacobsson (2009), and Hellsmark (2010) TIS framework.

As previously discussed, TIS consist of structural components (actors, networks and institutions) and a set of key processes or functions as shown in figure 2-7. In addition to these, exogenous factors, like political agendas or the development of related technologies, can also influence its development. Hellsmark and Jacobsson (2009) contend, that the dynamics in a TIS can be explained through 4 main set of interactions (represented by the arrows 1 to 4 in figure 2-7).

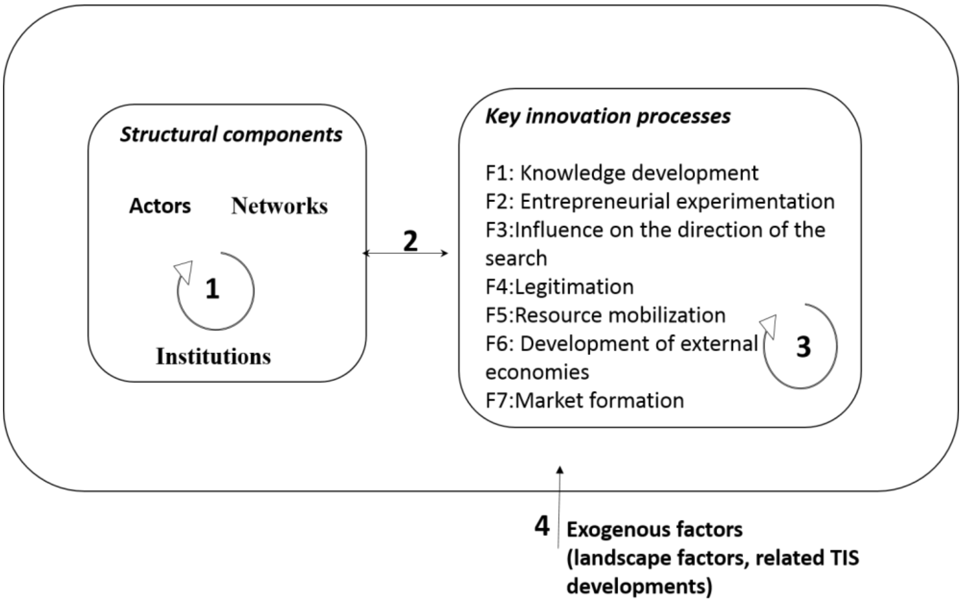

Figure 2-7 Overview of TIS dynamics. Adapted from Hellsmark and Jacobsson (2009) and Hellsmark (2010)

Interactions within the structural components (Arrow 1 in figure 2-7).

Actors and networks, are governed through institutions like: regulations, beliefs, culture, practices or routines. During the formative phase of breakthrough innovations, new institutions may need to be created and legitimated, as prevailing rules might not fit for the new technological innovations. As Hellsmark (2010) argues, the definition of a new institutional order might raise tension and conflict among the actors in the TIS. As defined in section 2.6.1, system builders, as institutional entrepreneurs (Kukk et al., 2016), are critical to align and shape institutions in the best interest of the technology. Moreover, Hellsmark (2010) contends that during the formative phase of a TIS, system builders are key agents in the development of the 4 structural processes (represented by arrow 1 in figure 2-7). These are:

(i) accumulation of knowledge and artefacts

(ii) entry of firms and other organisations

(iii) formation of alliances and networks

(iv) institutional alignment

Interactions between structural components and functions (Arrow 2 in figure 2-7).

System building activities enhance not only institutions and networks, but also other functions in the TIS (arrow 2) such as knowledge development, entrepreneurial experimentation, resource mobilisation and legitimation (Hellsmark & Jacobsson, 2009). As an example, new firms (acting as system builders) bring resources and knowledge to the TIS that strengthen entrepreneurial experimentation. They can also contribute to enhance legitimation if they have a good reputation and devote part of their resources to promote legitimacy. Interactions between structural components and TIS functions occur in both directions (double arrow). Following on previous example, if legitimacy is built, institutional alignment, in return, will be further enhanced (Hellsmark, 2010). Additionally, the strengthening of TIS functions such as entrepreneurial experimentation or resource mobilisation will also result in new actors entering the TIS and new networks being formed.

Interactions between functions (Arrow 3 in figure 2-7).

The functions in a TIS are not independent from each other. TIS functions can be mutually reinforced leading to positive feedbacks and the creation of "virtuous cycles" that make the system resilient to external negative forces (Bergek et al., 2008b). Hekkert et al. (2007) names "motors" to this dynamic of mutually reinforced functions. For example, legitimation requires the strength of other functions such as knowledge development and entrepreneurial experimentation (Hekkert et al., 2011). Additionally, visions and expectations, play a crucial role in building legitimacy. Visions and expectations are part of the function "influence on the direction of the search". Although it is not expected that all actors in the system share the same views on its potential, contested visions and expectations can block the strength of the legitimation process (Bergek et al., 2008b; Bergek et al., 2015).

Interactions with exogenous factors (Arrow 4in figure 2-7).

External factors, also contribute to the development of a TIS (Bergek et al., 2015; Markard et al., 2016) . External factors can manifest in different forms like: public debates addressing societal problems, changes in political agendas, economic crisis etc. As discussed in section 2.5.1, Geels (2005a) denominates these *landscape* factors. In addition to global or landscape factors, the development of complementarian or initially competing TIS, can also contribute to develop and legitimate the TIS in focus (Bergek et al., 2008b). This process, known in TIS literature as development of positive externalities or development of external economies, is critical too for the formative phases of TIS (Bergek et al., 2008a; Bergek et al., 2008b).

2.6.5 Criticisms to systems of innovation and TIS

Systems of innovation and in particular the TIS approach as described in the previous section, represent an important pillar of innovation research and policy since the early 1990s (Markard et al., 2015). One of its advantages in respect to other models, is that TIS contemplates the innovation phenomena as a dynamic and non-equilibrium process, where actors, networks and the institutions ruling them, shape the technological trajectories of innovation (Weber & Truffer, 2017). As a consequence, TIS has been extensively used by academics and policy makers who reject market factors as the sole basis for innovation failure (Bleda & del Rio, 2013). In particular, its adoption by the Organisation for Economic Cooperation and Development (OECD) has motivated a lot of resonance among policy makers (Weber & Truffer, 2017). However, despite success, different scholars, some of them in the TIS field, have raised a number of criticisms. These criticisms can be grouped around three main themes: (i) the TIS myopia towards external context structures (Bergek et al., 2015; Markard et al., 2015), (ii) its validity as an adequate tool to explain technological transitions (Geels, 2005a) and (iii) its lack of emphasis on politics. The rest of the section provides an analysis on the status and recommendations for these criticisms.

Myopia towards external context structures

Markard et al. (2015) identify as a recurring issue the critics to the inward orientation of the TIS approach: as a system, its performance relies mainly on the internal structures and the dynamics within the system, whereas the external structures and processes such as sectoral, landscape factors or related TIS developments are largely ignored (Smith & Raven, 2012; Geels, 2005a; Geeels, 2011). This limitation is also well acknowledged by scholars in systems of innovation (Markard & Truffer, 2008; Markard et al., 2015; Bergek et al., 2015). As Bergek et al. (2015) state: "structures and processes inside a focal TIS are generally well conceptualised in the literature. […] What happens outside and across the system boundary has been less systematically worked out." (Bergek et al., 2015, p. 54). As a response to this, they suggest further research under the consideration of four contextual structures: technological, sectorial, geographical and political. Technological structures define the positive or negative influence in the TIS in focus of other related TIS developments. This interaction is partially covered under the function development of positive externalities (Bergek et al., 2008b). Sectorial structures refer to the institutional context (cognitive frames, regulations etc.) and physical infrastructures that operate in the sector of which the TIS is a part. Geographical contexts refer to the spatial boundaries in the TIS of analysis. As suggested by Bergek et al.(2008a), delineating the boundaries in a TIS require at least three analytical decisions: (i) the breath of the technological field (broad or narrow), (ii) the spatial focus (local, regional, national or global) and (iii) the product versus knowledge field decision. Markard et al. (2015) suggest that these choices need to be guided by the research questions and the purpose of the study and adjusted during the course of the analysis by the accumulated empirical insights. Finally, the political context structures reflect the political dimension in which a "battle over institutions" takes place among the proponents and opponents of the TIS.

Markard et al. (2015), highlight the importance of further research on external context structures to understand how they influence legitimation and technological trajectories: *" If we regarded the context just as a background for TIS development, made up of barriers and driving factors, we would miss, for example, context dynamics that unfold both independently and as a consequence of TIS development. We would also miss institutional coherences in context structures, which tells us much about the resistance proponents of the new technology will face in their quest for broader institutional change. A further reason for a more differentiated context analysis is to understand how variation in context structures affects variations in TIS development, including different applications, designs, or pathways of a novel technology.*" (Markard et al., 2016, p. 78).

Validity to explain technological transitions

The lack of conceptualisation of contextual structures in TIS analysis has led to question whether it is a valid tool to explain technological transitions. Smith and Raven (2012), for example, criticise the lack of interaction between the TIS in focus and other socio-technical regimes. Authors like Geels (2005a, 2011) or Kern (2015), on the other hand, question its validity by arguing that it does not explain how the rigidity and inertia of incumbent socio- technical regimes is overcome by the new technological regime. In the words of Kern (2015, p.68): "*While many of the TIS functions of a variety of renewable energy technologies in several countries are now quite well developed, we see little evidence of processes of Schumpeter's 'creative destruction' in which these new technological systems replace incumbent ones […]. How can the TIS approach explain this finding? For me, part of the answer are the structural rigidities in sectors such as energy, mobility, agriculture or health, their embedding within society and the* *powerful agency of incumbents trying to protect their status. It is not clear to me that currently the TIS approach has much to say about these issues…*"

Markard et al. (2015, p.81) agree that further research needs to be conducted to understand how rigidity is overcome, as it: "*certainly deserves further theoretical elaboration within the TIS framework.*"

Politics

The lack of explanation about the politics involved in technological transitions has been criticised as a drawback of TIS approach. As previously discussed in sections 2.4 and 2.5, politics remains a criticism for all co-evolutionary approaches. In the case of TIS, the debate on the incorporation of politics is long and has been repeatedly suggested by many of TIS proponents as well as by other scholars in the innovation field (Jacobsson & Bergek,2011; Meadowcroft, 2011; Kern, 2011; Kern, 2015; Bergek et al., 2015; Markard et al., 2016). Politics in TIS are typically associated with the legitimation process (Bergek et al., 2008b). However, TIS frameworks lack a conceptualisation of politics over legitimation and institutional alignment. Markard et al. (2015) suggest that politics should be systematically incorporated in the TIS analysis in order to better explain the dynamics of technological transitions: "*We agree that the political dimension is of great importance and deserves more attention than is often given to it. We also agree that the concepts for dealing with struggles over institutional change are under-developed in the TIS framework.*" (Markard et al., 2015, p. 81).

Kern (2015, p.68) suggests as a future research avenue: "*the analysis of actors and actor strategies should go beyond firms focussing on market entry, generating knowledge etc. and should much more closely investigate the political agency of a diverse set of actors and how they shape the selection environment in which they operate. This needs to include activities like coalition building, lobbying, creating narratives and counter-narratives, etc*."

2.7 Conclusions

This chapter has analysed different innovation models with the aim of identifying the theoretical and analytical starting points that could better serve to answer the initial overall aim of this thesis: to explore the main dynamics in the early phases of development of breakthrough technological innovations (BTIs) that lead to success or failure. The analysis starts with a review of the theory of diffusion of innovations by Rogers (Rogers, 2003). Diffusion of innovations has been largely used to analyse BTI's like internet, e-commerce, mobile technologies etc. (Gerrard & Barton Cunningham, 2003; Hsu, Lu & Hsu, 2007; Lee, 2004). However, in this theory, the process of acquiring critical mass is dominated by the action of change agents in a social system where the beliefs, values or interests of main actors do not represent any conflict. In the words of Rogers, this bias, called pro-innovation bias is: "*the implication in diffusion research that an innovation should be diffused and adopted by all members of a social system."* (Rogers, 2003, p. 106). As Rogers argues: "*…the scope of future diffusion research should be broadened to include study of the entire process through which innovation is generated…*" (Rogers, 2003, p. 166). Following Rogers' recommendation to analyse more in depth the dynamics prior to diffusion, this literature review has looked into evolutionary approaches to innovation.

Evolutionary approaches to innovation analyse innovation and technological change in a wider system of users, organisations and institutions. They have their groundings in evolutionary economics (Nelson, 1994; Nelson & Winter, 2002) and the socio-technical system concept proposed by studies of science technology and society (STS). As shown in figure 2-4, socio-technical systems are formed by a cluster of elements that include technology (artefacts), regulations, user practices, markets, values, cultural meanings, infrastructure and maintenance and supply networks (figure 2-4). The analysed models: SCOT, ANT, LTS, MLP and TIS, operationalise the relations between the elements of the socio-technical system in different manners. Whereas SCOT and ANT are eminently social constructivist approaches that describe the closure process of innovation acceptance as a negotiation between the actors in the socio-technical system, LTS, MLP and TIS consider, to a certain extent and with some differences, the implications of the institutional context and the potential conflicts between different groups of actors.

2.7.1 Theoretical and analytical starting points

This research will take technological innovation systems (TIS) as the theoretical starting point, and more specifically the analytical framework by Hellsmark and Jacobsson (2009) as described in section 2.6.4. The rationale for choosing TIS in preference to the other models analysed is twofold. The first reason is related to epistemological considerations. As postulated by Hughes (1994), the innovation process starts as a socially constructed phenomenon that later on evolves into a more technological deterministic one, as long as technology is legitimated and consequently, the innovation is able to transform firms and markets. This suggests that although sociological factors are very important in the very early phases of BTIs, other forces like institutions, market, power or politics should be taken into account too. With this, co-evolutionary approaches of technology, society, firms and institutions seem more appropriate constructs rather than purely social constructivist's approaches like ANT or SCOT. As Winner (1993) suggests, artefacts have politics. The second reason relates to the balance between structure and agency and the level of analysis: ANT, SCOT and LTS are eminently agency-oriented models. As largely discussed in this chapter, innovation perspectives benefit from approaches that also include a more structuralist analysis, like MLP and TIS. MLP and TIS draw on common theoretical roots and use similar concepts to explain innovation and technological transitions. Whereas the former builds on the notion of regime, an interpretative analytical concept to describe intangible deep structures and dynamics, the latter grounds on the concept of system to describe more tangible components and relations (Markard & Truffer, 2008). From a level of analysis perspective, MLP focusses on describing the macro patterns of transitions

(Geels, 2011). TIS, and particularly Hellsmark and Jacobsson (2009) framework, provide more level of detail on the dynamics occurring at meso (system) level, as well as at micro level, through the analysis of system builders' contributions.

From all of the above, the researcher considers TIS approach an optimal starting point to further unfold the early dynamics of BTIs.

2.7.2 Identified gaps and refined research questions

The previous section concluded that TIS approach (Hekkert et al., 2007; Bergek et al., 2008a; Hellsmark & Jacobsson, 2009) represents an optimal starting point to analyse the early dynamics of BTIs. As discussed in section 2.6.3, legitimation, the process of acquiring acceptance among relevant institutions and actors, is critical to transition TIS from the formative phase into the growth phase. (Bergek et al., 2008b; Hekkert et al., 2011). Legitimation is necessary for the TIS to form demand, to mobilise resources and for system builders to gain political strength and shape institutional alignment (Bergek et al., 2008b; Hellsmark, 2010). However, despite its importance, there is a paucity of research on legitimation in systems of innovation literature (Bergek et al., 2008b; Markard, 2016).

As discussed in section 1.3, this thesis aims to contribute to unfold the mechanisms that lead to BTIs successful trajectories. Consequently, research aim can be achieved by conducting novel empirical research of the legitimation function in the formative phases of TISs. As Edquist (2005) suggests: "*Making the systems of innovations approach more theory-like does not require that all components and all relations among them must be specified. Such an ambition would certainly be unrealistic. […] Even the much more modest objective of specifying the main function of SIs, the activities and components in them and some important relations among these, would represent a considerable advance in the field of innovation studies. Used in this way, the SI approach can be useful for the creation of theories about relations between specific variables within the approach.*"(Edquist, 2005 p.111).

In addition to the lack of empirical research on legitimation, some scholars, as discussed in section 2.6.5, have pointed to the poor knowledge of external contexts and power structures in TIS and the lack of a conceptualisation of the effects of power and politics over legitimation and institutional change (Meadowcroft, 2011; Kern, 2011; Kern, 2015; Bergek et al., 2015; Markard et al., 2015). Although politics and conflict are much present in TIS literature, TIS scholars agree that the conflicts over institutional change in the TIS should be further developed (Markard et al., 2015). As an example, Hellsmark (2010), describes three typical conflicts affecting legitimation: (i) different networks might advocate for different innovation trajectories according to divergent beliefs and solutions, (ii) incumbent firms entering a new TIS might force to preserve part of the existing rules structure to keep their business models and (iii) a conflict might arise between advocates of the emerging TIS and other competing emerging or mature TIS. However, despite recognising the existence of political conflict, TIS studies do not inform much on the strategic actions that system builders can put in place to overcome such conflicts. Kern (2015) suggests that in future research avenues: "*… the analysis of actors and actor strategies should go beyond firms focussing on market entry, generating knowledge etc. and should much more closely investigate the political agency of a diverse set of actors and how they shape the selection environment in which they operate. This needs to include activities like coalition building, lobbying, creating narratives and counter-narratives, etc.*"

From above discussion, this research will attempt to address the main legitimation gaps in TIS literature. These gaps can be summarised as follows:

(i) The need for empirical studies on legitimation as a key function to move TISs from the formative phase to the growth phase. (Bergek et al., 2008; Markard, 2016).

(ii) Further analysis on the influence of external context structures, conflicts and politics over legitimation and institutional change (Markard et al., 2015).

(iii) Empirical research on strategies followed by system builders to develop legitimacy and build institutional alignment (Kern, 2015).

Therefore, the initial broad topic of this research: to unfold the mechanisms that lead BTIs to successful diffusion trajectories, can be narrowed down into a set of research questions addressing the identified gaps in TIS literature. These research questions are:

R.Q.1: how do and the extent to which system builders contribute to establishing legitimacy within a TIS?

R.Q.2: what are the principal mechanisms aiding the legitimation of a TIS?

R.Q.3: what are the key legitimation strategies capable of overcoming the 'liability of newness'?

Chapter 3 - Methodology

3.1 Introduction

The previous chapter recognised technological innovation systems (TIS) as an appropriate theoretical and analytical framework to analyse the early phases of breakthrough technological innovations (BTIs). In particular, legitimation was identified as a critical process for BTIs to move into market growth phase. Within legitimation, three research gaps were highlighted:

(i) the paucity of empirical studies on TIS legitimation (Bergek et al., 2008; Markard, 2016).

(ii) the necessity to further develop how external context structures, conflicts and politics influence legitimation and institutional change (Markard et al., 2015).

(iii) the recommendation to analyse system builders' strategies more closely to the mechanisms that they develop to shape the environment (Kern, 2015).

In order to address those gaps, an empirical research on two different breakthrough technological innovations (BTIs) were undertaken. The first BTI analysed is Computational Fluid Dynamics (CFD). CFD is a technology developed during the 1970s-80s that has transformed a number of industries and has created a multibillion-dollar market in software sales and services (Hanna, 2015). The second BTI is mobile Health (mHealth). mHealth is a technological field that despite its great transformational potential, hasn't been widely adopted todate (Labrique et al., 2013; WHO, 2106). Both studies, CFD and mHealth, aim to contribute to TIS theory by exploring the mechanisms and strategies that system builders have developed to legitimate these BTIs.

This chapter covers the main methodological aspects of the research. In the next section (3.2), the underpinning ontological and epistemological considerations of the study are described. Section 3.3, discusses the research approach and methods. In section 3.4, the research parameters for the two BTIs under analysis are extensively illustrated, (e.g. rationale for the research context and unit of analysis, choice of interviewees, etc.). Sections 3.5 and 3.6 detail respectively the methods for data gathering and data analysis. Section 3.7 provides the reader with a detailed discussion concerning data validity and reliability. Finally, the last section of the chapter (3.8), covers the details regarding the research ethics of the study.

3.2 Philosophical considerations

The assumptions and views of a researcher about the nature of the social phenomena studied, impacts the research strategy and method used. Therefore, the researcher should be aware of the potential biases derived from the philosophical standpoints adopted while conducting the investigation (Lincoln & Guba, 1985). As Bryman (2012) points out, the assumptions and views are mainly influenced by two philosophical stances: *ontology* and *epistemology.*

Ontology is the study of the nature of the social entities constituting a certain social phenomenon. It addresses the questions of what reality is and what is the nature of the world and its causal relationships (Saunders et al., 2007). Bryman (2012) indicates that the central point about ontology is the question of whether social entities should be considered objective and external to social actors or on the contrary, should be interpreted as social constructions built up from the perceptions and actions of involved social actors. Within this distinction, two main ontological perspectives serve to characterise social science studies: *objectivism* and *constructionism*. *Objectivism* asserts that social phenomena have an existence independent of social actors. Therefore, this perspective recognises that reality is objectively observed and analysed by the researcher (Bryman, 2012). *Constructionism,* also known as *constructivism*, is an alternative ontological position that asserts that "*Social phenomena and their meanings are continually being accomplished by social actors. It implies that social phenomena and categories are not only produced through social interaction but that they are in constant state of revision.*" (Bryman, 2012, p. 33). Reality, in a constructionist approach, is subjective and constructed by the actors participating in the study rather than by objective and external factors (Lincoln & Guba, 1985).

Epistemology, on the other hand, refers to the grounds of knowledge. It asks: what is, or should be, regarded as acceptable knowledge? In particular, the epistemological stand questions whether knowledge in social science can be acquired through the same principles, methods and ethos as natural sciences (Bryman, 2012). Therefore, explaining the researcher's epistemological assumptions is critical to clarify and justify the research design, the methods that are suitable and the way the empirical evidence is gathered and interpreted (Gray, 2013).

Bryman (2012) classifies epistemological perspectives into two main categories: *positivism* and *interpretivism*. A *positivist* stance, states that social science should imitate natural science principles and methods. The researcher following a positivist orientation will most likely use a structured methodology on quantifiable data to facilitate the replicability of the research (Saunders et al., 2007). Therefore, a positivist approach seeks facts to generate hypotheses that can be tested and can generate theory.

Interpretivism, is a contrasting epistemology to positivism. An interpretivist approach states that the object of research in social sciences is fundamentally different from that of natural sciences, and therefore, the study of the social world *"…requires a different logic of research procedure, one that reflects the distinctiveness of humans as against the natural order."* (Bryman, 2012, p.28). In an *interpretivist* approach, the researcher needs to get involved in the social world under study to interpret and understand it (Saunders et al., 2007). As Weber (1947) proposed, social science should attempt to understand social action in an interpretative manner in order to arrive at causal explanations. Research methods in interpretivist approaches are mainly qualitative (Bryman, 2012).

Realism, and in particular *critical realism (CR)* (Bhaskar, 1989), can be considered as a middle way between positivism and interpretivism (Zachariadis et al., 2013). Unlike positivism, critical realism recognises researcher's conceptualisation of reality as a way to understand it

(Bryman, 2012). Therefore, the comprehension of reality and the generation of knowledge requires the identification of structures that generate the events and discourses in the social world. In the words of Bhaskar: *"These structures are not spontaneously apparent in the observable pattern of events: they can only be identified through the practical and theoretical work of the social science."* (Bhaskar, 1989, p.2).

The ontological grounds of critical realism share with objectivism the notion of a reality that exists independently of the researcher's perceptions and beliefs (Bhaskar, 1989). However, reality is divided in three different domains as shown in figure 3-1: *the real, the actual and the empirical* (Bhaskar, 1989). The domain of the real consist of all objects and structures that create the causal powers and generative mechanisms that determine the world. These mechanisms might not always be visible in the *actual* world, but the events they generate are the visible phenomena we observe in the *empirical* world. As Zachariadis et al. (2013, p.3) summarise: "*Structured things [physical objects or social processes] possess causal [or emergent] powers which, when triggered or released, act as generative mechanisms to determine the actual phenomena of the world. While generative mechanisms are not necessarily constantly empirically observable, their potentialities may still exist whether they are exercised or unexercised."* Following on these nested domains of reality (*real, actual* and *empirical*), the overall goal of critical realistic research is the identification of the mechanisms that generate the observable perceptions and events (Bryman, 2012; Zachariadis et al., 2013, p.3). In other words: *"… as a result, the critical realist view on causality should not be about a relationship among distinct events (e.g. the fact that event "A" by and large has been followed by event "B") but about realising the process and conditions under which "A" causes "B", if at all. "*

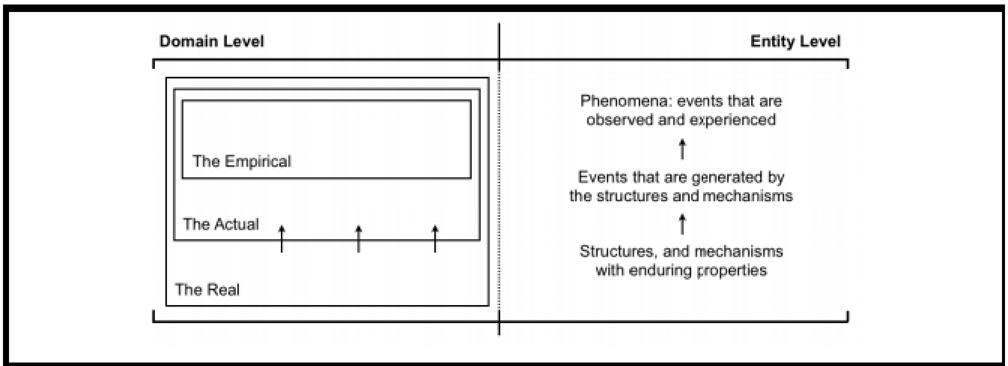

Figure 1. The Stratified Ontology of Critical Realism (adapted from Bhaskar 1975)

Figure 3-1 Overview of the different levels in critical realism ontology. (Zachariadis et al., 2013,p.4)

As Bryman (2012) argues, the critical realist reasoning to identify generative mechanism from events and observed phenomena, is neither inductive or deductive. It has been defined as a **retroductive** analysis (Blaikie, 1993). Retroductive analysis *"…entails making an inference about the causal mechanism that lies behind and is responsible for regularities that are observed in the social world."* (Bryman, 2012, p. 29).

This research will adopt critical realism as its philosophical position. The choice reflects the aim of this study, which is to investigate the mechanisms of legitimation in the formative phases of BTIs. As a result of the investigation, system builders and policy makers will be better informed to develop strategies for the legitimation of BTIs. Therefore, the research goal is also coherent with the critical realist approach, as the recognition of the *generative mechanisms*, "*…offer the prospect of introducing changes that can transform the status quo.*" (Bryman, 2012, p. 29).

The next section discusses in depth, the consistency of critical realism with TIS as the theoretical starting point of the research.

3.2.1 Critical realism as an appropriate philosophical orientation for this research

While the literature on technology and information systems has been traditionally dominated by the two antagonist epistemologies of positivism and interpretivism, the interest on critical realism (CR) as a more appropriate stance to guide research in the technological field, has increasingly grown over the last years (Mingers, 2004; Dobson, 2001; Smith, 2006; Easton, 2010). As Smith (2006, pp. 199, 206) points out: *"This growing popularity stems in part from its ability to transcend some of the classic dualisms in the social sciences such as positivism vs. interpretivism, and structure vs. agency. […] the critical realist notion of tendencies makes possible the reconceptualisation of the technological determinism vs. the social construction of technology debate, effectively dissolving it."* The transcendence of the positivist vs. interpretivist epistemologies or the technological determinism vs. social constructionism debate, is also of critical importance for the theoretical and analytical starting points of this research: TIS. As discussed in the section 2.6, TIS encompasses different theoretical perspectives to explain innovation phenomena like evolutionary economics, institutional theory or socio-technical systems. The affinity of these theoretical perspectives with the critical realist stance has been substantially discussed in the literature (Foss, 1994; Hughes, 1994; Vega & Brown, 2011; Wynn & Williams, 2012). For example, Foss (1994) argues that the critical realist orientation of evolutionary economics is what sets it apart from the neoclassical approach. Additionally, Hughes (1994) theorises that the development of socio-technical systems is both a socially constructed and determinist process. Moreover, as the goal of critical realism is to explain the underlying mechanisms that generate a certain event, this philosophical approach is adequate to provide more in-depth causal explanations to innovation system approaches. As Wynn and Williams (2012, p.787) point out, this can be accomplished by identifying the mechanisms that connect events and complex interactions in the analysis of the technological, organisational, environmental and social aspects of a socio-technical system: " …(critical realism) *allows* *researchers to develop and support in-depth causal explanations for the outcomes of specific socio-technical phenomena that take into account the breadth of information technology, social, organisational, and environmental factors which may have played a causal role in their occurrence."*

The critical realist essence of TIS is also present in the reflections of many of its proponents. In response to some criticisms of TIS, Markard et al. (2015, p.79) state that: "*Finally, we want to add that the debate about analytical and empirical boundary setting also touches upon the issue whether to regard the TIS as a purely analytical construct or model or as an object that exists 'out there' and can be identified and described empirically. In our view, a TIS is neither purely abstract nor objectively identifiable in empirical terms but a combination of both. In that regard it is similar to concepts such as sector, industry, technology, or firm.*" Moreover, Vega and Brown (2011, p.253) defend that as compatible as critical realism and systems of innovation are, a more systematic approach of critical realism should be put in place to reduce weaknesses and criticisms over the systems of innovation field: *"While the commitment to methodological pluralism is positive, it has a negative connotation if we consider that the conceptual base of the SIA (systems of innovation approach) is still evolving and confusion exists about some of its components […]. For instance, it is up to the researcher to decide the boundaries of a system, which could be as diverse as the country, the region, the sector, the technology or a mix of them (e.g. Edquist, 1997, 2005). Another example is multiple definitions of institutions […]. As a result, SIA researchers have been presenting very different, too descriptive, and superficial accounts of the systems […] Against this situation, the adoption of the CR paradigm allows the reconciliation of a variety of systems given the identification of the underlying causal mechanisms that generate and integrate them […]. For this reason, the focus of research should be on deeper structures and mechanisms using multiple methodologies more than accounting the visible and discrete factors that directly affect innovation processes.*"

The discussions printed above suggest that critical realism offers a rational philosophical stance, enabling the researcher to unfold the mechanisms of legitimation in the formative phases of technological innovation systems. The next section presents the research design and methodology derived from this stance.

3.3 Research approach and method

The aim of this section is to describe in greater detail, the decisions about research approach and method, that follow from the ontological and epistemological strand discussed in section 3.2. The section is divided into two separate subsections that provide the rationale for the main research approach and method considered for the study.

3.3.1 Research approach- qualitative methodology

In critical realism, the selection of methods is determined by the nature of the research problem. Therefore, the question is not whether a particular methodological approach (quantitative, qualitative or mixed methods) is relevant and utilised, but how they are applied (McEvoy & Richards, 2006).

This research has adopted a qualitive approach. The decision is twofold: on one hand, the research questions posed in section 2.7.2 suggest to adopt qualitative research to unfold events and understand actors' actions (Bryman, 2012). On the other hand, TIS empirical studies and frameworks imply also a qualitative research (Bergek, 2008b; Hellsmark & Jacobsson, 2009; Hellsmark, 2010; Hekkert et al., 2011; Markard et al., 2015).

As previously stated, qualitative research analysis aims to unfold events and to understand the interconnections between the actions of participants of social settings. In contrast, quantitative studies focus on the causal relationships between two or more variables (Bryman, 2012). In qualitative analysis, the researcher develops concepts and insights from the observed patterns in the data, instead of using collected data to assess preconceived models or theories (Taylor et al., 2015). This type of theorising in qualitative research, known as "emergent analysis", is compatible with the critical realist stance. As McEvoy and Richards (2006) point out: "*The key strength of qualitative methods, from a critical realist perspective, is that they are open ended. This may allow themes to emerge during the course of an inquiry that could not have been anticipated in advance. Qualitative methods can help to illuminate complex concepts and relationships that are unlikely to be captured by predetermined response categories or standardised quantitative measures.*" (McEvoy & Richards, 2006, p. 71).

3.3.2 Research method- multiple-case design

Yin (2003) defines a case study as: "… an empirical inquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident." (Yin, 2003, p. 13). In the words of Eisenhardt (1989), the case study is a research strategy: "… which focuses on understanding the dynamics present within single settings." (Eisenhardt, 1989). This research utilised a multiple-case design, which is a variation of a single case design within the same methodological framework (Yin, 2003). The purpose of multiple-case study design is to enhance validity as compared to a single case study (Herriott & Firestone, 1983; Eisenhardt, 1989).

The two selected case studies for this research: (i) the origins of Computational Fluid Dynamics (CFD) and (ii) mobile Health technologies (mHealth) for diagnostics and chronic disease management, represent two BTIs with very different legitimation dynamics: while CFD was smoothly accepted as a new industrial practice across many sectors in the 1980s (Runchal, 2009), mHealth technologies, on the other hand, are still struggling to overcome important acceptance barriers (Labrique et al., 2013; WHO, 2016) to transitioning from niche or nursing markets (Geels, 2005a; Bergek et al., 2008a) to growth or mass markets.. Therefore, the selection of contrasting cases in this research is not unintentional. As Eisenhardt (1989) states, as the number of cases that can be studied are limited, it makes sense to select contrasting cases.

The choice of a multiple-case study strategy is consistent with the critical realist paradigm adopted in this research. Although critical realism is flexible with research methodologies and does not recommend any in particular, numerous critical realist scholars recognise the case study as the best approach to explain causal mechanism through the analysis of interactions in structure, events and context (Wynn &Williams, 2012; Ackroyd, 2009; Easton, 2010; Miles & Huberman, 1994; Mingers, 2004). In particular, Wynn and Williams (2012, p.795) point out that: "*For the purpose of studying contemporary socio-technical phenomenon to uncover the causal mechanisms and contextual factors that combined to generate them, case study research is well-suited to conduct critical realist research.*"

Finally, the choice of multiple- case study method is also consistent with TIS approach and the research questions posed in section 2.7.2. As main proponents of TIS point out, Markard et al. (2012), the big majority of empirical studies in the TIS field have adopted case study as the research method. Additionally, as Yin (2003) argues, case studies are the preferred method when dealing with 'how' or 'why' questions, and when the research focus is on a phenomenon present in a real-life context. As Gillham (2000) points out, the impact of a case study can be greater than any other form of research: case studies have the power to lead major policy and organisational changes.

3.4 Research parameters

Once the rationale for the overall research approach and method has been provided, this section specifies the research parameters of the study. The section starts providing the reader with an overview of the context of the research (subsection 3.4.1). Then, it presents the justification for the choice of the case studies, the unit of analysis, and the selection of interviewees (subsections 3.4.2 to 3.4.4). Finally, the last subsection (3.4.5) details the details involving data access.

3.4.1 Choice of research context

As repeatedly argued (see for example sections 1.3 and 2.7), this research has adopted TIS (Carlsson & Stankiewicz, 1991; Hekkert et al., 2007; Bergek et al., 2008a; Hellsmark &Jacobsson, 2009) as an appropriate approach to study the mechanisms that lead BTIs to successful legitimation trajectories.

As discussed in section 2.6, a TIS consists, as in any system, of two main parts: (i) components and (ii) the relations among them. The components of a TIS are the actors, networks and institutions, both formal and informal, that rule them. The interactions in a TIS are grouped under a set of sub processes named *functions*. Bergek et al. (2008a) identifies seven different functions or processes that help to identify inducing and blocking mechanisms in the development of a TIS. Legitimation, defined as the process of acquiring social acceptance and compliance with the relevant institutions, is a critical function for the successful transition of technological innovation systems (TIS) from the formative phase to the growth phase (Bergek et al., 2008b; Hekkert et al., 2011).

Therefore, the research context of this study is the legitimation process of TISs in their transition from the formative phase to the growth phase. The choice is justified by the following considerations:

(i) The role of legitimation as the critical process to move TIS from the formative phase to wider diffusion, as previously discussed.

(ii) The lack of empirical research on TIS legitimation. In particular, as discussed in section 2.6.5, both TIS proponents and critics call for the need of more systematic research on the role of system builders, and on the influence of politics and external contexts (political, institutional, geographical or technological) in the legitimation process.

(iii) The possibility of using organisational and institutional studies on legitimation, like Suchman (1995), to understand the different strategies used by system builders to build legitimacy.

3.4.2 Choice of CFD and mHealth as case studies

As Ghauri (2004) argues, deciding how to select the cases is probably the most important issue in this type of research. As the scholar suggests, the selection of the case(s) should be based on criteria that are consistent with the aim of the research, the theoretical framework and the concepts under analysis. As previously, discussed, the aim of the present study is to unfold the mechanisms of legitimation of BTIs, using TIS as a theoretical framework. Eisenhardt (1989), contends that when the purpose of the research is to extend existing theory or fill theoretical gaps, as is the aim of this research, the selection of cases should be based in theoretical sampling instead of statistical reasons. This implies, that random selection is not the preferable option for case study selection. Instead, and due to the limitation in the number of cases that a researcher can incorporate, "*It makes sense to choose cases such as extreme situations and polar types in which the process of interest is 'transparently observable'. Thus, the goal of theoretical sampling is to choose cases which are likely to replicate or extend the emergent theory."* (Esienhardt, 1989. p. 537).

Following Eisenhardt's recommendation, this research selected two extreme case studies in relation to the legitimation dynamics of their respective technologies: while in the first case study CFD, the technology was widely accepted and legitimated as a new industrial paradigm, in the second case study, mHealth is still in its formative phase, striving to overcome a number of different barriers (Labrique et al., 2013; WHO, 2016).

The next two subsections present an overview on the particularities of each case study. The commonalities can be summarised as follows:

- They both represent breakthrough technological innovations (BTIs) with the capability to create new technological trajectories and transform organisational and industrial structures (Garcia & Calantone, 2002; Dosi, 1982; Anderson & Tushman, 1990).
- The boundaries for the analysis can be defined as further detailed in the next subsections.
- The researcher has the means to access relevant participants.
- As far as the researcher is able to ascertain, the technologies selected for the case studies have not been analysed from the TIS perspective previously. Whereas most of the TIS empirical research is circumscribed to the field of sustainable energy transitions (Markard et al., 2012; Markard et al., 2016), this research offers the opportunity to expand the TIS field into other technological areas.

3.4.2.1 Choice of the origins of CFD a case study

Computational Fluid Dynamics (CFD) can be defined as *" …a set of numerical methods applied to obtain approximate solutions of problems of fluid dynamics and heat transfer."* (Zikanov, 2010). As an industrial discipline, it entitles the use of computational software tools to solve complex flow problems for which analytical solutions are not available. CFD provides predictive "what if scenarios" on how a liquid or gas will flow under different conditions, and how this flow will affect the surrounding objects.

The development of CFD over the last four decades is considered pivotal for many radical advances in industries like the nuclear, automotive and aerospace. (Gerard & Runchal, 2013; Harlow, 2004; Runchal, 2013). According to Hanna and Parry (2001), at least half of engineering design problems presented in the industry are flow related. The emergence of CFD in the 1970s and 1980s brought the possibility to simulate precise industrial prototypes at a much faster pace and significantly lower costs. CFD substituted expensive prototyping techniques, like wind tunnel or water tank, by computer simulations. Therefore, CFD is considered by many as a paradigm shift that led to the advent of cheaper, safer and greener industrial designs (Johnson, Tinoco et al., 2005; Hanna & Parry, 2011; Economist, 2015). Figure 3-2 shows aerodynamic simulation using CFD software in the design of a Tesla Roadster vehicle.

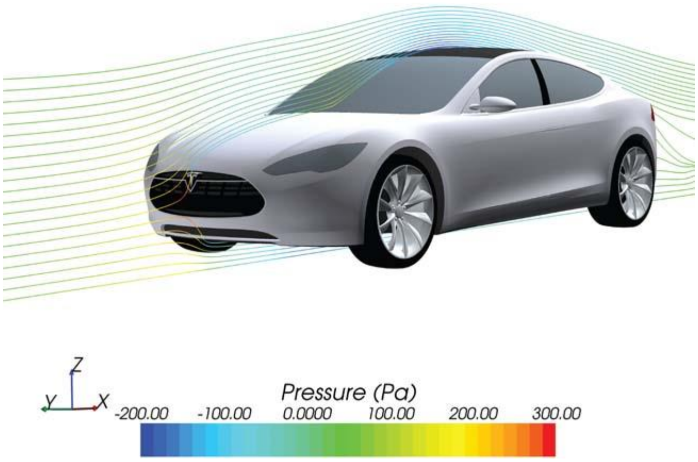

Figure 3-2 CFD simulation for Tesla Roadster design. (Johnston, 2010)

As shown in figure 3-3, CFD is nowadays a market with estimated annual revenues beyond USD 1 billion only in software sales. A combination of automotive and military/aerospace accounts for about 50% of the total revenue, while electronics, power generation, chemical processes, materials and manufacturing account for the rest. (Hanna, 2015).

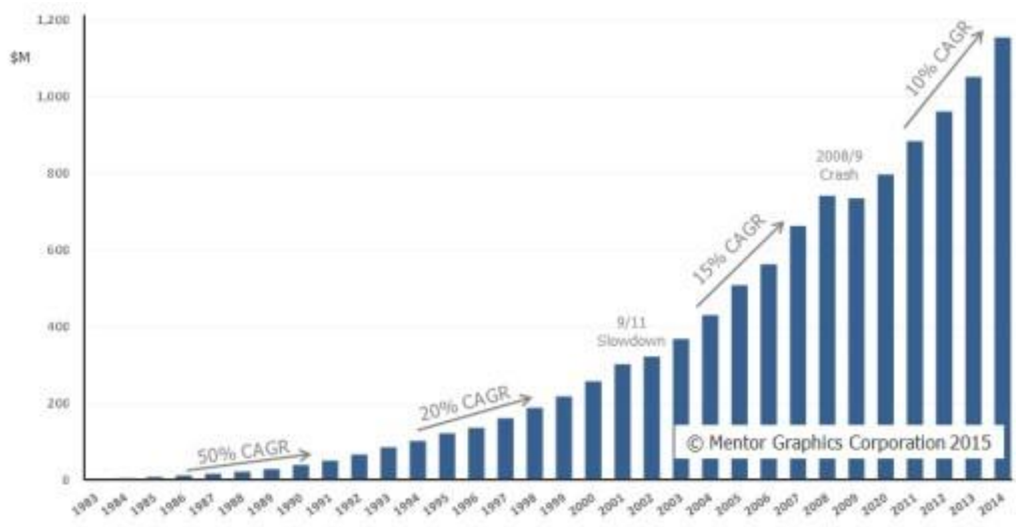

Figure 3-3 Estimated Revenues of CFD. (1984 – 2014) (Hanna, 2015)

Another relevant reason to choose CFD as a case study, is the fact that the technology was developed simultaneously at 2 different research centres: one was the National Lab at Los Alamos (USA), and the other, the department of mechanical engineering at Imperial College (UK). For a long period of time, both centres worked on the same physical problems without being aware of each other's research (Runchal, 2009). Moreover, whereas the researchers at Los Alamos were pioneers in the development of theoretical knowledge, the group at Imperial College was recognised for being the one that legitimated the use of CFD in the industry, and in consequence, for the creation of the multibillion market previously discussed.

Therefore, analysing the differences between the two centres (Los Alamos and Imperial College), makes CFD a unique choice to explore the transformative capacity of system builders to legitimate BTIs.

3.4.2.2 Choice of mHealth for diagnostics and chronic disease management as a case study

Mobile Health (mHealth) is a term originally coined to describe *"…mobile computing, medical sensor and communications technologies for healthcare."*(Istepanian, Jovanov & Zhang, 2004).

Nowadays, mHealth includes any medical and public healthcare practice supported by mobile devices such as mobile and smartphones, wireless portable medical devices or computers, tablets etc. (WHO, 2011).

The idea of providing healthcare through technological artefacts is not new. In fact, mHealth is considered to be the evolution of telemedicine and electronic healthcare (eHealth) technologies. mHealth poses an important advantage in respect to telemedicine and eHealth, as it can make use of standard mobile devices capabilities without the need of additional technological infrastructure. As a consequence, healthcare access can be put in the hands of any individual with a connected device (ibid). The potential of mHealth to transform healthcare has attracted an extraordinary amount of attention from public and private institutions over the last years. For example, the World Health Organisation, see in mHealth, the enabler towards universal healthcare *"mHealth has the potential to transform the face of health service delivery across the globe. […] If implemented strategically and systematically, mHealth can revolutionise health outcomes, providing virtually anyone with a mobile phone with medical expertise and knowledge in real-time."* (WHO, 2011). Aligned to this, the European Commission argues that mHealth can contribute to empowering citizens by helping to create a more patient-oriented healthcare, while at the same time tackling global challenges such as ageing of the population or budgetary pressures (European Commission, 2014). On the industrial side, mHealth represents an attractive emerging market, expected to reach a global value of USD 49.12 billion by 2020, with a compound annual growth rate (CAGR) of 47.6% in the 2013 to 2020 period (Grand View Research, 2015). Within this context of public institutional interest plus remarkable market prospects, mHealth has drawn the interest of many entrants in the ICT industry.

However, despite its claimed potential, after more than a decade since its commencement, mHealth remains primarily in the pilot sphere, with very low levels of large scale adoption (Labrique et al., 2013; WHO, 2016). The extant literature has already identified significant barriers. The green paper on mHealth by the European Commission (2014) collected the main perceived barriers across different mHealth stakeholders. These barriers include: data privacy and security concerns, interoperability issues, lack of evidence in cost and clinical efficiency, unclear regulatory framework or lack of reimbursable mechanisms (ibid). More recently, Gagnon et al. (2016) conducted a systematic literature review on reported barriers of mHealth from the point of view of healthcare professionals. These include individual barriers like time issues or not welcome attitude, organisational barriers like lack of training and managerial support or concerns about the quality of the provided service.

From the above discussion, mHealth represents an excellent choice to analyse the underlying mechanisms in the sometimes "painful", uncertain and conflicting process of legitimation and institutional alignment (Hellsmark, 2010).

3.4.3 Choice of unit of analysis

The unit of analysis in a research can be defined as *"...the kind of case to which the variables or phenomena under study and the research problem refer, and about which data is collected and analysed."* (Collis & Hussey, 2003, p. 68). The choice of unit of analysis is usually driven by the nature of research, the research questions and the research focus (Sekeran, 2003). The unit of analysis can be artefacts (such as software, books, photos etc.), individuals, groups, geographical items (such as town, country,) and social interactions, (e.g. relations, divorces, arrests, etc.) (Trochim & Donnelly, 2001).

Bergek et al. (2008a) point out that the criticality of defining an adequate unit of analysis for a TIS is twofold: on one hand, the choice of the unit of analysis is key to focus the purpose and outcomes of the study. On the other hand, it is a requisite to obtain consistent and comparable results in respect to other TIS empirical analysis. The authors suggest three types of choices to be considered by the researcher: (1) the choice of a knowledge field or product(s) as a focusing device, (2) the choice between the breadth and the depth and (3) the choice of the spatial domain. In a first instance, they suggest that depending on the focus of the study and the questions raised, the researcher should choose between the analysis of a specific product, a group of products, or a technological knowledge field. Having decided this, a second related choice needs to be made to define the breath of the research. For this, it is important to set an appropriate level of aggregation of the study when the researcher has chosen a group of products or a technological knowledge field. In this case, the researcher needs to determine the range of technologies that are relevant and decide whether to include a vast range of technologies to get a holistic picture (e.g. IT), or on the contrary, be more specific in order to get more level of detail (e.g. 3D printing). Finally, the researcher should also consider the spatial focus of the research. However, the authors recommend to make it as international as possible, because TIS in concept is global and "…a spatially limited part of a global TIS can neither be understood, nor assessed, without a thorough understanding of the global context." (Bergek et al., 2008a, p.413).

3.4.3.1 Unit of analysis for case study 1: CFD

Based on Bergek et al. (2008a) previous recommendations, the unit of analysis for the CFD case study is the field of knowledge of CFD. The breath of the research extends to main CFD general purpose codes developed during the 1980s like PHOENICS, Fluent, Flow-3D, StarCD as well as the developed norms, standards, practices for knowledge diffusion etc. The spatial domain encompasses two geographical sites: Los Alamos in USA and Imperial College in UK.

The justification for this choice is based on the following arguments:

(i) The overall aim of the study implies that the focal TIS needs to meet the criteria of BTIs. As defined by Garcia and Cantalone (2002), BTIs are radical technological innovations that result in new market infrastructures. CFD general purpose codes meet BTIs principles as they created a completely new market and transformed many existing industries such as automotive, aeronautic or nuclear (Hanna, 2015).

(ii) The boundaries of CFD can be easily delimited. Moreover, the number of main CFD firms providing general purpose codes during the 1980s is relatively small (5 to 6).

Therefore, the breath of the unit of analysis permits not only a holistic view on how CFD legitimated across different sectors, but also a more detailed analysis on the legitimation activities and strategies of each involved firm.

(iii) The decision on the spatial domain of the unit of analysis (Los Alamos and Imperial College research centres) encompasses the two main research centres where CFD knowledge was primarily developed. (Runchal, 2009; Hanna, 2015).

3.4.3.2 Unit of analysis for case study2: mHealth

The term mHealth encompasses a vast number of technologies that provide a wide range of healthcare services. As shown in figure 3-5, these vary from online health campaigns to self-diagnose disease kits. To narrow down the boundaries of the research, the unit of analysis for the mHealth case study is the field of knowledge of mHealth technologies for diagnostics and chronic disease management across the EU region.

The justification for this choice is based on the following arguments:

(i) In order to accomplish the BTI criteria (see the discussion for CFD in the previous section), the mHealth technologies included in the study (those for diagnostics and chronic disease management) are the ones with higher potential to disrupt the existing healthcare landscape (Steinhubl, 2015). Therefore, other applications like wellbeing and fitness, prevention, informational campaigns or administrative are out of the scope. Nevertheless, their influence as positive externalities in the legitimation process of the ones in scope, diagnostic and chronic disease management, will be analysed.

(ii) As in the case of CFD, the unit of analysis is not limited to a particular technology or firm. The decision on selecting a broader unit of analysis corresponds to the aim of the study in understanding the underlying mechanisms that are hampering the diffusion of mHealth technologies for chronic disease management and diagnostics.

(iii) The spatial domain includes the European Union (EU) region as its market is expected to be the largest regional market by 2020. (Grand View Research, 2015), and within Europe, the EU members states are the most active in the development of mHealth initiatives (WHO, 2016). Additionally, they possess important commonalities such as comparable public healthcare systems, shared overarching healthcare strategies and regulatory frameworks or similar societal challenges like aging of population (WHO, 2016).

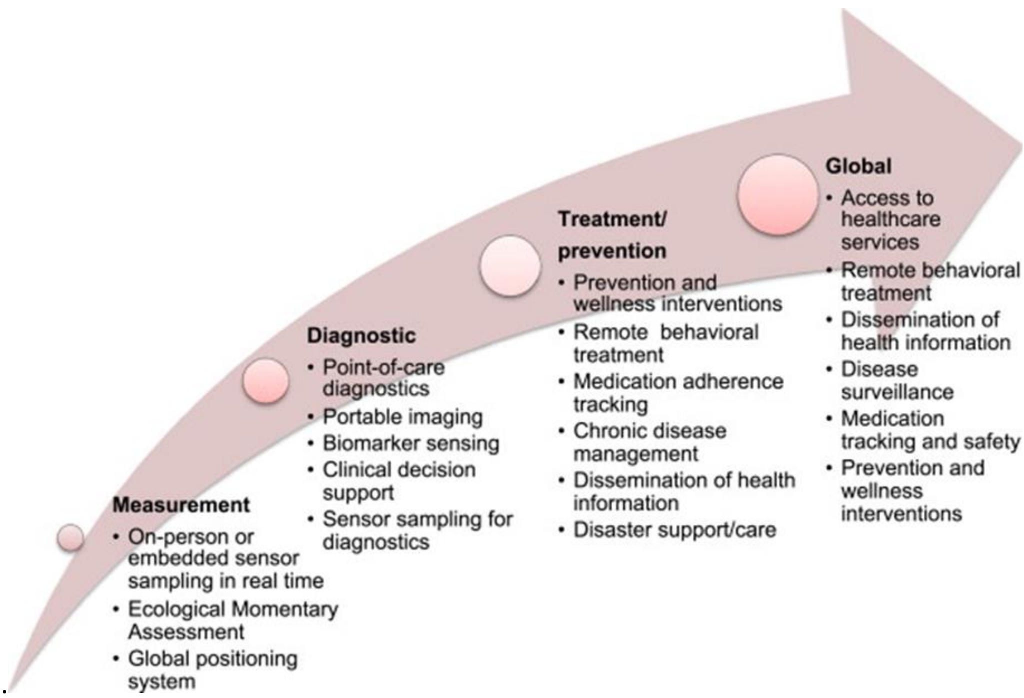

Figure 3-4 Classification of mHealth applications. (Kumar et al., 2013, p.229)

3.4.4 Choice of interviewees

Following Bergek et al. (2008a) recommendation to interview field experts in TIS analysis, this research has taken experts' interviews as the main source of data for both mHealth and CFD case studies. Together with the proven expertise of participants, the selection criteria have also followed the principle of ensuring that all groups of actors are represented.

The next two sections discuss in detail the rational for the choice of subject matter experts for both CFD and mHealth case studies.

3.4.4.1 Rationale for the choice of Interviewees - CFD case study

For the CFD case study, the researcher conducted thirteen in-depth interviews with top system builders and experts during the early years of CFD. The interviews gathered their motivations, impressions and reflections on how CFD legitimated as a new industrial paradigm. The experts were located in the United States and in the United Kingdom. As it was discussed in sections 3.4.2.1 and 3.4.3.2, the two main CFD centres emerged in these two countries: the T3 Lab in Los Alamos, and the CFD group at Imperial College, London.

As shown in table 3-1, participants from both sites, Los Alamos and Imperial College, can be classified in four main groups. The first group, includes the founders of one of the top five CFD companies in the 1980s (Hanna, 2015). All of them had an academic background on CFD and a majority were directly involved in the development of the first general purpose codes. Similarly, the second group represents those CFD experts who were also involved in the development of CFD and founded a CFD company of small or medium size. The third group, includes experts closely involved in the development of CFD who didn't take an entrepreneurial stake. In addition, three of the participants of these groups hold managerial positions at Los Alamos or Imperial College. Finally, the fourth group incorporates the voice of the early CFD adopters through the testimonies of a CFD customer and the manager of customer relations in one of the top pioneer CFD companies.

List of CFD interviewees (13)			
Stakeholder group	Los Alamos (USA)	Imperial College (UK)	Other UK location
CFD pioneer and founder of top CFD company (Hanna, 2015)	1	2	1
CFD pioneer and founder of CFD, SME size company	0	2	0
CFD pioneer – Academic profile	3	1	1
Early CFD customer and customer mgr.	0	2	0

Table 3-1 Profile of participants in the CFD case study.

3.4.4.2 Rationale for the choice of interviewees- mHealth case study

For the mHealth case study, the researcher conducted twenty in-depth interviews with top mHealth experts. The interviews gathered their experience, motivations and reflections on the current status and plausible future of mHealth as a new healthcare paradigm. The experts were located across different European countries like: United Kingdom, Belgium, Spain, Germany, Italy and Greece.

As shown in table 3-2, the participants represent main stakeholders' groups like entrepreneurs, ICT entrants, incumbent pharma reps, EU regulators and policy makers, presidents of patients, practitioners and mHealth associations etc.

The criteria for selecting the participants varied depending on the stakeholder group:

- For mHealth entrepreneurs, participants had to have at least two years of experience developing a mHealth product or service, with a real registered company and at least one productive pilot.
- The representatives of ICT entrant and incumbent healthcare companies were required to be in charge of the mHealth division in their respective corporations or be responsible for the mHealth projects pipeline.
- The independent mHealth strategists were required to have a proven solid background as experts in the field. This was measured through their professional resume, participation as speakers in congresses, publications etc.
- Policy makers had to be responsible or actively involved in the top EU digital healthcare initiatives, such as the development of regulation for medical devices, the mHealth code of conduct, the EU healthcare digital agenda etc.
- Finally, for the healthcare practitioners, patients and mHealth associations, the criteria was to engage executive or high ranked profiles, like president or vice president, to ensure that only the right spokesman was brought onboard.

Stakeholder group	# of experts	Expertise criteria
mHealth entrepreneurs	6	-+ 2 years in mHealth field - 1 productive pilot or mHealth innovation award
ICT entrant companies	3	mHealth division mHealth pipeline
Incumbent healthcare companies	3	mHealth division mHealth pipeline

Independent mHealth strategists	2	Publications Public speakers Congress attendance
Policy makers from European institutions	3	Responsible or involved in EU digital healthcare programs
President of patients' associations	1	Seniority
President of European healthcare practitioners association	1	Seniority
Vice president of mHealth association	1	Seniority

Table 3-2 Profile of participants in mHealth case study.

3.4.5 Access

Accessing the experts for the two case studies, resulted in an intensive and time-consuming task that lasted for almost two years (from January 2015 to July 2016).

For the mHealth case study, in the first stage, access was gained through the use of LinkedIn groups and professional contacts of the researcher. Additionally, the attendance at different mHealth events as observer, propitiated new contacts with different authorities and subject matter experts. Over two hundred potential participants were screened, more than 80 emails were sent and dozens of telephone calls were made to those experts meeting the criteria referred to in the previous section. In very few cases, some of the experts pointed to more experts, following a "snowballing" method.

For the CFD case study, the initial access was gained through the professional contacts of Professor Abby Ghobadian with the CFD group at Imperial College (UK). The first participants in the Los Alamos group (USA) were contacted through LinkedIn and email. From that initial stage, participants from both sites pointed to additional experts through the "snowballing" method. Some of the main CFD pioneers in Los Alamos were retired, suffered from bad health conditions or had passed away, making it very difficult to count on a bigger group of participants.

The majority of interviews were conducted via telephone and video Skype. When possible, face to face interviews were held. Additionally, one of the participants in the CFD case study, requested to submit a written response to the interview questions.

Table 3-3 Type of media used for research interviews.

	CFD case study (13 interviews)	**mHealth case study (20 interviews)**
Video Skype	3	3
Telephone	6	16
Face to face	3	1
Written questionnaire	1	0

3.5 Data collection

This section provides the reader with the details on the three sources of data utilised in the research: interviews, participant observation and documents. First, section 3.5.1, presents the rationale and guidelines for the 33 semi-structured interviews conducted in the two case studies. Then, section 3.5.2 provides the details on the professional events where the researcher participated as an observer. Finally, section 3.5.3 discusses the documents used as a complementary data source for the research, together with the qualitative context analysis approach taken.

3.5.1 Interviews

The majority of the primary data was collected through 33 semi-structured and in-depth interviews that lasted between 45 minutes and an hour and a half. Semi-structured interviews combine specific and open-ended questions with the double objective of gathering foreseen and unexpected types of information (Hove & Anda, 2005).

Before the interviews, all participants received in advance a briefing with the research purpose and main topics for the interview, and when requested, a more detailed set of questions was also sent so they could familiarise themselves with the questions and recollect any relevant information (Gubrium & Holstein, 2002). The interviews were semi-structured as this interviewing approach minimises variations among participants, without compromising the emergence of new concepts and themes as a result of the interview process (Moyser, 1988).
As Hertz et al. (1995) suggest, phone calls and video conferences are appropriate media for "elite interviewing" as they offer high levels of flexibility and convenience in terms of time and location. Additionally, as a large number of the participants were located outside the UK (Europe and USA), the logistics counted against face-to-face interviews. Therefore, interviews occurred principally through phone calls and Skype video calls.

The researcher conducted the interviews in an open and relaxed manner, acting as a "participating listener" (Davies, 1997). At the beginning of each interview, the researcher reminded the interviewee the purpose of the study and the anonymity of the interview to avoid self-report bias by the interviewees (Maxwell, 1996). Also, a few informal questions were asked, to help the participant feel comfortable and "break the ice" (Davies, 1997). During the course of the interviews, new themes emerged leading to the introduction of new questions (Bryman, 2012). Moreover, the interview questions were not completely fixed from the beginning. As recommended by Seale et al. (2004), the researcher updated and refined the interview guide with the observations of previous interviews as she moved from one interviewee to another. Finally, in order to facilitate the transcription process, all interviews were voice recorded through appropriate software for face-to-face meetings, Skype and telephone calls.

3.5.1.1 Preparation and structure of the interview guide

During the preparation phase of the interviews, the professional information about the interviewees (their role, position, published papers and books, company information etc.) was collected and used to adapt and personalise the interview (Moyser, 1988). Additionally, and as previously discussed, the semi-structured interview guide was refined from one interview to the other (Seale et al., 2004). The interview guide was organised around the set of topics that needed to be covered to answer the research question: legitimation as the core theme, plus the role of system builders, the influence of other functions and relevant factors as suggested in TIS literature (Bergek et al., 2008a; Bergek et al., 2008b; Hellsmark & Jacobsson, 2009; Hekkert et al., 2011). Following Bryman's (2012) recommendations, the researcher avoided directly formulating the research question in order to prevent the premature close off of alternative avenues. Additionally, the proposed questions followed the principle of being as simple as possible, avoiding double barrelled questions or questions with academic or unfamiliar terms (Bryman, 2012).

As Charmaz et al. (2012) point out, the different stages of the interview lead to different types of questions: at the beginning of the interview, *initial open-ended questions* were asked in order to gather as much information as possible and to give the interviewee an opportunity to recall from his or her personal experience. As the interview advanced, more specific or *intermediate questions* were asked. Finally, the interview was typically closed with an *ending* *question,* where the interviewee could summarise his or her views and feel free to talk on any important aspect not yet covered.

As previously discussed, the research guide was structured around legitimation and the core functions and factors suggested by TIS literature (Bergek et al., 2008a; Bergek et al., 2008b; Hellsmark & Jacobsson, 2009; Hekkert et al., 2011). Following this, the interviews first focussed on the visions and expectations of participants (function guidance on the direction of the search). Then, the discussion moved into exploring how knowledge creation and entrepreneurial activities were conceived and how they contributed to reinforcing legitimation. After this, the discussion moved to acceptance and legitimation of the innovation: whereas in the CFD case study, these discussions were more explorative (how resistance was overcome, why do you think customers adopted CFD?), in the mHealth case study, they evolved into more specific enquiries (reasons behind reported barriers, type of actions contributing most to the acceptance of their products, regulatory/cultural barriers and actions to overcome them etc.). After the legitimation block, the discussion centred on the extent of individual and collective system building capabilities. Finally, a closing question was asked to ensure that no relevant accounts from interviewees were missing.

Following on from the discussed interview guide, the next two sections discuss the particularities of the questionnaires for the CFD and mHealth case studies.

3.5.1.1.1.1 Interview guidelines for the CFD case study

The main purpose of the CFD interviews ,was to gather information on how CFD legitimated and created a new unintended market that provides breakthrough solutions to different industries such as automotive, aerospace or nuclear. To do so, the main actors involved in the development of CFD were asked a set of common questions around their motivations to move from theoretical to applied CFD, the avenues they took to diffuse knowledge across different industries or the adopted strategies to overcome resistance and scepticism. Additionally, and depending on the role of the participant, further more specific questions were formulated. The table below shows examples of interview questions organised by topic according to the interview guide.

Table 3-4 Interview guidelines for CFD case study.

Topic	Question examples	Objectives
Introduction	▪ I've heard you founded (the first/one of the first) CFD companies in (USA/UK) (silence) ▪ I'm very pleased that you accepted this interview as you are considered by many as one of the top contributors to the development of CFD (silence) ▪ Do you remember any other key players?	▪ Break the ice ▪ Complete actors and networks map for CFD ▪ Get the contact of additional participants
Visions and expectations (influence in the direction of search function)	▪ What were your motivations to develop CFD as an applied discipline or found a CFD company? ▪ Did you have any breakthrough or 'Aha!' in terms of…" this is going to be something big"? ▪ What made you change from a business model based on consultancy to a business model based on proprietary software?	▪ Contrast different visions, expectations and appropriable conditions around the innovation
Knowledge development and entrepreneurial activities	▪ I've heard that Los Alamos and Imperial College were working on the same solutions without knowing each other… ▪ What avenues did you take to show the industry the capabilities of your code?	▪ Understand how theoretical knowledge moved into applied knowledge
Legitimation	▪ Was there any resistance or scepticism about CFD? From who? ▪ How was resistance overcome? ▪ What industries accepted it first and why? ▪ Who were the laggards? Why? ▪ Looking back, it seems that there hasn't been much innovation on CFD since the first commercial products 40 years ago…why do you think this happened?	▪ Understand legitimation barriers and inducement factors ▪ Unfold legitimation mechanisms and legitimation strategies ▪ Understand why after technological closure in the 1980s, no major

		breakthroughs have occurred
System builders	▪ How important do you think Spalding's vision and leadership was for the development of commercial CFD? ▪ Why do you think the T3 group was not interested in applied CFD?	▪ Analyse the extent of system building capabilities
Closing	▪ In your opinion, what were the key drivers that contributed most to the success of CFD?	▪ Gather additional relevant information

3.5.1.1.1.2 Interview guidelines for the mHealth case study

The great variety of roles in the mHealth case study resulted in a number of different guidelines created for the different profiles (entrepreneurs, incumbents, practitioners, regulators, ICT entrants etc.). As one of the purposes was to contrast their visions and expectations on mHealth, most of the questions regarding this topic were formulated to all participants. Regarding the questions on legitimation, a set of more specific questions were formulated to entrants and entrepreneurs. These included aspects like: collaboration with third parties, activities and strategies to get products acceptance, compliance with existing regulations, cultural barriers, the use of clinical trial and evidence base protocols, involvement of practitioners in the product development etc. The table below shows examples of some of the formulated questions organised by topic according to the interview guide.

Table 3-5 Interview guidelines for mHealth case study.

Topic	**Question examples**	**Objectives**
Introduction	▪ What are - in your opinion - the main benefits that mHealth can bring? ▪ Many voices, including the WHO claim that mHealth will be a revolution in healthcare. Do you agree with this statement? (Why?)	▪ Break the ice ▪ Allow interviewee to provide his overall position on mHealth as an innovation

Visions and expectations (influence in the direction of search function)	▪ What were your motivations to enter in the mHealth arena? ▪ When do you estimate that mHealth will become part of the mainstream healthcare practice? ▪ Who, in your opinion, will lead the change? ▪ Do you foresee a big bang change, or on the contrary, more of a slow and gradual change? ▪ In what manner do you believe mHealth will transform the role of healthcare practitioners? ▪ In what manner you think mHealth will transform the landscape of the healthcare industry?	▪ Contrast different visions, expectations and appropriable conditions around the innovation
Knowledge development and entrepreneurial activities	▪ What avenues do you take to show to your potential customers the benefits of your product? ▪ Do you involve practitioners or patients in the development of your product? ▪ Healthcare is an evidence-based practice. What type of studies do you conduct to probe the efficiency and reliability of your products?	▪ Understand the contribution of knowledge creation and entrepreneurial activities into legitimation
Legitimation	▪ What are, in your opinion, the main barriers that are preventing a wider acceptance of mHealth? ▪ Where is resistance coming from? ▪ What are the main barriers you face to put your product in the market? ▪ From your experience, what activities/strategies contribute most to get your products accepted? ▪ Do your products represent a big change in respect to current practitioners' and patients' routines? ▪ Are your products compliant with existing regulation?	▪ Understand current legitimation barriers and inducement factors ▪ Unfold legitimation mechanisms ▪ Analyse different strategies by different groups of stakeholders (entrepreneurs, incumbents, big entrants etc.)
System builders	▪ As an expert, how likely do you consider that entrepreneurs can succeed in a complex innovation ecosystem such as healthcare? ▪ Are you associated to any other entrepreneurs, SMEs or big companies?	▪ Analyse the extent of system building capabilities

	▪ How useful do you find the mHealth networks such as HIMMS, mHealth alliance etc.?	
Closing	▪ In your view as an expert, is there any particular strategy that mHealth entrepreneurs should take to get their products in the market? ▪ What missing policies, would in your opinion, foster a more rapid adoption of mHealth? ▪ If you (as an entrepreneur) could have your time again, would you change anything in respect to what you've done so far?	▪ Gather additional relevant information

3.5.2 Participant observation

Participant observation refers to a data collection method in which the observer gets involved in the daily life of the actors under study (Spradley, 2016). The researcher's participation can be either open in her researcher's role or secret in a masked role. Additionally, her involvement can vary from being a full member of the group under research, to being a participating observer (where she participates in the activities of the group) or even to being a non-participant observer (where the interaction with the group members is minimal) (Bryman, 2012).

For the mHealth case study, together with the 20 semi- structured interviews, the researcher took a participant observer role in 3 different congresses: the European mHealth Summit 2015 in Riga (Latvia) and the UK eHealth weeks 2016 and 2017 in London. The degree of participation varied across the different events. In the European mHealth Summit in Riga, the researcher was accepted by the organisers as a volunteer, which gave her access to the speakers and exhibitors as well as attendance at sessions, workshops and stakeholders meetings. The researcher informed them about the scope and content of the study and the organisation granted the researcher permission to record the sessions and conduct informal interviews. As an example, the researcher was allowed to record an important stakeholders' meeting with top EU regulators, healthcare practitioners and ICT and pharma industry lobbyists discussing the mHealth code of conduct. In the UK eHealth weeks in London, the role of the researcher was more as a non-participating observer (Bryman, 2012), with interaction limited to attendance at different sessions of interest and informal conversations with speakers and exhibitors.

All the field notes from the observations were written in a diary and the sessions of interest were recorded and incorporated to the data analysis.

3.5.3 Documents

The term "documents" includes a wide variety of different type of sources like personal documents, official public and private documents, mass- media-outputs, Internet resources etc. (Bryman, 2012). For the present research several documentary sources like market reports, institutional position papers, regulations, commercial presentations, books or academic papers related to the technologies under study etc. were analysed. All documents mentioned and scrutinised were produced without the researcher's intervention and for different purposes other than the present research.

The objective of incorporating documents in the research was to count on a complementary source of data. As Bowen (2009) states: "*Documents provide background and context, additional questions to be asked, supplementary data, a means of tracking change and development, and verification from other data sources. Moreover, documents may be the most effective means of gathering data when events can no longer be observed or when informants have forgotten the details.*" (Bowen, 2009. p.36).

The documents were analysed using qualitative context analysis, a method that refers to the search of underlying themes from the documentary sources (Bryman, 2012). In order to do so, a hermeneutic perspective was adopted. As Atkinson and Coffey (2004) argue, documents should not be taken as 'transparent representations' of reality. They should be examined in the context in which they are produced and taking into account the purpose for which they were created. Therefore, document content analysis in this research followed a hermeneutic approach, as in the words of Bryman (2012): *"…a qualitative content analysis can be hermeneutic when it is sensitive to the context within which the texts were produced."* (Bryman, 2012. p. 560).

3.6 Data analysis

The overall objective of data analysis was to generate themes around the topics related to the main research question: the legitimation of BTIs. In particular, the researcher looked for patterns, processes, shared and divergent views present in participants' responses, observations and analysed documents. Consequently, data analysis was conducted using thematic analysis. Thematic analysis is an approach that focuses on extracting key themes from data. It is widely used in most of the qualitative strategies including grounded theory, critical discourse analysis, qualitative content analysis or narrative analysis (Bryman, 2012).

As discussed earlier in this chapter, this research took a critical realist approach aimed at explaining causal mechanisms through the analysis of events, interactions and perceptions of actors involved in the TIS (Wynn &Williams, 2012; Ackroyd, 2009; Easton, 2010; Mingers, 2004). Therefore, thematic analysis constitutes an appropriate technique to identify the underlying mechanisms in the legitimation of BTIs.

As Yin (2003) recommends, data in multiple-case study needs to be analysed fully and separated before performing any comparative analysis. In consequence, each case study was initially analysed independently from each other. Following the same principle, the interviews, field notes and documents of each case study were also analysed separately. All the pieces of data were transcribed and uploaded into NVIVO 10, producing an initial set of codes that were grouped into 4 pre-defined areas of investigation.

As previously discussed in section 2.6.4 of the literature review chapter and illustrated in figure 2-7, legitimation (the focus of this research) does not occur as an isolated phenomenon, but through the influence of the following main dynamics:

(i) the capabilities of system builders to create structural processes like accumulation of knowledge and artefacts, entry of firms and other organisations, formation of alliances and networks and institutional alignment (Hellsmark & Jacobsson, 2009; Hellsmark, 2010).

(ii) the positive (or negative) influence of other TIS functions such as guidance in the direction of search, knowledge development or entrepreneurial activities (Bergek et al., 2008b; Hekkert et al., 2011; Hellsmark & Jacobsson, 2009; Bergek et al., 2015).

(iii) external factors like landscape factors or the development of related TIS (Bergek et al., 2008b; Hellsmark & Jabobsson, 2009; Hekkert et al., 2011; Markard et al., 2016).

In consequence with the above discussion, and as figure 3-5 shows, the areas of investigation in the research were: area of investigation1: system building capabilities; area of investigation 2: TIS functions; and area of investigation 3: external factors. In addition to these, a 4th area of investigation named *legitimation*, was added. This 4th area of investigation collects participants' accounts on perceived legitimation barriers and drivers and developed strategies to build legitimacy. In a first and second read of all collected data, information was coded around these four areas of investigation.

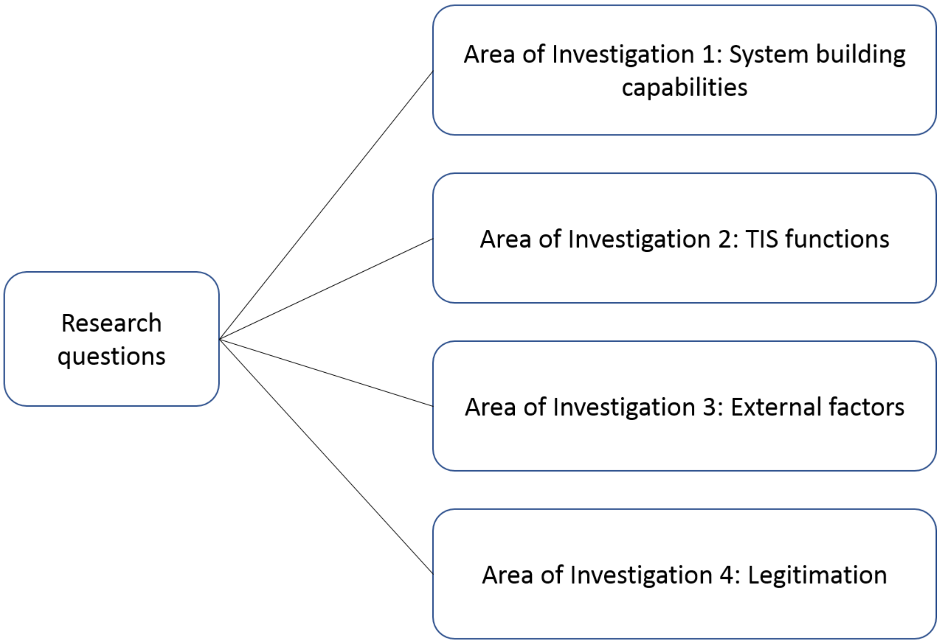

Figure 3-5 Research areas of investigation.

Once the initial codes were added to the areas of investigation, codes were added to more than one area of investigation when pertinent, a second and third round of analysis led to the categorisation and identification of emergent themes. Following Bryman's (2012) definition of a theme, the ones identified in the research met the following criteria: *"(i) [it is] a category identified by the analyst through his/her data, (ii) that relates to his/her research focus […] and (iii) that provides the researcher with the basis for a theoretical understanding of his or her data that can make a theoretical contribution to the literature relating to the research in focus."*(Bryman, 2012, p. 580).

As figure 3-6 shows, the fourth and subsequent readings led to a nested theme structure with 1st, 2nd and 3rd level themes organised from broader (1st level) to more specific (2nd and 3rd level).

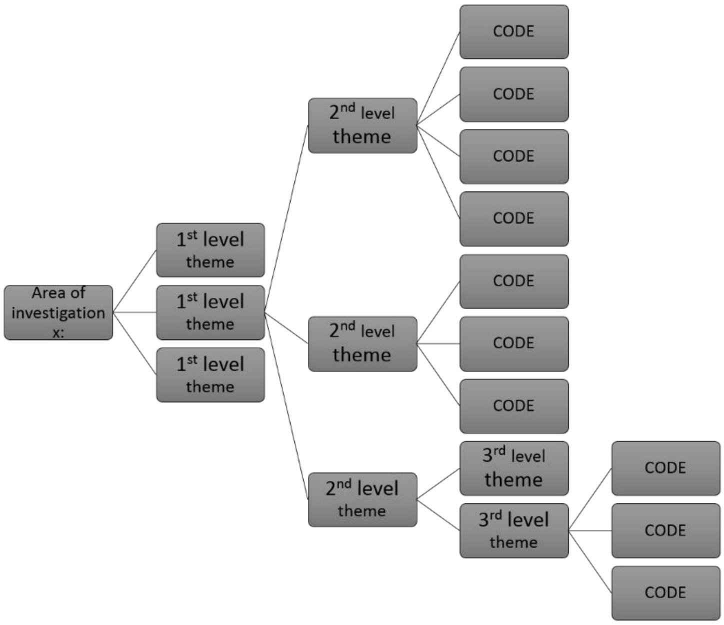

Figure 3-6 Representation of code structure for an area of investigation.

The data analysis phase concluded once saturation was reached. As Lincoln & Guba (1985) pointed out, saturation refers to "the point of redundancy" where no new findings are obtained or no new themes or categories can be identified or reorganised.

3.7 Reliability and validity

According to Bryman (2012), reliability and validity constitute the two main criteria to evaluate social research. *Reliability* refers to the consistency of the measures that are devised to gauge a concept and on whether the obtained results are repeatable at a different point in time. *Validity,* on the other hand, refers to the integrity of the conclusions of the research. Bryman (2012) distinguishes 3 different types of validity: *measurement validity* (also known as construct validity) that reflects whether the defined measures reflect the concepts they are measuring, *internal validity* that relates to the issue of whether the causal relations between variables are sustained or not, and *external validity* that deals with the question of whether the results of a study are generalisable beyond its research context.

Reliability, validity and external validity in particular, are important issues for the case study method since data is generated in a limited sample within a specific context (Gray, 2013). As a consequence, the case study method has been criticised as a method to generate theory (Tellis, 1997). Conversely, case study scholars like Yin (2003) and Williams (2000) consider that validity and reliability criteria are met as the aim in a case study methodology is to engage in a theoretical analysis from rich and in-depth data examination. Moreover, Eisenhardt (2007) argues that case studies that build theory are among the most cited pieces in Academy of Management Journal with "impact disproportionate to their numbers." (Eisenhardt, 2007, p. 25).

Nevertheless, the aim of the present research is not to generate new theory from a multiple case study design, as much as to contribute to TIS literature by unfolding the mechanisms and strategies that lead to the legitimation of BTIs. For that purpose, validity and reliability have been enhanced by using TIS as a starting point for data analysis, as well as by binding emergent themes to additional literature. As Eisenhardt (1989) contends: "…*overall, tying the emergent theory to existing literature enhances the internal validity, generalisability and theoretical level.*"(Eisenhardt, 1989. p.545).

Additionally, as Yin (2003) argues, multiple data sources contribute to provide research validity. This approach of using multiple data sources is known as triangulation. Although triangulation is mainly associated with a quantitative research strategy, it can also take place in qualitative research (Bryman, 2012). As previously discussed in the data collection section, this research made use of interviews, participant observation and document analysis to enrich data validity.

Data reliability, related to the consistency between the concepts under research and the measures used to gauge these concepts, requires the accurate description of concepts under examination to ensure that the results can be accepted as valid representations of the data (Maxwell, 1996). This was achieved through providing an in-depth description of the context of the two case studies (that will be presented in the next two chapters) through a number of different data sources. Additionally, the technique of member checks (Lincoln & Guba, 1985) was applied. This technique is based on asking feedback to the people being studied about collected data and conclusions (Maxwell, 1996). This was accomplished during the interviews and further post-interview communications.

3.8 Research ethics

This research complies with the ethical procedure of the University of Reading, and all required measures were taken during the data collection phase to guarantee the participants' consent, confidentiality and data protection.

In the first place, and regarding informed consent, all interviewees were presented with a summary of the study that included the scope and purposes of the study. Also, it was explicitly mentioned that their identities and company names would remain totally anonymous. In the case of Brian Spalding, internationally known as the father of commercial CFD (Runchal, 2009), the researcher got approval from the interviewee to disclose his name. As the figure of Brian Spalding is of high relevance to understand how CFD legitimated, his name appears several times in data analysis and discussion. Secondly, the interviewees were asked before each interview if they agreed to being recorded. Additionally, the interviewees were also asked for a verbal consent to take part in the research during the interview that was recorded. For the sessions in the European mHealth Summits in Riga and London, the researcher requested verbal permission from the HIMMS Organisation and speakers to record the sessions. All collected data (including recordings, notes and transcriptions) was kept locked at all times and did not circulate in accordance with the ethical guidance of the University of Reading.

Finally, confidentiality in the present document was guaranteed as the participants' names were totally anonymised by the use of generic titles referring to the quotes used in the data analysis chapter (i.e. entrepreneur, pharmaceutical company rep., European institution rep. etc.).

3.9 Conclusions

This chapter has detailed the methodological choices and research design made by the researcher to explore the legitimation dynamics of BTIs. As discussed in section 3.2.1, the theoretical grounds of the study and the nature of the research questions suggest a critical realist approach (Bhaskar, 1989).

The proposed method is a multiple case study for two different BTIs: CFD and mHealth. The research parameters for both case studies were discussed in section 3.4. A thematic analysis on three different sources of data (elite interviews, participant observation and document analysis) was proposed to enhance validity of qualitative data (Yin, 2003). Data analysis tools and strategy were also detailed in section 3.6.

The next two chapters, chapters 4 and 5, present respectively the results of the thematic analysis for each case study together with a discussion in relation to relevant literature.

Chapter 4 - Case study 1: The origins of Computational Fluid Dynamics (CFD)

4.1 Introduction

This chapter presents the analysis of the data collected for the first case study of the research. The first section provides the reader with an overview of the historical evolution of Computational Fluid Dynamics (CFD), the technological field under research, from its origins in the 1960s to today. From this, and with a focus on the legitimation dynamics in the formative phase, CFD is analysed as a TIS (Carlsson & Stankiewicz, 1991; Hekkert et al., 2007; Bergek et al., 2008a) following Hellsmark and Jacobson (2009) framework on TIS dynamics. Firstly, section 4.3 discusses the content and limits of system builders in the development of TIS structural processes (Hellsmark, 2010). More specifically, section 3.4.3 presents a set of technological, organisational, institutional and leadership factors extrapolated from the data analysis. Secondly, section 4.4 analyses the dynamic interplay of TIS functions and its influence to legitimate and develop CFD as a successful TIS. The third area of investigation, section 4.5, studies how external factors and related TIS impacted on the development of CFD. After that, in section 4.6, the study centres on legitimation, the key topic of the study. The analysis presents the drivers that contributed to create pragmatic, moral and cognitive legitimacy (Suchman, 1995). In addition, legitimation strategies are discussed. Finally, section 4.7 provides a summary of the main points emerging from the analysis.

4.2 Overview of CFD: historical evolution and TIS considerations.

As introduced in section 3.4.2.1, Computational Fluid Dynamics (CFD) encompasses a variety of software tools used to solve complex flow and heat related problems. CFD tools are able to predict "what if scenarios" on how a liquid or gas will flow and how surrounding objects will be affected. Consequently, they can be used to model a diverse range of scientific and engineering phenomena of interest such as: turbulences, liquid and gas flows in a pipe, air flow around wings, ocean currents, weather, pollution, blood flow etc. (Zikanov, 2010).

The predictive capabilities of CFD bring the possibility to develop more efficient and accurate engineering designs. Moreover, production costs and time to market are significantly reduced, as computer simulations substitute former expensive prototyping techniques like wind tunnel or water tank (Hanna & Parry, 2011). Therefore, the adoption of CFD gave rise to many radical advances that have resulted in safer, greener and cheaper products in a range of industries like automotive, nuclear or aerospace sectors (Johnson, Tinoco et al., 2005; Hanna & Parry, 2011; Gerard & Runchal, 2013; Economist, 2015).

This section expands the context for the case study outlined in section 3.4.2.1. It provides the reader with a historical analysis of the evolution of CFD and a review of key considerations for its analysis under TIS lenses. The chronology is divided into 3 phases. The first phase covers the birth and early years of CFD, where two main research groups were formed and the first primitive ad hoc codes were developed. The second phase, starts with the emergence of CFD multipurpose software and the foundation of CFD companies. Finally, the third phase, focuses on analysing the evolution of CFD from the 1990s to present time.

4.2.1 The formation of the main development centres and first CFD codes

The science of fluid flows, dates from the 19th century when Claude Navier and George Stokes postulated the Navier-Stokes equations to describe fluid motion. However, the complexity of the Navier-Stokes equations, makes them impractical to provide analytical solutions for most of flow related problems, especially when high Reynolds numbers are involved, as it is in the case of turbulences (Hanna & Parry, 2011).

During the second half of the 20th century, the arrival of computers propitiated that different groups of researchers started to work on numerical solutions to address the Navier-

Stokes equations. The pioneers in addressing them through numerical methods were placed at two distant locations, not only geographically, but also in their scientific approach, as it will be later explained. These groups were the T3 group in Los Alamos National Laboratory (USA) led by Dr Francis Harlow, and the Imperial College group (UK) led by Professor Brian Spalding.

4.2.1.1 Los Alamos T3 lab group

Los Alamos T3 lab was the first group that developed numerical codes to solve flow related problems (Harlow, 2004; Runchal, 2009). The first code was named PIC and produced by Dr Francis Harlow in 1957. The success of PIC in the lab paved the way for the formation, in 1958, of a dedicated fluid dynamics group with Dr Francis Harlow as the group leader.

The group was located in the former secret National Weapons Research Laboratory (aka Project Y) where the Manhattan project had been terminated a decade ago[5]. Hence, Harlow's group was funded by the weapons research division, and as such, their initial orientation was to solve problems related to national defence (Harlow, 2004). They counted with the most advanced computer resources at that time and produced a variety of codes to solve specific physics problems as shown in figure 4-1 (Johnson, 1996).

Physics	Codes or Projects	Numerical Methods/ Regimes
A. Chemistry	KIVA & No-Utopia (A, B, C, D, E, 1, 3, 8, 11, 12, 13)	1. ALE
B. Turbulence	Wildfire Modeling (A, B, 1, 2, 4)	2. Adaptivity
C. Mixing	CFDLIB (A, B, C, D, G, I, 1, 2, 3, 4, 5, 6, 7, 8, 9, 12)	3. Compressible
D. Interfacial phenomena	FLIP (A, E, F, G, I, 1, 2, 3, 7, 8, 9)	4. Incompressible
E. Phase Changes	Granular Flow (D, F, H, 7, 9, 11)	5. Multi-field
F. Solid deformation	TELLURIDE metal casting (B, C, D, E, F, H, 1, 4, 6, 8, 13)	6. Interface Tracking
G. Electromagnetic	Global Modeling (B, C, E, F, H, 4, 12)	7. Particles
H. Visco-elasticity	Mantle Modeling (E, F, 4, 8, 10, 12)	8. Implicit
I. Radiation	Composites (D, F, H)	9. Lagrangian
	Plasticity (F, H, 8, 9, 10)	10. Finite Elements
	Turbulence (A, B, C, D, 3, 4, 5)	11. Variable Connectivity
		12. Block Structured
		13. Unstructured

[5] See https://www.atomicheritage.org/location/los-alamos-nm

Figure 4-1 Main CFD codes and projects developed at Los Alamos. (Johnson, 1996, p.4)

During the first decade, the codes produced in the lab remained confined. The group in those days was primarily focused in the resolution of theoretical problems through innovative numeric methods. However, in 1969, the weapon funding that was supporting the lab was cut and the group took the decision to move from theoretical to applied CFD. With this change of orientation, the T3 Lab obtained new ways of funding by developing projects for different governmental agencies. After a short period of time, in 1973, Tony Hirt replaced Francis Harlow as the lab manager. As one of the core scientists in those days, summarises: "*Everything changed in 1969, when funding was cut. Harlow came and said to the team: 'We have to decide whether we move to applied CFD or not. We will all vote: you are twelve and I have 13 votes (laughs).' […] At that time, we started looking into other forms of funds. We started to collaborate with government agencies. Collaboration was for many years only with other governmental agencies. No private companies. […] We moved from experimental CFD to applied CFD as a matter of necessity."* (T3 Researcher).

The public distribution of the codes developed at the T3 group, started in the mid 1970s, through the US National Energy Software Centre (Runchal ,2009). However, the codes were not very popular at the beginning. The T3 lab manager in that period reflects the complexity of the codes and the difficulties that end users faced: *"They weren't user friendly codes. There were lots of nice software but they (the users) didn't have pre-processors or big post processors, so they were hard to use. They sought of an expert. No graphical interfaces…"* (T3 Lab manager). Aligned to that, Runchal (2009) suggests that the fact that T3 codes were developed using the most advanced computing capabilities at that time, made them unaffordable for the large majority, who in the early days of computers, had very limited access to big and expensive equipment.

In summary, Francis Harlow and Los Alamos pioneered the development of codes for what it later was coined as Computational Fluid Dynamics. During more than one decade, their interest remained in the realm of scientific innovation, keeping their discoveries within the weapon's national lab. Later, and as a matter of necessity, they shifted their focus to applied CFD, looking for governmental funds to different areas other than the national defence. As it will be discussed in the next sections, it wasn't until the late 80s and early 90s, that they got in touch with different industries. Moreover, as a T3 lab scientist argues, it was the industry who looked for them:

"*Los Alamos is isolated, in the middle of nowhere. It had its own rich funding […] We lived in a very self-contained huge system. By the time we published more around the world, we were already well known. People just came…"* (T3 Lab scientist).

4.2.1.2 The thermofluids group at Imperial College

The group at Imperial College was led by Brian Spalding, Professor of Heat Transfer and Head of the Thermofluids section, later renamed as Computational Fluid Dynamics Unit. At the beginning of the 1960s the group consisted of Spalding plus two faculty members. However, by the end of the decade, the group had grown up to 30 researchers, which became the largest CFD research group at that time (Runchal, 2009). During the initial years, the group worked on the same problems and developed similar ideas as the Los Alamos group but without knowing about each other. It wasn't until 1969 that they got in contact and shared their discoveries. Some of the innovations first explored by Harlow's team were incorporated in the early codes developed at Imperial College (Runchal, 2009).

"There was Francis Harlow in Los Alamos, New Mexico…I didn't know him. I discovered years later we were doing the same things, same ideas, but quite unconnected to each other." (Brian Spalding).

Despite the fact that the two groups were working on similar types of problems, the orientation at the Imperial College was very much applied from the beginning. They had a strong focus on engineering problems as Spalding envisioned that numerical methods could contribute to addressing important industrial challenges, even when the results obtained were approximate and rough. His scientific approach was less rigorous than Harlow's and his group at the T3 Lab (Runchal, 2009). As it will be further analysed in section 4.6, Spalding's view of developing approximated solutions to solve complex problems was severely criticised in many academic circles.

The Imperial College received the first IBM mainframe around 1963, almost a decade later than Los Alamos. In the period between 1963 and 1969, the group developed two codes: ANSWER and SIMPLE. Although the term CFD was not formally coined until 1972 by (Roache), Runchal (2009), places the birth of CFD in 1969. By that year, 1969, Spalding and his collaborators had already published two books with the codes (Spalding & Patankar, 1967; Gosman et al., 1969) and organised a Post-Experience Course inviting both academic and industrialist groups. Additionally, in the same year, 1969, Spalding founded the first CFD consulting company named CHAM, standing for Combustion, Heat and Mass Transfer. The original CHAM was superseded by Spalding in 1974 with a new CHAM standing for Concentration, Heat and Mass Transfer Ltd (Runchal, 2009).

During the first years of CHAM, Spalding developed customised CFD codes for his first customers in the automotive and nuclear industry. By the end of the 1970s, he and his collaborators in CHAM developed PHOENICS, the first general purpose CFD commercial software, that was launched to the market in 1981. PHOENICS could predict a large range of scenarios involving fluid flow such as: problems on engines, fire propagation in buildings, human fluids, pollution distribution, rivers and ocean currents etc.[6]

[6] Source: What PHOENICS is (2005) at http://www.cham.co.uk/phoenics/d_polis/d_docs/tr001/tr001.htm#what

4.2.2 General purpose codes and market take off

In the years right after the introduction of PHOENICS by CHAM, a number of CFD companies were created, launching different variants of CFD software to the market.

Position	1984	1994	2004	2014
#1	CHAM (Phoenics)	FLUENT Inc. (FLUENT)	FLUENT Inc.* (FLUENT)	ANSYS INC. ** (CFX, FLUENT)
#2	FDI (FIDAP)	FDI (FIDAP)	CD-ADAPCO (StarCD)	CD-ADAPCO (CCM+, StarCD)
#3	FLUENT Inc. (FLUENT)	CD-ADAPCO (StarCD)	ANSYS Inc. ** (CFX)	MENTOR GRAPHICS *** (FloTHERM, FloEFD, Flowmaster)
#4	FLOW SCIENCES (Flow-3D)	AEA TECHNOLOGIES (Flow3D)	FLOMERICS LTD (FloTHERM)	EXA CORP. (PowerFLOW)
#5	SOFTWARE CRADLE (Scryu)	FLOMERICS LTD (FloTHERM)	EXA CORP. (PowerFLOW)	SOLIDWORKS (Solidworks Flow Simulation)
CFD market Size ($M)	~10	~100	~430	~1,155
CFD Industry average growth rate	~50%	~20%	~15%	~10%

* Fluent Inc. acquired Fluid Dynamics International (makers of FIDAP) in 1996.

** Fluent Inc. was acquired by Ansys Inc. in 2006. Ansys had also acquired AEA Technology's CFX Division in 2003 (CFX having been named Flow3D originally in the 1980s and 1990s)

*** Mentor Graphics acquired Flomerics Ltd. in 2008 and Flowmaster Ltd. in 2012; Flomerics in turn had acquired NIKA GmbH in 2006.

Figure 4-2 Ranking of CFD companies in the period 1984-2014. (Hanna, 2015)

As shown in figure 4-2, PHOENICS by CHAM, the company founded by Brian Spalding, was the leader in the incipient market of 1984. In the second position was FIDAP, a CFD company based in Illinois (USA). The researcher hasn't found any link between FIDAP and the developments carried out at Los Alamos. A different case is Flow-3D, the fourth company in the ranking. Flow-3D was founded by Tony Hirt, the successor of Francis Harlow as lab manager in T3 Los Alamos. Moving up one position in the ranking, the third software, FLUENT, was launched in 1983 by Professor Jim Swithenbank from Sheffield University (UK). Professor Swithenbank adapted the main bulk of PHOENICS code and sold it to Creare Ltd., later Fluent Ltd. (Runchal, 2009). Finally, a Japanese company based in Tokyo, software Cradle, occupied the fifth position on the list.

The ranking in figure 4-2, shows that CHAM led the emerging CFD market in the 1980s. However, its advantage as a first mover (Kerin et al., 1992), didn't last long. As it will be discussed over the next sections, CHAM (which exists today and at the time of data collection was still run by Professor Spalding), was the only CFD pioneer company that didn't partner with incumbent engineering companies. On the contrary, the rest of the firms in figure 4-2 established different partnerships, went through processes of merges and acquisitions and led the growth market of CFD. A good example of this, is CD-Adapco: in 1986, David Gosman and Raad Isa, two Spalding disciples', founded Computational Dynamics Ltd, (CD) later acquired by Adapco Ltd to become CD-Adapco. The CFD software developed by Gosman and Isa - called StarCD - presented an innovative methodology known as unstructured meshes, which became very popular in the automotive industry to solve engine combustion problems. By 1994, they were already the third CFD company as figure 4-2 shows. More recently, in 2016, Siemens acquired CD- Adapco for $970 million[7].

Apart from CHAM and CD-Adapco, different CFD companies mushroomed out of Imperial College. Flomerics, as an example (see figure 4-2), was founded by Harvey Rosten and David Tatchell, Spalding's disciples and former managers at CHAM. Some other companies focused on niche applications like electronics and HVAC (heating, ventilation and air-conditioning).

4.2.3 Current status of CFD field

Nowadays, CFD is a market surpassing the billion dollars per year in software sales (Hanna, 2015), with an estimated rate of average growth (CAGR) of more than 9% until 2020 (Technavio, 2016). The principal market drivers for CFD, are the need to reduce time and costs in product

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7 https://www.plm.automation.siemens.com/en_gb/about_us/newsroom/press/press_release.cfm?Component=244055&ComponentTemplate=822

development. Aerospace and defence are the sectors contributing most to CFD revenue with approximately a 40% of the total market share (Technavio, 2016). These sectors are highly dependent on CFD as manufacturers are facing elevated levels of competition and pressure to reduce product development cycles. Additionally, another important sector for CFD, the automotive, is making use of CFD simulations to improve engine CO2 emissions and developing the next generation of hybrid/electric cars (The Economist, 2015; Technavio, 2016). Finally, the use of CFD in the electrical and electronics industry is increasing because of the growth in R&D, especially in Asian countries like China and South Korea.

The CFD market landscape shows a high degree of fragmentation. The leading providers, Ansys, CD-Adapco[8] and Mentor Graphics,[9] coexist with a plethora of small and medium CFD companies primarily focused in niche solutions like HVAC, for data centres cooling (Technavio, 2016). The market leaders, as explained in the previous section, have their origins as companies created close to Imperial College: CD-Adapco was initially founded by two scientists from Spalding's group and Ansys, an American engineering company, acquired Fluent which is a version of Imperial College software distributed from Sheffield University.

Moreover, the software and methods used today in CFD don't differ much from those developed during the 80s (Runchal, 2012; Hanna & Weinhold, 2017). As Hanna and Weinhold contend: *"The traditional process for doing CFD has not really changed in 30 years, and the bulk of CFD done today (as much as 80% we estimate) complies with this accepted norm of creating a geometry in CAD, exporting it to a meshing tool, meshing it, setting up and running a CFD solver, post-processing results, going back into the geometry, altering it and continuing to do these design loops again and again."* (Hanna & Weinhold, 2017, p.4).

[8] CD-Adapco was acquired by Siemens in January 2016

[9] Mentor Graphics was acquired by Siemens in November 2016

Following on from this, a co-founder of one of today's CFD market leaders, argues that there hasn't been any disruption since the 80s in terms of new capabilities provided by CFD:

"*I think that even the unstructured mesh has all been incremental […] some increments have bigger impact than others, but since then I would say that the big jump[…] the big jump secured the place of (CFD software). There had been a lot of new developments like a new language instead of using FORTRAN, people use C++, but that is not really an innovation that creates a revolution in application or in capability.*" (Co-founder CFD leader company).

Therefore, as Abernathy and Utterback (1975) postulated in their model of cyclical innovation, following the lock-in of CFD in the 1980s, there has been a long ferment phase of incremental innovations as no new breakthroughs had succeeded over the last three decades. This stagnation in the innovation path for CFD, appeared as an emergent theme during the data analysis phase and it will be further developed over the next sections of this chapter. As the experts participating in the study reflected, different root causes contributed to it. These include the complexity of the physics involved in flow dynamics, the consequent difficulty to change established practices, or the elimination of the knowledge networks between academics and industry.

As an example, Brian Spalding, recurrently emphasised how inertia in securing adopted practices hindered the introduction of new innovations, and how adopters, at the same time, take established practices as an unquestionable given for granted:

"Yes, that's when innovation came and it is still going (in the 1970-80s). I'm hoping for a new kind of CFD, a new practice of CFD because this success of CFD is in my mind a rather fraudulent success, and I see it happening here in my own company. Young people come in, they learn how to use the computer code and they do the calculations and they believe the results! […] People now, they expect the answers to be as accurate as they are used to on the solid side." (Spalding). In a later excerpt of the interview, Spalding suggested that leading CFD firms do not show much interest in new breakthroughs. In the same direction, the creator of one of the first prominent

CFD codes, argued that the advent of commercial CFD transformed the relations between academy and industry and made knowledge exchange more difficult.

"*CFD research made great strides in the 1970s. After the 1980s, there has not been significant advance in CFD. In my opinion, the root cause is the availability of commercial CFD products. […]. Before the products came on the scene, CFD was a cottage industry. With the advent of commercial CFD, the cottage industry community became much smaller. Now an innovator could not take his/her invention directly to the users. The innovator could publish the new idea, but it remained unused and largely ignored. The immediate applause was not available. This drastically reduced the motivation for innovation […] If most of the world is going to use CFD through commercial products, the innovations will have to come only from the people who work in the CFD software companies. Whether these people are qualified to come up with the required advances and whether such work makes business sense for them will determine the progress of CFD*. "(IC researcher and founder of a CFD SME).

The stagnation of knowledge and breakthroughs' developments once incumbent firms take control and the market is stabilised, represent an interesting avenue for future research. Although the topic is slightly out of the scope of this research (legitimation in the formative phase), it opens a good opportunity to study the impact on innovation of the "asymmetric power relationships" (Kukk, 2016; Gulati & Stych, 2007) between system builders and big firms. This is further discussed in section 6.6 of the conclusions chapter.

4.2.4 TIS considerations

As discussed in section 3.4.3, the definition of the technological boundaries of a TIS is the starting point of its analysis. As discussed in section 3.4.3, the researcher needs to consider three types of choices: (1) the choice between a knowledge field or a product as a focusing device, (2) the choice between breadth and depth, and (3) the choice of spatial domain.

The focus of this research is to analyse how CFD legitimated as a new practice across different industries. Therefore, the knowledge field of CFD is considered, as the study is not limited to a particular code. Different products like PHOENICS, Fluent, Flow-3D or Star-CD have been analysed. Moreover, the research is not restricted to any particular target industry and all sectors that adopted CFD have been considered for the analysis. Finally, the spatial domain is primarily focused around the two main CFD research centres: the T3 Laboratory at Los Alamos (USA) and the Heat Transfer Unit at the Imperial College (UK).

Once the boundaries of the technology in scope are defined, Bergek et al. (2008), propose to identify the main structural components of the TIS. As described in section 2.6, the structural components of a TIS are: *actors, networks and institutions.*

Actors include individuals, firms and organisations that contribute to the development of the TIS such as universities, research institutes, public bodies, industrial associations, venture capitalists etc. As discussed in section 2.6.1, system builders (Hughes, 1987) are a critical subset of actors that contribute most to developing TISs and building legitimacy: they create new sources of capital, work with regulators and incumbents, persuade adopters or solve problems when one part of the system does not develop in step with the rest (Palm &Fallde, 2016). System builders can develop their capabilities individually or collectively. As Musiolik et al. (2012) contend, in the very early phases of the innovation process or in highly institutionalised contexts, system building will most likely succeed as a collective effort.

Networks are constituted by the non-market relations between actors. They include formal and informal associations, like standardisation networks, professional networks, public–private partnerships, industry-university links etc. Networks can have different purposes like the development and diffusion of knowledge, market formation or the development of system building capabilities to influence and change the prevailing institutional framework (its norms, regulations, practices etc.).

Institutions, regulate the relations between actors, networks and firms (Hekkert et al., 2011). They can be formal like: regulation, laws, policies, business models etc. and informal like: culture, beliefs, norms, routines and practices.

Table 4-1 presents the main TIS structural components considered for this study. The actors column, lists the profiles of the main actors including, key researchers and group leaders at Los Alamos and Imperial College, scientists involved at Cambridge and Sheffield Universities, founders and key staff at pioneer and incumbent companies like CHAM, Fluent, Star-CD and Flow Sciences, early industrial adopters, such as the UK National Nuclear Corporation, General Motors, Canon etc. The networks column, shows the different formal and informal associations like NAFEMS and ERCOFTAC, organisations oriented to the development of CFD best practices and standards, the links between the development centres and the industry including post-experience courses, conferences etc. Finally, the institutions column, presents the main formal and informal institutions taken into account. These include culture, norms and regulations at the main research centres, software patents norms, business models etc.

Actors	Networks	Institutions
• T3 National lab researchers • Imperial College researchers • Sheffield University researchers • Cambridge University researchers • T3 group leaders • Imperial College leader • CFD firm founders and key staff (CHAM, Fluent, Star-CD, Flow Sciences)	• University – industry networks • Intra academic networks • Post-experience courses • T3 National lab links • NAFEMS • ERCOFTAC	• T3 Laboratory norms, culture, US National Labs regulation • Imperial College norms, culture and regulation • Sheffield norms, culture and regulation • Software patents • Business models

• Incumbent engineering firms (Creare, Adapco, Ansys) • Early industrial adopters		

Table 4-1 Structural components of CFD as a TIS.

4.3 Area of investigation 1: System building capabilities and development of TIS structural processes

This area of investigation addresses the extent and limits of system builders in the development of TIS structural processes. As defined in section 2.6, system builders are a key class of actors that play a critical role in the formative phases of a TIS. System builders act as institutional entrepreneurs and with their transformative capacity, they align institutional forces such as norms, culture or regulations in the best interest of the innovation (Kukk et al., 2016). As Hellsmark and Jacobsson (2009) argue, the role of system builders in the formative phase is twofold. First, they contribute to create four main structural processes in the TIS: (i) accumulation of knowledge and artefacts, (ii) entry of firms and other organisations, (iii) formation of alliances and networks, and (iv) institutional alignment. Second, and as a consequence of the development of the TIS structural processes, system builders also strengthen TIS functions like knowledge development, entrepreneurial experimentation, legitimation etc.

As discussed, this section focuses on the analysis of the development of the four TIS structural processes defined by Hellsmark and Jacobsson (2009). Its impact in the development and performance of TIS functions is analysed in section 4.4.

4.3.1 System building capabilities at Los Alamos

Los Alamos National Laboratory was very advanced in accumulation of knowledge and technology. They counted on cutting-edge computing resources, and Frank Harlow and his group are credited for being the first scientists who developed algorithms and codes to solve turbulences and other complex flow related problems (Johnson, 1996). Moreover, some of their findings were later incorporated in the first commercial codes produced at Imperial College (Runchal, 2013). However, data suggests that the T3 Lab at Los Alamos, as a group, didn't act as system builders during the formative phase of CFD. The lab remained for many years as an isolated and self-contained research centre oriented to solving complex theoretical problems. As it will be presented in this section, participant's accounts point to a combination of organisational, cultural and legal factors leading to their isolation and lack of interest in developing a commercial use for CFD, at least during its formative phase (1970s and early 1980s).

As discussed in section 4.1, the Los Alamos T3 Lab was founded as a spin-off of the Manhattan project, probably one of the most secret projects in contemporary history. As the Atomic Heritage Foundation explains: *"Los Alamos, New Mexico was the site of Project Y, or the top-secret atomic weapons laboratory directed by J. Robert Oppenheimer. The site was so secret that one mailbox, PO Box 1663, served as the mailing address for the entire town. The mountains allowed the scientists ample opportunity to relax by skiing, swimming and hiking. But they spent most of their time in laboratories, overcoming challenge after challenge to develop the Little Boy (gun-type) and Fat Man (implosion) atomic bombs."*[10]

As one of the T3 researchers declares, after separating from the weapons division in the 1960s, the lab maintained their orientation as a theoretical research centre focused in finding innovative paths to solve complex physical problems. They still benefited from generous funds and didn't perceive the need to guide their research towards applied research.

"*We were at Los Alamos and it is a weapons laboratory, you know, the theoretical division started as a one of the main divisions, and it was actually where the first atomic bomb was*

[10] Source: https://www.atomicheritage.org/location/los-alamos-nm

designed and even though [...]But then in the probably 60s, the weapons division separated, so T3 division became just scientist and really not fully tighten with the weapons program […] but still benefited from the money flow. And that is maybe what did Los Alamos very different from Imperial College […] (We) had lots of money. The funding issues only came in the last maybe decade or so, and apart to that there was infinite computer resources to try things and funding." (T3 Lab researcher).

The above sentiment is shared by another researcher:

"*At the beginning there was no interest in going to the industry. We were a funded lab. Spalding went to the industry but we didn't.*" (T3 Lab researcher).

However, later on, in 1969, the weapons fund was cut and Francis Harlow took the decision to shift into applied CFD to provide financial support for the lab. As the researchers indicated, they only were allowed to be involved in governmental projects. Any engagement in private or commercial activity was forbidden by law. The Federal Technology Transfer Act, allowing US government agencies and universities to work with private companies, was not approved until 1986. As the manager of the T3 Lab in those days declared:

"We were not allowed, as a government laboratory, to do any work for private companies, only with government agencies." (T3 Lab manager).

Another T3 scientist suggested that even after the Federal Technology Transfer Act, they had limitations in the type of companies they could be involved with: *"Our relationships with the industry were always very careful to work with industries that had nothing to do with weapons or other countries that were purely American countries."* (T3 Lab researcher).

The collaboration of the T3 Lab with other academic and research centres was also unusual in the early days. An interesting exception, is the travel that Brian Spalding and some of his collaborators from Imperial College did around 1968-1969. Both groups had been working on the same problems for some years without knowing about each other. According to Runchal

(2013), one of the IC scientists, Brian Spalding incorporated some of the algorithms learnt at Los Alamos into PHOENICS, the first CFD commercial code.

Related to this, all the participants from the T3 Lab, mentioned that a more proactive collaboration with other research centres or a higher visibility of T3 discoveries were probably hampered by the fact that the group leader, Francis Harlow, didn't travel:

"Brian Spalding said at one time that he gave Harlow the credit for having first developed the turbulence transport, but I think his reputation is based on that. I mean, he is identified with those equations and I think Frank is much less visible to people and the reason is that Frank never travels. He never leaves Los Alamos: he didn't go to meetings, he doesn't give talks [...]You know, people comes to Los Alamos to talk to him. He doesn't travel." (T3 Lab researcher).

"Frank Harlow and Brian Spalding hit upon the same kind of thing including the critical phenomena of turbulence into the computation. […] But Harlow did not travel. So, Brian Spalding came to Los Alamos, and spent time and shared with all T3 […] and you know, through David Gosman who was at that time very close friend with Tony Hirt, we kept that connection up. It was...you know....it was competition, but it was stimulating as well." (T3 Lab manager).

The first reported collaboration of the T3 Lab with the industry happened around the mid 1980s. General Motors requested the participation of the T3 Lab in an automobile consortium, that later would be named USCAR[11]. KIVA, the T3 Lab code for reactive flow and combustion modelling, had just been presented in a contest organised by the National Science Foundation. By that time, as explained in section 3.2, the CFD market had already taken off, with several CFD companies selling software and services, few of them in partnership with incumbents like Creare and Adapco.

[11] According to USCAR website (http://www.uscar.org/guest/about), its origins date back to 1984 when Chrysler Group, Ford and General Motors acknowledged the need of collaboration as their competitors overseas (Japan and Europe) were doing.

"About that time, the company was realising what the National Labs could bring. […] They were trying to encourage the National Labs to work with industry. […] They formed a consortium between the National Labs and the car companies called USCAR (*). And USCAR was formed by General Motors and the big three (companies) in the automotive sector and they were doing business with the labs and the labs brought various thundering novel things to the automotive industry. We brought the Computational Fluid Dynamics. […] I think it was General Motors maybe being the first one. They could work on our computing codes, and they could do it themselves…" (T3 Lab manager).

In summary, despite their seminal contribution to knowledge, the Los Alamos T3 Lab didn't act as system builders during the formative phase of CFD. Table 4-2 summarises their level of achievement in the creation of the four structural processes as defined by Hellsmark and Jacobson (2009). Evidence shows that despite their relevant role in knowledge accumulation, they didn't significantly contribute to create networks, establish alliances, attract firms or align the institutional environment.

Processes developed by system builders (Hellsmark & Jacobsson, 2009)	**Degree of accomplishment at Los Alamos**	**Data evidence**
Accumulation of knowledge and artefacts	High	▪ Highly skilled scientists ▪ Cutting-edge computing resources ▪ First pre -CFD codes developed at Los Alamos ▪ Algorithms of commercial CFD codes developed at Los Alamos
Entry of firms and other organisations	Low	▪ Theoretical lab: no interest in industrial problems ▪ Self-contained environment: lab originally funded as part of a secret project ▪ Legal constrains: National labs not allowed to be involved in commercial activities before 1986

Formation of alliances and networks	Low	▪ Self-contained environment: lab originally funded as part of a secret project ▪ Group's leader didn't travel
Institutional alignment	Low	▪ Lack of interest in industrial problems ▪ Legal constrains: National labs not allowed to be involved in commercial activities before 1986

Table 4-2 Development of system building structural processes at T3 Lab. Adapted from (Hellsmark &Jacobsson, 2009).

As previously discussed , evidence points to a combination of factors that involve organisational, insitutional (norms, culture etc.) and leader's preferences. The organisational factors include the orientation of the T3 Lab, as a theoretical laboratory dedicated to solving complex theoretical problems or the culture of working in an isolated and self-contained environment. Institutional factors refer to the legal limitations of the lab to be involved in commercial activities[12]. As an example reported by one of the participants, entrepreneurial activities were prohibited and scientists had to leave the lab before they could start any entrepreneurial venture. This was the case of the lab manager in the early 1980s, who left his position in the lab and founded a CFD company named Flow-3D. Finally, as participants pointed out, leaders' preferences, like the fact that Francis Harlow didn't travel, also influenced their low contribution as system builders. These factors are further analysed in section 4.3.3 once the data analysis for Imperial College is discussed in the next section.

4.3.2 System building capabilities at Imperial College

Brian Spalding and his group at Imperial College are recognised as key system builders in the development of CFD as a novel industrial practice. As it is presented in this section, they were key agents in the development of the four main structural processes that enhanced the strength of CFD as a technological innovation system: accumulation of knowledge and artefacts, entry of

[12] The Federal Technology Transfer Act allowing US government agencies and universities to work collaboratively with private companies was approved in 1986.

firms and other organisations, formation of alliances and networks, and institutional alignment (Hellsmark & Jacbsson, 2009).

As one of Spalding's collaborators and founder of one of the big CFD companies argues, the starting point as system builders was Spalding's vision on how numerical codes could help the industry to solve important design problems:

"I think Spalding is, a lot of people would credit him to be the father of industrial CFD. He started in this department in fact, developing a numerical methodology to solve fluid problems and he pioneered this field in targeting it at industrial applications. He didn't invent CFD, there were other groups as in Los Alamos in the United States articulating it, who started developing numerical techniques before […]those were primarily driven by applications to the defence and nuclear explosions[…]but it was Spalding who saw the opportunity in developing or applying these numerical techniques to solving industrial problems." (Spalding's disciple and CFD company founder*).*

The participant's statement is aligned to the reflection of Runchal (2009, p.4072) regarding Spalding's role in the development of CFD.

"*In my view it will be true to say that Brian did not invent the ''science" of CFD but he is still the person who honed the ''art" and ''technology" of CFD for engineering design and practice. In Newton's words: 'Spalding stood on the shoulder of giants and saw farther than his peers. He foresaw that unifying flow, heat and mass transport will lead to practical tools for engineers. He foresaw that looking at the physics rather than the mathematics will lead to wider acceptance of CFD tools. He foresaw that CFD, once turned into to a design tool, would revolutionise engineering. He foresaw that there were commercial opportunities in CFD. ' […] He simply found a way to devise a practical solution to deal with the essence of the problem.*"

Spalding also confirms how it all started with his desire to explain the potential of numerical methods for industrial purposes:

"I saw the future approaching to express that, but not a great moment I think I would say. […] In any particular scientific topic, I've always seen it as: what is the use that it matters...to whom does it matter to solve the problem? So that's always been...to look for an interesting utility. […] I wanted to know, then it became that that knowledge was useful knowledge, and then I explained it so people could use it […] Computers came on the scene and made possible to solve mathematical problems that we've done with difficulty in the former way. […] I recently had to look at some old papers, and I've seen that in the conclusions I had drawn: Yes, this could be applied to industrial purposes." (Brian Spalding).

To pursue his vision, Spalding and his collaborators undertook a number of activities to demonstrate the possibilities of CFD. Chief among them was the publication of two books with two relevant CFD codes for industrial engineering : SIMPLE and ANSWER (Spalding & Patankar, 1967; Gosman et al., 1969). These books drew the attention of many academics and industrialists. As Spalding pointed out, the publications were critical to demonstrate the capabilities of CFD codes and consequently, to attract more actors into CFD:

"The most important was to get published problems in a book, because that means others could do what we've been doing. So I think that was.... probably the most important thing.... People point to me as an innovator, I think we all innovated too...but they didn't spread the word around […] People could buy the book and copy the program, so they could start doing themselves. […] I think that spread the word a lot, because they could copy it and get the same results...so that's an important way of communication, I think." (Brian Spalding).

Additionally, in 1969, Spalding organised a Post-Experience Course involving academics and industrialists. This course was the seed for the creation of a network of academics and industrialists around CFD.

"By the end of 1968, Brian had realized the potential of the developments that had taken place. He decided to organize a Post-Experience Course at Imperial College in 1969 targeted at both academic and industrial communities. The Post-Experience Course at IC in 1969 reached a large

number of researchers in the UK and later abroad through a series of courses and seminars at various universities in the US and Europe. It should also be noted that the first conference with CFD as its theme was held at Monterey in 1968."(Runchal, 2013. p.4).

The academy-industry network had a critical influence in the dissemination of knowledge. In the succeeding conferences, standards were developed and new ideas and algorithms presented. As one of the participants reflects, the network facilitated the creation, refinement and adoption of new ideas between academics and final users in the industry:

"Professors, graduate students, and even researchers in industry wrote their own computer programs. There was a free and vigorous exchange of ideas among the members of this cottage-industry community. If an innovator described or published an improved algorithm or a new mathematical model, the others were quickly able to implement those ideas in their programs and get benefits." (IC researcher and SME CFD founder).

In parallel to the creation of a network of academic and practitioners, Spalding founded CHAM in 1969. CHAM, standing for Combustion, Heat and Mass Transfer, was the first CFD company (Runchal, 2009). Through CHAM, Spalding attracted firms and other organisations into CFD. CHAM developed ad-hoc codes and provided consultancy services. As Spalding stated, the automotive industry and nuclear governmental organisation were among the early adopters:

"It was Rolls Royce and other engine companies the first to apply the technology, and nuclear industry of course and by now CFD is widely used elsewhere... At that time, we had the Atomic Energy Authority...they had no numerical capabilities, so that's how they came to us. We were quite big in the nuclear industry. Yes, nuclear industry was an important area." (Brian Spalding).

The normative and legal framework at Imperial College, was less rigid than in the T3 Lab. Although academic's involvement in private activities was disliked, Spalding got permission to set up his company:

"There was certain hostility in some parts at Imperial College […] At that time I had to get permission to setup a company and it was Lord Penney[13] who was director at that time and he was in favour of it and he said:' Go ahead.' Later on, others came who were not so approving …" (Brian Spalding).

When participants were asked about the drivers for the rapid creation of the structural processes around CFD, they argued that they could demonstrate the usefulness of the technology to solve industry problems:

"It happened quite fast. Once people could see what the codes can do for different industries, aerospace were the first one, but other industries: the glass industry, the nuclear industry was also another user…so people began to see the uses…so I think the main catalyst was one, that specially our group, but also Harlow's group later, that the industrial penetration became very high…our group worked forefront with the industry in getting industry realise how we could solve some of their problems. […] But, nonetheless one of the main factors was that the industry saw the usefulness of that." (SME CFD founder).

In addition to proving evidence on CFD capabilities, Spalding points to the lack of alternatives for many industries, as another important factor for the rapid formation of CFD structures. In the words of Spalding:

"*It was easier in those days because there wasn't any* competition […] *There was nothing* […] *so that early ideas were quickly accepted and spread out. The most important was to get published problems in a book, because that means others could do what we've been doing.*" (Brian Spalding).

The participants from Imperial College reported that the alignment of CFD into existing industrial practices and norms occurred smoothly for most industries. As the initial codes were

[13] Lord Penney was Rector of Imperial College in the period 1967-1973. He was a mathematician who took part in the Manhattan project. This research wasn't able to verify whether his professional connections or expertise in related fields to CFD favoured his decision (Sources: IC website and Wikipedia)

developed in conjunction with industrialists to solve their specific problems, industrial qualified procedures and other standards and regulations were integrated into the routines of the code. As one CFD expert in CHAM contends:

"I think the procedures were around since we started developing code...so you linked it to those basically." (CFD developer).

Finally, it is interesting to highlight the influence of Spalding's personality and leadership in the formation of the TIS structural processes. As argued at the beginning of this section, his vision was key to lead the group towards developing applied knowledge, attracting industrialists and forming with them collaborative networks. However, Spalding refused to form alliances with incumbent engineering companies, as other CFD companies did later. Interestingly enough, some of these later companies were founded by Spalding's disciples who abandoned CHAM to establish their own ventures. As it will be discussed in section 4.4.5 (market formation), CFD startups that established alliances with incumbent engineering companies succeeded and became market leaders.

The statement below from one of Spalding's most notorious collaborators summarises how his personality influenced the development of CFD:

"*Brian Spalding was certainly a man of great vision and ambition, and certainly his role was very important in getting things started. He had the vision on what was needed. I think from the bifurcation that occurred within his group, though you'll recognise, that he didn't...I mean, on matters of procedure and details and so on, it had to be done his way and consequently the group broke up with different people...David Gosman was I guess specially the person who in a sense benefited most in that...he formed what was the most successful company than Brian Spalding.*" (IC researcher).

In summary, Brian Spalding and his team at Imperial College were key system builders, and as such, the group was critical in the development of the structural processes during the formative phase of CFD. As table 4-3 shows, they made important efforts to communicate and demonstrate the capabilities of CFD to solve industrial problems. With this, more actors got into the TIS and networks of academics and practitioners were formed. The alignment to industrial practices or norms occurred smoothly as codes were developed taking into account each industry norm.

Processes developed by system builders (Hellsmark & Jacobsson, 2009)	Degree of accomplishment at Imperial College	Evidence and contributing factors
Accumulation of knowledge and artefacts	High	▪ Large group of highly skilled scientists ▪ Development of first codes solving engineering problems: ANSWER and SIMPLE (1968-1969) ▪ Launch of first general-purpose code
Entry of firms and other organisations	High	▪ Publication of books containing SIMPLE and ANSWER codes ▪ Evidence on usefulness ▪ Lack of substitution products ▪ Post-experience courses from 1969 onwards ▪ Consulting and customised codes for early adopters
Formation of alliances and networks	High	▪ Post-experience courses from 1969 onwards ▪ Creation of a research community between academy and industry
Institutional alignment	High	▪ Spalding's leadership to change academic norms ▪ Collaboration in the development of standards (ERCOFTAC) ▪ Customisation of CFD codes to adapt them to industrial procedures

Table 4-3 Development of system building structural processes at Imperial College. Adapted from Hellsmark and Jacobsson (2009)

4.3.3 Contributing factors to the development of system building capabilities

The previous two subsections (4.3.1 and 4.3.2) provided the reader with evidence on the extent (and lack of) system building capabilities at Imperial College and Los Alamos respectively. For example, tables 4-2 and 4-3 outlined the degree of accomplishment in the development of TIS structural processes at each research centre. Therefore, whereas the previous two sections focussed on the "what" did system builders achieve, this section analyses the "how", that is, it looks for the factors contributing to develop system building capabilities. Data analysis suggests that contributing factors can be grouped into four categories: (i) technological and knowledge driven factors, (ii) organisational factors, (iii) institutional factors and (iv) leadership factors.

Technological and knowledge factors

Data analysis suggests that the early and active collaboration between academics and industrialists was critical for the success of CFD. As discussed, during the formative phase (1969 onwards), there was a vigorous exchange of knowledge through the academy-industry networks. Additionally, establishment of CHAM by Spalding offering consulting services, resulted in a set of ad-hoc codes that were developed in close collaboration with industrialists. Interviewees pointed to the involvement of early adopters in the knowledge development process as a key contributor to the success of CFD. This form of actively involving customers as collaborators early in the innovation process is often called co-creation of knowledge. The extant literature on ***co-creation of knowledge*** (Lusch et al., 2007; Kristensson et al., 2008) suggests that involving users as co-creators produces innovations that are more easily implemented and perceived as of higher value by adopters. Co-creation of knowledge allows flexibility to adapt the innovation to customer needs, norms etc. As Ram (1987) argues, allowing the possibility to modify an innovation to better satisfy adopter's needs, reduces risk and consequently adopter's resistance. Therefore, co-creation of knowledge contributed directly to the formation of two structural processes (Hellsmark & Jacobsson, 2009): on one hand it enhanced the accumulation of applied knowledge, and on the other, it contributed to build legitimation (as it will be further analysed in section 4.6.1) and align technology to industrial norms, practices and standards (institutional alignment).

Another important contributing factor relating to the co-creation of knowledge, points to the fact that CFD system builders could provide ***evidence*** from the very early phases on the capabilities of CFD. This fact, attracted interest from industrialists, and contributed to strengthening the development of the other structural processes. As discussed in the literature review chapter, Rogers (2003), establishes 5 attributes on how an innovation is perceived by users. Roger's attributes are: relative advantage, compatibility, perceived risk, trialability and communicability. Through the co-creation of knowledge and providing evidence on CFD capabilities, system builders enhanced at least three of Roger's attributes: firstly, trialability was improved as potential adopters were able to test the codes themselves (for example, executing the codes published in books). Additionally, they could assess whether the codes were solving their existing problems (relative advantage). Finally, as they participated in the development of the methodologies, the codes proved compatible with the existing industrial practices (compatibility).

Finally, another important technological factor emerging from data analysis, suggests that the ***lack of substitute products*** contributed to create industrial interest on CFD across different sectors.

Organisational factors

The analysis presented previously points to the critical role of organisational factors in the development of system building capabilities. Particularly when both groups, Los Alamos and Imperial College, are compared. As previously discussed, although both groups had the necessary resources to develop knowledge, data suggests that these were not sufficient to support the transformation of knowledge into innovation. Los Alamos acted as an isolated organisation, with a formal structure, rigid procedures and poor communication networks with other organisations. Literature suggests that these conditions obstruct the development of breakthrough innovations (Burns & Stalker, 1961; Utterback, 1994). In contrast, organisations with more flexible structures, procedures and collaboration channels are recognised for being more innovative (Chesbrough, 2006).

Together with ***organisational structure***, organisational culture is also important to guide the innovation process (Pinto & Prescott, 1988). ***Organisational culture*** refers to organisational values that are communicated through norms, artefacts, and observed in behavioural patterns (Hogan & Coote, 2014). The Imperial College group culture was shaped by Spalding's vision: "…always think who can benefit from this knowledge, to whom it can be useful…". This, in turn, translated into artefacts and behavioural patterns oriented to communicate knowledge (books with codes, consultancy services, post-experience courses etc.) and solve industrial problems creating innovative momentum. These patterns of communication contributed to the development of CFD structural processes, as they attracted more actors into the TIS resulting in the creation of academy-industry networks as was pointed out previously.

Organisational factors such as organisational structure and organisational culture are closely related to the next two categories of contributing factors: institutional and leadership.

Institutional factors

As defined in the literature review chapter, institutions refer to both formal and informal rules such as regulations, beliefs, values, practices, business models etc. (Bergek et al., 2008a). Institutional rules operate at different levels: geographical, sectoral, organisational etc. Data analysis suggests that the institutional environments in which system builders and adopters are embedded play an important role in the successful or unsuccessful development of TIS structural processes during the formative phases of the innovation process. Moreover, as it will be further analysed in sections 4.6, 5.5.3 and 6.3.1, this research evidences the dependency between innovation legitimation and the different institutional contexts that surround system builders and adopters.

Regarding the institutional context or institutional environment in which system builders are embedded, data evidences, as previously discussed, that the institutional environment at Imperial College was less rigid than at Los Alamos. Whereas in the former there were no impediments to cooperate with industrial organisations or even creating startup ventures, in the latter it was prohibited by law until 1986. As Edquist (2001, p.6) contends, organisational and institutional factors are interrelated and mutually shaped: *"…organisations can be said to be 'embedded' in an institutional environment or set of rules, which include the legal system, norms, standards, etc. But institutions are also 'embedded' in organisations. […] a lot of institutions develop inside firms. Hence, there is a complicated two-way relationship of mutual embeddedness between institutions and organisations, and this relationship influences innovation processes. "*

Previous discussion confirms the concept of system builders "*general structure"* proposed by Hellsmark (2010). Following on Giddens' (1984) structuration postulates of actors embedded in structures, Hellsmark (2010) contends that system builders are embedded in a structure named *general structure* that enables or constrains their capabilities to address weaknesses and strengthen the TIS. Data analysis evidences that Los Alamos' rigid *general* *structure* had a negative impact in the transformative capacities of system builders, whereas, on the contrary, the more flexible *general structure* at Imperial College, enhanced system builders' transformative capacity.

On the adopters' side, data analysis suggests that CFD adoption succeeded as a smooth process for the majority of sectors. According to data analysis, CFD early adopters were firms that had previously worked with Imperial College and were familiarised with the use of numeric solutions for the resolution of engineering problems. Contributing factors to institutional alignment, point to the co-development of standards between academics and industrialists and the adaptation of CFD codes to fulfil organisations' norms and practices. However, Spalding and other system builders indicated that they didn't succeed in those sectors with substitutive products to CFD. This topic is analysed in the next section 3.3.4: limitations to system building capabilities.

Leadership factors

Data analysis suggests that system building capabilities are intrinsically related to leadership. Using a close concept to system builder, scholars like Waldman and Bass (1991) or Kanter (2006) highlight the importance of leaders as innovation champions. According to Waldman and Bass (1991) transformational leadership is key during the initial phases of the innovation process. Transformational leadership is exerted if leaders accomplish four characteristics towards their teams: (1) individualised consideration, (2) intellectual stimulation, (3) charisma and (4) inspirational leadership (Bass, 1990). Participants in the study reflect that both Harlow and Spalding were charismatic leaders.

CHARACTERISTICS OF TRANSFORMATIONAL AND TRANSACTIONAL LEADERS

TRANSFORMATIONAL LEADER

Charisma: Provides vision and sense of mission, instills pride, gains respect and trust.
Inspiration: Communicates high expectations, uses symbols to focus efforts, expresses important purposes in simple ways.
Intellectual Stimulation: Promotes intelligence, rationality, and careful problem solving.
Individualized Consideration: Gives personal attention, treats each employee individually, coaches, advises.

TRANSACTIONAL LEADER

Contingent Reward: Contracts exchange of rewards for effort, promises rewards for good performance, recognizes accomplishments.
Management by Exception (active): Watches and searches for deviations from rules and standards, takes corrective action.
Management by Exception (passive): Intervenes only if standards are not met.
Laissez-Faire: Abdicates responsibilities, avoids making decisions.

Figure 4-3 Transformational and transactional leaders. From Bass (1990, p.22)

In consequence, data analysis suggests that leadership differences between Los Alamos and Imperial College relate more to leaders' vision than to leadership style. Data analysis suggests that Spalding's personal vision of applying numerical methods to solve industrial problems, influenced an innovative culture at the Thermofluids group, while at the same time, the flexible culture at Imperial College allowed Spalding to pursue his vision. As Bass and Avolio (1993) argue: "*the organisation's culture develops in large part from its leadership while the culture of an organisation can also affect the development of its leadership.*" (Bass & Avolio, 1993. p.112).

Another interesting topic regarding leadership, relates to the influence of leaders' reputation to attract actors in the TIS and create knowledge networks. Data analysis suggests that Spalding's reputation in the industry was a contributing factor to the development of CFD structural processes. System builders' reputation, as an aspect of personal legitimacy, is analysed in more depth in section 4.7.

Figure 4-4 summarises the discussed contributing factors to the development of system building capabilities and CFD structural processes.

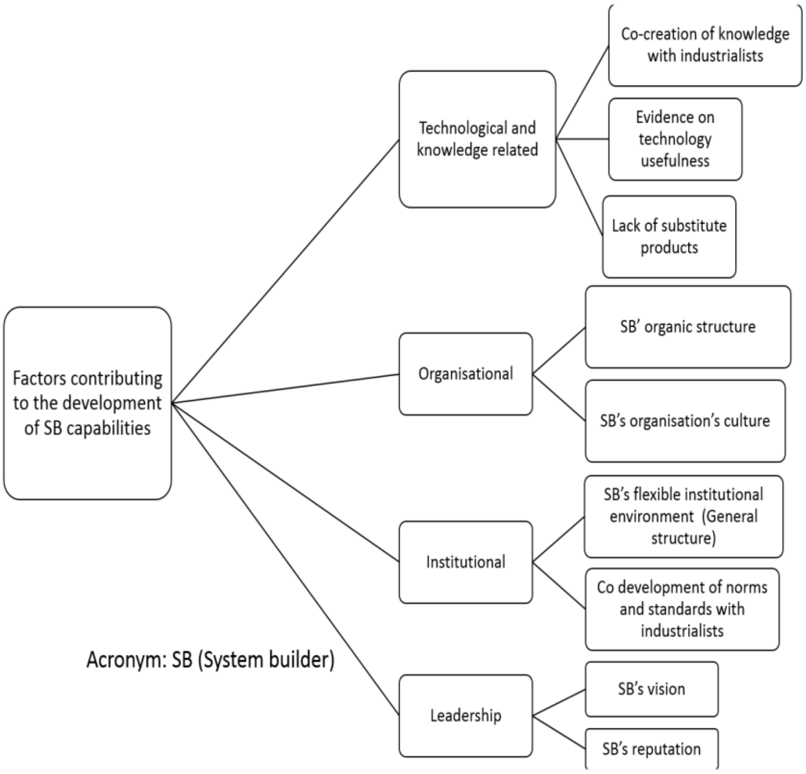

Figure 4-4 Contributing factors to the development of system builders' capabilities. Developed by the author

4.3.4 Limitations to system building capabilities

The previous section has analysed the factors contributing to the development of system building capabilities and structural processes in the formative phases of a TIS. As a part of the discussion, it was argued that system builders embedded in rigid general structures (Hellsmark, 2010) are less likely to exploit system building capabilities and develop TIS structural processes. Additionally, it was contended that co-creating knowledge and co-development of norms and standards, lead to a smooth institutional alignment, particularly in industries with no substitute products for CFD.

However, data suggests that system builders didn't succeed in industries where substitute products (primitive numeric methods), were already established. According to Spalding, industries like chemicals or heat exchangers haven't yet transitioned to CFD and are still using much less accurate methods:

“There is an enormous population of heat straightening industries in the world. They are very important because that's where the fuel goes, that's how global warming comes and it is very important for the whole of us. Very interestingly, heat exchangers are to this day designed on what they call Pre-CFD methods. They went before into methods, bought the computers and they took approximatively a design of eight figures. Then, when the computers came along, those persons who were being using the PL methods, said: ’Ok, we can write computer programs which will express those results and we then decide to change heaters.’ Those who went a little bit more deeply into what happened inside the exchanger, derived numerical methods still not used to this day. It's a story...but the fact is that to this day, heat exchangers are designed in pre CFD methods and therefore are either too big or they are excessing someway. They are not efficient enough and therefore, they are heating the atmosphere […]” (Brian Spalding).

Spalding suggests a combination of organisational inertia and conflicting interests with incumbent manufacturers as the factors hampering the adoption of CFD in this sector:

“Those who manufacture heat exchangers are smaller companies. […] There is certain inertia also. Things happen as they've happened before. […] I had visited them for education and they said: ’Yes, yes, yes... CFD is good, we should use it’, but they still don't. It is inertia. They are seeing it inertially. They are selling it, they wouldn't like some CFD coming and taking their business, so they just continue. ...why to do something different like CFD if we have something that it works?” (Brian Spalding).

The factors argued by Spalding are consistent with those described in TIS literature. Following on Barbalet’s (1985) work, Hellsmark (2010) points out that the transformative capacity of system builders in a TIS is limited by three main obstacles: (i) frictional resistance, (ii) intentional resistance and (iii) lack of interest in the technology. *Frictional resistance* refers to system-internal problems like inadequate networks or biases towards incumbent technologies into existing institutions. *Intentional resistance* relates to obstacles that come out as the intentional actions of actors with opposing interests. Finally, other barriers might come not by resistance, but due to the *lack of interest* of actors in the technology. Spalding's account with respect to his limitations as system builder in the heat exchange industry reflects a combination of *frictional resistance* and *intentional resistance*. The former comes as organisational inertia to maintain the use of incumbent technologies. As discussed in section 4.2.3, CFD requires highly skilled experts to define problem's boundary conditions and interpret results. This leads to difficult learning curves that could explain frictional resistance towards adoption if substitute products are already in place. The latter comes by manufacturers, who have been exploiting incumbent technologies and perceive the entrance of new actors in their business as a threat. As a consequence of the difficult learning curves, CFD is a knowledge-based industry, where consultancy is an important part of the total revenue (Hanna, 2015).

To avoid intentional and frictional barriers in the heat exchanger industry, Spalding proposed to lower down the difficulty of CFD simulations and put technology in the hands of industrialists:

"… So, there is a task as such getting done in transforming the way in which heat exchangers are designed and that's active on now, and it depends on making the CFD simulations easier to use…" (Brian Spalding).

In summary, data suggests that in presence of substitutive products, system building capabilities are much more limited, and strategies that worked in industries with no substitutive products, for example providing evidence on technical superiority of CFD, didn't work where primitive numeric methods were already established. Data points to two main types of resistance: frictional (in the form of organisational inertia) and intentional (incumbents perceiving CFD as a threat to their businesses).

4.4 Area of investigation 2: TIS functions

The previous section has shown the extent and limits of system builders to develop structural processes during the formative phase of CFD as a TIS. As discussed, Brian Spalding and his team at Imperial College played a critical role by co-developing knowledge with industrialists, attracting new actors into the TIS, forming academy-industry networks and developing standards to align CFD codes with industry norms and practices. As a consequence of the development of these structural processes, TIS functions like knowledge development, entrepreneurial experimentation, influence on the direction of search or legitimation were also strengthened. Therefore, this second area of investigation focuses on the dynamic interplay of the TIS functions, and in particular, how they influenced the legitimation of CFD. Aligned to the TIS functions discussed in section 2.6.2, this area of investigation analyses the following: knowledge development, entrepreneurial experimentation, influence on the direction of search, resource mobilisation, development of positive externalities and market formation. Legitimation, as a key topic of this research, is analysed in-depth in a separate area of investigation (section 4.6, area of investigation 4).

4.4.1 Knowledge development

Knowledge development function captures the breadth and depth of the knowledge base in the TIS and its evolution over time: how it is developed, diffused and combined (Bergek et al., 2008a). This function is typically placed at the core of the TIS. Its development during the formative phase is a pre-requisite for legitimation (Hekkert et al., 2011).

Bergek et al. (2008a) distinguish between different types of knowledge: scientific, technological, production, market, logistics, design etc. As previously outlined in sections 4.3.1 and 4.3.2, the T3 Lab and the Imperial College group, made significant contributions to knowledge but in very different manners.

The T3 Lab was key in the development of scientific knowledge. The T3 Lab started in 1958 with 7 core members. In 1970 they grew to 15 and by 1990 there were 25 researchers (Johnson, 1996). A search in Google scholar yields more than 60 published articles by Harlow and his team in the period 1960-1970. However, as Runchal (2009) points out, the knowledge developed in the T3 Lab was scientific knowledge oriented towards understanding the physics of the problem rather than finding solutions to complex engineering challenges. Moreover, for many years, they only published their achievements in scientific journals. It was not until the mid-70s that the group started to distribute their codes to other research centres and universities.

"*Harlow made little attempt to distribute them (the codes) to outside researchers. He was more interested in innovative research than in disseminating his technology or spending his time teaching others how to use it. The excellent and path-breaking work done at Los Alamos was not widely used outside a select research community. It was not till Tony Hirt became leader of the T3 Group, around 1973, that computer programs developed at Los Alamos became generally available to outside researchers though the US Department of Energy distribution sites*." (Runchal, 2009, p. 4068).

On the other hand, data analysis suggests that the group at Imperial College, was seminal in transforming scientific knowledge into different forms of technological and industry-applied knowledge. Despite the fact that the group at Imperial College was formed later than the T3 Lab, by 1969 it consisted of more than 30 researchers becoming most probably the largest CFD group in the world at that time (Runchal, 2009). As previously discussed, the orientation of the IC group was to develop and disseminate applied knowledge. A search in Google scholar yields more than 80 published papers by Spalding and his team in the period 1960-1970. By 1969, Spalding and his group had published two books containing the source codes to solve practical engineering problems related to turbulences and heat and mass transfer (Spalding & Patankar, 1967; Gosman et al., 1969).

According to Spalding, the publication of the books was critical to knowledge diffusion: "*We published two books with two computer programs and I think that made the difference. […] I suppose that books made us known, and as a consequence we were approached...*" (Brian Spalding).

It is interesting to mention that during those early days there were no code compilers or intellectual property over software, so the whole source code was distributed from the IC group to anyone interested.

"We didn't think about CFD. Somebody wanted a code, you sent it to them. Essentially, my supervisor in London, my external supervisor for the PhD, insisted on including the code in my thesis. It was a big code. He said somebody wouldn't do the equations if he didn't have the code. So I had to include it." (IC researcher and founder of CFD SME).

According to Spalding, distributing the codes had a positive effect for diffusion, as users could try themselves testing the predictable capabilities of numeric methods. In addition to book publications and distribution of codes, the group at IC innovated in providing additional means for knowledge diffusion, like the organisation of post-experience courses since 1969:

"I think Spalding […] he was the first one to say: 'Hey, let's give it to the industry' and like having a post experience course at Imperial College in those days was unheard of…" (CFD pioneer and founder of CFD SME).

Besides the efforts to diffuse knowledge through books, papers, conferences and distribution of codes, co-creation of knowledge (Lusch et al., 2007; Kristensson et al., 2008) between academics and industrialists was critical to lowering the legitimation barriers for CFD. As discussed in section 4.3.2, data analysis suggests that the co-creation of knowledge enhanced institutional alignment and ultimately acceptance, as CFD codes were shaped not only to solve customers' problems, but also to comply with customers' routines, practices and standards.

In summary, data analysis suggests that the co-creation of knowledge and the efforts to diffuse knowledge by Spalding and his group, is at the core of the development of the TIS. As discussed, the co-creation of knowledge between academics and industrialists accelerated the development of different forms of applied knowledge. Moreover, it directly influenced the development of legitimation and other functions like entrepreneurial experimentation, influence on the direction of search, market formation etc. These are discussed in the following sections.

4.4.2 Entrepreneurial experimentation

As discussed in the previous section, knowledge development influences other TIS functions, like entrepreneurial experimentation. Co-creation of knowledge between IC and industrialists succeeds not only through conferences and seminars, but also through consultancy services provided by Spalding and his team. The initial goal of these consultancy services was to develop ad-hoc codes to solve customer specific problems. This activity became the seed for entrepreneurial experimentation, as it will be analysed in this section. Entrepreneurial experimentation and knowledge development acted as intertwined functions. Both contributed to reducing uncertainty and acting as a pre-requisite for the legitimation of the CFD TIS (Hekkert et al., 2011). As Bergek et al. (2008a, pp.414-415) argue, entrepreneurial experimentation: "...*implies a probing into new technologies and applications, where many will fail, some will succeed and a social learning process will unfold.*"

CHAM (Combustion, Heat and Mass Transfer) was the first commercial CFD company founded in 1969 by Spalding. Later on, in 1974 Spalding renamed it as CHAM (Concentration, Heat and Mass Transfer Ltd). During a decade, Spalding and collaborators faced little competition, offering consultancy services to different industries. They developed ad-hoc codes to solve specific customers' problems. As discussed in section 4.2.2, CHAM launched PHOENICS, the first CFD multi-purpose code in 1981. Its launch represented a key milestone in the development of the entrepreneurial experimentation. Initially conceived as a repository of all "solvers" that CHAM had been developing for a decade, PHOENICS led to many other entrepreneurs and big firms entering the arena of commercial CFD.

The relation between knowledge development and entrepreneurial experimentation is also present in the development of PHOENICS. As Spalding reflects, PHOENICS was originally created to transmit knowledge more efficiently inside CHAM without the need to start from scratch for every new requested code:

"(Industrialists) came down to visit us and also there was a practicality of turning one problem on another. So, before we had PHOENICS, each problem was treated as a new program. We were continuously starting new and then it was too expensive, and we learnt sufficiently, then learning the new problem. What you have done is in people's mind, but if you have a single computer program which you use for everything, then the learning goes into that and it is transferred to the new problem. Yes, I think that is very important about a general-purpose program. It is a knowledge transmit there. You can take what you or others have learnt about it and because it is in computer code, you can use that code for the new benefiting....it is a means of condensing human knowledge and collecting it." (Brian Spalding).

As stated, the development of a general-purpose code targeted to solve a variety of problems across different industries, opened an interesting market opportunity. A number of CFD experts saw this opportunity and founded different CFD start-up firms imitating what Spalding had done at CHAM. The majority of these new entrepreneurs had previously worked for Spalding. On the T3 side, Tony Hirt resigned as lab manager at Los Alamos and founded a CFD company called Flow Sciences. In 1985 he launched a CFD general-purpose code named Flow-3D.

The advent of general-purpose codes attracted not only entrepreneurs into the TIS, but also incumbent engineering companies. Two main companies entered into the CFD TIS. One was Adapco, an American company interested in a CFD software produced by two of Spalding's disciples and specialised in combustion engine problems. The other company, Creare, also American, launched in 1983 a CFD multipurpose code named Fluent. Runchal (2009) suggests that Fluent code was developed in Sheffield University from the codes and turbulence models originally produced at Imperial College and CHAM.

The incorporation of incumbent firms like Creare and Adapco into the CFD TIS had important implications as they significantly contributed to strengthening several TIS functions like resource mobilisation, influencing the direction of the search and market formation. These are analysed in the next sections.

4.4.3 Resource mobilisation

This function measures the extent to which actors in the TIS are able to mobilise the required resources for its development. These include experts along the value chain in technical, marketing, logistic or managerial knowledge, financial capital and complementary assets such as complementary products, services, networks and infrastructure (Bergek et al., 2008a).

Data analysis suggests that CFD didn't require massive mobilisation of infrastructure, services or complementary products, at least during its formative phase. As previously discussed, Los Alamos and Imperial College significantly increased the number of researchers in the 1960s . From the industry side, the advent of personal computers and workstations favoured that industrialists could afford the required investments in computing resources. Access to codes and technical knowledge were available through books, networks and consultancy services.

However, data suggests that later mobilisation of resources accomplished by incumbent companies, had an important influence in the development of the CFD market. While some entrepreneurs founded their businesses without any external help:

"*We had no venture capital, no grants, we just put all the money we had and bootstrapped ourselves alone. It was an interesting way to go."* (CFD company founder).

Others, like CD and Sheffield University, decided early to partner with incumbent engineering companies: Adapco and Creare respectively. These incumbent companies provided human and capital resources. As one of the founders of CD pointed out, the partnership consisted mainly in a labour division where they kept doing the technical developments and the incumbents used their capabilities to market the product:

"They (Adapco) invested money and they became part owners of the company. They helped in the development of the graphical user interface and they were doing much of the consultancy

[…] The only thing is that CD could not do a lot of consulting at the same time as development. So they allowed a certain degree of separation or collaboration between the two companies to produce something that was attractive to industry at large. […]. PHOENICS and CHAM were doing both consulting as well as development and sales at the same time whereas there was a division of labour if you like in Star-CD."

Similarly, Creare and Sheffield University established a partnership where financial support was provided and technical and market activities were separated:

"Sheffield University decided as a matter of policy, that the University did not wish to market the software. At the same time, I, as a Professor of engineering, didn't want to be involved directly in marketing, but I'm very interested in developing something to the market. […] They were paying us for the use of the software. They were effectively validating the software and then they took over the software and commercialised it in America, and now is commercial all over the world. In fact, the turnover of Fluent in this last year was over a hundred thousand million euros. […] I have worked for them a way back in 1958 to 1961[…]. I had friends that I knew I could sent the software and they wouldn't copy it, or cheat or anything like that. They were a professional body and they actually took the software to market." (Sheffield University Professor).

In summary, data suggests that along the very early years, CFD didn't require high levels of resource mobilisation, as entrepreneurial experimentation was initiated mainly out of the personal resources of entrepreneurs. However, data suggests that later on, incumbent firms made an important resource mobilisation in form of capital and human expertise along the value chain (marketing, sales, managerial etc.). This, in return, influenced the market growth of CFD. More evidence of this analysis is provided in the next sections: influence on the direction of the search and market formation.

4.4.4 Influence on the direction of search

The function *influence on the direction* of search focusses on the elements that reinforce the incentives and pressures to enter the technological field. Therefore, this function includes a variety of topics for analysis like entrepreneurial visions, expectations of growth potential, appropriable conditions for key actors, alignment to political agendas, regulations, policies and business models that create new opportunities for the innovation to arouse (Hellsmark, 2010). Influence on the direction of search and legitimation, as discussed in sections 2.6.3 and 2.6.4 in the literature review chapter, are two related functions. As an example, a shared vision on the potential of the technology among key actors will reinforce legitimation, whilst contested visions, expectations or appropriable conditions can harm its acceptance (Bergek et al., 2008b).

This section analyses two main themes. The first refers to how the visions and expectations of key CFD stakeholders contributed to reinforcing legitimation. The second, focuses on the adoption of business models during the formative phase.

4.4.4.1 Visions and expectations

As discussed in section 3.4, data analysis suggests that Spalding's vision in the usefulness of numeric methods to solve industrial problems, was critical for the development of CFD as a new industrial practice. With Spalding translating his vision to the team, he built up an innovative organisational culture at Imperial College that yielded multiple technological advances. Additionally, these advances were proactively presented to industrialists who could see the evidence and advantages of the capabilities of the codes.

However, as Hellsmark (2010) suggests, system builders' visions might not be sufficient to strengthen legitimation if institutional frameworks are too rigid and confronted interests are in place. Data analysis does not suggest the existence of confronted interests. Most probably, the lack of substitute products for most industries, prevented this type of *intentional* resistance (Barbalet, 1985). Regarding, institutional rigidity, this was sorted mainly through the co-creation of knowledge between academics and industrialists. Co-creation of knowledge contributed to articulate customers' demand and to align expectations. As discussed, expectations on the technology were realistically formed by showing evidence on the capabilities of the technology. As one of the early adopters reflects, in this context, it was easy for them to perceive the benefits or appropriable conditions that CFD offered:

"At that time, you didn't know what the problems were going to be because during the design process … you couldn't say in advance what the problems would be.... We needed a very versatile code, a one code that we could interact with to solve this variety of problems that we were potentially faced with. That was the attraction of it." (early CFD adopter).

The appropriable benefits of CFD also reached the incumbent companies, as they saw the opportunity that selling CFD software could represent. This aspect is the topic of analysis in the next section: business models.

4.4.4.2 Business models

As Osterwalder and Pigneur (2010, p.14) define, a business model: "describes the rationale of how an organisation creates, delivers, and captures value." As previously discussed, entrepreneurial experimentation was originally developed through consultancy business models between system builders and early adopters. During the 1970s and 1980s , software was not clearly protected by intellectual property (Lemley, 1995). As participants pointed out, in those days, codes were distributed to anyone interested, or even published in books, as discussed. Entrepreneurs didn't consider the possibility of obtaining revenue from the codes, but from helping customers to properly formulate the boundary conditions of the problems to be solved. However, as participants pointed out, this business model approach was risky and not scalable:

> "*So what we originally intended for our company was to conduct contract research not to sell software. But we found out that is very difficult when you only have few people: if you*

have enough contracts you will run busy and if you lose one, you have to either fire someone or to find others...so that's hard." (Founder of CFD company).

Data analysis suggests that the transition from consultancy to software selling was propitiated by the incumbent companies entering the TIS (Adapco and Creare). One of Spalding's closest collaborators explains how Spalding and others didn't see the opportunity to sell software as Creare did:

"*We supplied a code to (a professor in Sheffield University) […] He was consulting with a company called Creare. […] So he used our software and supplied the software to Creare. Before long, Creare began to see how useful the software was and they started marketing the software to others, which it was basically our software going to others through Creare at that time. […] They saw the possibilities that other people didn't see early on […] Actually, our group in Imperial College was well behind in spotting that opportunity. […] We saw consulting opportunities at Imperial College like someone from the industry coming and saying …'could you help us to solve this problem?' but we did not market it from Imperial College as software. Fluent did it before we did.*" (IC researcher and founder of CFD SME).

Later on, entrepreneurs followed what Creare and Adapco did, and transitioned into software selling business models too.

"I started in 1980, so by 1984 or 1985 we went into debt to do our payroll because we have had one contract but we didn't have another one...so this is the history in a nutshell. I sold a copy of our software to IBM Japan in Japan, and then I sold one to Exxon Mobil [14][…], and that solved the debt and the light came up and we said:' we ought to be selling software and not doing contracts'." (CFD company founder).

[14] *Note: Exxon Mobile was founded in 1999 as a merger of Exxon and Mobil*

Data analysis suggests that the adoption of business models based on software selling favoured the growth of the CFD market. This topic is analysed in the next section "market formation". As a founder of a big CFD company argues, software selling provides higher returns and it is less labour intensive:

"The code was the main revenue stream and in fact is actually. Consulting can give good revenue, but it is labour intensive, so the return on consulting is not as high as code licensing. So that is the margin you get is a lot bigger." (IC researcher and founder of CFD company).

4.4.5 Market formation

Bergek et al. (2008a) suggest that market formation goes through three differentiated phases. In the very early phases, the TIS develops *nursing markets,* typically in the form of demonstration projects and related activities that can open a learning space for the TIS. Then *nursing markets* evolve to *bridging markets* as market volume increases and new actors enter the TIS. Finally, if the TIS succeeds, *bridging markets* evolve into *mass markets*.

Data analysis indicates that early system builders like Spalding, succeed in the creation of nursing and bridging markets. They opened the learning space for CFD, conducted seminars, demonstrations and pioneered the incipient CFD market providing consultancy services to a few industries. However, the transition to mass markets came mainly through the human and financial resource mobilisation that incumbent companies did in partnership with a few CFD entrepreneurs. Additionally, as discussed, the adoption of business models based on software selling led to higher returns. One of the founders of Computational Dynamics (CD) describes the importance of their partnership with Adapco to form CD-Adapco:

"So they (Adapco) were instrumental in helping conquering the market. They did consulting, demonstrating the capability of the code, and that of course induced the industry to actually buy licenses to use the code. And eventually, well not eventually, actually, soon after the setup the company, they started developing the user interface for the code. So whereas in London the CD was focussing on the development of the methodologies for CFD, the solver…Adapco in the

United States developed the user interface which eventually became a graphical user interface, which actually sometimes is the major heart of the software." (CD co-founder).

As the interviewee later points out, Spalding and CHAM opted to continue their journey alone, without partnering with other companies:

"*The only thing is that CD could not do a lot of consulting at the same time as development. So they allowed a certain degree of separation or collaboration between the two companies to produce something that was attractive to industry at large. […]. PHOENICS and CHAM were doing both consulting as well as development and sales at the same time whereas there was a division of labour if you like in Star CD. […] They didn't partner with anybody. In CD the partnership came because of two aspects: one is the partners, because they provided the finance, and the other is they provided the outlet and the sales." (CD co-founder).*

In addition to the adoption of a software selling business model and the partnership between entrepreneurs and incumbents, data analysis also points to specialisation as a key factor contributing to the growth of the CFD market. As discussed in section 4.2.3, CFD is a highly fragmented and specialised market where the majority of firms focus in providing ad-hoc solutions to very specific industrial problems. Spalding provides an interesting reflection with this regard, discussing how specialisation by his competitors led to market success:

"Well, it changed the situation: there were many others who could do better than I could but...part of my problem is that I innovated too much, I looked into many different directions so whether with the successful competition, I think they took it a little bit different. For example, there is a successful company coming out of this building (CHAM Ltd), that contributed to one particular area in electronics cooling and then they concentrated on that and they did quite well. It was lately bought. It was called Fluomerics at that time, I don't know how is it called now.... But yes, specialisation led to success.... while I looked into many different directions….so that is still what happens." (Spalding).

As figure 4-2 in section 4.2.2 shows, CFD leading firms changed during the market formation process. In the early years of commercial CFD, nursing and bridging markets were dominated by CHAM, the company founded by Professor Spalding. Second was FDI, an American company, and Fluent, formerly Creare (Sheffield University partners), was third. A decade later, in the mid-1990s, CD-Adapco entered into the top 3, and CHAM and Flow Science disappeared from the ranking. Today, CD-Adapco and Fluent, together with CFX[15], are market leaders. These companies have been through different processes of mergers and acquisitions, and nowadays, the three of them: Ansys, CD-Adapco and Mentor Graphics, have been acquired by Siemens.

In summary, resource mobilisation, partnership with incumbents (for financial and human capital), specialisation and business models based on software selling, drove the transition from bridging to mass markets. Data analysis suggests, that as postulated by Lieberman and Montgomery (1998), incumbents took advantage as late entrants. They followed the well-studied path of merging their marketing and manufacturing capabilities with the scientific and technological knowledge developed by system builders:

"Pioneering is likely to be a desirable strategy for firms whose relative skills are in new product development, whereas firms with relative strengths in marketing and manufacturing may prefer to enter later, after the initial market and technological uncertainties have been resolved. […] Moreover, later entrants may be able to acquire pioneers, thereby linking their own resource base with the pioneer's market position, resources and skills." (Lieberman & Montgomery, 1988, p.1113).

4.4.6 Development of positive externalities

This function measures how the generation of external economies influence the development of a TIS. Bergek et al. (2008b) define external economies as the mutual benefits obtained when two or more different TISs share part of their structural components: actors and networks,

[15] CFX is a CFD multipurpose software developed by the UK Atomic Energy Authority (AEA) and later acquired by Ansys

technology or institutions. The scholars point to three main sources of positive externalities: emergence of pooled labour markets, information flows and knowledge spill-overs, and emergence of specialised intermediate goods and service providers.

Following on the previous definition, data analysis doesn't show any relevant theme applicable to the development of positive externalities for CFD. The underlying reason is the boundaries and level of analysis selected for this study. As defined in the methodology section, the unit of analysis of this research, is the field of knowledge of CFD around its two main development centres: the T3 Lab at Los Alamos and the Imperial College group. Consequently, as the study is not restricted to any specific code, target industry or CFD company, all relations regarding knowledge, labour and complementarities rely within the CFD TIS and have been analysed accordingly in the previous sections.

In spite of this, data analysis shows relevant external factors that influenced the development of CFD as a TIS. As they do not share structural components with CFD, they are discussed in the next section.

4.5 Area of investigation 3: Exogenous factors

TIS literature suggests that external factors can influence positively or negatively the development of a TIS (Hellsmark, 2010; Bergek et al., 2015). The definition of what an exogenous factor is, is determined by the geographical boundaries and the breadth and depth of the unit of analysis of the study (Bergek et al., 2015). For the present analysis, exogenous factors relate to those elements that do not share structural components (in the form of actors, networks, institutions or technology) with the field of knowledge of CFD at its main research centres (T3 Lab at Los Alamos and Imperial College). Exogeneous factors have been divided into two different categories. The first, relates to the development of other technologies that contributed to the diffusion of CFD. The second, refers to those dynamics that are beyond the direct influence of the actors in the CFD or any related TIS. They typically include macro-economic and political issues or deep cultural patterns like financial or political crisis, public debates, changes in political agendas etc. (Geels & Schot, 2007).

The following sections highlight the most relevant themes around both types of exogenous factors.

4.5.1 Development of related technologies

The development of CFD is tightly connected to the development of computer capabilities during the last half of the 20th century (Hanna & Parry, 2011). Data analysis suggests that advances in the computing industry had a critical impact on the development and legitimation of CFD. Firstly, as predicted by Moore's law, the density of transistors in circuits increased to the point that big mainframe computers, like the ones originally placed at the T3 Lab at Los Alamos and Imperial College, were substituted by workstations, a much more affordable option. This enabled the entrance of many industries into the CFD TIS. Additionally, in the early 1980s the first parallel compilers were launched. [16] As a consequence of this, simulations were executed in less time, while at the same time, the intellectual property of the codes was more easily protected, as there was no need to distribute the source code, only a compiled executable. As a consequence, compilers opened the possibility of developing business models based on selling software as previously discussed in section 4.4.4.

In addition to cheaper and more powerful computational resources, CFD benefited from the development of graphical user interfaces. These facilitated demonstrations and simplified the learning curves for final users, and this contributed to legitimation. An early CFD adopter explains the influence of computational advances for CFD users:

"I remember when I was working at Manchester University in the late 60s and early 70s...I mean it was a fairly new program punched cards: you had to take it over to the computer centre and

[16] Source: The History of the Development of Parallel Computing: https://parallel.ru/history/wilson_history.html

there computers there were huge thing. They were in a room. They were massive....and it was a fairly new program and you had to wait a few hours or even a day for the results to come back. If you made a mistake in the code you had to start again, and when you had the results, you had to print them in big piece of paper with very limited graphics. So it was all a lot more difficult to do things then. And what it changed in the 80s was the developments in computing power, you know, it could make computations far more cheaper and far quicker. You could get the results back almost immediately with remote computing...We had these big computers and also we had the beginning of graphical interfaces....so all of that came through in the late 70s and early 80s. And that made a big change in the use of CFD." (CFD early adopter).

Aligned to the previous participant, another highlights the "virtuous cycle" (Bergek et al., 2008b) around external technical developments:

"The allied fields began to make progress which became useful and available to CFD, so the CFD became more powerful because of mathematicians developing better m solvers. And the graphic industry, display industry, grid computing …so all these industries emerged around CFD…" (IC researcher and SME CFD founder).

In summary, data suggests that computational advances contributed to: (i) attracting more actors into the TIS, (ii) legitimate CFD by producing more accurate results and shortening learning curves through graphical user interfaces etc. and (iii) enabling business models based on selling software. Aligned to other TIS studies (Bergek et al., 2015; Markard et al., 2016) data analysis shows that external factors contributed to the creation of virtuous cycles that boosted the legitimation of CFD TIS.

4.5.2 Landscape factors

Participants from the T3 Lab reported a number of landscape factors that contributed to opening the institutional constrains and favoured regulatory changes allowing the collaboration with other organisations and private firms. These include macro-economic aspects such as loss of competitiveness in the US automotive sector, nuclear accidents and public debates on nuclear energy safety, oil crisis and green technologies etc. However, data analysis suggests that the influence of these landscape factors and regulatory changes, didn't have a significant impact on the legitimation of CFD, as they arose when the CFD market had already sprung.

As an example, in 1979, a nuclear accident in the US nuclear plant of Three Mile Island [17] caused by a cooling malfunction, provoked a big concern and public debate around nuclear safety. As one of the T3 Lab researchers recalls, the situation led the T3 Lab to get actively involved in the investigation of the accident. Through this collaboration the T3 Lab researchers got in touch with industrialists and nuclear experts to whom they could demonstrate the potential of CFD to improve nuclear reactors safety.

"Nuclear safety was a big thing in the United States, especially after Three Mile Island. It happened in the seventies and there was lot of work to be done […] and that was a big interaction with the industry, with the Nuclear Laboratory Commission and for many number of people who were interested in what was happening. One of the things that was of particular interest...I think it was at Three Mile Island, they had observed pressure spikes." (T3 Lab researcher).

Another very relevant related testimony, explains how the energy crisis in the 1970s made possible the involvement of the T3 Lab with car manufacturers.

In the words of a T3 Lab researcher:

"First, we (worked) through governmental organisations rather than those in the industry. But that changed basically. For me it changed when there was an energy crisis in the mid-seventies. There was big lines for gas because there was not enough for all of them, and then, there was an interest in trying to conserve energy and make cars go further and things like that, and there was a contest, I think it was sponsored by NSF, the National Science Foundation, but it involved the industry and National Labs and universities and they just got together. I think it was in

[17] http://www.world-nuclear.org/information-library/safety-and-security/safety-of-plants/three-mile-island-accident.aspx

Malibu, California, and we talked about what could we bring to help people. […] . One of those persons, was Floriano Blanco, he became a Professor in Princeton… and he saw potential for it and he already had an in with working with automotive industry. So, he encouraged this to go further. […] About that time, the company was realising that the National Labs could bring...they were trying to encourage the National Labs to work with industry on a number of things... So they formed a consortium between the National Labs and the car companies called USCAR with General Motors and big three for the automotive sector." (T3 Lab researcher).

USCAR, the consortia mentioned by the T3 Lab researcher was officially formed in 1992. However, their works started a decade previously, when two important challenges emerged: competition from overseas markets and the necessity to improve fuel efficiency. As they explain:

"*Historically, technical collaboration involving the U.S. automakers - Chrysler, Ford and General Motors was unthinkable because they dominated the U.S. market and viewed each other as tough competitors. […] With competition from both Japanese and European automakers intensifying, Chrysler Group LLC, Ford and GM recognised that technical collaboration was already occurring among their overseas competitors and that it made good business sense for themselves as well.*

In the late 1980s, a common technology need was the development of lightweight materials to improve fuel economy. Thus, the U.S. automakers created the Automotive Composites Consortium (ACC) in 1988 to work together on the emerging need for composites. ACC's success spawned more consortia to address other technical issues, including advanced batteries and vehicle recycling."[18]

Two Congress acts favoured the consortia between car manufacturers and government agencies, and indirectly, the possibility for the T3 Lab to collaborate with private companies and

[18] http://www.uscar.org/guest/about/

not only government agencies. In 1984, the US Congress passed the Cooperative Research Act, a bill that eliminated the antitrust laws on the collaboration between private companies towards research and innovation development. Two years later, in 1986, the Federal Technology Transfer Act allowed government agencies and universities to work collaboratively with private companies on research and development. [19] However, as previously discussed, regulatory changes came to the scene when the CFD market was a growing market, so analysed data cannot provide evidence that they effectively contributed to the commercial development of CFD.

4.6 Area of investigation 4: Legitimation

The former areas of investigation have provided the reader with an analysis of the development of structural processes, the dynamic interplay of functions and the impact of exogenous factors on the strength of the TIS. Now, this last area of investigation, takes the input from the previous areas, and focuses on legitimation, the key topic of this study.

As previously defined, legitimation is the process of acquiring acceptance and compliance with relevant institutions (Bergek et al., 2008b). To accomplish the study of legitimation, this section is divided into three main parts: the first part analyses the drivers that contributed to create legitimacy. The second discusses the barriers and finally the third reviews the strategies adopted by system builders to legitimate CFD.

As discussed in the literature review chapter, legitimation is influenced by the capabilities of system builders to develop structural processes, the performance of the rest of TIS functions and external factors that contribute to strengthen the TIS. Therefore, some of the topics discussed in this section emerged previously during the analysis of the other areas of

[19] Source: https://www.govtrack.us/

investigation. These are now compiled and evaluated through the lenses of legitimation studies by Suchman (1995).

4.6.1 Legitimation drivers

As Hellsmark and Jacobsson (2009) argue, the development of structural processes plays an important role to build legitimacy. As discussed in section 4.3, CFD system builders were key agents in the development of knowledge and networks, in attracting more actors into the TIS, and in mutually shaping CFD technology and industrial institutional frameworks. As summarised in figure 4-4, data analysis points to a set of technological, organisational, institutional and leadership factors that contributed to the development of TIS's structural processes, and directly or indirectly, to legitimate CFD. As an example, co-creation of knowledge reduced resistance and perceived risk, as it allowed customers to adjust the codes to their real needs and test the benefits (Rogers, 2003). Related to this, formation of networks between academy and industry, the co-development of new CFD standards or the adaptation of CFD methodologies to industrial norms and practices, favoured the institutional alignment and ultimately legitimation.

However, not all contributing factors were intentional or attributable to the actors in the system. For example, the lack of substitutive products became a key and unintentional factor not attributable to actors' actions or system dynamics. Similarly, exogenous factors, as analysed in section 3.6 contributed to build legitimacy around CFD. In particular, the advances in computing capabilities with cheaper and more powerful processors and storage units, resulted in more industries and universities being able to test and develop new software.

Together with the development of structural processes or exogenous factors, TIS functions also contributed to build legitimation. As analysed in section 4.4 (area of investigation 2), *knowledge development* and *entrepreneurial experimentation* progressed very closely through consultancy services initially provided by system builders. As Hekkert et al. (2011) argue, a good performance of these two functions is required for a TIS to legitimate. *Resource* *mobilisation* accomplished by incumbents and his association with entrepreneurs also had an impact in the legitimation of CFD: although Spalding and his group were seminal in building institutional alignment and legitimation, it can't be obviated that companies like Creare and Adapco also legitimated CFD across different wider sectors and regions. Finally, *influence on the direction of search* played an important role in the legitimation of CFD, as the aligned visions of key actors in respect to the potential of the technology, contributed to its acceptance. Visions' alignment was probably influenced by the fact that all key actors could obtain benefits from the technology. Whereas for entrepreneurs and incumbents CFD brought the possibility to commercially exploit knowledge, on the customer side, interviewees alluded to the appropriable benefits in the adoption of CFD. As the founder of a CFD company in the USA described, CFD was providing competitive advantage by allowing the production of better products at a lower cost and in less time:

"In Japan it was Canon. They were interested in inkjets. So a lot of our early customers were inkjet people modelling inkjet toners. They were trying to develop better products, cheaper, faster and with higher resolution ... So it was the competition […] Automobile companies, again and metal casting, and there was competition of course, they were trying to make better products with less scrap and less waste for the best money....so I think people in these industries they realised they were gaining an advantage." (Founder of CFD company).

As introduced in section 2.6.3 of the literature review, organisational studies have largely studied legitimation, and scholars on TIS usually refer to these studies to describe the legitimation dynamics within a TIS. For some examples, see the work of Bergek et al. (2008b), Bergek et al. (2015) or Markard et al. (2016). As argued in section 2.7, this gives the possibility to further explore whether the principles for building legitimacy in new industries apply in the same fashion to TIS.

As discussed in section 2.6.3, Suchman (1995), classifies legitimacy into *pragmatic, moral and cognitive*. When applied to an innovation, *pragmatic legitimacy* relates to the self-interest or the benefits obtained through the adoption of the technology. *Moral legitimacy* reflects that the novelty is desirable or 'the right thing to do'. Finally, *cognitive legitimacy* represents the final stage of legitimation when the routines or standards embedded in the new technology are uncontested and taken for granted. As summarised in table 4-4, Suchman (1995) divides the three main types of legitimation into a set of subtypes. For example, *pragmatic* legitimation is divided into *influence* and *dispositional* legitimation. *Influence legitimacy,* reflects that the adopter perceives he can influence the innovation as his demands are accepted and taken into account. *Dispositional legitimacy*, reflects a perception on whether the innovation is trustworthy, honest etc. (this type of legitimacy can overlap with moral legitimacy). *Moral legitimacy* is divided into *consequential, procedural, structural* and *personal*. *Consequential legitimacy* relates to the moral dimension of the produced outputs, as it could be the case of, for example, sustainable or organic products. *Procedural legitimacy* evaluates the procedures employed to develop the innovation. It is therefore related to the normative dimension of legitimacy. *Structural legitimacy* denotes a positive evaluation of the structures supporting the innovation, for example, the size or service level of the support department. *Personal legitimacy* is represented by the charisma and reputation of the leaders. Finally, *cognitive legitimacy* is divided into *comprehensibility* and *taken for granted*. *Comprehensibility legitimacy* reflects that the plausibility and meaningfulness of the legitimacy can be explained through existing cultural models. *Taken for granted legitimacy* represents, as said, the last step in the legitimation process, when the use of older alternative technologies becomes unconceivable.

Types of legitimacy	**Definition**	**Subtypes**	**Definition**
Pragmatic	Based on self - interests Legitimation given in exchange of something beneficial **“It provides a benefit”**	Influence	Innovation is responsive and adaptable to audience demands. The adopter perceives he can have an influence.
		Dispositional	Audience perceives it as “sharing their values, being honest, trustworthy, decent.” (can overlap with moral legitimacy).
Moral	Based on evaluation **“It is the right thing to do”**	Consequential	Moral evaluation of the produced outputs. Ex: greener designs.
		Procedural	Evaluation of the employed procedures, norms. Ex: quality control and validation processes.
		Structural	Evaluation of the structures. Ex: size of research or customer support department.
		Personal	Evaluation of the charisma and reputation of the leaders.
Cognitive	Based on cognition **“It is understood, taken for granted and inevitable”**	Comprehensibility	Cultural models can explain its plausibility and meaningfulness.
		Taken for granted	Alternatives become unthinkable.

Table 4-4 Types and subtypes of legitimacy. Adapted from Suchman (1995)

Participant’s narratives about the benefits and competitive advantage in the adoption of CFD, represent a pragmatic legitimation dynamic. Moreover, the fact that adopters participated in the development of the codes by defining the problems, testing results etc., symbolise, according to Suchman (1995), influential and comprehensibility legitimation dynamic. Additionally, moral and cognitive dynamics emerged in aspects such as the creation of academia and industrial networks, the role of leaders/system builders, or the association between entrepreneurs and incumbent companies.

Table 4-5 provides the reader with a summary of the legitimation drivers extrapolated from the analysis of the different dynamics in the TIS. Consistently with the classification given in section 4.3.3, drivers are divided into: technological/knowledge related, organisational, institutional, and leadership. In addition to it, exogenous factors, have been included. The legitimation drivers are linked to the types of legitimation proposed by Suchman (1995) and supported with quotes from participants. As data shows, CFD legitimated as a combination of factors that build pragmatic, moral and cognitive legitimacy.

Legitimation factors		Type of Legitimation (Suchman, 1995)	Quotes
Technological and knowledge related	Co-creation of knowledge	Pragmatic (influential) Moral Cognitive (comprehensibility and taken for granted)	*"Spalding had been consulting with the industry, and he was much more of an industry associate. So…we were solving industrial problems from 1968 onwards. We were consulting with them. By 1969 , 1970, …we had courses then in the US in many other countries and we invited the industry to see how new technology could help them."* (IC researcher and SME founder).
	Lack of substitute products	Pragmatic Moral	*"Before CFD, the customer didn't have anything. It's pretty grateful and the customer can see the improvements, the new ideas […], even if it is inaccurate in some respects."* (IC researcher). *"I suppose that if you are in an organisation where you already have a complete suite of programs as it is in the aircraft industry...then there might be some reluctance, but […]we had a range of problems that needed solution."* (CFD early adopter).

	Proactive evidence demonstration	Pragmatic Moral (procedural) Cognitive(comprehensibility)	*"I think seeing the evidence. We were publishing the calculations and came and say...and then they bought the program and... it was just seeing the evidence."(Spalding).* *"There was lot of verification and validation done to the successful use of CFD."* (IC researcher and SME founder).
Organisational	Aligned visions	Pragmatic Moral	*"But, nonetheless one of the main factors was that the industry saw the usefulness of that. Once the industry started coming in, then other researchers in other allied fields, which were not purely not limited by fluid dynamics, people like in the mathematical field in turbulences, applied m solvers, they began to have a lot of interest because now there were these huge m equations to be solved, and the computers were available."(*CFD SME founder).

	Competitive advantage	Pragmatic	*"It was the competition, because they couldn't make measurements on those small scales...so they needed to have some way to understand what was going on. Same in the space. They needed some way they could do the testing in the ground and they needed something some way to try to understand the fluids in zero gravity."* (T3 researcher and company founder).
	Alliance incumbents-entrepreneurs	Pragmatic Moral (structural)	*"We were approached by an American company called Adapco […]With them, we managed to enter in the market. They were doing the consulting for the industry, driving the development of CFD methodology."* (IC researcher and founder of big CFD). *"It was very early days of getting the system out of the market, and the first step was at Creare, one of the section leaders there, decided that he would look after the marketing of the software."* (Professor Sheffield University).

	Academy/industrial networks	Cognitive	"CFD was a cottage industry. Professors, graduate students, and even researchers in industry wrote their own computer programs. There was a free and vigorous exchange of ideas among the members of this cottage-industry community. If an innovator described or published an improved algorithm or a new mathematical model, the others were quickly able to implement those ideas. " (IC researcher and SME founder).
Institutional	Co-development of standards	Moral (procedural)	"Through acquiring exposure of the university developing these methods that industry obviously they talk to each other so they realised there is something that is novel and can be used to solve their problems and that's how they became to it." (IC researcher and CFD company founder).
	Adaptation of codes to industry procedures	Moral (procedural)	*"There was lot of verification and validation done to the successful use of CFD."* (IC researcher and SME founder).

Leadership	System builder's vision and reputation	Moral (personal)	*"(Spalding's code was accepted) I* think through his reputation." (IC researcher and CFD company founder). *"(Spalding) was a very good leader. Very capable and he had a sense of what was possible in terms of industry and applications and…you know…he was a good engineer, and he built what practically not even today has been able to match."* (IC researcher and SME founder).
	Leader industries as early adopters	Moral (structural and personal)	*"Companies adopting the code encouraged other companies. […] like:'Rolls Royce is using it so it must be good, so we want to use it […]' That's how the word spread, with people going to exhibitions etc. The word spread and that's how proliferated."* (IC researcher and CFD company founder).

External	Development of related technologies	Pragmatic Cognitive (comprehensibility)	*"Back in the 80s the issue was computer storage… …so only small meshes could be used, hundred thousand cells mesh was quite a quite fine mesh…now people are talking about hundred million […]. Parallel computing places a major part in making that happen."* (IC researcher and SME founder). *"IBM did the first computer that came to Los Alamos and they only made seven of that model of computer...So Universities had no students doing computational fluid dynamics, there were no professors who knew what you're talking about.[…]As computers became more everyday things, universities started buying and students started programming and so on."* (T3 lab researcher).

Table 4-5 Factors contributing to pragmatic, moral and cognitive legitimacy.

4.6.2 Legitimation barriers

As discussed in section 4.3.4, data suggests that legitimation became more difficult and even impossible in industries with substitutive products. As Spalding pointed out, factors that contributed to legitimation in other industries, like providing evidence on technical superiority of CFD, didn't work if primitive numeric methods were already established. Another source of resistance, came from academic circles, who considered that the approximate solutions provided by numeric methods couldn't be of relevance. As a researcher from Cambridge University recalled[20]:

"*In Cambridge, there was a lot of scepticism about Spalding. He wasn't much appreciated as a scientist. They considered that his numerical solutions were useless as they only yielded rough and very simple results. No one thought that numeric methods could have any applicability at all. Then, when he succeeded and his codes became a reality in the industry, they criticised his morality for creating a company out of his academic work.* " (CFD researcher at Cambridge).

This interpretation is corroborated by Spalding, who declared that academic resistance didn't have any impact on industrial adopters:

"I already moved from Cambridge to Imperial College, but in Cambridge there was a lot of resistance and they didn't approve use of numerical methods. […] (Resistance) was in academy. They didn't think that numerical methods are quite right. […] I don't think the industry cared." (Brian Spalding).

Although not strictly related to the formative phases of CFD, data suggests that the lock-in in the methodologies and routines of CFD codes, prevented the adoption of further innovations in the field. As briefly described in section 4.2.3, the software and methods used today in CFD are practically the same as those developed in the 80s (Runchal, 2012; Hanna & Weinhold, 2017).

When asked for the reasons behind the lack of further innovations, some of the participants reflected that users prefer to stay with the models and methodologies they feel comfortable with, even if there are more accurate alternatives. As, an Imperial College researcher reflects:

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[20] Brian Spalding initiated his numerical methods thesis in Cambridge University, where he stood until 1954 (Runchal, 2009)

"*(k-epsilon is still used) simply, because it is so simple. I mean... A very successful, what it is known as nonlinear viscosity model. That is used in some software, but the plausible scheme that solves transport equations for the Reynold stresses that does very well...it is much less used. I guess there are also many competitors out there. I mean, the model I'm referring to, there have been groups that have produced simpler but less general versions of it, and these simpler schemes tend to be used in preference to the ones that I think are the best.*" (CFD researcher).

In the same direction, Spalding expresses beautifully how users are unwilling to try unknown novelties if there is an alternative that they know and feel safe about:

"I developed this new idea, it is like old Eddy break up model which everybody uses, but more accurate and interesting, but people use the Eddy breakup-model. So, it is a strange experience I've had lots of times. Things that are produced one time are preventing the next advance. People understand that, so the next stage they don't follow up. … CFD picked up quickly because there was nothing...novelty didn't seem so bad at that time, but now Eddy development, as a novelty is not liked." (Brian Spalding).

Aligned to the above, Spalding suggests that taking for granted CFD practices and routines (cognitive legitimacy), had a drawback that users do not question results and consequently CFD science transformed into a belief for which "reality will obey". In his words:

"The idea that CFD is only a very approximatively subject, that the numeric are accurate, but they are based upon models, representations.... That idea has been lost. People get the computer code, they do the calculations...ups! I did it, and they believe them to be true. So really, I've tried to change things, so results should always come now as approximations, you should know the sensitivity, if I change this part a lot of it will be different. […] Yes, in part, it is because all the interconnection between CFD and CAD -Computer Agent design - which is the representation of shape buildings and alike. That side, the mechanical side, the solid side of computer agent design is much more exact, you know what the processes are and you know what it will break and what it won't. […] They expect the answers to be as accurate as they are used to on the solid side and

I'm afraid there is in the CFD industry a willing to feed that expectations by not stressing the doubt of the fluid dynamic part. So that is a natural revert to me. There is too much belief that what we do is .... That reality will obey." (Brian Spalding).

In summary, and as contended by Hellsmark (2010) and introduced in section 4.3.4, data points towards two main types of resistance: *frictional resistance* (in form of organisational inertia) and *intentional resistance* (actions of actors with opposing interests). On the one hand, frictional resistance, hampering for example the legitimation of new innovations in the field, has its roots in the complex and long learning curves of CFD, as data suggests that once cognitive legitimacy was acquired and CFD algorithms were locked in, technology superiority (pragmatic legitimacy) didn't overcome the barrier of realigning the institutional framework towards new models and routines. Intentional resistance, on the other hand, might be represented, for example, by firms developing primitive numeric solutions for heat exchangers as discussed in section 4.3.4. Additionally, data points to intentional resistance in some academic circles. However, data analysis suggests that academy intentional resistance didn't have any negative impact in the legitimation of CFD. As Hellsmark (2010) argues, only actors with bargaining power can block the development of a TIS.

4.6.3 Legitimation strategies

As discussed in the literature review, Suchman (1995) proposes to classify strategies to acquire legitimacy into three categories: (i) strategies to ***conform*** to the needs of existing audiences and institutional environments, (ii) strategies to ***select*** audiences and institutional environments that will better support the novelty, and (iii) strategies to ***manipulate*** institutional environments to create new legitimating beliefs (Suchman, 1995). Building on Suchman's (1995) categories, Zimmerman and Zeitz (2002) add a fourth one: ***creation***. Creation involves developing new institutions that did not exist. Creation strategies typically apply in the creation of new industries, as more likely there will be a lack of existing rules, norms, values and models. As

Zimmerman and Zeitz (2002, p.425) argue: "*New ventures need legitimacy, but the basis from which they derive legitimacy may not necessarily be established.*"

Suchman (1995, p.587) suggests that realistic strategies move in a continuum of all categories: "*All three clusters involve complex mixtures of concrete organisational change and persuasive organisational communication (cf. Dowling & Pfeffer, 1975); however, they clearly fall along a continuum from relatively passive conformity to relatively active manipulation.*" Aligned to this, Zimmerman and Zeitz (2002, p. 426) argue that "*New ventures can also combine selection and manipulation with creation and conformance*."

According to Suchman (1995) and Zimmerman and Zeitz's (2002) observations, data analysis suggests that CFD system builders combined different legitimation strategies along the spectrum creation-conformation. For example, CFD created new beliefs to solve problems that a number of audiences were facing. As discussed, system builders proactively evangelised "new explanations of social reality" (Suchman, 1995, p. 591). In addition, system builders selected audiences in industries where they already had a good reputation (personal legitimacy) due to previous collaborations. Interestingly enough, in these environments substitutive products didn't exist, making "manipulation" a simple exercise of demonstrating evidence on the appropriable benefits of the technology. Finally, legitimation strategies followed by CFD system builders, also present a conformation component. As discussed, CFD methodologies and standards were co-created with industrialists to conform to the existing industrial norms.

4.7 Conclusions

CFD is today a multibillion dollar market (Hanna, 2015) that traces back to the late 1960s and 1970s, when a group of scientists led by Professor Brian Spalding introduced the idea of using numerical methods to solve industrial problems related to flow, heat and mass transfer. CFD represents an exceptional case to study the formative phases of a TIS. As introduced in section 4.2.1, the scientific principles of CFD were developed across two different research centres: the

T3 Laboratory at Los Alamos (USA) and the Thermofluids group at Imperial College (UK). Both groups were, for more than a decade, working on the same problems and came to the same conclusions without knowing about each other (Runchal, 2009). Moreover, data analysis shows that while the T3 Laboratory at Los Alamos pioneered in knowledge development, they acted as an isolated centre constrained by a rigid organisational and institutional environment. This, most probably hampered their orientation towards collaborative and applied knowledge. On the contrary, the Imperial College group, led by Professor Spalding, were recognised for being the key system builders in the development of TIS structural processes and several TIS functions. They developed applied knowledge, attracted industrialists into the TIS, created networks of knowledge sharing between academy and industry, aligned technology to industrial problems, methodologies or standards and by acting as the first entrepreneurs, they formed the CFD entrepreneurial ecosystem.

As figure 4-4 summarises, data analysis suggests that the institutional and organisational environment in which system builders are embedded, influences their transformative capacity. Following on Giddens' (1984) structuration postulates of actors embedded in structures, Hellsmark (2010) contends that system builders are embedded in a structure named *general structure* that constrains or enables their capabilities to address weaknesses and strengthen the TIS. System builders' *general structure* is composed of different factors that exist in the structures in which they are embedded. These factors can be: organisational, institutional, sectoral, geographical etc. Consistent with Hellsmark (2010), data analysis in section 4.3.3 suggests that rigid *general structures* have a negative impact in the transformative capacities of system builders, whereas, on the contrary, more flexible *general structures*, as in the case of Imperial College, enhance their transformative capacity.

In addition to system builders' general structure, figure 4-4 points to different intentional technological and leadership factors that enhanced Spalding's group system building capabilities. Chief among them were their proactivity to disseminate *and co-create knowledge,* their ability to provide *evidence* on technology usefulness and the group's *leader vision*. As Kristensson et al. (2008) argues, the early involvement of customers as co-creators reduces resistance and contributes to innovation acceptance. Coherently, *co-creation of knowledge* favoured the orientation of CFD codes to solve real customer problems, while at the same time these were smoothly adapted into industrial practices and standards. Using Rogers' (2003) attributes of innovation, co-creation of knowledge enhanced trialability and compatibility. From a legitimation perspective, as discussed in section 4.6.1, co-creation of knowledge contributed to build pragmatic (influential) moral and cognitive legitimacy (Suchman, 1995). Providing *evidence* on the capabilities of the codes attracted more actors into the TIS and boosted the possibility to demonstrate its relative advantage (Rogers, 2003). With this, pragmatic legitimacy was also enhanced, as adopters could perceive the appropriable benefit of the new technology (Suchman, 1995). Finally, as discussed, Spalding's vision *(leader's vision)* was key to influence his group towards diffusing and developing applied knowledge, as it also was to *influence on the direction of search*, through aligning visions and expectations of TIS actors during the formative phases of CFD. Moreover, data analysis suggests, as discussed in section 4.6.1, that Spalding's reputation was key to building moral legitimacy.

Besides the discussed intentional factors driven by system builders, another unintended important factor in CFD legitimation success, relates to the lack of substitutive products. This is important as data suggests that it set the limits of individual system building capabilities. As discussed in section 3.4.4, system builders reported that they failed to legitimate CFD in sectors where numeric methods were already in place, as in heat exchangers industry. According to Hughes' (2012) definition:

"One of the primary characteristics of a system builder is the ability to construct or to force unity from diversity, centralisation in the face of pluralism, and coherence from chaos. This construction often involves the destruction of alternative systems. System builders in their constructive activity are like heterogeneous engineers." (Hughes, 2012, p.46).

Spalding and his team achieved many of the system builder traits exposed by Hughes (2012). However, they didn't manage to "destruct alternative systems". Their capabilities to persuade adopters in industries with substitute products were largely unsuccessful. Moreover, once the lock-in of CFD happened, system builders also failed in persuading the adoption of new breakthroughs among existing CFD users. As Spalding argued, organisational inertia has hampered the advance of CFD over the last 30 years. Therefore, data analysis suggests that legitimation becomes more difficult to obtain when technological or institutional structures (in form of technological substitutes, embedded practices, routines, norms etc.) are already in place. This finding is aligned to the point postulated by Tushman and Anderson (1990), who stated that innovation will take longer time and be more problematic to succeed if existing know-how needs to be destroyed. This aspect is of particular interest in the CFD practice, where the operationalisation of CFD software requires a high level of expertise. Most likely this explains the high fragmentation of the CFD market, with many SME companies providing niche and ad-hoc solutions and consultancy services being an important part of CFD industry revenues (Technavio, 2016).

As discussed in section 4.6.3, data analysis suggests that system builders developed legitimation strategies along the conformation – creation spectrum (Suchman, 1995; Zimmerman &Zeitz, 2002). As an example, they *created* new beliefs to solve existing engineering problems and at the same time they managed to align these new beliefs into products that *conformed* with industrial regulations. Moreover, they started a selective legitimation process in niches where they had a good reputation and previous collaboration experiences.

In addition to the role of system builders in the development of CFD TIS during the formative phase (1970s), data shows the relevance of the alliances between entrepreneurs and incumbent engineering companies who came on the scene a decade later. In particular, as discussed in sections 4.4.3 to 4.4.5, incumbents were key in developing *resource mobilisation*, *influence on the direction of search* and *market formation* functions. With this, they also contributed to legitimate CFD in new industries and regions. As an example, the partnership between Creare, an American company, and Sheffield University (who developed their code from PHOENICS), introduced and led the CFD market in the United States.

Figure 4-5 summarises the contribution of system builders and incumbents in the development and legitimation of TIS. As it is shown, data suggests that system builders like Spalding and his team, were key in knowledge development by proactively diffusing and co-creating knowledge. They, as well, initiated entrepreneurial experimentation and led niche bridging markets. They contributed to the function "influence in the direction of search", aligning visions and expectations around the possibilities of CFD. Moreover, as previously discussed, they were seminal in building pragmatic, moral and cognitive legitimation (Suchman, 1995). On the other hand, the later alliances between some entrepreneurs and incumbent companies, became of critical importance to develop resource mobilisation and market growth. As discussed in section 4.4.3, incumbents infused capital and specialised marketing and sales resources in the TIS. They also anticipated a business model based on software selling instead of consultancy services (influence on the direction of search) and legitimated CFD in new industrial areas and regions. With all of this, incumbents lead the evolution of CFD from niche and bridging markets into growth markets. As Lieberman and Montgomery (1998, p.1113) postulate, incumbents took advantage as late entrants, joining their marketing and manufacturing capabilities with system builders' resources and technical skills.

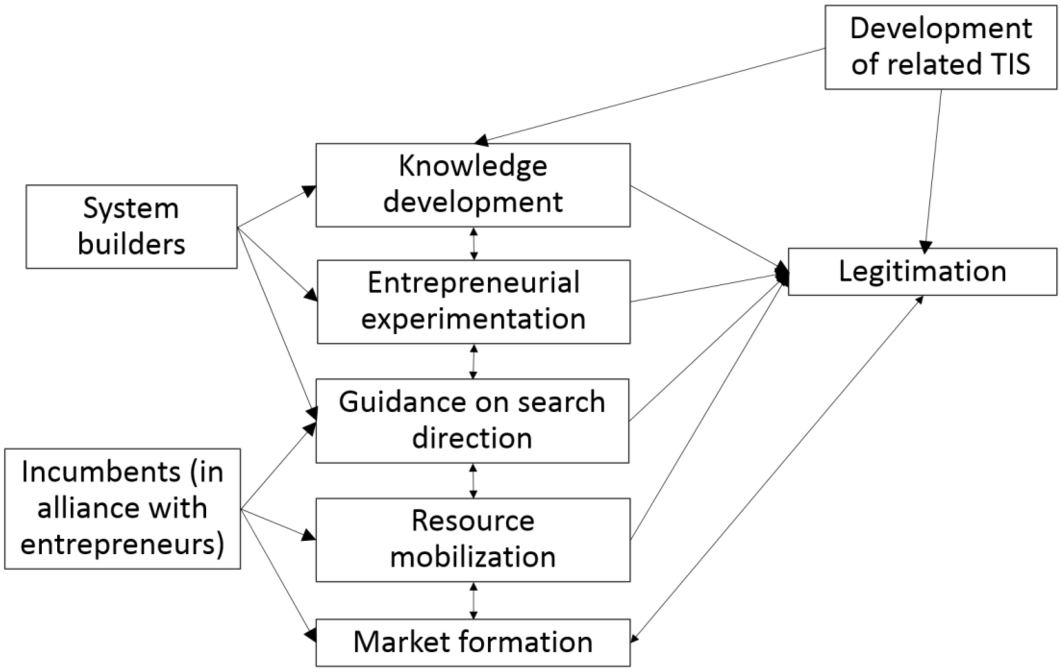

Figure 4-5 Role of system builders and incumbents in the development of CFD. Developed by the author

Chapter 5 - Case study 2: mHealth technologies for diagnostics and chronic disease management

This chapter provides the reader with the analysis of the second case study: mobile Health technologies for diagnostic and chronic disease management (mHealth). The first section (5.1), sets the context for the study and expands the mHealth overview provided in section 3.4.2.2 of the methodology chapter. It analyses relevant TIS considerations, such as identified structural components for the study, geographical boundaries, and a summary of the reported adoption barriers in the literature that will be later contrasted with the analysis of the primary data of this research. The second section, section 5.2, analyses system building capabilities and the development of the structural processes of the mHealth TIS (Hellsmark & Jacobsson, 2009). The section pays special attention to the institutional misalignment between mHealth proposition and traditional healthcare institutions. The third area of investigation (section 5.3), examines the performance and dynamics of the TIS functions as defined by Bergek et al.(2008a). The central points covered in this area of investigation, relate to the function influence on the direction of search (section 5.3.4) and the different visions, motivations and technology value across the different groups of actors in the system. The next area of investigation (section 5.4), explores the influence of external structures, like related TIS or political agendas, in the development of the mHealth TIS. The fourth and last area of investigation (section 5.5), focuses on legitimation, the key topic of this research. It analyses the underlying technological, organisational and institutional factors that obstruct the legitimation of mHealth, as well as the strategies undertaken by different groups of actors. Finally, section 5.6 summarises the main points emerging from the analysis and compares findings with the most recent studies on TIS and legitimation (Bergek et al., 2015; Markard et al.,2016).

5.1 mHealth: TIS considerations

The section 3.4.2 in the methodology chapter offers a state-of-the-art overview of mHealth, and its suitability as a case study to analyse the formative phases of a TIS. As defined, mHealth is a term used to encompass a variety of technologies oriented to provide healthcare services. These technologies are embodied in mobile devices like smartphones, tablets, wearables etc. and bring the possibility to provide healthcare services to any individual with a connected device (WHO, 2011). The high penetration rates of mobile devices and the advances in sensors and wearable technologies, have spotlighted the potential of mHealth to disrupt healthcare (WHO, 2011; Topol & Hill, 2012). As an example, Cisco[21] estimates that by 2020, 70% of the world population (around 5.5 billion people) will be mobile users. If accomplished, this would represent a higher percentage in respect to the population with access to basic services like electricity or running water. However, and as it also was discussed in section 2.4.4, recent studies show that despite the potential and expectations around mHealth, its level of adoption is still very low (Labrique et al., 2013; WHO, 2011; WHO, 2016). Different studies have pointed to a number of adoption barriers (European Commission, 2014; Steinhubl et al., 2015; WHO, 2016). These adoption barriers could be summarised as follows:

(i) lack of clinical evidence

[21] Cisco Global Mobile Data Traffic Forecast Update, 2016–2021 White Paper available at: https://www.cisco.com/c/en/us/solutions/collateral/service-provider/visual-networking-index-vni/mobile-white-paper-c11-520862.html

(ii) lack of cost efficiency evidence

(iii) lack of financial support (reimburshment) and viable business models

(iv) regulatory constraints

(v) standardisation, interoperability and security issues

(vi) lack of leadership

In addition, Gagnon et al. (2016) conducted a systematic literature review on reported barriers of mHealth by healthcare professionals. Table 5-1 provides a summary of the main barriers at technological, individual, organisational and contextual level. The presented barriers from extant mHealth literature will be further contrasted in sections 5.2.4 and 5.5.1 with the findings resulting from the analysis of mHealth as a TIS.

Individual barriers	Organisational barriers	Contextual barriers
Time issues	Time issues	Reduced quality in patient/practitioner interaction
Resistance / not welcome attitude	Organisational support	
Familiarity with technology	Training	

Table 5-1 Barriers perceived by healthcare professionals. Adapted from Gagnon et al. (2016)

The first consideration when conducting a TIS analysis is the definition of the technological boundaries. As Bergek et al. (2008a) suggest, the researcher needs to reflect on three types of choices: (1) the choice between knowledge field or product as a focusing device, (2) the choice between breadth and depth, and (3) the choice of spatial domain. As presented in section 3.4.3.2, the unit of analysis of the present case study is the field of knowledge of mHealth technologies for diagnostics and chronic disease management across the EU region. Although the arguments for the selection of unit of analysis are discussed in the methodology chapter, the following reflection by Steinhubl et al. (2015, p.1) depicts how diagnosis and chronic disease management epitomises the breakthrough transformation that mHealth can bring:

"…*Now are mobile health (mHealth) technologies making initial inroads into health care and, in so doing, are providing the foundation to radically transform the practice and reach of medical research and care. Through progressively miniaturised and increasingly powerful mobile computing capabilities, individuals are becoming increasingly capable of monitoring, tracking, and transmitting health metrics continuously and in real time. This metamorphosis has provided the potential for acute disease diagnosis and chronic condition management to take place outside the standard doctor's office or hospital.*"

After defining the technological boundaries, Bergek et al. (2008a) suggest to identify the main structural components of the TIS: *actors, networks and institutions*. mHealth represents a complex ecosystem with a plethora of structural components. Therefore, analysing all of them is out of the scope of this research. Table 5-2 incorporates those that directly or indirectly have been considered for the study. The actors' column includes entrepreneurs, ICT firms, consultancy firms, healthcare provider firms, venture capitalists, policy makers, regulators and patients. The network column includes formal and informal mHealth related associations like HIMMS, mHealth Alliance, mHealth LinkedIn groups, European Health Connected Alliance and European mHealth Summits. The institution column includes hard and soft institutions like EU medical devices regulation, EU mHealth code of conduct, ICT culture, ICT R&D practices, healthcare culture, healthcare industrial practices etc.

Actors	Networks	Institutions
• Entrepreneurs • ICT firms • Consultancy firms • Healthcare providers • Venture capitalists • Policy makers • Regulators • Patients	• HIMMS • mHealth Alliance • mHealth Linkedin groups • European Health Connected Alliance • European mHealth Summits	• EU medical devices regulation • EU mHealth code of conduct • ICT R&D practices • Healthcare R&D practices • Healthcare culture • ICT culture

Table 5-2 Structural components of mHealth for the study.

After identifying reported barriers and mHealth structural components, the rest of this chapter analyses mHealth as a TIS with a special focus on the legitimation dynamics during its formative phase. To do so, it follows Hellsmark and Jacobsson (2009) framework on TIS dynamics discussed in section 2.6.4. As in the previous case study, the sequence of the analysis will be as follows: first, the development of structural processes and the role of system builders will be analysed (arrows 1 and 2 in figure 2-7). Then, the second area of investigation will examine the development and contribution of TIS functions to legitimation (arrow 3 in figure 2-7). The third area of investigation will look into the impact of external factors on legitimation (arrow 4). Finally, in the last area of investigation, legitimation drivers, barriers and strategies will be compiled and discussed in depth through the lenses of organisational studies (Suchman, 1995; Zimmerman & Zeitz, 2002).

5.2 Area of investigation 1: system building capabilities

As Hellsmark (2010) contends, the formative phase of a TIS is characterised by the development of four structural processes: (i) accumulation of knowledge and artefacts, (ii) entry of firms and other organisations, (iii) formation of alliances and networks, and (iv) institutional alignment. System builders, as discussed in the previous chapters (see sections 2.4.3, 2.6.4, 4.3), are key actors contributing to the development of TIS structural processes. An important clarification is that whereas in the previous case study (chapter 4), the identification of system builders didn't present much complication, in the current study the researcher was not able to identify any relevant system builders, at least influencing the development of all structural processes at the broad unit of analysis of the study. A potential reason for this, could be the fact that the present research is a prospective study for a TIS that is currently in its formative phase. Therefore, most probably, the outcomes derived from system builders' actions haven't happened yet. Moreover, as recent research points out, lack of leadership is identified as one of the barriers for mHealth adoption (Steinhubl et al., 2015; WHO, 2016). Aligned to this, one of the participants in the study reflects:

"*I think all of us, including the pharma sector, we still have to demonstrate a lot. We need to demonstrate that we can do it, and once we have demonstrated, we will reach the leadership phase."* (Pharmaceutical representative). Furthermore, in a highly institutionalised context, as in the case of healthcare, the transformative capacity of system builders is more likely to be exerted as a collective effort of networks of actors (Musiolik et al., 2012).

Therefore, despite not being able to focus the analysis of this first area of investigation on the role of system builders, the rest of the section presents the state- of- the- art overview of the mHealth TIS structural processes, with a special focus on the institutional misalignment between mHealth and the traditional healthcare institutional framework (section 5.2.4).

5.2.1 Accumulation of knowledge

Since Istepanian (2004) coined the mHealth term more than a decade ago, a vast number of mHealth artefacts like apps, devices and wearables have been developed. As an example, according to the estimations of Research2guidance (2017), there are currently about 97,000[22] mHealth apps targeting health professionals, patient records, patient consultation, monitoring, diagnostic, drug information etc. However, according to the same report, use ratios and revenues are still very low with only 24% of applications registering more than 50,000 downloads. The implementation of mHealth technologies into EU healthcare systems is also below expectations. According to the WHO (2016), despite the variety of technologies available and the high rates on mobile devices penetration, only 11 mHealth patient monitoring initiatives are implemented across the European region.

The majority of mHealth apps are developed by entrepreneurs or SMEs (European Commission, 2014), and technological market players constitute the biggest group within the mHealth market (Research2guidance, 2017). Bergek et al. (2008a) distinguish between different types of knowledge: scientific, technological, design, production, market, logistics etc. Data analysis suggests that whereas technological knowledge is well developed for mHealth, industrial knowledge is still developing. For example, according to Research2guidance (2017), the majority of mHealth apps publishers are considerably inexperienced, with 28% having less than 2 years of experience in the mHealth field.

[22] Estimation from a total of 325,000 mHealth apps and a 70%-30% split between wellbeing and medical apps

5.2.2 Entry of firms and other organisations

Accumulation of knowledge and expectations on the potential of mHealth have attracted a large number of firms and organisations. Figure 1 presents a distribution of mHealth players including health insurance companies, IT/Technology firms, governmental organisations, consultancy companies, NGOs, pharmaceutical and medical devices organisations, digital health companies, venture capitalists etc. As the figure shows, traditional healthcare players represent only 32% of the ecosystem[23] which is dominated by digital healthcare and technological companies. According to the European Commission Green Paper (2014), entrepreneurs and SMEs are the largest group in the market, primarily oriented to the development of mobile apps. On the other hand, the majority of big ITC and technological firms are primarily focused on the integration of mHeatlh into healthcare systems. Research2guidance (2017), states that the interest of traditional healthcare companies in mHealth is increasing. Aligned to this, the three pharmaceutical companies participating in this study, reported the creation of mHealth accelerators to capture internal and external value from the mHealth entrepreneurial ecosystem. Finally, the potential of mHealth to provide universal and more efficient healthcare, has also attracted the attention of governments and public organisations like the World Health Organisation and the European Commission.

In summary, data analysis suggests a rich and diverse ecosystem of firms and organisations entering the mHealth TIS.

[23] Data obtained by Research2guidance from a survey of n=2,400 participants

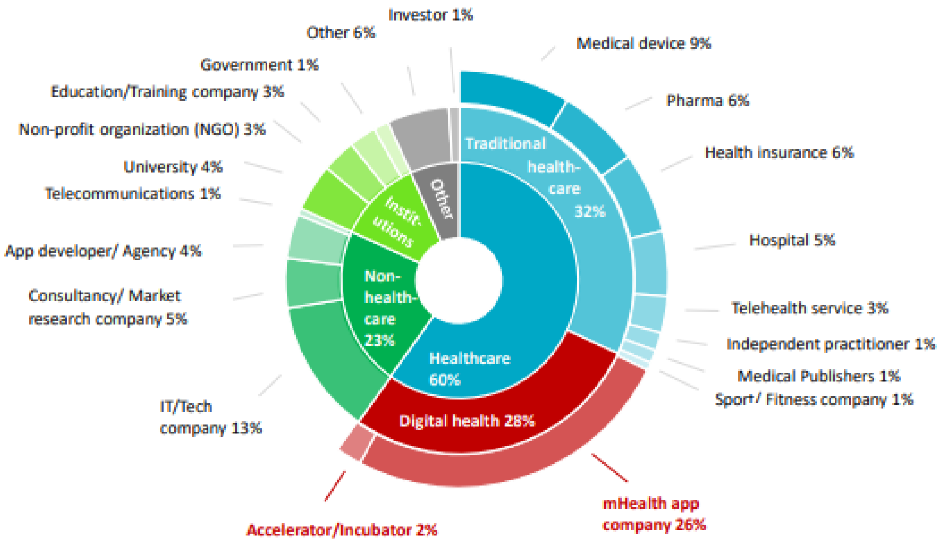

Figure 5-1 Global mHealth market players. (Research2guidance, 2017)

5.2.3 Formation of networks and alliances

Over the last decade, a plethora of networks have been formed around mHealth. They include formal networks sponsored by public and private organisations as well as informal knowledge networks through, for example, groups of experts in social media like Linkedin and Researchgate. A look into the different mHealth networks, allows differentiation between networks dedicated to knowledge exchange and promotion of mHealth as an innovative practice, and networks oriented to addressing existing adoption barriers like lack of evidence, interoperability or security issues. An example of the former, is the mHealth Alliance, founded in Italy in 2008 by the UN and sponsored by a private initiative.

"The mHealth Alliance (mHA) bridges diverse communities to mobilise innovation for global health. Launched by the UN Foundation, which houses the Alliance, and the Rockefeller and Vodafone Foundations in 2009, the mHA is dedicated to enabling quality health at the farthest reaches of wireless networks. By building public-private partnerships that address health needs in underserved communities, the mHealth Alliance and its partners are developing new ways for mobile health, or mHealth, to increase the availability, accessibility, and effectiveness of health

information and services."[24] Additionally, professional digital healthcare associations like HIMMS Europe or the European Health Connected Alliance, also act as knowledge hubs through the periodic organisation of seminars and summits involving key market players and public authorities.

On the later type of networks (those oriented to addressing adoption barriers), the European Commission is facilitating different working groups with representatives of patients, healthcare professionals and providers, industry, public authorities and academy. As an example, the code of conduct for mHealth apps initiative, aims to improve trust on mHealth by agreeing on a set of standards for mHealth developers to comply with best practices and EU data protection rules. In addition, the mHealth assessment guidelines workgroup, is working on a set of standards to improve the reliability and quality of mHealth apps. These activities illustrate the collective system building capabilities occurring in the mHealth TIS. As one of the participants in the development of the Code of Conduct describes, the purpose of the initiative was to build trust through harmonising the development of mHealth apps into the EU data protection normative:

"(The purpose is) to take by hand the app developers to the legal details and how to make these legal details easy, and embed them in their developing exercise. So this is one purpose, the other one, which is also the purpose of the European Commission, is to foster trust in users. […] We struggled a little bit to find the correct structure between all the organisations that were involved. But we came up with it and we submitted to the National Data Protection Authorities and to the Commission. So, in the end, we made it." (ICT entrant and mHealth lobbyist).

More recently, in 2017, The European Commission has sponsored the EU mHealth Hub, an alliance between the WHO and the International Telecommunications Union (ITU) to work on the evidence of mHealth for its integration into the healthcare systems.

[24] http://mhealthknowledge.org/

On the entrepreneurial side, data analysis suggests that entrepreneurs prefer to interact in informal knowledge networks of companies they know. Moreover, some of the participants in the study, questioned the usefulness of formal networks to overcome their biggest barrier: access to healthcare professionals.

"There is a couple of other start-ups here and we meet quite regularly and share information. We meet regularly with a number of healthcare companies to share information. So definitely there is a community of mobile health companies that are working together...and even with competitors sometimes we share information, because we all know how difficult this area is. So I think the challenge sometimes is to find the time to see these networks." (mHealth entrepreneur).

"(the usefulness) is sharing knowledge definitely. Take regulation as an example. Because there is a lot of grey area there... and you know a company that went through and they were able to share how they did it. You get a huge amount of insight. It is such a new area that the acceptance from the regulatory point of view can rest on the way you present your company." (mHealth entrepreneur).

"I don't think mHealth networks are very useful. They organise events and so on, but at the end of the day, they do not facilitate the access to healthcare professionals that they claim." (mHealth entrepreneur).

In addition to networks, different alliances have been formed in the last decade. Data suggests that they primarily have a market orientation. On one hand, big ICT companies and incumbent healthcare providers like pharmaceutical companies, have established several alliances to accelerate the development of mHealth products. As an example, Novartis and Google announced in 2014 a partnership to develop a smart contact lens to monitor blood sugar levels. The agreement included the licensing of Google's smart lens technology. As the Financial Times (15th July 2014) stated: *"…the agreement is among recent moves into the health care* *sector by technology giants including Apple and Samsung as they develop devices and mobile applications to track people's daily lives."*

One of the participants in the study, an mHealth manager in a big pharmaceutical company, provides an interesting reflection on how main mHealth players have established an alliance to collaborate, while at the same time they are still competing to lead the incipient mHealth market.

"I see 4 titans in this fight: we have the pharmaceutical companies, we have the consultancy companies…all are doing very powerful initiatives in this arena...we have the TELCO, and as they have access to patients, to citizens, they take advantage of that access to the market and (finally) we have the technological companies as it can be IBM, Siemens etc... We are all fighting for the same. All of us from a different angle, but we are all fighting mainly for the same. What are we doing now? We are doing alliances...looking into what makes more sense for a partnership that can lead us to the final objective and see who positions better. […] I believe the four of us are trying to see who do better movements... Siemens launched a couple of years ago Siemens eHEalth, Telefonica has Telefonica eHealth....so all of us are trying to position ourselves on this, because we all see a clear market opportunity. As of today, I don't see a clear winner." (Pharmaceutical representative).

In addition to alliances with competitors, ICT companies and incumbent health providers are establishing accelerators to capture value from the mHealth entrepreneurial ecosystem. For example, the three pharmaceutical companies participating in the present study confirmed the recent creation of mHealth accelerators. On the entrepreneurial side, many participants recognised that one of their main goals was to sell their technology to an incumbent company. As one the participants pointed out:

"I think that most of the mHealth companies are in the process of trying to sell to a big partner or trying to find a big partner. For that you need credibility and that credibility has to be built in

the process, so you have to be very careful in the relationships you hold. So definitely you have to have in touch with companies that can mean future partnership for us." (mHealth entrepreneur).

In summary, data analysis suggests a vigorous and rich ecosystem of networks and alliances that, as it will be discussed in section 5.3, has contributed to enhance knowledge development, entrepreneurial experimentation and resource mobilisation.

5.2.4 Misalignment between mHealth and healthcare institutions

Data analysis evidences a high misalignment between mHealth and traditional healthcare formal and informal institutions (values, beliefs, norms, regulation etc.). As Hellsmark (2010, p.10) contends, the process of institutional alignment in environments dominated by few large incumbents: "…*is often a painful one marked by great uncertainty, conflicting interests between advocates of the old and new technologies and between proponents of various designs alternatives of the new technologies.[…] Studying this painstaking process of alignment involves unfolding the evolutionary interactions between institutions, technology, organisations, and their entrepreneurs."*

Taken from Hellsmark's (2010) statement, this section provides the reader with an in-depth analysis of the institutional misalignment between the mHealth TIS and healthcare institutions. As an outcome of the analysis, legitimation blocking mechanisms will be unveiled and further discussed in section 5.5.1.

Previous mHealth studies, as discussed in section 5.1, point to a set of barriers affecting formal institutions like: unclear regulatory frameworks, lack of clinical evidence or lack of viable business models. However, data analysis in this study points not only to formal institutions as a source of institutional misalignment. Data suggests that informal institutions (norms, beliefs, culture and adopted business models) are also a source of institutional alignment. As one of the experts participating in the study contends:

"Technology is ready and mature and could just be used. It is not about the technology. The problem we have is the change in the processes and in the culture of the healthcare institutions." (ICT participant).

Aligned to this, an EU policy maker refers to the slow-adoption pace of mHealth as compared to other regulated sectors like banking. Very interestingly, the expert suggests that the dimension of mHealth change is of bigger impact, as the new institutional framework requires a power shift from professionals to patients:

"It is a slow revolution in the making. So although might be revolutionary or transformative, it goes slowly, much more slowly than we see in some of the other sectors, where likewise also mobile and other digital technologies enter...banking for example go faster to mention a thing[…] But it is also *a much more revolutionary change. (mHealth) is changing the delivery and the power relationships around health and bringing it much closer to individuals. […] It brings lots more of opportunities to do a personalised health rather than the general health provision, and that means that the centre of gravity can shift more towards the consumer or the citizen or the patient... and also reverses the direction of the power from the professional towards the citizen in a number of cases."* (EU policy maker).

The analysis of institutional misalignment is organised around 4 main themes emerging from data analysis. These are: (i) the clash between the ICT and healthcare institutions, (ii) the technology-push orientation of mHealth, (iii) the impact of organisational inertia in complex and professionalised healthcare systems and (iv) the divergent interests among TIS actors.

5.2.4.1 Clash between the ICT and healthcare institutions

Data analysis importantly points to institutional misalignment between the formal and informal institutional environments in the technology industry (the main providers of mHealth solutions) and the healthcare industry (the main receptors of mHealth solutions). On one side, the technology industry, and in particular the software industry, is fast changing with very short time to market periods and rapid obsolescence of products. On the other side, traditional healthcare is a slow-paced industry, characterised by costly and long periods in the development and validation of new products (the average time for a new product development in the pharmaceutical industry is 10 years). As pointed out by Research2guidance (2017, p.7): *"…the two environments are very different, and yet, the fast-paced digital industry and the slow-paced healthcare industry have been colliding to produce digital health."*

As participants suggested, the different approaches with respect to quality, test and validation procedures, makes the alignment difficult between both environments. One of the participants summarises it as:

"Software and particularly apps fly and see.... It's just build an app and see what happens. Put it out there, get your minimum viable product, pivot your project. All these things are anathema to doctors and as soon as you try to put that kind of attitude, for innovation in software world with the need for safety and security in the medical world, they just hit the wrong direction every time (laughs). So the two professions if you like, have a huge culture clash, which means you can't even have the initial conversation. So the doctors want something that goes through the trial and testing clinical process, and the developers don't have time or money to actually do that." (mHealth advisor).

Data analysis suggests that the cultural clash between technology and healthcare institutional frameworks, has created distrust and resistance in the healthcare sector. For example, this researcher attended a meeting organised by the European Commission during the European mHealth Summit in Riga(Latvia) in May 2015. On the meeting's agenda was the discussion on the mHealth code of conduct (described in section 5.3.3). In the meeting, representatives from big ICT firms, the pharmaceutical industry and healthcare professional associations were present. The researcher's notes evidenced the lack of trust of clinicians and incumbent pharmaceutical representatives towards big ICT firms:

"*This task should be led by someone who knows well the sector. We should have been leading this, we are the experts in healthcare.*" (Clinicians' representative).

"*You don't understand healthcare. You don't know patients and you don't care. You just talk about savings.*" (Pharmaceutical representative).

Aligned to this, the representative of a healthcare practitioners' association participating in this study, also points out the lack of understanding of healthcare culture by entrant technological firms:

"They are selling business, while if you really want to be successful, I think you need to look at what does the population need, what do the European citizens need, what are the needs of the Romanian people, what are the needs of the UK people, and try at a global level...because...you know, for them it is all about business. It's about billions...So I think, there's still a long way to go. Because the (technology) industry has not really understood the culture of working in this field, I think." (Healthcare practitioners' representative).

This last reflection on how mHealth solutions should be focused on citizens' and patients' needs, links with the next topic of analysis: the technology- push orientation of mHealth solutions.

5.2.4.2 Technology-push orientation of mHealth

In addition to the clash of institutional environments previously described, data suggests that another cause preventing institutional alignment comes from an excessive technology-push orientation of the mHealth solutions. As Vallespin et al. (2016, p. 249) state: *"…too frequently, studies on mHealth solutions have been based on 'How can these technologies be introduced in* *the healthcare system?' instead of 'How the healthcare systems can be more sustainable, more secure and efficient with the help of mHealth technologies.'..."*

As the president of a patients' association recalls:

"We don't use mHealth to make inefficient processes more efficient, but we actually look at whether the processes themselves should be completely redesigned with the abilities of mHealth ....I have the concern that we're looking at the current paths that we have and putting information technologies or mHealth into that, as opposed to standing back and saying: 'let's look at something with a blank sheet of paper, completely a fresh...and let's see what we can build and then see where does mHealth fit into that.'..." (Patients' association representative).

An interesting case exemplifying failure due to technology-push orientation, is the 3millionlives program started in the UK in 2011[25]. The UK Government Department of Health (DH) set up the initiative with the objective to remotely monitor 3 million people with long term conditions and/or social needs. The estimations were that Telecare could save the NHS up to £1.2 billion over five years, while at the same time it would provide better patient care service and significant reductions in mortality rates. After a few years, the programme was dismantled as it didn't reach the expected objectives. The report below produced by the Welsh National Assembly[26], points to the reasons for the program failure which include the lack of contrasted evidence on the benefits, the industry driven approach and the orientation to invest in certain technologies "*rather than practitioners and users/patients identifying areas where technology could help them, and so inform the development of appropriate new technology.* "

[25] www. http://3millionlives.co.uk/

[26] Report found at http://www.senedd.assembly.wales/documents/s43139/MT%20AI8%20ADSS%20Cymru.pdf

3. Current position and lessons to learn

The partners in 3 million lives, including the industry body Telecare Services Association (TSA), have recognised that the initiative has not progressed as hoped, despite high profile launch from the UK Prime Minister David Cameron. There are a number of different reasons for this:

* Some of the claims being made from the WSD programme were challenged by bodies such as the BMA, with a number of different articles published with specific criticisms
* No final report on telecare impact was ever published under WSD – fuelling concerns that the methodology used was flawed or the results inconclusive
* The approach taken was very top down – with little engagement of front line practitioners, so that there was little sense of ownership or engagement
* More detailed analysis showed that positive outcomes were not wholly attributable to technology, but due to a number of factors (such as more regular clinician contact to support taking readings). Using a randomised control approach (so some patients received monitoring equipment and others did not) meant that there was some increase in hospital presentations from those who *did not* have equipment.
* The three million lives approach was perceived as being very industry led and, as such, a 'sell' to care practitioners and service users/patients, with positives over emphasised and negatives glossed over.
* Industry was asked to drive investment in technology – rather than practitioners and users/patients identify areas where technology could help them, and so inform the development of appropriate new technology

Figure 5-2 Excerpt from 3millionlives report. National Assembly of Wales, Health and Social Care Committee

5.2.4.3 Organisational inertia

As Hellsmark (2010) points out, prevailing institutions tend to favour incumbent technologies. Data analysis suggests that lack of interest and organisational inertia hampers the alignment of mHealth and the health institutions. As an expert suggests, inertia does not come only from healthcare practitioners, but also from IT healthcare professionals:

"Inertia. Inertia is what it holds it back. I think most of the other issues like regulation and this and that are being resolved....Also, I think IT policies hold it back...actually. That is what it holds it back... Whenever you want to do something for mHealth you come with great ideas that are safe, that are sensible....and there is always some problem with the IT people saying; 'This has

to be like this, because we have some policies on what can go in people's devices.'...and there is always the bureaucratic obstacles. And that's how it is in the NHS." (mHealth entrepreneur).

Additionally, as Gagnon (2016) identifies, another factor related to inertia is the lack of time practitioners have to deal with mHealth on top of their normal workload. A representative of a healthcare practitioner association, declared that under a context of pressure for optimising resources, professionals can't absorb the extra effort of adopting mHealth:

"*You know, we can't do our profession with the commitment that we have tried to do in many years. You know, there is too much performance measures. Everything is performance measured...even your breathing is performance measurement. […] So, mHealth should be considered as something that is enjoyable to have. And not as a stress factor. mHealth is something you should pick up because you benefit from it, and not as a burden. And I think also it cannot be a top-down decision. It needs to be a bottom-up decision."*

5.2.4.4 Divergent interests

Hellsmark (2010) contends that conflicting interests among system actors can undermine institutional realignment, especially in sectors dominated by a few incumbents with a high quota of bargaining power. According to North (1994, p.3), maintaining the institutional structure: "…*is the source of the existence of the organisation and also determines the competitive conditions*."

As already discussed, data analysis suggests that mHealth legitimation and institutional alignment is compromised by divergent actors' interests. Power shift at organisational (entrants vs. incumbents) or professional (practitioner vs. patients) level is perceived by some experts as a blocking factor in the development of mHealth. As an example, an mHealth lobbyist from the ICT industry relates how the lack of business models satisfying all the key actors, has blocked the development of digital health initiatives.

"…It can't happen the same as it happened to eHealth (previous technology to mHealth). With eHealth there were incredibly good initiatives that passed through the development phase, they passed through the clinical evaluation phase and through the pilot phase and result analysis, and from that moment on, either they were left on the shelf, or they got closed and never mentioned again. And that happened because there is an enormous barrier that it has to do with the generation of sustainable business models that can somehow benefit all participants." (ICT alliance representative).

In addition, the same expert reflects on how mHealth can potentially increase competitiveness among healthcare providers:

"I firmly believe that the (healthcare) finance model needs to change. I believe that there are models capable of benefiting all parties and we need to look for them. It can happen that those models will make that some actors will have to play from now on in a much more competitive environment. Those actors have made up until now huge amounts of money through monopolistic practices. It is probably that they won't make those enormous amounts of money anymore...but this is what happens in a lot of sectors." (ICT alliance representative).

One of the participants describes how his mHealth product, a mobile device for skin cancer detection, could potentially jeopardise other actors' earnings:

"Reducing the cost of that treatment might very well reduce the amount of money that goes into the pockets of people in the healthcare system such as specialists and GPs and...In the US we talked to a couple of people and they said; 'Hang on, you are going to reduce the number of biopsies that get done. We make all our money from biopsies and oncology reports. We don't want to care on what you are doing (laughs)'...And that is not the line to improve healthcare...So I think there are many cases of misalignment in the practice." (mHealth entrepreneur).

In summary data suggests that the existing misalignment between mHealth and the prevailing healthcare institutions is driven not only by conflicting formal institutions like regulation or validation procedures, but also by opposing informal institutions like the cultural clash between the technology and healthcare sectors and the push orientation of mHealth solutions. Additionally, frictional resistance (in form of organisational inertia), intentional resistance (in form of divergent interests) and lack of interest in the technology by some healthcare professionals, constitute, as postulated by Hellsmark (2010) and previously discussed in section 4.3.4, a limitation for the development of system builders' transformative capacity

5.3 Area of investigation 2: TIS functions

The previous section has shown the status of mHealth structural processes, the blocking factors in the re-alignment of the healthcare institutional environment, as well as the indiscernible role of individual system builders in the development of such structural processes. As a consequence of the barriers for institutional realignment, a certain level of malfunctioning in some of the TIS functions should be expected. For example, frictional and intentional affect functions like influence on the direction of search, market formation and legitimation.

Therefore, this second area of investigation focuses on analysing the dynamic interplay of the TIS functions and particularly, on how they influence legitimation. The functions analysed in this area of investigation include: knowledge development, entrepreneurial experimentation, influence on the direction of search, resource mobilisation, development of positive externalities and market formation. Legitimation, as a key topic of this research, is analysed in greater detail in area of investigation 4.

5.3.1 Knowledge development

This TIS function captures the breadth and depth of the knowledge base in the TIS and its evolution over time. It focuses on how it is developed, diffused and combined (Bergek et al., 2008a). Knowledge development is at the core of any technological innovation. It constitutes a pre-requisite, together with entrepreneurial experimentation, for the legitimation of any TIS (Hekkert, 2011).

Data analysis indicates, as discussed in section 5.2.1, that technological knowledge is well developed for mHealth. However, data suggests that many entrants lack specific knowledge regarding the healthcare sector. According to the research company Research2guidance (2017), 28% of mHealth app publishers declared not having any information on the healthcare sector. The diffusion of mHealth knowledge through academic papers, blogs, reports etc. is very extensive, and mostly oriented to describe mHealth potential, socio-economic benefits or barriers for its implementation. As Vallespin et al.(2016) point out, an analysis of mHealth publications in the period 2000-2010, yield only 2% of papers offering clinical evidence. In a later systematic review by Zapata et al. (2015), only 22 studies of the total of mHealth publications performed usability evaluations of mHealth applications in the period 2010-2014. Moreover, the majority of these studies lacked automated design-evaluation methods, as authors found that 73% of the papers used only interviews or questionnaires to evaluate the applications.

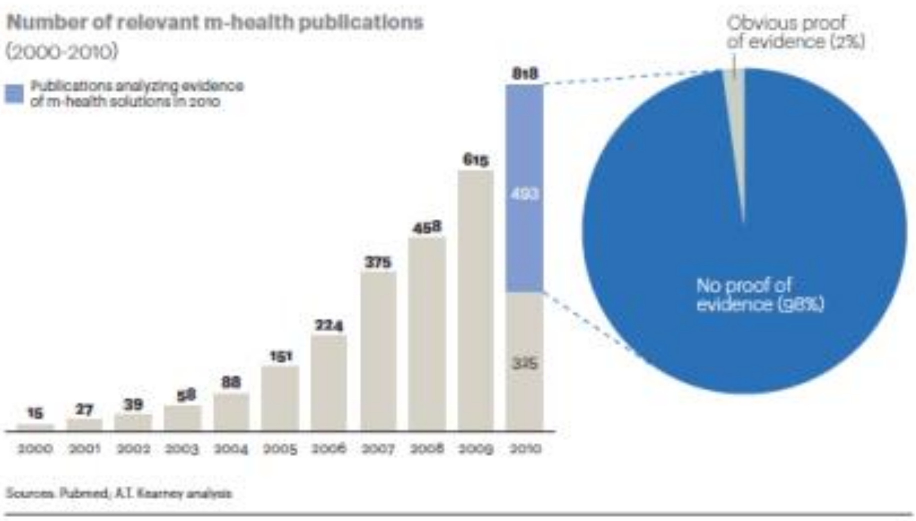

Figure 5-3Rates of mHealth publications providing evidence. From Vallespin et al. (2016, p.258)

As discussed in section 5.3.4.2, mHealth has been predominantly a technology-push innovation advocated by big ICT entrant firms. Contrary to CFD, mHealth has been largely away from a co-creation of knowledge approach. Co-creation of knowledge refers to the early involvement of users in the innovation development process (Lusch et al., 2007; Kristensson et al., 2008). As it was concluded in chapter 4, co-creation of knowledge enhances legitimation, as on one hand, technology is oriented to solve customer problems (pragmatic legitimation is enhanced) and on the other, it smooths the conformance with existing beliefs, norms and practices (moral and cognitive legitimacy are boosted).

Data analysis suggests technology-push solutions, have been mainly developed by big ICT entrant firms. As a participant from a big ICT recalls:

"*We have all the pool of entrepreneurs and start-ups oriented exclusively to the rapid and agile creation of solutions oriented to solve the day to day problems of healthcare professionals. They have the advantage that they are very familiar with the development of solutions in collaboration with the clinical professionals, and this is something that the big companies are not doing. So this helps to understand the problem from the beginning, it helps to involve the professional during the development of the solution while at the same time it ensures better adoption rates as compared to a solution that is imposed and closed beforehand, and this is the way in which the big companies are working until now.*" (big ICT representative).

The representative of a healthcare practitioners' association confirms this sentiment:

"I trust more the small SMEs to be honest...because these are young people. These are people who start from scratch, from nothing, and they have young ideas. They know local environments, they want to produce something...They are very up to the point to the needs. […] Yes, I think SMEs are closer to the people than the big organisations." (Healthcare practitioner's association representative).

Meddicapps represents an interesting example of an SME that successfully co-developed an mHealth app named Mersey Burns. Mersey Burns, became in 2014, the first mobile software certified as a medical device in the UK (www.merseyburns.com). Meddicapps, the company producing Mersey Burns, was founded by a physician who specialised in burns, and two software developers, one of which has participated in the present research. The application provides a diagnosis and medical decision by automating arithmetical operations on medical tables, to calculate the amount of resuscitation fluids that a patient needs in the event of a burn.

One of the creators of Mersey Burns participating in this study, pointed to co-creation of knowledge as a key success factor. He describes three important related aspects:

(i) the relevance of looking into real and existing problems.

(ii) the importance of providing evidence using accepted practices, like in this case, the publication of a paper showing clinical evidence.

(iii) the involvement of practitioners in the development and testing of the application, as a way to build trust and legitimacy.

"We tried to look for the real problems that (practitioners) generally had... […] You can't expect that people will just accept the new way you are recommending. It is exactly the same for apps. There is no difference. So, if I come out with a new way of injections for people, people won't just start using it...you have to share how it is backed up...it is exactly the same with apps....no difference. You come up with a new technique, which is what an app is, you just need to show evidence that it is better, how it works and then let them use it. We published a paper showing that the app was more reliable and was producing better results than the pen and paper method. So following the usual rules to do something... So again, showing the people the way, producing a paper and showing evidence...so you don't need to vary that approach just because it is an app." (mHealth entrepreneur).

The above discussion suggests that Mersey Burns was developed following the same principals of co-creation of knowledge as CFD software discussed in chapter 4. This reinforces the point (discussed in section 4.3.3) that co-creation of knowledge is seminal to build legitimacy. In opposition, data suggests that technology push solutions and ultimately *technological solutionism,* can become systemic barriers for the development of mHealth. Technological solutionism (Morozov, 2013) refers to the tendency of looking for the solution of non-existent or extremely complex problems through relatively simple technological applications.

5.3.2 Entrepreneurial experimentation

Knowledge development and entrepreneurial experimentation are a pre-requisite for the legitimation of a TIS (Hekkert et al., 2011). Both functions contribute to reducing uncertainty about the new technology and with that, they stimulate the entrance of new actors to the system. Moreover, as Bergek et al.(2008a) suggest, entrepreneurial experimentation contributes to unfolding the social learning process through the exploration of different technologies, much of which will never pass from the demonstration and pilot phase.

Technological knowledge development, expectations on the potential of mHealth, and the rapid smartphone penetration have propitiated a vigorous entrepreneurial ecosystem around mHealth. As discussed in section 5.2.3, many incumbent firms are creating mHealth accelerators to capture value from the entrepreneurial landscape. The European Commission (2014), states that the majority of mHealth firms are constituted by individuals or small companies of up to 9 employees with a technological background.

The large majority of mHealth devices developed by SMEs rarely pass the pilot phase. On the mobile application side, the majority of existing mHealth apps have very low rates of download and usage (Research2guidance, 2017). The Mersey Burn example discussed in the previous section represents an exception to the rule. Entrepreneurs participating in this study reported a number of barriers to successfully move from the experimentation phase. These can be summarised as:

(i) access to healthcare professionals

(ii) complexity to comply with existing regulation

(iii) impossibility to negotiate a reimbursement model

When asked how they were dealing with these barriers, a big majority suggested that they were positioning their solutions to the end-user market rather than the clinical. This aspect is further discussed in section 5.5.3 legitimation strategies.

5.3.3 Resource mobilisation

This function measures how actors in the TIS are able to mobilise the required resources for the development of technology. Mobilised resources include experts along the value chain with technical, marketing, logistic or managerial knowledge, financial capital and complementary assets such as products, services, networks and infrastructure (Bergek et al., 2008a).

As previously discussed, big firms in the TIS (both entrants and incumbents) are mobilising a large amount of resources to fund pilots, accelerators, form lobbyist groups etc. On the other hand, policy makers are also actively promoting initiatives and groups of experts to discuss and agree on mHealth guidelines and standards across Europe. Finally, according to Research2guidance (2017) venture capital for mHealth keeps increasing globally. On the negative side, some participants pointed out that funding from the pharmaceutical industry will only increase as long as viable business models are found and reimbursement issues are solved. This aspect is further discussed in section 5.3.5 (market formation).

"…The only people with money in healthcare are the drug companies. And the drug companies have money and invest money to do new drugs, and until the drug companies start investing money to develop apps in the same way, and find reimbursement for their investments, you won't have any significant move forward....You get lot of small changes and it will go very gradually, and you have apps like the one we were talking about, but you won't find a mass take-up until either the government or drug companies put money into it." (mHealth advisor).

"I believe that until big players like Apple, Google decide to enter, but to enter decidedly, or until the big pharma don't enter into technology for medical devices, we are not going to see the change." (mHealth entrepreneur).

In summary, evidence suggests that resource mobilisation, although increasing, is not yet the optimal because some of the key players (healthcare firms, big ICT companies) are not investing in a substantial and systematic way. Data also suggests that this situation will change once mHealth business models are defined and involved players can positively evaluate investment returns.

5.3.4 Influence on the direction of the search

This function analyses the elements that reinforce the incentives and pressures on actors to enter the technological field. Therefore, the function includes a variety of topics for analysis including actors' visions, expectations of growth potential, appropriable conditions, alignment to political agendas, regulations, policies and business models that create new opportunities for the innovation (Hellsmark, 2010).

As discussed in the literature review chapter, legitimation and influence on the direction of search, are closely related functions. As Bergek et al.(2008b) contend, formation of expectations and a shared vision on the technology are central aspects in the formation of legitimacy. This section provides the reader with the analysis of two different topics: the first reviews the evolution of expectations on mHealth and the different visions of the potential of the technology across main groups of actors. The second topic, focuses on business models, as data analysis suggests it is one of the main barriers for the development of mHealth TIS.

5.3.4.1 Visions and expectations

The analysis of visions and expectations represents a key aspect in the study of the dynamics of innovation and technological change in socio-technical studies. In the formative phases of a TIS, expectations of technology outcomes act as a key force that reduces uncertainty and provides structure and legitimation by attracting actors and resources. As Borup et al. (2006, p. 285) state: "*novel technologies and fundamental changes in scientific principle do not substantively pre-exist themselves, except and only in terms of the imaginings, expectations and visions that have shaped their potential. As such, future-oriented abstractions are among the most important objects of enquiry for scholars and analysts of innovation.*"

The present research has analysed a number of reports on mHealth prospects and has confronted them with the visions of the experts participating in the study. The analysed documents have been sponsored by public bodies and mHealth entrants like mobile operators or IT firms. As discussed in the methodology chapter, the analysis has been done through a hermeneutic perspective (Bryman, 2012). This means that instead of taking the reports as an accurate representation of reality, the analysis has considered the context, its purpose and the impact on other groups of stakeholders.

The majority of the analysed mHealth reports are focused on the benefits that mHealth can bring to solve landscape and societal problems (Geels, 2005a). These include among others cost savings, citizens' empowerment, democratisation of healthcare, opportunities for entrepreneurs etc. Cost savings represent an important topic in many of the mHealth reports. As an example, figure 5-4 shows a forecast on mHealth savings by Price Waterhouse Coopers (2013), estimating that by 2017 mHealth could potentially save €99 billion in the EU region. The low levels of adoption of mHealth initiatives (WHO, 2016), suggest that these forecasted savings haven't materialised.

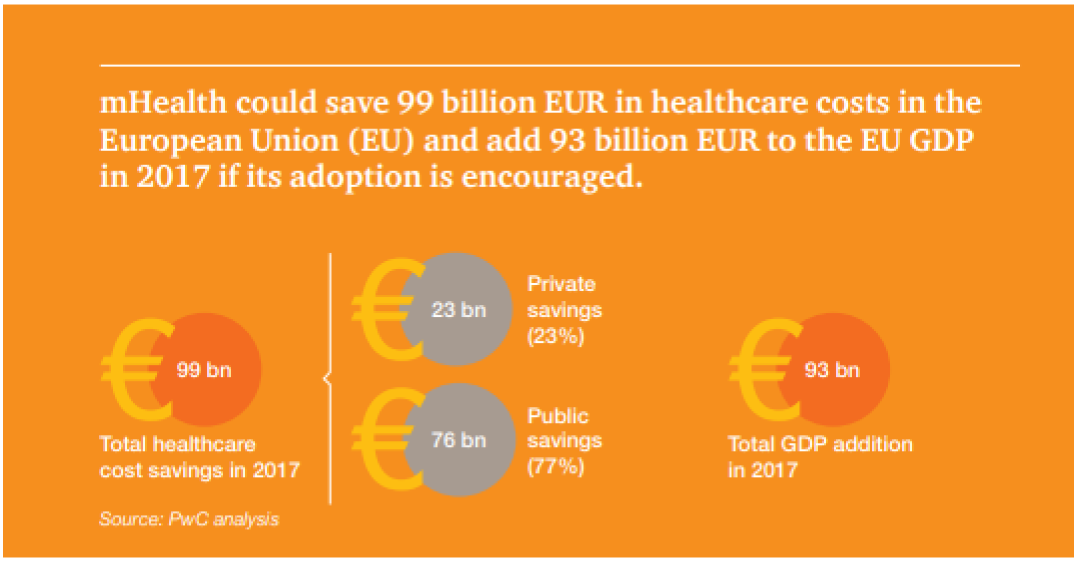

Figure 5-4 PWC mHealth savings forecast by PWC (2013)

Data analysis suggests that entrant firms and policy makers are more aligned to the economic expectations generated by mHealth reports. As discussed, these groups of actors appeal to problems in the existing regime or landscape (Geels, 2005a), such as aging population, sustainability, pressures to control public expenditure etc. to envision a technological solution through mHealth. On the contrary, practitioners and incumbents, manifest more cautiously on the economic benefits of mHealth.

As some of mHealth entrants refer:

"Of course, patient empowerment (through mHealth) goes along with an economic outcome which is saving costs from patients' side and the medical institutions side…" (big ICT representative).

"There are some clinical savings in terms that if you treat someone better, that will bring savings…We know (our application) helps people to be treated better, we know it helps to be more accurate…so that's where I think the savings will come from." (mHealth entrepreneur).

"(Cost saving) It is one of the key factors. The healthcare model as it is known today is completely unsustainable. At least as we know it in the developed countries. Hospitals need to be for healing and not for prevention. Palliatives and prevention should be done from home, and for this

mHealth will be of great help. If we can help in a manner that these patients do not have to go to the hospital, that they don't have to be hospitalised, or doing a surgery because we couldn't prevent it before it etc....we will be saving a lot in the healthcare bill. It is one of the big drivers, of course." (mHealth SME).

"Population is getting older and mHealth monitoring systems prevent older people from being in the hospital and incurring higher costs. Yes, definitely mHealth is going to save costs and it is something that is going to grow in the future." (mHealth association representative).

As discussed, healthcare providers and clinicians' representatives are less optimistic about the impact of mHealth on cost savings.

"I don't think it will help to reduce budget. I believe that it can help to do a more efficient management. In fact last year we made a consultancy with Oblique to assess the cost/efficiency of mHealth model. The report concluded that you need to invest differently to get better results, but it is not going to bring any savings because at the end you need to keep doctors and nurses. [...] The patient will have more knowledge and will be more demanding, so will ask for more, or even ask for specialists he hasn't asked before." (Pharmaceutical representative).

"I think mHealth is going to have an impact but is not the solution. The solution comes from lifestyle changes from the population." (Pharmaceutical representative).

"Prevention, should lead to saving in one way or another. I don't know if that will immediately be the case because I think mHealth is quite competitive, and the industry...I don't know how well the industry will cope with the development of mHealth and if everybody goes their own

way, perhaps then it is not so cost effective[27]*. We do not need to exaggerate because sustainability and cost effectiveness have different angles."* (Practitioners' representative).

An mHealth expert and firms' advisor also provides a sceptical view about mHealth's claimed savings:

"Cost saving come from being able to manage patients remotely, comes from patients being able to monitor their own conditions, which is slightly controversial when you talk to the doctors on how to effectively manage patients. […] If you are talking of savings in terms of preventative medicine, that's a different thing all together, and that has huge savings if you can have some sort of form to prevent people from getting ill in the first place, but nobody has cracked that yet." (mHealth expert).

Data analysis suggests that during the formative phases of mHealth, advocacy coalitions have been very active in influencing the expectations and desirability of the new technology. Evidence suggests that forecast reports produced by big entrants have influenced the agenda of policy makers. As an example, figure 5-5 shows an mHealth leaflet by the European Commission including the benefits and potential market size of mHealth by 2017. Most of the data supporting this leaflet, as it can be read in the paragraph below, has been obtained from a market report by the GMSA (the association of mobile operators and telephony firms) and Price Waterhouse Cooper. As Jacobson and Bergek (2011, p.50) argue: "*…ultimately, the objective is to shape expectations of policy makers. This is done in many ways, some of which are subtle and difficult to unmask."*

"*The worldwide mobile health revenue is expected to reach about US$ 23 billion across all stakeholders – mobile operators, device vendors, healthcare providers and content/application*

[27] (Researcher note): When asked for clarification on what industry the participant was referring to, he stated it was the big IT companies.

players - by 2017. By 2017, the largest markets for mobile health services will be Europe and Asia Pacific (APAC) with 30% market share each, followed by the developed markets of North America (USA and Canada) with 28% share. Latin America and Africa will comprise 7% and 5% share respectively." (GSMA &PWC, 2012. p.4).

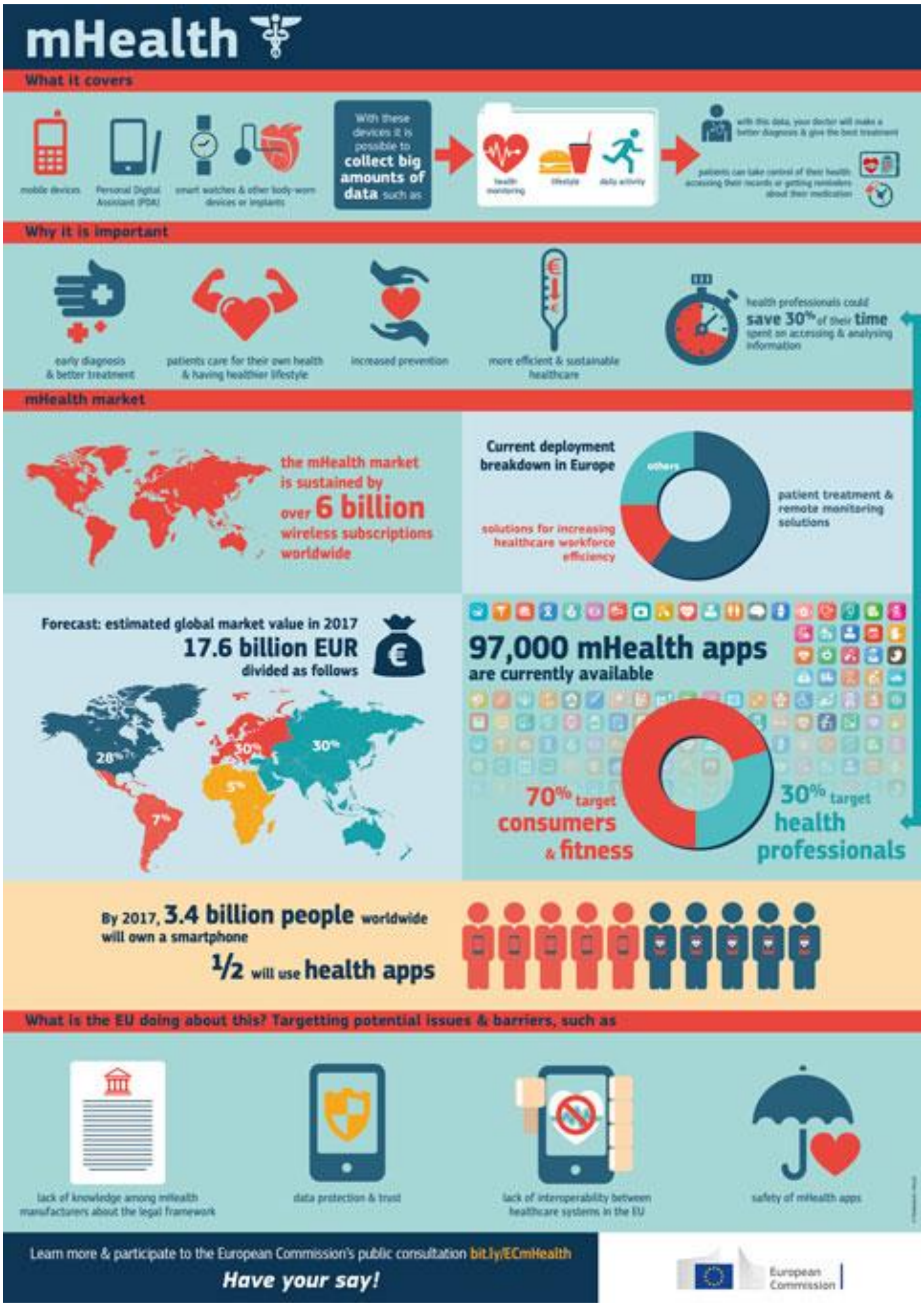

Figure 5-5 European Commission mHealth leaflet. (EU digital single market website)

However, data suggests that influencing policy makers in the potential of mHealth, might not be sufficient if confronted interests among relevant groups of actors exist. As an expert in the telecom industry points out, one of the complexities of mHealth rests on the divergent values and interests among key actors:

"*One of the particularities of mHealth is that some actors have completely different objectives respect to other actors, and they have to work together and in a coordinated manner. As an example, on one side we have the healthcare system formed by government, regulatory agencies etc…and for this group of actors, the use of mobile technologies in healthcare would mean cost reduction. When we talk to professionals like clinicians, the use of technology to monitor and treat their patients generates the possibility of giving them much more information respect to what they currently have…" (*ICT representative).

The rest of this section offers an in-depth analysis of the conflicting visions and expectations across the different groups of actors in the system. Firstly, data is presented around three main subthemes: (i) value and benefits of mHealth, (ii) motivations to enter into the field and (iii) potential disruptiveness of the technology. After this, and to facilitate the reading, the analysis of the three subthemes and its comparison with extant theory is presented all together in a conclusions subsection.

5.3.4.1.1 Value and benefits

Data shows that different groups of actors provide a different value to the technology. Whereas for entrants and policy makers mHealth is seen as an enabler to empower citizens and change the centre of gravity from professionals to patients, healthcare incumbents and practitioners envision the technology as a way to improve existing healthcare pathways.

As the CEO of a SME on mHealth devices states:

"That capability of wearing the data with you and being constantly monitored is, on my view, one of the big technological disruptions that we are going to see in the next years in healthcare. It is not about going to your GP or to the clinical lab to do a blood test, now it is all about doing it yourself at any place." (mHealth entrant representative).

The representative of a big ICT company argues:

"From the industry perspective, which is the one I'll advocate for, mHealth will empower users, and this is a very important element, especially when you are referring to chronic disease management." (big ICT representative).

In a similar vein, the manager of the mHealth competence centre at a telecom consortium, states:

"mHealth offers the possibility to self-manage patients' conditions, hence, taking a more active role. So we are talking about better informed patients, about more active patientsin their health management, while at the same time, they are generating very valuable information for clinicians." (big ICT representative).

An mHealth entrepreneur provides an example on how mHealth can put healthcare into patients' hands:

"Patients will be empowered. For example, there is a device called IphoneECG, and you can check your ECG (electro Cardiogram) on your hands using an iPhone. This is great. [...] Of course, it will change everything because the consumers are empowered and consumers start to understand more..." (mHealth entrepreneur).

Policy makers agree on the view of empowering citizens and patients through technology:

"People have a lot more of information and can start increasing their personal involvement and personal control on health in this case, and conversely there are lots more opportunities to do a personalised health rather than the general health provision." (Public mHealth policy maker).

"I think you are going to see more empowered citizens and more empowered patients but also healthcare professionals who have access to more information and are able to have a discussion

on the same level. So I think in some cases there'll be a little more responsibility on the part of the citizen or the patient." (Public mHealth policy maker.)

The representative of the patient's associations, also points to that capability of putting healthcare into patients' hands, although not necessarily as a positive aspect:

"*We are assuming that people have a mobile device, you've got something that it is held in their hands and it is always on and it gives them an 'always access' opportunity. It is something that they are addicted to, and this brings advantages and disadvantages."* (Patients' association representative).

In contrast to the disruptive vision of shifting healthcare centre of gravity from professionals towards patients, the representative of a clinicians' association places the value of mHealth technologies in the improvement of current clinical practices:

"I see one big advantage for mHealth, especially in the field of prevention.... not in the health intensive care… but more in the soft care data for the clinical pathways that we should develop for different conditions. mHealth could bring in the big data in order to streamline the existing clinical pathways." (Practitioners' association representative).

The representatives from the pharmaceutical industry, also place the main value of mHealth as an enabler to improve existing services through more data and better patient-professional communication.

"The main objective is to reach the patient… […] On one side, to bring healthcare to patients and on the other side to get information from the patient. To get data so when the patient arrives to the clinician, it is not only treated over the symptoms he presents that day, but also on how the patient was 4 months before going to the clinician." (Pharmaceutical representative).

Aligned to this, another expert from the pharmaceutical industry, states that:

"I think mHealth can connect the health providers with the patients more easily...so we can have a more active communication and monitoring of the disease that it is being treated. So this gives

a benefit for the patient as you provide a better service at the end of the day." (Pharmaceutical representative).

Finally, data analysis suggests that participants who had already participated in mHealth and telehealth projects are more sceptical about the transformative potential of the technology. As an example, an ICT expert who was part of the 3millionlives program, reflects that:

"…It is difficult to demonstrate the cost savings. I mean, we were enthusiastic about what people like Phillips were saying about the savings and revenues they could take...but it all faded out." (big ICT representative).

An expert mHealth advisor also shows scepticism about mHealth reports and the potential of the technology to reduce healthcare costs:

"Cost saving come from being able to manage patients remotely, comes from patients being able to monitor their own conditions, which is slightly controversial when you talk to the doctors on how to effectively manage patients. […] If you are talking of savings in terms of preventative medicine, that's a different thing all together, and that has huge savings if you can have some sort of form of preventing people getting ill in the first place, but nobody has cracked that yet." (mHealth advisor).

5.3.4.1.2 Motivations

Data suggests that actors' motivations and interests to enter into the mHealth arena are related to the appropriable benefits they can obtain from the technology. As North (1994, p.2) states: "*Organisations and their entrepreneurs are the actors; they will introduce new institutions or technology when they perceive that they can improve their competitive position by such innovation. Their perceptions are a function of the belief systems they possess.*"

For example, the practitioners' representatives are guided by the belief that mHealth, if well developed, can assist the healthcare professionals to better discharge their duties:

"I hope that mHealth will support the mHealth professions in making their jobs easier, in making sure that time is freed up for them in order to do the real work that they have to do. So I hope that technology is a support to the workforce, and not a barrier to the workforce. […] Technology is for us a support to automate the health records and everything, the communication between physicians and nurses, the inter-professional development...and all these things are really a support for us, but only if they lower down the workload." (Practitioners' representative).

The representative of a patients' association acknowledges that patients would prefer, in certain circumstances, to consult a device rather than a professional:

" (mHealth) is something you have an increasing relationship with...so, you know, there is evidence showing that people is sometimes more honest to an inhuman device than they are to a human doctor in terms of their feeling on anxiety, depression etc..."(Representative of patient's association).

For the pharmaceutical industry, mHealth is perceived as a 'must' to compete in the field of integral healthcare services.

"Pharmaceutical and diagnose companies, as we want to call them, what they typically do is to treat specific episodes: either a drug or a measurement. But....this leaves lots of uncovered gaps with respect to what treatment or patient's trajectory is. […] So I believe that in the short term it will be a 'must'. It is not something they want or don't want to do...as they will be forced to compete in that arena and offer an integral patient management covering from treatment, to diagnostic and maintenance." (Pharmaceutical representative).

Moving into the entrants' space, experts reported a combination of factors. Some entrepreneurs pointed to personal rewarding motivations making a difference in healthcare, while others referred to new market opportunities in the saturated ICT space. Again, the resolution of problems existing at landscape level were present in many entrants' reflections:

*"We looked at the age demographics, we looked at the healthcare spent and we looked at what is happening in the developed world, what could happen in the third world...and we looked into finding the general solution for (participant's company name) and then we settle the product finding something with a European focus. So that was the thinking. At the time the UK government started the 3miillionlives issue. NHS England had a 1.2 billion short fall in its budget, but they believed that 3 million people with health conditions could benefit from telecare. And we saw an emergence of players in this space starting to develop products. So that was the basis… and we had a need as well, we had to source some innovation, and we opened an innovation centre in Germany and in the UK, and we wanted just a project to work within our group. So that's where we came essentially. Vodafone as well were developing a portfolio. So, we saw this as an opportunity, and very much now, when in the ICT space everyone is competing much more and the budget pool is getting smaller…" (*big ICT firm representative).

"I would say it is the marketplace ...I want to bring innovations to patients in the way they are looked after. So for the last 50 60 years we used the same old-style devices to measure our physiological performance. […] I look at the digital revolution and I think we should be applying all the technology to physiology... The answer is I want to bring new technology. I want to bring high fidelity readings of our physiology...so that we might understand our health better." (mHealth entrepreneur).

5.3.4.1.3 Disruptiveness

A recurrent topic in mHealth reports refers to its disruptive capabilities to revolutionise the healthcare landscape (WHO, 2011; European Commission, 2014; WHO, 2016). This vision was contrasted with the view of experts participating in the study, who were asked whether they considered mHealth as a revolution for healthcare. Once more, data suggests that entrants and policy makers, with some nuances, are the most optimistic actors about the transformational capabilities of the technology.

*"**Y**es, I think it will be a revolution, it will be a paradigm change. […] I think the market is going to change massively." (mHealth entrepreneur).*

"I believe that healthcare as we've understood it up until now is going to radically change. And we believe that this change is unstoppable. That is, it can take 5, 10 or 20 years, but this is going to come. It is totally doubtless and due to a number of reasons: the first one is that healthcare as we know it today …it is completely unsustainable. Therefore, we need to look for new models and new ways of maintaining quality in the healthcare systems. And no doubt mobile technologies are one of the tools that will facilitate this change." (big ICT entrant).

"I agree with the WHO statement that mHealth can revolutionise healthcare because definitely the market is already booming. There is so many of these mHealth apps out there. I just read a new article just today about mHealth potential and the new kind of innovations that for instance intelligent contact lenses for diabetic patients or some other things....it is very big. It is coming very big in the treatment of mental health issues and it is, indeed, it is more and more in use with the clinical practice. I believe the quality of these apps will become better and better." (EU policy maker).

Divergently to entrants and policy makers, the representative of the clinicians, disagree on the revolutionary potential of mHealth.

"No, no. (emphasised). I think mHealth is part of the development. […] For me mHealth is not as such an innovation. Innovation for me is something that has never been known. […] So change in the healthcare sector is there because of many factors that are changing, and mHealth is a contributor to it, but we cannot exaggerate." (Health practitioners' representative).

Disruptiveness of mHealth also lead to the topic on whether participants considered that mHealth could substitute clinicians' roles in the near future. Whereas entrepreneurs and entrants agree on this possibility, the participants on the healthcare side do not contemplate it as a realistic possibility.

As an example, an entrepreneur explains how his product could replace doctor's roles in the future:

"In this service you take an image and we will tell you whether you need or not to visit an oncologist. That is not replacing the role of the doctors in the short term but it might end up doing it in the long term...So in the long term we can capture an image and send it to a diagnostic service better than a GP and that it is usually disruptive." (mHealth entrepreneur).

A representative from the pharmaceutical industry disagrees on this possibility:

"They (practitioners) can't be replaced because I don't think that anyone or any company that provides a service wants to take the blame if something goes wrong, because medicine is not an algorithm only. You can be based on that but at the end of the day someone with experience has to decide if it is correct or not to do that. I think those systems will only give advices to users on what to do, but the final decision should be on professionals and not on people." (Pharmaceutical firm representative).

Aligned to the pharmaceutical representative, the representative of the clinicians' association does not contemplate the possibility of being replaced by technology:

"We are not afraid that a robot will replace us...a robot will never (emphasised) replace the human contact...but we can use technology to support us at some moments." (Healthcare practitioners' representative).

5.3.4.1.4 Conclusions

Data analysis evidences important divergences in the visions and expectations that participants have on mHealth. On one hand, entrant firms including entrepreneurs, SMEs and big ICT companies show higher expectations on mHealth, and advocate for a disruptive use of the technology. In many cases, these actors consider mHealth as the solution to landscape or societal problems (Geels, 2005a), in what it could be described as a form of technological solutionism (Morozov, 2013). Moreover, evidence shows that mHealth reports sponsored by big ICT entrant firms forecasting savings and market opportunities, have influenced policy makers and attracted more entrepreneurs and firms into the mHealth TIS. On the other hand, actors closer to the existing healthcare practice like practitioners and pharmaceutical firms' experts, perceive mHealth not as a radical or breakthrough innovation, but as a tool to improve existing healthcare practice. Finally, actors who have already participated and experienced failure in mHealth projects, also present a more sceptical view on the disruptive potential of mHealth.

Swanson and Ramiller (1997) propose the concept of ***organising vision*** in information systems innovation. An organising vision is defined as *"a focal community idea for the application of information technology in organisations"* (Swanson & Ramiller, 1997, p. 460). Organising visions describe from an institutional perspective, how shaping a shared view of the technology contributes to its diffusion. Organising visions serve three main functions:

(1) *Interpretation:* A commonly shared explanation on the innovation purpose to reduce uncertainty.

(2) *Legitimation:* A shared rationale on why the innovation is desirable and should be adopted.

(3) *Mobilisation:* The coordination of stakeholders to activate the diffusion of the innovation.

However, in many breakthrough innovations, as is the case for mHealth, the organising vision needs to include a large number of actors with different views, values and interests on the technology. In the study "The organising vision for telehealth and telecare: discourse analysis" by Greenhalgh et al. (2012), the authors identify the different organising visions in the extant literature for telehealth and telecare (former technologies to mHealth). The study suggests that the limited uptake of telehealth and telecare can be partially explained by four contested organising visions or discourses. In the ***modernist or utopian*** discourse, technology is envisioned as the solution to existing healthcare problems and presented as a rational cost-effective solution in a future where users are empowered by its use. In the ***Humanist*** discourse, the centre is not technology, but the patient and his/her lived experiences of the illness. The future is not dominated by high-tech solutions but based on the existing ones. Technology, with its benefits and disadvantages, only provides partial solutions to complex healthcare problems. In the ***political/economical*** discourse, telehealth is presented as a construction of existing techno-economic regimes to perpetuate their interests with the acquiescence of policy makers. This discourse neglects that healthcare problems can be fixed through technological intervention. Moreover, they are seen as a form of social control transferring responsibility from the system onto the patient. Finally, the ***change management*** discourse, is posed by those on the frontline who already have experienced failure or resistance in the implementation of the technology. Although still seeing a transformative potential in it, their discourses have nuances in respect to the technological determinism of the utopians, as they acknowledge the existing complexity and the need to integrate technology in a service model (Greenhalgh et al., 2012).

Three of the different organising visions suggested by Greenhalgh et al. (2012) are evidenced in the responses of participants in the present case study for mHealth. These are: utopian or modernist, humanist and change management. Data analysis however, did not support any political/economical discourse from participants. According to Greenhalgh et al. (2012), political/economical discourse corresponds to social scientists, sceptical academics and clinicians. As previously discussed, data shows the scepticim of some participants about the possibility of solving healthcare problems through technology. However, their overall visions and discourses fit better into the other three categories as discussed in the next paragraphs.

One of the most evident findings in data analysis is the breach between the utopian and humanist discourses: while entrants and policy makers focus their discourse on rational and economic factors contributing to solving existing healthcare problems, clinicians together with the patients' association and pharmaceutical experts on the other side centre their discourse on patients, experiences and improved or personalised treatments. Change management discourse is present too, by those experts who have worked on the frontline and had experienced failure in the development of mHealth or IT health projects. Although they still envisage high potential in the technology, these actors emphasise the difficulties to implement mHealth projects and the need to look for business models that facilitate adoption. This aspect is discussed in the next section 5.3.4.2, business models. A difference with respect to Greenhalgh et al. (2012) findings, is that participants in the present study acknowledge stakeholders conflict pointing to different cultural and organisational misalignments . This could be partially explained because in the present study, participants are interviewed confidentially whereas in the Greenhalgh et al. (2012) study, data comes from published documents.

Table 5-3, summarises the main findings of the present study mapped into the organising visions classification by Greenhalgh et al. (2012). Together with the focus of the discourse, the value of the technology, its intended use and level of expected disruptiveness', and the groups of actors' belonging to each group, are compiled.

Table 5-3 Organising visions in mHealth study. (Adapted from Greenhalgh et al., 2012)

	Utopian/ modernist	Humanist	Change management
Focus of the discourse	Technology oriented	Person/illness centred	Service model oriented
What is considered of value?	• Technology capabilities • Resolution of healthcare societal problems • Cost efficiency • Technological democratisation (citizen empowerment)	• Patient and professional experience • Integral care • Personalised care • Relationships	• Adoption • Integration • Assimilation into business-as-usual • Sustainability
Main intended use of the technology	• Monitoring • Self-diagnosis • Put healthcare in to patients' hands	• Prevention / soft care • Improve existing clinical pathways • Improve communication • Reduce practitioner workload	• Supporting activities: Administrative, personal, family, healthcare provider
Disruptiveness	High	Mid-Low	Mid-High
Stakeholders	• Policy makers • ICT firms (big entrants and SMEs) • IT Health associations • Entrepreneurs (with IT background)	• Clinicians • Patients • Incumbents (pharmaceutical companies)	• Front-line implementers and consultants

5.3.4.2 Business models

Experts participating in the study pointed to the lack of viable business models as one of the main barriers for mHealth adoption:

"mHealth won't take off until somebody fixes a business model that can work. Because at the moment there is no business model. There is no reimbursement model that actually enables anybody to take on doing the work that needs to be done." (mHealth firms' advisor).

"(mHealth) requires new innovative models to buy, maintain and manage payment...new business models is - as of today - the main drawback that mHealth has for the industry and for the healthcare systems." (big ICT firm representative).

This aspect is well acknowledged in the literature on digital health and mHealth (Topol & Hill, 2012; Hwang & Christensen, 2008). To present an in-depth analysis on mHealth business models, this section is organised according to business model components as defined by Christensen (2008): (i) value proposition, (ii) processes and resources and (iii) profit formula.

The value proposition defines how the innovation delivers more efficient, affordable or convenient jobs for its adopters. In the case of mHealth, and as discussed in the previous section, different actors pointed to divergent value propositions on mHealth. As an example, practitioners expect that mHealth technologies will contribute to facilitating their jobs, whereas policy makers for example, place the value of the technology on cost effectiveness and citizens' empowerment. Therefore, one of the complexities for mHealth is to align the 'for whom' and 'for what' of its value proposition. Moreover, as pointed out by some participants and acknowledged in the existing literature (Topol & Hill, 2012; European Commission, 2014), mHealth would require a change in the overall value proposition of healthcare from illness-centred to prevention:

"*There is no way of building a reimbursement model today for preventative medicine. Our entire medicine culture is based on illness culture not on a wellness culture. So, to achieve the sort of savings that people are talking about, it is more about to turning around our health provision into a wellness provision rather than fixing illness if that make sense.*" (mHealth entrant).

Regarding the resources and processes component of a business model, the majority of entrepreneurs and ICT entrants pointed to regulatory barriers as the main obstacle. However, on the clinical, policy makers and pharmaceutical side, experts didn't consider regulation as a blocking factor. As an mHealth expert summarises:

"*If you are looking at the existing business model, it is locked-in. And it is locked-in not just because of business, it is locked in because of regulation and because if you do things differently people die...So, it's harder to change how doctors treat a patient than it is to order a taxi.*" (mHealth firms' advisor).

An entrepreneur on mHealth medical devices, reflects on the advantages that existing regulation has for incumbent companies:

"I'm a strong supporter of regulation because we are talking about people's healthcare....so I'm a strong supporter, but I also believe that we are taking it too far with bureaucracy and regulation. I'm convinced that if we do a top down review, and we manage to eliminate certain powers who are interested in such a strict regulation, we could make it much simpler […]. You shouldn't be Roche to put a glucometer in the market. At the end, it is an extremely simple product that it has its complication in the validation in the manufacturing and the reimbursement […] I believe that regulation should be reviewed to make it simpler and more sensible, so patients can benefit of new technologies. […] The industry has a strong interest in regulation, but they also have an interest in keeping the barriers high, because the higher they are, the less competitors will be.[…] That's precisely why the incumbent industry try to make these barriers as high as possible: first to protect patients but secondly also to be able to compete easily." (mHealth entrepreneur).

The debate on how existing institutions act in favour of incumbent companies is well acknowledged in TIS literature (Hellsmark & Jacobsson, 2012). Business models are institutions as they establish the rules of operations for an industry. As Hwang and Christensen (2008, p.1334) contend, over time, established business models determine acceptable value propositions and the types of organisations that can deliver them. Therefore, only propositions fitting into existing values, processes and profit formulas can be taken to the market:

"*The firms that grew to become successful under specific regulatory conditions subsequently worked very hard to make sure that those conditions remained in their favour. […] However, although often written with good intentions, these regulations unintentionally trap health care in high-cost models of care. For example, many states do not allow nurses to interpret simple test results or write basic prescriptions, leaving care delivery to be performed by physician(s)."*

On the profit formula*,* participants referred to the difficulty of developing mHealth profitable business models without a reimbursement scheme from healthcare authorities. As an mHealth entrepreneur explains:

"*patients are not used to paying for healthcare. Healthcare is free, it is actually not, but they perceive it as free. So it is very complicated to get reimbursement for a device of these characteristics. Only big pharma like Roche, Abbott or Johnson & Johnson can get reimbursement for their medical devices, but for a start-up company like ours, getting reimbursement is impossible. So our product needs to be paid for at the pharmacy, and patients do not want to pay for them.*" (mHealth entrepreneur).

The lack of financial viable models is also described by an expert from an ICT firm:

"There are projects that have demonstrated clinical efficiency, and that contribute to reduce costs and increase patients' quality of life, but the fact of not having managed to provide a business model that answers the very basic question of: Who pays for this service? has lead to the closure of the project. […] This is one of the most important barriers." (ICT big entrant).

Another expert on mHealth reflects on the difficulties to make mHealth apps profitable:

"So, you might see something flash up, but it will die again because it won't ever happen. The trials come up, but they never turn into real businesses. You need to make real businesses out of it, either with scale of numbers or with a reimbursement model from the organisations, governments or drug companies... the app developers will play it because it is fun and sexy, but nothing will ever succeed out of it." (mHealth firms' advisor).

In summary, data analysis suggests that replacement of existing healthcare business models represent an important barrier for moving mHealth from the formative to the growth phase. The reasons for this difficulty encompass a set of intertwined factors that include:

- A complex ecosystem of actors posing different values on mHealth technologies. In this context, value propositions seem to diverge when answering the questions: value for who? and value for what?
- Strict regulatory barriers that contribute to create entry barriers for competitors and act in favour of established business models.
- Difficulties to implement financially viable models without reimbursement from public healthcare systems.
- Many mHealth technologies require a radical change of orientation in the healthcare system, from illness centred to prevention centred.

5.3.5 Market formation

According to Bergek et al. (2008a) market formation goes through three different phases. First, in the very early days of TIS formation, markets take form by providing demonstration projects and related activities that can open a learning space for the TIS. They are called *nursing markets*. Later on, *nursing markets* evolve into *bridging markets* as operation volumes increase and new actors enter the TIS. Finally, if the TIS succeeds, *bridging markets* evolve into *growth* or *mass markets*.

The majority of experts participating in the study, contented that the evolution of mHealth into a mass market will be a slow and gradual process. As previously discussed in section 5.3.5, the definition of viable business models becomes critical to reach growth markets. An interesting emerging aspect is that the majority of participants, as will be further discussed in section 5.5.3, consider that moving mHealth to growth markets won't change the landscape of key players in the healthcare sector. As in the case of CFD, mHealth experts foresee collaborative models between incumbent and entrant firms. These results partially question the postulations of some theories on innovation and firms' competition (Anderson & Tushman, 1990; Chirstensen, 1997). These theories postulate that radical technological change, causes the displacement of incumbent firms in favour of entrants. However, as stated, experts participating in the study do not foresee a displacement of incumbent healthcare providers, and as discussed in the previous chapter, this was not the case for CFD either.

5.3.6 Development of positive externalities

This function accounts for the influence of external economies in the development of a TIS. External economies in the context of a TIS, occur when two or more different TISs benefit from sharing part of their structural components: actors, networks, technology or institutions (Bergek et al., 2008b). As a consequence, the main sources of positive externalities are: emergence of pooled labour markets, information flows and knowledge spill-overs, and emergence of specialised intermediate goods and service providers (Bergek et al., 2008b).

Experts participating in the study, contend that mHealth for fitness and wellbeing in the consumer market, will act as a positive externality for clinical mHealth in the diagnostics and chronic disease management (the focal TIS of this research). However, the foreseen impact of the former on the later varies among participants. For example, and EU policy maker foresees uneven effects on healthcare systems:

"I think that what it will come rapidly from the citizen side will be an increase in the use of wellness and monitoring […]. I think this demand will come up relatively quickly and we'll be

hearing that the extent to which the (healthcare) systems can and do to take it into account will be diverse." (EU policy maker).

Entrepreneurs' views are also aligned to the idea of a positive influence of the fitness and wellbeing market into clinical mHealth:

"I have the feeling, and this is a very personal opinion, that the big revolution will come from the IT companies. They will start with the wearables for fitness, then for wellness and they will end up entering into healthcare. Then is when the disruption will happen in telemedicine." (mHealth entrepreneur).

"*A lot of what happens so far in mHealth is starting from the consumer market...from wellbeing and fitness. We have very nice fitbands, we have Apple watches ...If you look at the cyclists of the world, they look at their heart, they track their speed, they also have a GPS...There is a consumer revolution that starts from fitness and wellbeing and moves into health. So when you start tracking everybody's motion, heart rate etc. for the fun, then eventually you will lead on to clinical studies and you will lead onto more and more sort of data push.*" (mHealth entrepreneur).

Despite the entrepreneurs' views, it is difficult to determine at this point in time, the extent of the impact of the fitness and wellbeing consumer market on the mHealth TIS. As the policy maker contends, it seems plausible to assume that the effect will be uneven across healthcare systems. In any case, it is a fact that the wellbeing and fitness market is contributing to creating pooled labours, expertise, knowledge spill-overs and in addition, it is an extremely valuable source of patients' data. As an example, Rudner et al.(2016), report the first registered spill-over from a non-regulated fitness medical device (wrist-worn activity tracker) into a medical decision tool on a patient attending the emergency department in need of defibrillation.

5.4 Area of investigation 3: Exogenous factors

TIS literature highlights the influence of external factors in the development of a TIS (Hellsmark, 2010; Bergek et al., 2015; Markard et al., 2016). The definition of an exogenous factor is determined by the geographical boundaries and the breadth and depth of the unit of analysis of the study (Bergek et al., 2015). For the present study, this section focuses on the influence of global or landscape issues (Geels, 2005a) beyond the direct influence of the actors in the TIS like socio-economic crisis or debates, changes in political agendas etc.

Data analysis suggests that concerns like aging population or sustainability of public healthcare systems have influenced the development of some mHealth TIS functions. In particular, they have contributed to knowledge development (see section5.3.1), entrepreneurial experimentation by attracting more firms and organisations (see section 5.3.2) and resource mobilisation (see section 5.3.3). As discussed in section 4.3.4, the expectations created on the potential of mHealth to alleviate public healthcare issues, have been incorporated in the agenda of EU policy makers and have led to the development of a set of initiatives to overcome existing adoption barriers. In this respect, and as will be further discussed over the next section (5.5 legitimation), positioning mHealth as an enabler towards sustainable healthcare has contributed to building moral (consequential) legitimation for policymakers (Suchman, 1995). However, data analysis doesn't show any evidence of a similar effect among healthcare professionals. Moreover, benefits and cost-effective analysis by mHealth proponents have been criticised as self-interested.

Markard et al.(2016) contend that TIS developments and 'virtuous cycles' can be affected by changing problem agendas at societal level. As will be further discussed in the next sections 5.5. and 5.6, data analysis suggests that landscape factors might result in being insufficient to build legitimacy if pragmatic legitimation for adopters is not built.

5.5 Area of investigation 4: Legitimation

The previous sections have provided an analysis of TIS's structural processes, functions, and exogenous factors in the development of mHealth technologies for chronic disease management and diagnostics. This last area of investigation focuses on legitimation, the key topic of this thesis. Legitimation, the process of acquiring socio-political strength and acceptance within relevant institutions and actors, is key for the growth and success of any TIS (Bergek et al., 2008b). As discussed in the literature review chapter, legitimacy is built through actors' actions plus the result of positive systemic feedback in the form of virtuous circles. Moreover, recent TIS literature has recognised the influence of external context structures (sector, geographical etc.) and societal problems as a determining factor of TIS legitimation and growth (Bergek et al., 2015; Markard et al., 2016). Therefore, some of the topics already discussed like institutional misalignment, divergent visions, expectations or influence of exogenous factors are now put together and evaluated through the lenses of legitimation studies (Suchman, 1995; Zimmerman and Zeitz, 2002).

This area of investigation is divided into three main parts: the first two analyse the blocking mechanism and drivers for mHealth legitimation, whereas the last section focuses on the legitimation strategies undertaken by the different actors in the TIS.

5.5.1 Blocking mechanisms for legitimation

As discussed in section 2.6, Suchman (1995) classifies legitimation into pragmatic, moral and cognitive and provides a number of subtypes that are the starting point of this analysis. They were already discussed in section 4.6.1 and summarised in table 4-4.

As previously argued in this chapter, data analysis points to different technological, organisational and institutional blocking mechanisms hindering mHealth legitimation. For a clearer analysis, they are presented in table 5-4 together with its perceived barriers and the affected types of legitimation as proposed by Suchman (1995).

For example, data analysis suggests that the technology-push orientation of mHealth acts as a blocking mechanism. As discussed in section 5.3.4.2, different participants as well as mHealth scholars (Topol & Hill, 2012), contend that mHealth technologies have been typically advocated by entrant technological companies as closed solutions to the existing healthcare problems. As a consequence, this has generated distrust among healthcare professionals and has led to a lack of pragmatic (influential) legitimation (Suchman, 1995). Additionally, mHealth entrants have built expectations on mHealth as an enabler to solve issues like sustainability of public healthcare systems, or as a tool to democratise healthcare and empower citizens. This utopian vision has influenced the creation of moral (consequential) legitimacy for policy makers (European Commission, 2014; WHO, 2016), but, as said, it hasn't contributed to building pragmatic legitimation among healthcare professionals. Different organising visions (Swanson &and Ramiller, 1997), have produced, in consequence, a misalignment in the different value propositions around mHealth. With this, pragmatic legitimation (benefits on the adoption) are diluted for healthcare practitioners. Additionally, divergent visions and opposing interests among different groups of actors block the implementation of viable business models, which also affect pragmatic legitimation. In addition to these barriers, that emerged during the analysis of previous sections in this chapter, participants pointed to the organisational inertia of the complex healthcare systems that manifests in high levels of bureaucracy, lack of time for professionals to deal with change etc. As a consequence, cognitive and moral legitimacy are damaged. As one of the entrepreneurs participating in the study contends:

"The NHS is the main barrier. There are 227 clinical commissioning groups, so you need to sell your services to every single one. So it's like having one customer with 227 sales people to go to. So, that's the biggest problem: the bureaucracy of the NHS." (mHealth entrepreneur).

The president of a European practitioners' association, points to lack of time:

“In our profession, everybody is running behind schedule. There are cuts in the healthcare sector […]. Time is not on our side.” (Practitioner’s association representative).

On the institutional side, data analysis points to the clash between the technological and healthcare institutional frameworks as a critical blocking mechanism. The clash affects both formal and informal institutions like regulation, validation procedures, beliefs, organisational culture etc. As a consequence, moral legitimacy (structural, procedural and personal) is undermined. For example, compliance with the existing clinical regulation and evidence-based procedures represent a big debate in mHealth TIS (European Commission, 2014; Villaespin et al., 2016). As participants in this study pointed, technological industry is characterised by continuous product launches with agile development practices and short time to market lead times, whereas regulation in the healthcare industry slows developmental processes in favour of safety.

“*The software world, has a remarkably different view to the medical world. The medical world knows that they need to go down... for anything new, they go down to clinical trials, they test a few things...it takes years to sort out a new treatment, a new drug, whatever....because the impact, the side effects, the down side can be catastrophic and indeed literally fatal.*” (mHealth advisor).

Table 5-4 Blocking mechanisms for mHealth legitimation.

Blocking mechanisms		**Consequences (Perceived barriers)**	**Types of legitimation affected (Suchman, 1995)**
Technological and knowledge related	Technology-push orientation of mHealth	• Low involvement of healthcare professionals • Poor perception on the benefits of mHealth by professionals	Pragmatic (Influential) Moral

Organisational	Contested organising visions	• Misaligned value propositions	Pragmatic Moral
	Divergent interests	• Lack of business models • Lack of reimbursement	Pragmatic
	Organisational inertia	• Bureaucracy • Lack of time • Low access to healthcare professionals	Moral Cognitive
Institutional	Clash between healthcare and technological institutional frameworks	• Lack of trust • Negative evaluation of mHealth solutions • Low compliance with healthcare practices and norms (ex. evidence based, regulatory framework)	Moral (structural, procedural and personal)

As discussed in section 4.1, the extant mHealth literature points to a number of barriers affecting the adoption of mHealth. Figure 5-6 shows a graph containing the categories of the most important perceived barriers from a survey conducted by the World Health Organisation. Each of the represented category, includes more refined barriers like: legal issues, lack of evidence on cost–effectiveness, competing priorities, lack of legislation and regulation, lack of clinical evidence on the effectiveness of mHealth, lack of demand, human and/or technical capacity issues, reimbursement, interoperability and standardisation, privacy concerns and lack of leadership. (WHO, 2016).

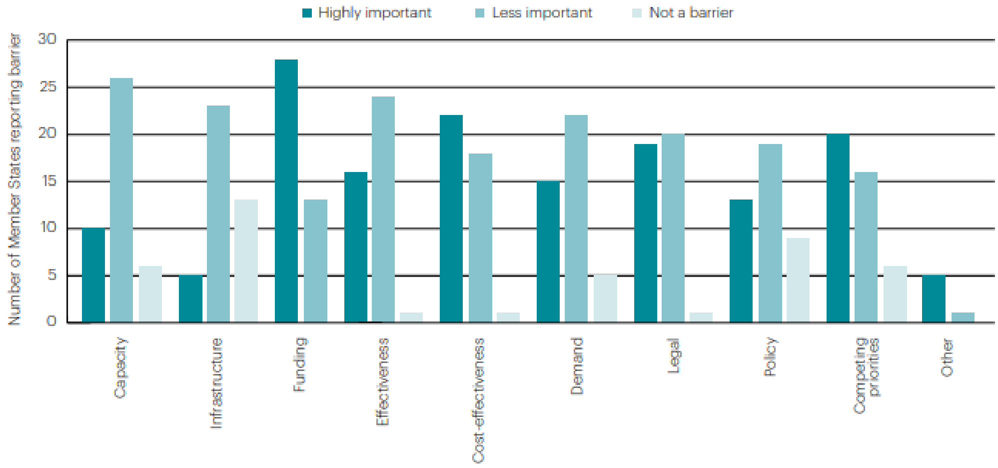

Figure 5-6 mHealth adoption barriers in Europe. (WHO, 2016, p.49)

The aim of the present analysis is to identify the underlying root causes of these barriers. As an example, data analysis in this study suggests that lack of clinical evidence, a main reported barrier in mHealth literature, is a consequence of the clash between the technology and healthcare institutional frameworks. Moreover, lack of clinical evidence is a legitimation block as it negatively affects moral legitimacy. Another example is the lack of reimbursement methods and lack of viable business models. As shown in table 5-4, these act as a block for pragmatic legitimacy. Moreover, data analysis suggests, as discussed in section 5.3.4.2, that the difficulty to establish innovative business models comes in part from the strict regulatory barriers that act in favour of incumbent business models.

In summary, table 5-4 shows the main mechanisms blocking mHealth TIS legitimation. The majority manifest in different barriers affecting pragmatic and moral legitimation. These two types of legitimation are a pre-requisite before cognitive legitimacy can be obtained (Laïfi & Josserand, 2016). Cognitive legitimacy represents the last step in the legitimation process as when it occurs, the innovation is taken for granted and alternatives become irrelevant (Suchman, 1995).

5.5.2 Legitimation drivers

The previous section has analysed the legitimation barriers for mHealth. As data evidences, expectations created by entrants on the potential of mHealth had a positive legitimation impact on policymakers. However, data analysis points to a set of technological, organisational and institutional aspects impeding the legitimation of mHealth.

Now, this section analyses in more depth, the case of Mersey Burns. Mersey Burns, as introduced in section 5.3.1, became the first mHealth application certified as a medical device in the UK. Therefore, it constitutes a good example for the analysis of the legitimation drivers of mHealth. The application calculates on a mobile device (typically a tablet), the type and amount of resuscitation fluids that doctors need to prescribe to patients in cases of burn injuries. The application prescribes the fluids through analysing pictures of the burning surface area. Mersey Burns was created by a plastic surgeon MD. Mr Rowan Pritchard Jones and two IT experts. One of the creators of Mersey Burns participated in this study.

Data analysis suggests that the drivers enhancing Mersey Burns' legitimation are very similar to the ones found for CFD (see section 4.6.1 in chapter 4). First of all, the application was developed to help burn specialists deal with problems they face in their daily practice. To do so, MD. Mr Rowan Pritchard Jones involved his colleagues and students during the development and tests of the application, following a knowledge co-creation pattern as opposed to a technology push orientation. Through this, pragmatic legitimation was enhanced, as practitioners could see the benefits of the application. Moreover, as they participated in its development, pragmatic influential legitimacy, moral and cognitive legitimacy were enhanced also. Secondly, the development process complied with the norms and regulations of the healthcare system: clinical trials were conducted and a paper was published. This contributed to getting a quick acceptance by the regulatory bodies (less than 6 months according to the participant), and from a legitimation perspective, it contributed to enhancing moral and cognitive legitimacy. Thirdly, MD. Mr Rowan Pritchard Jones is a reputed plastic surgeon and the application was endorsed by the Plastic Surgeon Association, which contributed to building moral(personal) legitimacy.

In summary, Mersey Burns legitimated by conforming to customers' requirements and healthcare practices and regulations. Although on a different scale, MD. Mr Rowan Pritchard Jones, acted as a system builder in a similar way as Professor Spalding did for CFD (chapter 4).

5.5.3 Legitimation strategies

The previous section presented Mersey Burns as an example of how conforming with the prevailing institutions contributes to building legitimacy. As Zimmerman and Zeitz (2002) contend, conforming to existing norms and practices is the most convenient legitimation strategy. However, innovations frequently come with new rules of the game (Suchman, 1995) and conforming to incumbent institutional rules might undermine the transformative potential of the innovation. As Steinhulb et al. (2015, p.5) reflect:

"Attempting to fit disruptive technologies into existing systems has historically been shown to prevent anticipated gains. Similarly, the implementation of mHealth technologies only as adjuncts to existing systems of care likely will lead to results that fall well short of demonstrating their true impact."

As repeatedly discussed in sections 2.6.3 and 4.6.3, Suchman (1995) defines in addition to *conform* strategies, two additional ones: *selection* and *manipulation*. *Selection* refers to opt for audiences where the novelty will fit or be supported better by the institutional environment. *Manipulation*, on the other hand, defines the process of changing the existing institutional environment in favour of the innovation. Suchman (1995) suggests, that realistic strategies fall in a continuum from conformity to manipulation. In addition to Suchman's (1995) strategies, Zimmerman and Zeitz propose a fourth one, ***creation*** of new institutions that did not exist.

Contrary to Mersey Burns' strategy, the 3millionlives program, as discussed in section 5.2.4.2, attempted, without much success, a manipulative strategy for changing healthcare practices in favour of the technology. As discussed, the program was driven by technology firms without the involvement of practitioners in the decision-making process.

In between Mersey Burns and 3millionlives projects, data analysis suggests that the majority of strategies undertaken by participants in the study (entrepreneurs, entrant and incumbent firms), fall in the conformation-selection space. Data suggests that they look for favourable contexts with less institutional constraints. The reported strategies can be summarised as:

I. Selection of less regulated and professionalised areas of healthcare

Data analysis suggests that entrant firms, and particularly entrepreneurs and SMEs, tend to develop mHealth solutions in areas with blurred regulation resting between the clinical healthcare and wellbeing space. As an example, Brown et al.(2016), analyse the increase of mHealth solutions to treat common mental health disorders like anxiety or depression, an area where therapies are probably less regulated. Moreover, the analysis on mHealth economics conducted by Research2guidance (2017, p.6), confirms that mHealth app companies, which have a predominantly technological background, are focused on mental health and weight:

"… pharma companies are concentrating on providing products and services for 'medication', 'diabetes' and 'heart, circulation, blood', whereas hospitals are developing apps for 'hospital efficiency'. mHealth app companies are specialising in areas like 'weight management' or 'mental health'. Health insurers are active above average in 'health & fitness'."

Additionally, data suggests that big ICT companies have pivoted their orientation towards mHealth to avoid regulation. As an example, in a conversation with the representative in one of the top ICT firms, he stated:

"We've changed our orientation towards mHealth. We try not to play in the medical space anymore. It is very difficult to compete there. We are (in this summit) presenting a solution for the integral care of elderly people once they leave hospital. There is a big gap there to ensure

they have food when they arrive home, that the house is warm etc…We also monitor that they take their pills, that they feel well and can talk to their nurse from home…"

II. Position of products and services for the consumer market

The majority of entrepreneurs participating in this study manifested the intention to position their mHealth products for the end user market. The reasons for their strategic decision were to avoid regulatory issues and facilitate direct access to their target customers. At the time of data collection, EU regulation for mHealth applications and mobile devices presented many grey areas, and entrepreneurs could market their products and obtain a CE Mark complying with the Radio and Telecommunications Terminal Equipment (RTTE) Directive. The requirements of this directive are much less strict compared with those of the EU Medical Devices Directives (MDD).

III. Collaboration between entrants and incumbent healthcare providers

Despite the competition and technological firms' push, data analysis reveals, as discussed in section 4.2.3, important alliances and collaboration between entrants and incumbent organisations. According to some participants, collaboration enhances moral and cognitive legitimacy. As an EU policy maker contends:

" What we see happening now is that there are certain let's say...companies that are good in IT and in citizen interaction and they are teaming up with professionals from the field like doctors....So there are that companies that are providing for example remote diagnosis and remote health consulting....that have a professional team of doctors who are willing to offer their services […]. So it is the partnership arrangement where the professionalism is coming from the medical field partnering with the professionalism coming from the IT field." (EU policy maker).

An interesting aspect related to collaboration, is that the majority of participants didn't foresee a shift of key players in the healthcare field as a consequence of mHealth. As an expert from a big ICT firm contends:

"I don't tend to think that we will see another Kodak moment... So I don't think we're going to see something like that for a very simple reason, those are consumer electronic devices technologies. […] whereas medical devices are very expensive...I see here more a collaborative model where you have these big companies and lot of medium app developers providing innovative solutions. But I don't envision at least in the short term -as it happened to Kodak or Nokia - a total shift of actors in the market for the very simple reason that the nature of the technology is different....and it is way more expensive than others and it requires a lot of time for developments, certifications....it is very different." (big ICT company representative).

IV. Sell innovation to incumbent healthcare companies

All entrepreneurs participating in the study confirmed that they had contacted, or at least tried to be, by pharmaceutical and medical device companies to offer them their products. Participants from the pharmaceutical side confirmed the vigorous activity in their mHealth accelerators, where they evaluate innovation coming from entrepreneurs and SMEs. As the mHealth manager at a big pharmaceutical industry summarises:

"I think the big majority (of entrepreneurs and SMEs) will end up selling their product. In fact, I receive almost on a daily basis, SMEs and entrepreneurs offering their ideas and products. Why? Because you can have a great idea, but when it comes the moment to commercialise it, you need a big injection of venture capital. You need the backup of a big firm. […] There are small companies that are working very well […] and they are having a high impact at patient level. What happens then? That they fail in reaching the healthcare practitioners and managers. But from patient's perspective they are having a lot of impact […] (Healthcare systems) are very traditional environments. They don't contemplate these visits of people offering them a new idea. If you have an idea...to whom do you offer it? It doesn't exist that figure in healthcare systems that you go and if they like your idea they fund it...At the end, it is us, the industry, who fund this type of projects." (Pharmaceutical representative).

V. Move to geographical areas with less rigid regulatory frameworks

Some participants in the study pointed out that emerging regions with low or non-existent public healthcare systems are experiencing faster levels of mHealth adoption. As the representative of an ICT alliance contends:

"In emergent countries, in some regions in South America or Africa, where public healthcare as we understand doesn't exist, and where to some extent they start from scratch, adoption is much more rapid and easier, because they don't have to coexist with the previous healthcare system." (ICT alliance representative).

However, this vision, backed up by other participants in the study and several consulting firms' reports, is contrasted by different academic studies raising several technical, economic and cultural barriers for the legitimation of mHealth in emerging countries (Mechael et al., 2010; Iwaya et al., 2013).

Despite this, one of the big pharmaceutical companies participating in this study, confirmed the creation of different mHealth accelerators in Africa arguing a more flexible institutional environment:

"*There are lots of opportunities for mHealth (in Africa). We've got great results in the pilots we've conducted so far […] There is less red tape involved. It is easier to work with doctors too…*" (Pharmaceutical representative).

In summary, data analysis reveals that successful mHealth legitimation strategies move in the conformation – selection space. Manipulative strategies for mHealth, on the other hand, present important difficulties to succeed. Particularly if these strategies are undertaken by entrepreneurs and firms outside the healthcare sector. Evidence suggests that entrepreneurs will strategically select contexts with lower institutional barriers. Consequently, data analysis shows that legitimation strategies are influenced by the institutional constraints in the different contexts (geographical, sectoral, organisational etc.) where the TIS needs to be legitimated. This aspect is further discussed in the next section 5.6, and in section 6.3.1.

5.6 Conclusions

The surge in mobile connectivity and wearables over the last decade, has created unprecedented levels of expectation around the opportunities to transform traditional healthcare pathways through the provision of mobile healthcare products and services. mHealth offers among other choices, the possibility to supply ubiquitous monitoring and diagnostic devices with automated clinical decision tools. Furthermore, in some cases, through a fraction of the cost of traditional medical equipment or services.

In spite of this, mHealth technologies for clinical care present low levels of adoption due to significant barriers and challenges (European Commission, 2014; WHO, 2016). This suggests that at the present time, mHealth, as a TIS, is in its formative phase (Bergek et al., 2008a). Therefore, mHealth for diagnostics and chronic disease management, represents an exceptional case to study legitimation in the formative phases of a TIS. However, the endeavour is not exempt from difficulties, as conducting TIS prospective research presents certain limitations. Chief among them, is the study of the dynamics of a system that is still evolving and for which its final configuration might be different from that observed at the time of data collection. As an example, this study hasn't succeeded in identifying mHealth system builders as defined by Hughes (1987).

One of the main overall conclusions of the study is the uneven development and performance of the mHealth TIS functions. On one hand, data analysis suggests that knowledge development, entrepreneurial experimentation and resource mobilisation (to a more limited extent than the others), are well developed and performing functions. On the other hand, influence on the direction of search, legitimation and market formation present important blocking mechanisms. These results are consistent with the findings by Hellsmark and Jacobson (2009) in their study on the Austrian gasified biomass TIS. The authors made use of the "motors of the TIS" expression (Hekkert et al., 2007) to group closely related functions of similar performance and outline their underlying blocking factors.

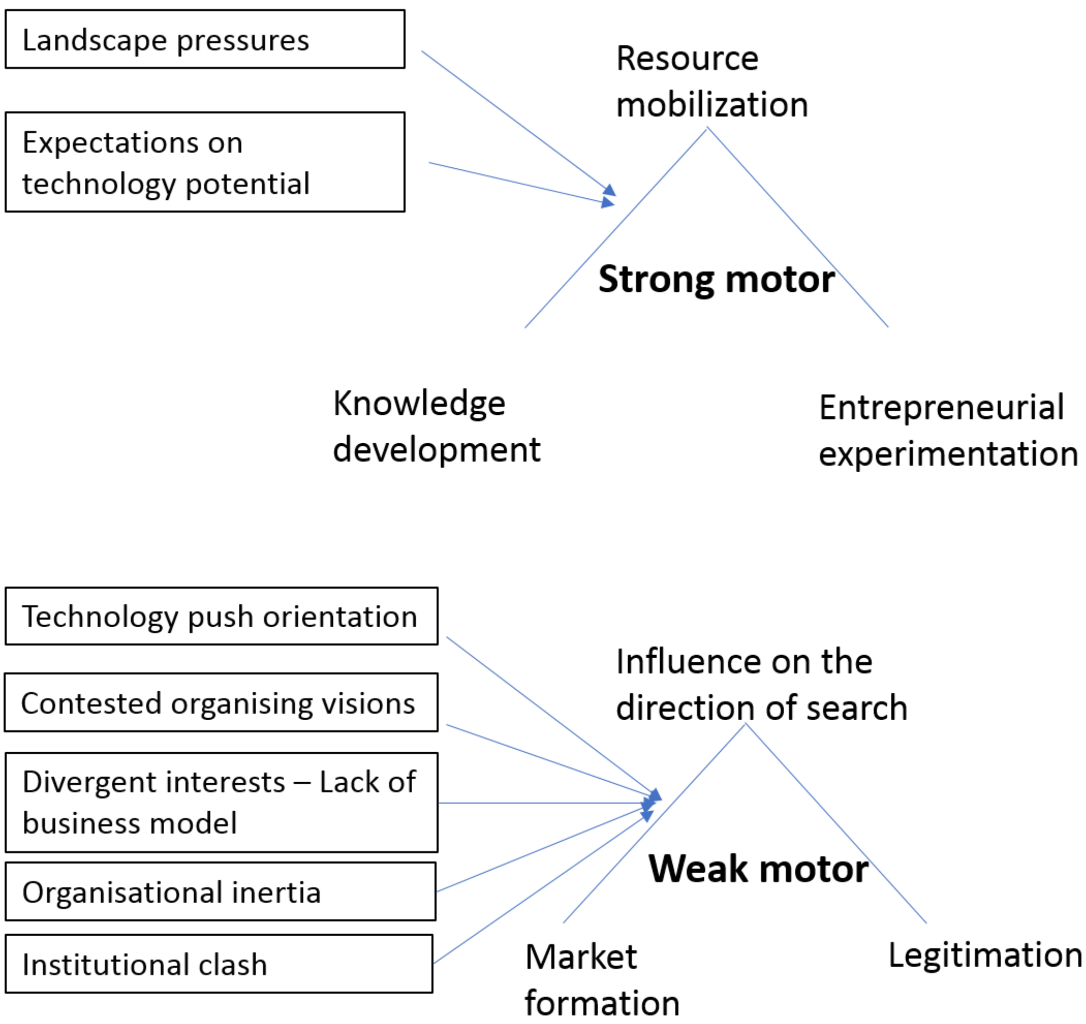

Figure 5-7 mHealth motors of innovation. Developed by the author

Figure 5-7 shows the motors of innovation for mHealth. As discussed, the knowledge development, entrepreneurial experimentation and resource mobilisation functions constitute the "strong motor of the TIS", whereas the influence on the direction of search, market formation and legitimation constitute the "weak motor of the TIS". The boxes on the left side of the figure represent the mechanism inducing or hampering the motors. For the strong motor, data analysis points to two main inducement mechanisms: landscape pressures in the form of socio-economic problems in the incumbent health systems (Geels, 2005a), and market opportunities raised by the potential of the technology. The weak motor is obstructed by a set of blocking mechanisms like the technological push orientation of mHealth, contested organising visions (Swanson & Ramiller, 1997), organisational inertia, divergent interests among key actors leading to lack of innovative business models, and the clash between healthcare and technological institutions. These blocking mechanisms produce in consequence, observable barriers as reported by mHealth literature (European Commission, 2014; WHO, 2106). Furthermore, data analysis evidences lack of pragmatic and moral legitimation due to the blocking mechanisms in the system. As Suchman (1995) and Laïfi and Josserand (2016) contend, pragmatic and moral legitimacy are prerequisites to building cognitive legitimacy, the last step in the legitimation process.

Expectations created by mHealth advocates on the potential of the innovation to solve healthcare systems' problems, have contributed to creating pragmatic and moral legitimation among policy makers. However, the technological push orientation of mHealth and the lack of viable and innovative business models have turned into a lack of pragmatic legitimacy (in the form of appropriable benefits) for healthcare professionals.

Data analysis suggests that building moral legitimacy (i.e. mHealth is the right thing to solve healthcare problems), might not be enough if pragmatic legitimation for adopters and other key actors is not built. Furthermore, the arguments provided by mHealth entrants to build moral legitimacy, are grounded on a utopian discourse (cost efficiency, citizens' empowerment, technology as a transformational tool), that has not been bought by healthcare professionals with a humanist organising vision (centred on patients, illness experience, relationships etc.) (Greenhalgh et al., 2012). On the contrary, some participants in the study perceived claimed mHealth benefits as self-interested. Data analysis evidences that whereas expectations can contribute to build a shared vision about a desirable future, and might also fulfil a performative function attracting attention and investment (Bergek et al., 2008a; Borup et al., 2006), they need to be contrasted with high quality evidence to avoid self-promoter paradoxes and recurrent disappointments that can result in credibility damage (Brown & Michael, 2003), and consequently in a loss of moral legitimacy. Therefore, building pragmatic and moral legitimation requires the sustainment of expectations supported with evidence.

Data analysis suggests that building pragmatic legitimation among TIS key actors is crucial for the success of the TIS. However, organisational studies beyond Suchman (1995), see Zimmerman and Zeitz (2002) for a review, or TIS studies, have neglected the role of pragmatic legitimacy. This omission has probably hidden the political dimension and conflicting interactions inside the TIS, an aspect much criticised by TIS contestant scholars like Kern (2015) or Meadowcroft (2011). As an example, in a recent TIS legitimation study by Markard et al. (2016), the interactions that contribute to build or destroy pragmatic legitimation are not taken into account.

This chapter has also brought to discussion an example of successful and unsuccessful mHealth projects. The unsuccessful project, named 3millionlives, reported barriers that are consistent with the findings in blocking mechanisms of the study (see table 5-4 and figure 5-6). The successful project, -the mHealth app Mersey Burns, reported legitimation drivers that are consistent with those found for CFD (chapter 4) like: (i) knowledge co-creation (enhancing pragmatic moral and cognitive legitimacy), (ii) adherence to healthcare norms and practices (enhancing moral and cognitive legitimacy), (iii) endorsement from professional surgeons' association (enhancing moral/personal legitimacy) and (iv) provide evidence (enhancing pragmatic, moral and cognitive legitimacy).

This case study reveals interesting insights regarding the influence of institutional constraints in the development of legitimation strategies. As discussed in section 5.5.3, data analysis evidences that mHealth entrants strategically search legitimation in favourable contexts like: end user market, clinical practices with lower regulation and lower level of professionalisation, geographies with non-rigid regulations etc.

As discussed in section 2.6.5, TIS has been criticised for its myopia towards external contexts, and different TIS scholars have urged for the need of empirical research on external contexts (Bergek et al., 2015; Markard et al., 2015). Bergek et al. (2015) define contexts as external organisational fields that share dominant technological paradigms, common held beliefs and culture, and shared problem agendas that translate into common institutional arrangements. Contexts can be sectoral, geographical, technological etc. Data analysis reveals, as discussed, that entrepreneurs and entrant firms will strategically look for favourable contexts where the institutional barriers or the institutional clash between proponents and adopters is low. This finding is also supported by the CFD case study, where data analysis showed that system builders succeed to legitimate in contexts with no substitutive products for CFD. A further discussion on external contexts, and its impact on legitimation is provided in section 6.3.1.

Finally, data analysis suggests that the adoption of mHealth won't necessarily come with a displacement of incumbent firms as key players. As in the case of CFD (chapter 3), collaborative models between incumbents and entrants contribute to enhance legitimation in wider contexts. Collaborative innovation models (Chesbrough, 2006), as the ones evidenced in this research, question different theories of firms' competition. Theories of firms' competition (Anderson & Tushman, 1990; Christensen, 1997) argue that "competence-destroying" or disruptive innovations give an attacker's advantage to entrant firms and displace incumbents.

The next chapter will present the propositions and empirical framework resulting from the themes that emerged in this and in the previous chapter. In addition, a discussion of the theoretical, methodological and practical contributions arising from this thesis will be provided.

Chapter 6 - Research conclusions and contributions

6.1 Introduction

This chapter brings this thesis to a conclusion. The next section, section 6.2, presents a summary of the research and a discussion on the attainment with respect to the research primary objective and the research questions. This is followed by section 6.3, where a summary of the key research findings and associated propositions are discussed. These propositions ground a framework (discussed in section 6.4), that attempts to explain the mechanisms contributing to building legitimation of BTIs. Section 6.5, presents the contributions to theory, methodology and practice. The next section6.6, discusses the limitations of the study and suggests the agenda for future research. Finally, section 6.7, brings the chapter to an end with a summary.

6.2 Summary and research aim attainment

The research aim and objectives set out at the beginning of this study (see section 1.3) are largely met, and as a consequence, the research questions posed in section 2.7.2 have been answered. The following subsections provide a summary of the research and the rationale supporting the statement of achievement.

6.2.1.1 Research aim and objectives

Guided by the importance of understanding why most BTIs at the formative stage (past the pilot phase and with a fledgling market presence), fail or remain in niches without acquiring critical mass on one hand, and the paucity of studies on the early phases of the innovation phenomena on the other, the broad research aim of this thesis was set out to identify and unfold the critical processes in the formative phase of BTI's before they acquire critical mass and start their diffusion trajectory. In order to accomplish such an ambitious aim, the researcher conducted a critical and analytical literature review to identify, among the different strands of innovation studies, what theoretical and analytical starting points could best serve the study's overall purpose. As a result of the literature review process, the researcher selected TIS (Carlsson & Stankiewicz, 1991; Hekkert et al., 2007; Bergek et al., 2008a; Hellsmark & Jacobsson, 2009) as the most suitable theoretical and analytical starting point to unfold the early phases of the innovation phenomena. However, and to some extend surprisingly, the researcher found that TIS studies have largely ignored the insights of legitimation, a critical process in the formative phase of TIS. (Bergek et al., 2008b; Hellsmark, 2010; Markard et al., 2016). Consequently, the research aim was narrowed into three research questions, for which the degree of achievement is discussed in the next subsections.

Overall, the research aim and objectives of this thesis have been achieved as:

(I) Legitimation has been identified as a critical process in the formative phase of TIS.

(II) Empirical data has corroborated the contextuality of the legitimation process as suggested by recent research in the field (Bergek et al., 2015; Markard et al., 2016).

(III) The interdependency of legitimation with other external and internal processes in the TIS has been refined.

(IV) The relevance of system builders (Hughes, 1987) in the legitimation process has been confirmed.

(V) As the result of all the above, this research proposes a framework portraying the mechanisms contributing to developing legitimacy. The framework and the developing propositions grounding it, are further discussed in sections 6.4. and 6.3 respectively.

6.2.1.2 Research Question 1: how do and the extent to which system builders contribute to establishing legitimacy within a TIS?

This thesis confirms the critical role that system builders play in the formative phase of a TIS. The analysis of empirical data reveals that the extent of their transformative capacity to build institutional alignment and legitimacy depend on different intentional, unintentional, internal and external factors. In terms of internal factors, this study identifies that both the internal organisational and institutional structures in which system builders are embedded, aka ***general structure*** (Hellsmark, 2010), influence their transformative capacity. Data reveals that system builders embedded in *flexible general structures*, will more likely develop higher levels of transformative capacity than system builders constrained in *rigid general structures*. In relation to the external factors, data analysis suggests that the extent of their transformative capacity will be determined by the constraints of the different contexts in which legitimation needs to be accomplished. The study suggests that system builders are more likely to start building legitimation in contexts with low institutional constraints, or in contexts where formal and informal institutions do not represent a clash with respect to system builders' general structure.[28]

Therefore, this study confirms that system builders contribute to legitimacy mainly through developing knowledge, leading entrepreneurial experimentation, attracting actors, creating informal networks of knowledge and setting the basis for institutional alignment across "aligned contexts". However, the study reveals that their transformative capacity acting individually might be limited in contexts with significant institutional barriers. In these contexts, data reveals that alliances with incumbent firms will increase the possibilities of transitioning the TIS from the formative to the growth phase.

[28] Sections 6.3.1 and 6.3.2 provide more insights on the definition and conceptualisation of general structure and institutional contexts

As a consequence of the above discussion, research question 1: how do and the extent to which system builders contribute to establishing legitimacy within a TIS? is answered.

6.2.1.3 Research Question 2: what are the principal mechanisms aiding the legitimation of a TIS?

This thesis suggests that mechanisms involved in the legitimation of a TIS come largely from: interactions inside the focal TIS, interactions between the focal TIS and the contexts where legitimation is required, and interactions between the focal TIS and exogenous factors. The propositions developed in section 6.3 together with the framework discussed in section 6.4, explain the identified mechanisms contributing to developing pragmatic, moral and cognitive legitimacy (Suchman, 1995), and therefore, they answer research question 2. To highlight a critical mechanism, this study finds that the way knowledge is developed during the formative phase of TIS has a critical influence in the likelihood of a successful legitimation. Data analysis reveals that co-creation of knowledge as opposed to technological solutionism or technology push solutions, contribute to creating pragmatic, moral and ultimately cognitive legitimation.

6.2.1.4 Research Question 3: what are the key legitimation strategies capable of overcoming the 'liability of newness'?

Understanding the mechanisms that contribute to building legitimacy (RQ2), it becomes critical to take informed strategic decisions. As discussed in sections 2.6.3, 4.6.3 and 5.5.3, Suchman (1995) defines three types of legitimation strategies: conform, selection and manipulation. Zimmerman and Zeitz (2002) adds creation to account for the development of new institutional contexts that did not exist. Whereas conforming to adopters' institutional contexts becomes the most straight forward strategy, technological innovations often require new game rules, and as such, conforming strategies might not be an option. On the other hand, data analysis suggests that manipulative strategies to modify institutional contexts in benefit of the innovation might not be a realistic entry strategy, particularly if system builders are entering into institutional contexts with high barriers. This thesis finds that successful system builders' entry strategies fall in the space *conform-selection*. As evidence suggests, system builders will strategically select institutional contexts that fit well enough into what the new technology requires. In more complex contexts, this study shows that system builders will more likely create alliances with incumbent firms, combining knowledge developed by the former with the capabilities and resources of the latter, to build pragmatic and moral legitimacy, and therefore, "overcome the liability of newness".

As a consequence of the above discussion, research question 3 is answered.

6.3 Key findings and developing propositions

This section summarises key findings from data analysis and develops a set of propositions aimed at grounding a framework on legitimation (section 6.4). Findings are organised following a similar logic as the data analysis in chapters 4 and 5. In chapters 4 and 5, Hellsmark and Jacobsson's (2009) framework on TIS dynamics discussed in section 2.7 (figure 2-7), was used as a guide to organise data analysis into four main areas of investigation: system building capabilities, TIS functions, exogenous factors and legitimation. In this section, the discussion starts with the analysis of exogenous elements influencing legitimation. Consistently with recent TIS studies (Bergek et al., 2015; Markard et al., 2015; Markard et al., 2016), data analysis reveals a strong influence of external structures into legitimation. An in-depth discussion of the different external structures and its developing propositions is presented in section 6.3.1. After this, the rest of the subsections focus on the findings and developing propositions around system building capabilities, TIS functions, and legitimation dynamics and strategies.

6.3.1 Findings and propositions regarding external structures

Data analysis evidences that the process of innovation legitimation depends heavily on external elements to the TIS: for example, as discussed in section 4.3.4, the pace of legitimation of CFD varied across sectors and was more readily acquired in those with no substitutive products. Similarly, section 5.3.3, identified that system builders orientate their legitimation strategies towards less professionalised areas of healthcare or regions with underdeveloped services and less rigid regulations. Additionally, the development of other technologies, suggests a positive influence on the legitimation of a TIS, as discussed in sections 4.5.1 and 5.3.6.

The external factors and structures outside the TIS (like sectors, related technologies, geographies etc.) are named as “contexts” in recent TIS literature (Bergek et al., 2015; Markard et al., 2015). Therefore, from the above discussion, this research evidences that legitimation is a context dependent process. And context extends beyond the internal dynamics of TISs encompassing external structures including technological, sectoral, geographical etc.

As defined in section 2.6.5, TIS literature conceptualises contexts as organisational fields that share common institutional arrangements including: dominant technological paradigms, common held beliefs, practices etc. (Bergek et al., 2015). As areas of higher order than the TIS, contexts exhibit a degree of coherence and stability (Markard et al., 2016). Bergek et al. (2015) identify 4 different context structures: *technological*, *sectoral*, *geographical* and *political*. *Technological* contexts refer to related and surrounding TISs. As different technologies can compete and complement each other, they mutually influence each others development dynamics. Consequently, a TIS can become a technological context for other related TISs. *Sectoral* contexts are associated with the pre-existing infrastructures and institutions in a specific sector. Sectors are characterised by well-defined institutional settings (norms and practices, specific regulations, developed technologies etc.) and developed infrastructures. Through their institutionalisation, sectors become stable contexts. Breakthrough innovations might change, or on the contrary adapt to, these established contexts (further insights on the adaptation/change process are discussed in section 6.3.4). *Geographical* contexts relate to the links and resources that may exist in a territory out of the boundaries of the TIS. Finally, the *political* contexts in which a TIS is embedded, is also of key importance for its development. As an example, political agendas in support of a TIS are of key importance to mobilise resources and to some extent, to build legitimation as will be further discussed at the end of this section.

This research finds that whereas technological contexts (in the form of related TIS) and landscape pressures like political and societal debates (as part of the political context) are relatively simple to identify, other external factors and structures emerging from data analysis overlap between sectoral, geographical or political contexts. As Bergek et al. (2015, p.61) argue: "*the four context structures might not be neatly separated in an empirical setting. The point made here is, however, that depending on the purpose of the study we can focus on a particular context structure to investigate its dynamics and links to the focal TIS".*

As the focus of this research is on legitimation, a process tightly bounded to formal and informal institutions, this research names a new external context: ***"institutional context"*** to refer to the external institutions (formal and informal), that affect the legitimation process. As discussed, an *institutional context* can overlap between sectoral, geographical, and/or political settings that are not always possible to separate. The definition of a new external context is consistent with Bergek et al.(2015, p.61) postulations: " *We fully acknowledge that there are other relevant context structures than the four we discuss […] We still expect that the elaborations made in this paper provide a sort of template for analysing other context structures in the future.*"

In summary, this thesis finds three main differentiated external structures that influence TIS legitimation. These are: (i) institutional contexts defined as external formal and informal institutional structures, (ii) the development of related TIS and (iii) landscape factors or pressures at macro level like political or societal debates. These identified external structures serve as the basis for the first developing proposition discussed over the next paragraphs.

This research finds, that when a TIS needs to legitimate across different institutional contexts, (typically sectors or geographical areas with a coherent set of formal and informal institutions), the process will typically start in institutional contexts that present more favourable conditions for system builders. Previous TIS studies suggest that geographical or technological proximity factors might be relevant for system builders (Markard et al., 2016). However, TIS scholars haven't so far delved into the conditions that make an institutional context a favourable space to legitimate a new technology. This research finds that institutional contexts with favourable conditions for system builders, might be those with a low degree of institutionalisation. In particular, institutional contexts with:

- no substitutive products (or no dominant technological paradigms)
- low entry barriers
- low regulatory constraints
- low professionalisation (lack of deeply embedded beliefs, norms or practices)
- certain alignment to system builders' beliefs, values and norms (further discussed in section 6.3.2)

As discussed in section 4.3.3, the lack of substitutive products, was key in the smooth legitimation of CFD across different sectors. In addition, and probably also as a consequence of not having a technology to displace, low competition and low entry barriers boosted the entry of new entrepreneurs and firms in the TIS. On the other hand, as discussed, the mHealth case study reveals that entrants are preferably looking to legitimate in regions with more favourable regulations or regions with underdeveloped healthcare services, where mHealth does not replace existing practices. Moreover, entrants are also looking for low professionalised areas in healthcare like elderly care or mental health. Finally, data analysis also reveals that system builders try to take advantage of the grey regulatory areas by positioning their mHealth solutions in the wellbeing and fitness area, where regulation is less strict.

As a consequence of the above, a first proposition can be formulated:

P.1: The pace to gain legitimacy varies across the different institutional contexts. The process will most likely start in contexts that present less institutional constraints for system builders.

This research suggests that the development of related technologies has a positive impact in the legitimation of a focal TIS. The finding is aligned to other TIS studies (Bergek et al., 2015; Markard et al., 2016). As discussed in the CFD case study, the development of computational capabilities, graphical user interfaces, and even software compilers, facilitated the legitimation and development of CFD. On the other hand, in the mHealth case study, although maybe still too early to determine, the use of wellbeing products (wrist-worn activity trackers) as medical decision tools (Rudner et al., 2016) suggests the positive effect that related technologies can have in the legitimation of an emerging TIS. Moreover, as discussed in section 5.3.6, experts agreed on the positive impact of mobile fitness and wellbeing technologies into clinical mHealth.

Finally, as Bergek et al. (2008b) contend, even technologies that might be a priori seen as competing technologies, can act as complementarities and develop positive externalities. Therefore, a new proposition can be formulated:

P.2: The development of complementary technologies has a positive impact on the legitimation of an emerging TIS.

Markard et al. (2016), in a recent study of TIS legitimation, contend that mobilisation due to societal problems or political agendas is critical to create (or destruct) legitimacy of technologies. In their words: *"…What is relevant with regard to legitimacy is that context* *structures such as larger societal problems or political goals can be mobilised by TIS actors to motivate (and legitimate) the focal technology."* (Markard et al.,2016 p.333). Although this may be true in certain contexts, the data presented here did not reveal any causal link between societal issues and the legitimation of the technologies under scrutiny. In particular, in the case of mHealth, data shows that the expectations created on the technology as an enabler for affordable universal healthcare, have not contributed to building legitimacy among healthcare experts and practitioners. As discussed in section 5.3.4, data analysis evidences that mHealth networks and advocacy coalitions formed primarily by big technology firms, have influenced the agenda of EU policy makers, and as a consequence, public resources have been mobilised. However, as argued, on the practitioners' and healthcare experts' side, these expectations have been interpreted as a self-interested act of technology entrant firms, leading, as Suchman (1995) contends, to self-promoter paradoxes. Moreover, this research evidences that potential adopters of mHealth do not perceive an appropriable benefit in the use of healthcare solutions developed by technology firms, particularly, if healthcare professionals haven't been involved in the process.

In summary, this research finds that pressures at landscape level (Geels, 2005a) in the form of societal or political debates, contribute to creating expectations and mobilising resources. However, expectations can be perceived as self-promoter paradoxes if they are not supported with evidence. Moreover, potential adopters need to perceive an appropriable benefit for its adoption (pragmatic legitimacy), in addition to a positive moral evaluation of the technology. As a consequence of the above discussion, an additional proposition can be put forward:

P.3: Problems at societal level and public debates contribute to building legitimation as long as adopters perceive an appropriable benefit on its adoption (pragmatic legitimacy).

6.3.2 Findings and propositions regarding system builders' capabilities

The focus of this section, is to discuss the findings and developing propositions pertaining to the extent of the transformative capacity of system builders to build legitimacy in the formative phase of a TIS. As discussed in section 2.6.1, system builders are an important subset of TIS actors that contribute to the development of the TIS. They can be entrepreneurs, firms, organisations etc. or act collectively through networks and alliances.

According to Hellsmark and Jacobsson (2009), system builders are critical in the development of four structural processes during the formative phase of a TIS. These processes are: (i) accumulation of knowledge and artefacts, (ii) entry of firms and other organisations, (iii) formation of alliances and networks, and (iv) institutional alignment. The development of these processes is critical to legitimate the TIS and move it to the growth phase. In particular, institutional alignment is a core part of the legitimation process. System builders are key in shaping institutional alignment in the best interest of the technology (Kukk et al., 2016). The different forms of institutional alignment (from creating new institutions on one extreme, to adapting the TIS to the existing institutions), are further discussed in section 6.3.5.

Following Giddens' (1984) structuration ideas of agents (actors) embedded in structures, Hellsmark (2010) argues that system builders are embedded in a structure named *general structure*. According to Hellsmark (2010, p.48): "…system builders' '*general structure' both constrains and enables the system builder(s) to address system weaknesses, to reduce further uncertainties and to strengthen the TIS.*"

This research finds, aligned to Hellsmark's (2010) statement above, that system builders' general structure influences their transformative capacity. As discussed in section 4.3.3 and summarised in figure 4-4, this research finds that flexible general structures have a positive impact in system builders' transformative capacity. As discussed in chapter 4, although the Los Alamos National Laboratory was ahead in the development of knowledge, their organisational and regulatory constraints as a National Laboratory (like the culture of working in an isolated environment or the regulation prohibiting their involvement in industrial activities), prevented the transformation of scientific knowledge into applied innovation. In other words, Los Alamos' *general structure* inhibited their transformative capacity.

Moreover, this research finds the characteristics of the general structure in which system builders are embedded, conditions the innovation trajectories. As Bergek et al. (2008b, p.577) argue: "*actors are guided in what they think is right and what they want to do by what they know and are able to do. […] Taken jointly, normative and cognitive institutions influence decisions and actions in the form of frames (Bijker, 1995; Geels & Raven, 2006) or paradigms (Dosi, 1982) that structure learning processes (problem agendas, ways to do business, etc.).*"

In other words, the analysis on how knowledge was created both for CFD and mHealth, shows that system builders tend to develop knowledge drawing on the capabilities, beliefs, norms and values of the *general structure* in which they are embedded. As Hellsmark (2010, p.326) contends: "*the extent of the system builders' transformative capacity is conditioned, although not determined, by the general structure in which they are embedded*." Extending Hellsmark's (2010) assertion, this research finds that, in some cases, system builders' general structure might have a negative impact on legitimation. As an example, the discussion in section 5.2.4, the mHealth case study, reveals a strong clash between the *general context* of the main group of mHealth proponents (technology firms), and the rigid institutional context of the healthcare sector: whereas technology firms are embedded in a general structure specialised in rapid product developments, healthcare, on the other hand, is a slow-paced industry with high regulatory barriers and rigid organisational procedures and practices aiming at developing safe products. This misalignment between the general structure of technology firms and the institutional context of the healthcare industry, translates into a lack of trust and legitimacy of the solutions proposed by technology firms among adopters in the healthcare sector.

Based on the above discussion the following propositions are put forward:

P.4: System builders are embedded in a general structure that influence the extent of their transformative capabilities.

P.4.1: A flexible general structure has a positive impact on system builders' transformative capacity.

P.4.2:. Misalignment between system builders' general structure and the institutional context where the TIS needs to adopted, hinders legitimation.

As discussed at the beginning of this subsection, system builders can act individually or collectively through networks and alliances. This research finds that alliances between system builders and incumbent firms facilitate the transition of breakthrough technologies from the formative to the growth phase. For example, as discussed in chapter 4, although Professor Brian Spalding, the principal system builder in CFD, was key in developing knowledge and nursing markets, the transition to growth markets came propitiated by the alliances between other CFD system builders and incumbent engineering firms. The latter made use of their marketing and sales capabilities to legitimate CFD in wider sectors and geographies. Moreover, they also shifted CFD from an initial business model based on consultancy services, to a business model based on selling software.

Data analysis in the mHealth case study discussed in chapter 5, showed that incumbent healthcare firms such as large pharmaceutical companies, are establishing alliances with big technology and consultancy entrant firms and creating accelerators to capture value from entrepreneurs and SMEs. The formation of alliances and mobilisation of resources by incumbent healthcare firms entering mHealth, suggest that legacy healthcare are less interested in creating barriers and more interested in developing sensible options to take advantage of the potential offered by mHealth. Data suggests that incumbent firms mobilised resources to push a trajectory that can preserve their competitive advantage. This research suggests that whereas small entrants are more likely to develop new knowledge and build legitimacy in few initial institutional contexts with favourable conditions (see proposition 1), incumbent firms, sometimes taking late entrants' advantage (Lieberman & Montgomery, 1998), will mobilise resources towards the adoption of the technology in wider markets and more complex institutional contexts. This finding suggests that disruptive technologies, and particularly innovations that need to legitimate in complex institutional contexts, do not necessarily come with the destruction of incumbent firms as postulated by theories of innovation and firm competition (Anderson & Tushman, 1990; Christensen, 1997). On the contrary, this research evidences that incumbent firms might play a critical role if they mobilise resources and combine their capabilities with the knowledge primarily developed by system builders. This finding is aligned to the idea of Open Innovation coined by Chesbrough (2006) and the research on the automotive and gas turbine industries by Bergek et al. (2013, p.1210), who contend that theories of innovation and firm competition: *"...overestimate the ability of new entrants to destroy and disrupt established industries and underestimate the capacity of incumbents to perceive the potential of new technologies and integrate them with existing capabilities*."

As a result of the above findings, two additional propositions can be put forward:

P.5: Incumbent firms might take late entrant advantage of knowledge developed by system builders to legitimate the TIS in wider and more complex institutional contexts.

P.6: Incumbent firms will collaborate and compete with system builders, mobilising their resources and capabilities towards a trajectory that can better preserve their competitive advantage.

Finally, this research acknowledges, that as Kukk (2016, p.131) contends, alliances between system builders and incumbent firms are: "*often an asymmetric relationship that is difficult to balance and gives the larger partner a power advantage*." As an example, some participants in the CFD case study argued that once large firms took control over CFD, knowledge networks between academy and industry disappeared, and with them, new breakthroughs in the field. Although there is a wide consensus on the lack of innovation in the CFD field since the lock-in of multipurpose codes in the 1980s, this study hasn't been able to establish a solid causal link between lack of innovation and CFD market takeover by large firms. However, as discussed in section 6.6, this thesis suggests as an avenue for future research, to study the influence of the power advantage of large firms in innovation trajectories.

6.3.3 Findings and propositions regarding TIS functions

The third group of findings relate to the dynamic interplay of TIS functions towards the transition from the formative to the growth phase. From a methodological perspective, this research finds that TIS functional frameworks (Bergek et al., 2008a; Hellsmark & Jacobsson, 2009) present a number of limitations for the analysis of technological transitions, particularly, if the study, as in the case of mHealth, is not retrospective. These limitations can be summarised as:

(i) Translation of data into functions performance. Translating observed dynamics and experts' opinions into function performance indicators, might become a complicated endeavour. Firstly, because TIS frameworks do not offer thresholds on what is defined as a good or bad performance of a function, and secondly, because events occurring in the TIS usually affect a combination of functions, making in some cases the presentation of results confusing and repetitive.

(ii) Contextual differences. Aligned to the self-criticism by Bergek et al. (2015), TIS functional frameworks (Bergek et al., 2008a; Hellsmark & Jacobsson,2009) do not inform on contextual differences in the performance of functions.

(iii) Heterogeneity of the function "influence on the direction of search". This function encompasses a wide range of considerations associated with incentives and pressures faced by actors upon entering a TIS. These include visions, expectations, belief in potential growth etc., mechanisms in terms of competing technologies or business models, external factors like demographic or economic debates etc. This research finds that for better operationalisation, at least external contextual factors should be separated from internal incentives in the TIS.

In addition to Bergek et al.(2008) and Hellsmark and Jacobsson's (2009) frameworks, this research has also operationalised a similar, and maybe a more simple and visual approach, developed by Hekkert et al. (2007) and named "motors of innovation" . As discussed in section 5.6, motors of innovation represent similar performing functions together with the factors that support strong or weak motors. For example, figure 5-7, shows how expectations on mHealth to solve healthcare inefficiencies together with market opportunities raised by the potential of the technology, have created a strong motor in the TIS in the functions: *knowledge development*, *entrepreneurial experimentation* and *resource mobilisation*. However, divergent interests among key actors, technology-push orientation of the mHealth solutions, or different organising visions have created a weak motor in the functions: *legitimation*, *market formation* and *influence on the direction of search*. Although the analysis of motors of innovation doesn't solve the limitations of functional analysis outlined above, it provides a more visual tool to analyse the dependencies between functions in the TIS.

This research finds that, as Hekkert et al.(2011) contend, a good performance of "knowledge development" and "entrepreneurial experimentation" functions are a pre-requisite to building legitimacy. However, this condition might not be sufficient to form a strong motor of innovation around legitimation if, as in the case of mHealth, divergent interests, visions or beliefs exist.

This research finds that although it is not expected that all actors share the same visions and expectations on the technology (function "influence on the direction of search"), a certain level of alignment is a pre-requisite for a successful legitimation. This research finds that the *organising vision* concept (Swanson & Ramiller, 1997), represents a good tool to assess the level of convergence/divergence of the different visions in the TIS. As an example, in the mHealth case study actors were asked about their visions on the main use of the technology, its main benefits, degree of disruptiveness etc. The results show that the different groups of actors have contested discourses on the potential and best use of the technology. As an example of two contested visions, data reveals that whereas technology firms and policy makers envisage mHealth as a breakthrough innovation capable of solving existing healthcare problems, incumbent healthcare firms and healthcare practitioners, on the other hand, perceive mHealth as an incremental innovation useful to improve existing healthcare pathways. The following proposition can therefore be formulated:

P.7: Aligned organising visions among key actors in the TIS enable legitimation.

6.3.4 Findings and propositions regarding legitimation dynamics and strategies

As previously discussed, this research finds that legitimation is the result of the deliberate actions of system builders across different institutional contexts. As reflected in proposition 1, system builders will typically orientate their early actions towards institutional contexts where they perceive legitimation can be attained more readily.

In addition to contextual factors, this research reveals the importance of pragmatic legitimation (Suchman, 1995). As introduced in section 2.6.3, Suchman (1995) classifies legitimacy into three types: pragmatic, moral and cognitive (See table 4-4 for a description of Suchman's types and subtypes of legitimacy). However, pragmatic legitimation has been ignored by many scholars in organisational studies (Scott, 1995; Aldrich & Fiol,1994; Zimmerman & Zeitz ,2002), as well as in the TIS literature (Bergek et al., 2008b; Markard et al., 2016). Data analysis reveals, aligned to Suchman's (1995) postulations, that adopters need to identify an appropriable benefit in the innovation before they perform further moral or cognitive evaluations. In consequence, building pragmatic legitimacy is a pre-requisite for the legitimation of a TIS. As an example, CFD adopters could see important benefits in the adoption of the technology, like cheaper and faster product development cycles. Contrary to this, in the mHealth case, most of the blocking factors detailed in table 5-4 like: technology-push orientation of mHealth, contested organising visions, or divergent interests, have their roots in the lack of perceived pragmatic legitimacy by adopters (healthcare professionals) and to some extent, for incumbent healthcare firms. Therefore, the following proposition is formulated:

P.8: Building pragmatic legitimacy, in form of appropriable benefits for adopters, is a pre-requisite for the legitimation of a TIS.

As well as pragmatic legitimacy, positive moral evaluations of the technology are a requisite before cognitive legitimation can be acquired (Suchman, 1995; Laïfi & Josserand, 2016). This study evidences the influence of leadership in building moral legitimacy. This research finds that system builders' reputation contributes to building moral legitimacy during the early phases of the TIS. As discussed in section 4.6.1 and shown in table 4-4, personal legitimacy is a subtype of moral legitimacy (Suchman, 1995) related to the charisma and reputation of the leaders. Personal legitimacy in this research is exemplified in Professor Brian Spalding. On the other hand, the mHealth case study also reveals the importance of system builders' reputation in building moral legitimacy. As discussed in section 5.5.2, one of the factors leading to Mersey Burns becoming the first mHealth app certified in the UK, is the reputation, as a plastic surgeon, of his creator and the endorsement of the app by the Plastic Surgeons Association. Aligned to this, the majority of experts participating in the mHealth study contended that in a highly institutionalised context such as healthcare, moral legitimacy is also built through the positive evaluation of the procedures, practices, norms and resources employed by system builders. As table 4-4 illustrates, this type of evaluation corresponds to the procedural and structural subtypes of moral legitimation.

As a consequence, the following propositions are put forward:

P.9: Building moral legitimacy is a pre-requisite for the legitimation of a TIS.

P.9.1: System builders' reputation and positive evaluations of procedures, norms and resources contribute to build moral legitimacy.

This research provides new insights on the inducing and blocking mechanisms for pragmatic, moral and cognitive legitimacy. As shown in tables 4-5 and 5-4, legitimation mechanisms can be technology and knowledge related, or associated to organisational, institutional or leadership factors. Some of these mechanisms have already been covered in the course of the previous discussions. The next two propositions add two important levers that contribute to legitimation building.

Data analysis evidences, as shown in table 5-4, that providing evidence on TIS capabilities contributes to building pragmatic, moral and cognitive legitimacy. This research finds that whereas shared expectations on technology contribute to attract actors and investment (Bergek et al., 2008a; Borup et al., 2006), they need to be contrasted with high quality evidence to avoid recurrent disappointments that can result in a damage of credibility (Brown & Michael, 2003), and in consequence, in a loss of moral legitimacy.

The arguments presented above lead to the formulation of the following proposition:

P.10: Contrasting expectations on TIS potential with evidence, contributes to creating pragmatic, moral and cognitive legitimacy.

Aligned to the above discussion, this research finds that ***co-creation of knowledge*** (Lusch et al., 2007; Kristensson et al., 2008) is a critical lever for system builders to build pragmatic, moral and cognitive legitimacy. Developing knowledge involving potential adopters contributes to develop a technology that can better solve their problems. This increases pragmatic (subtype influential) legitimacy (Suchman, 1995). Showing the capabilities of the technology also contributes to building pragmatic legitimacy, as the relative advantage of the technology (Rogers, 2003) can be demonstrated and adopters can perceive the appropriable benefits. Moreover, trialability and compatibility (Rogers, 2003) are enhanced, and with this, moral and cognitive legitimacy. Examples of co-creation of knowledge are found in the analysis of Phoenics, the multi-purpose code developed by Professor Spalding, and Mersey Burns, the first mHealth certified app in the UK.

A new proposition can be put forward:

P.11: Co-creation of knowledge is critical to building pragmatic, moral and cognitive legitimacy.

As discussed, this research suggests that the dynamics to create a new order of things can be a long process, that starts with selective legitimation on "aligned" institutional contexts that act as niches of innovation. From this point, different trajectories might occur, depending on the characteristics of the institutional contexts where the TIS needs to be legitimated. If the remaining institutional contexts do not present high barriers, legitimation will most likely succeed by imitation, as described in epidemic models like Rogers' (2003). However, this research suggests that for trajectories faced with reaching complex institutional contexts, the process will be much longer and complicated. Under these circumstances, system builders are more likely to act collectively with other key actors like incumbent firms. As contended in proposition 6, the latter will mobilise their capacities and resources to build legitimacy towards a trajectory that can preserve their competitive advantage. Should this succeed, the TIS will legitimate and eventually transition from the formative to the growth phase.

System builders and other key actors will accomplish different actions to align technology to the different institutional contexts. Suchman (1995) and Zimmerman and Zeitz (2002) propose four main strategies, as examined in sections 4.6.3 and 5.5.3. These strategies can be summarised as: (i) ***conform*** to the needs of existing audiences and their institutional contexts, (ii) ***select*** audiences and institutional contexts that will better support the novelty, (iii) strategies to ***manipulate*** institutional contexts to create new audiences and legitimating beliefs, and (iv) ***creation*** of new institutional contexts that did not exist.

This research finds, aligned to Suchman (1995) and Zimmerman and Zeitz (2002), that realistic strategies are a combination of conformation, selection, manipulation and creation. For example, as discussed in section 4.6.3, CFD system builders created a new institutional context for CFD including norms, standards, best practices etc. The majority of the formal rules of CFD were developed by ERCOFTAC, a consortium formed by CFD experts, system builders and industrialists. This new institutional context conformed to the different industrial norms. In addition, CFD legitimation processes also followed a selection strategy, as system builders selected audiences among industries where they already had a good reputation (personal legitimacy) due to previous collaborations. As discussed in section 5.5.3, the mHealth case study suggests that in complex institutional contexts, as in clinical healthcare, initial legitimation will more likely succeed by strategies in the conformation-selection space. This research has not found so far, any evidence of successful "creation" or "manipulation" strategies for mHealth, neither through the analysis of primary data or through an exhaustive search on mHealth literature. Although manipulative or creation strategies might be present in the future, data suggests, as previously argued, that early successful strategies are those that conform with existing healthcare institutions or select niches where mHealth can better fit into existing institutional arrangements.

From the above discussion, a final proposition can be formulated:

P.12: TIS legitimation will come along as a combination of conformation, selection, manipulation and creation strategies. In institutional contexts with high constraints, early legitimation strategies will more readily succeed within the conformation-selection space.

This last proposition links with proposition 1 (P1) and reinforces the idea that system builders might typically start legitimating in "aligned" institutional contexts where technology can more easily fit into existing institutional settings.

The next section provides the reader with a framework, illustrating how the propositions developed in this section can contribute to unfold the underlying dynamics of TIS legitimation.

6.4 Legitimation framework for Technological innovation systems

As discussed in the previous section, the results from this research have enabled the development of a framework that attempts to illustrate the dynamics and mechanisms that contribute to building legitimacy in a TIS. This framework, as depicted in figure 6-1, is grounded on previous research in the TIS field (Bergek et al., 2008b; Jacobson & Hellsmark, 2009; Bergek et al., 2015; Markard, 2016), legitimation organisational studies (Suchman, 1995; Zimmerman & Zeitz, 2002) as well as in the propositions developed as a result of this study and presented in the previous section.

The proposed framework uses the notion of ***institutional context*** as discussed in section 6.3.1. Technological innovation systems are located in broader environments or contexts formed by institutional structures, actors etc. (Bergek et al., 2015). These contexts form areas of higher order at different levels: geographical, sectoral, technological etc. As Markard et al. (2016, p.333) contend: ***contexts*** *"exhibit some degree of institutional coherence as they are characterised with a host of regulations, organisational practices, user expectations, beliefs etc.".* Similar to the socio-technical regime concept (Geels, 2005a) discussed in section 2.5.1, contexts can be described "*as large sets of semi-coherent institutional and technological structures that affect (and often hinder) emerging technologies due to a rigid institutionalisation of their core structures.*" (Markard et al., 2016, p. 333).

As Bergek et al. (2015) contend, the distinction between sectoral, regional, technological or political contexts might be difficult, and to some extent artificial, in empirical research. As presented in section 6.3.1, data analysis in this research suggests a close relation between the legitimation and three external structures: (i) the development of related TIS (technological context), (ii) landscape factors (political context) and (iii) institutional contexts. This research defines institutional contexts as a coherent set of formal and informal institutions like values, beliefs, norms, industrial standards, regulations, technological paradigms etc. Institutional contexts can overlap between regional, sectoral or political dimensions.

Figure 6-1 presents the legitimation framework illustrating main interrelated dynamics. As proposition 1 contends (**P1**), legitimation will initiate with system builders tactically selecting institutional contexts where they perceive legitimation can be more readily attained. As discussed in section 6.3.1, examples of these "favourable" institutional contexts can be: (1) organisations or sectors where the TIS or system builders' general structure[29] does not represent a big clash with respect to the existing institutional arrangements (**P4.2)**, (2) geographical regions with non-rigid regulatory frameworks or, (3) market segments with low entry barriers or no substitute products for the TIS etc. These initial institutional contexts act as "niches" for legitimation. The concept of niche in this framework, is similar to the one developed by Geels (2005a). In both cases, niches represent spaces "that allow nurturing and experimentation with the co-evolution of technology, user practices, and regulatory structures." (Schot & Geels, 2008, p.538). However, they differ in the sense, that in the present framework, niches are mainly developed by system builders as plausible opportunities and not necessarily nurtured and protected, as in Geels' theory, by policy structures.

This research finds that developing pragmatic legitimation, is crucial to reach more adopters and legitimate in wider institutional contexts. This framework suggests that system builders will enhance pragmatic legitimacy if the expectations on the technology are contrasted with evidence of quality **(P10),** and knowledge is developed involving technology adopters through a co-creation of knowledge paradigm **(P11).** In addition, system builders should also work in the alignment of the different organising visions within the TIS (proposition 7) **(P7).**

The evolution of TIS legitimation from niches to wider contexts will largely depend on the institutional constraints in the remaining contexts. If the remaining institutional contexts

[29] See section 6.3.1 for a definition of system builders' general structure

do not present high barriers, legitimation will most likely succeed by imitation as described in epidemic models like Rogers' (2003). On the contrary, if as figure 6-1 shows, the TIS needs to gain legitimacy in complex institutional contexts presenting high constrains (see institutional contexts 5 to 11 in figure 6-1), system builders will most likely form alliances with larger or incumbent firms **(P6)**. As a consequence, the latter will mobilise resources and capabilities, sometimes taking late entrant advantage, towards a trajectory that can better sustain their business models and competitive advantage **(P5).** In this transition, pragmatic and moral legitimation will still be critical to gain legitimacy. Therefore, propositions 8, 10 and 11 **(P8), (P10) and (P11)** also apply to complex institutional contexts. Moral legitimacy, as contended in proposition 9.1 **(P9.1),** will more likely emerge through the evaluation of procedures, norms, firms' resources and structures of the incumbent firms.

Aligned to TIS literature (Bergek et al., 2008b; Bergek et al., 2015; Markard et al., 2016), this framework acknowledges that the development of related TIS **(P2)** (technological context) and landscape factors in the form of public debates, political agendas etc. **(P3)** (political context) contribute to reinforce the TIS and build legitimacy. However, as contended in proposition 3 **(P3),** positive moral evaluations of the TIS as a consequence of societal or political debates will might not be sufficient to build legitimacy if adopters do not perceive an appropriable benefit (pragmatic legitimation).

Finally, as proposition 12 contends **(P12),** the process of legitimation is one that combines different strategies in the spectrum conformation-selection-manipulation and creation (Suchman, 1995; Zimmerman & Zeitz, 2002). As an example, legitimation in niches with favourable conditions (P1) is a selective strategy. The final aim of co-creation of knowledge is to conform to adopters' needs and norms. Manipulative strategies to change institutional contexts in favour of the TIS will typically require lobbyist actions of networks. However, in highly institutionalised contexts, early strategies will more likely succeed if they remain in the conformation-selection space.

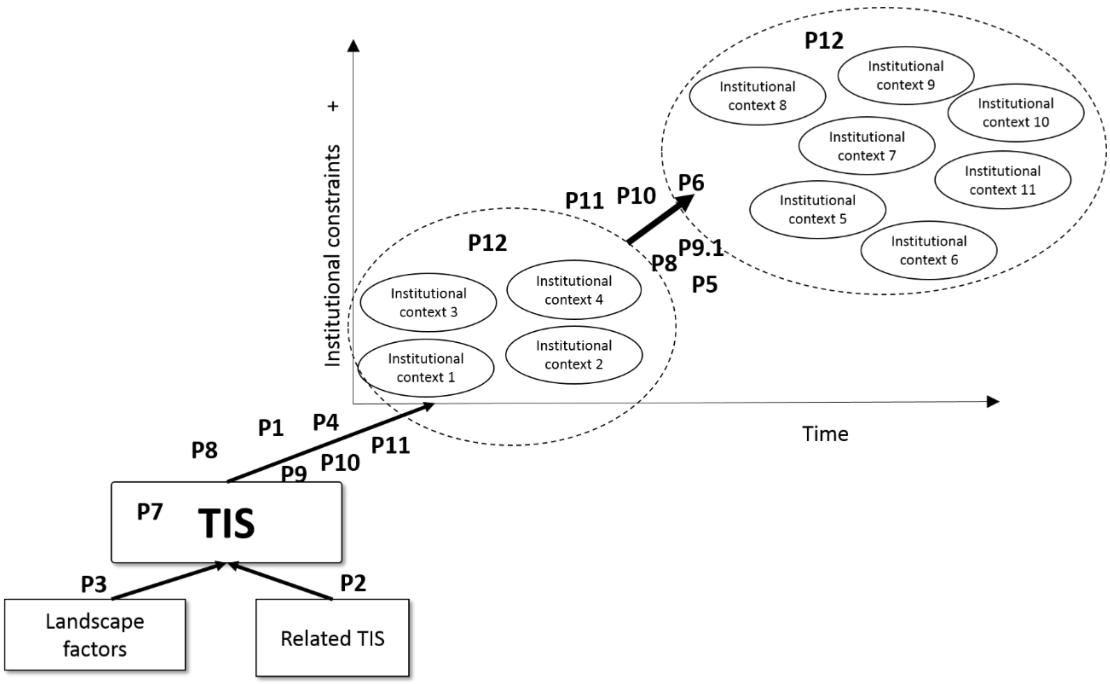

Figure 6-1 TIS Legitimation dynamics. Developed by the author

6.5 Research contributions

This thesis makes a contribution to theory, methodology and practice. On the theory side, it contributes to systems of innovation studies, by offering a broader understanding of legitimation in technological transitions. As discussed in section 2.7, despite its criticality, the process of legitimation of new technologies has been largely ignored in systems of innovation studies. This research presents a set of propositions and a framework that contribute to understanding the underlying mechanisms of legitimation. It also provides findings that challenge existing perspectives on innovation, like the role of public debates and political agenda, the importance of pragmatic legitimacy and co-creation of knowledge or the dynamics of competition and collaboration led by incumbent firms.

In addition to theoretical contribution, this thesis also contributes to systems of innovation methodologies, as it validates the principles of TIS for technologies outside the energy sector.

Finally, on the practical side, it provides applicable insights and recommendations for innovators and policy makers.

The next sections present an in-depth discussion of the contributions made by this study.

6.5.1 Contribution to theory

As contended by TIS scholars (Bergek et al., 2008b; Hellsmark, 2010; Markard et al., 2016), legitimation, despite being a critical function for the transition of TIS into the growth phase, has been largely ignored in the Systems of Innovation literature. There is a paucity of empirical research on TIS legitimation, with the exception of the recent study by Markard et al. (2016).

The overall theoretical contribution of this thesis, is a new framework illustrating the dynamics and mechanisms that influence TIS legitimation. This framework can be incorporated into the TIS literature strand, in addition to the recent study by Markard et al. (2016). A more detailed analysis on the theoretical implications of the framework, point to additional contributions to TIS studies, socio-technical transitions and theories of innovation and firms' competition. These are discussed in the next paragraphs and a summary is presented in table 6-1.

The first contribution of this thesis relates to the contextual aspects of the legitimation process. Recent TIS research acknowledges the influence of external contexts (geographical, institutional, sectoral etc.) in the evolution of a TIS. However, as contended by Bergek et al. (2015, p.52): "*we still lack a coherent framework that makes explicit how the interactions between a TIS and its contexts can be conceptualised.*" In the words of Markard et al. (2016, p.333): "*Which of the context elements matter for a focal technology has to be determined empirically.*"

As presented in section 6.4, this thesis proposes a framework centred in institutional contexts to understand TIS legitimation dynamics. The framework illustrates how during the early phases of a TIS, system builders will strategically select institutional contexts where they perceive legitimation can be more readily attained. For example, system builders will more likely look for contexts with lower regulatory barriers, with no substitute products for the TIS or institutional contexts where the innovation does not entail a large clash with respect to the values, norms and beliefs of those institutional contexts.

The second theoretical contribution of this thesis is the incorporation of pragmatic legitimacy into the TIS legitimation analysis. This research, extends the work of Suchman (1995) for the legitimation of new industries, by evidencing that system builders need to build legitimacy along 3 axes: pragmatic, moral and cognitive legitimacy. Moreover, as postulated by Suchman (1995), cognitive legitimacy represents the last step in the legitimation process: once cognitive legitimation is acquired, the innovation is taken for granted and incorporated into the beliefs and routines of adopters. As discussed in the literature review chapter, different branches of socio-technical studies define similar *closure* processes. For example, Bijker (1997) defines closure/stabilisation as the final stage where the technology is accepted by all the relevant social groups in its final layout. Similarly, Actor Network Theory (Callon & Latour, 1981) define closure as a process that results in artefacts that are given for granted and become irreversible. More recently, Markard et al. (2016), refers to *framing* as the process involving the generation of new interpretive frames and shared meanings through the intentional actions of actors. Suchman (1995) contends that legitimation becomes more difficult to obtain as one moves from pragmatic, to moral and to cognitive. Consequently, pragmatic and moral evaluations are a pre-requisite to building cognitive legitimacy and taking for granted the innovation. The pragmatic dimension of legitimation has been largely ignored by organisational and TIS studies. While different institutional and organisational studies on legitimacy, see Scott (1995), Aldrich and Fiol (1994), Zimmerman and Zeitz (2002), have generally analysed the cognitive and normative dimensions of legitimation, they've omitted the importance of pragmatic legitimation. In the same direction, Markard et al. (2016) distinguish between cognitive, normative and regulatory legitimacy, and neglect pragmatic legitimacy. This research finds that ignoring pragmatic legitimacy hinders the confronted interests and to some extent, the politics within the TIS. This aspect, as discussed in the literature review chapter, is one of the main criticisms of TIS construct (Jacobsson & Bergek,2011; Meadowcroft, 2011; Kern, 2011; Kern, 2015; Bergek et al., 2015; Markard et al., 2016). Therefore, this thesis suggests the incorporation of pragmatic legitimation in future TIS studies.

The third contribution to TIS studies, is the consolidation in a framework of a set of levers that contribute to building legitimacy. For example, the study unveils factors like system builders' reputation, alignment of different organising visions, contrasting expectations with evidence or the criticality of co-creation of knowledge as opposed to technology push solutions or technological solutionism.

The fourth contribution to legitimation studies, comes as a consequence of the theoretical implications regarding the relevance of pragmatic legitimation in the field of socio-technical transitions. Geels (2005a) contends that "landscape pressures" like societal problems or public debates can trigger technological change. Aligned to this, Markard et al.(2016) in their recent study on TIS legitimation, contend that legitimation can be positively (or negatively) influenced by problems at societal level. This research contributes to this strand of studies by suggesting that, although public debates and societal problems contribute to building (or destroying) moral legitimacy and mobilise resources around an innovation, they are insufficient if pragmatic evaluations on appropriable benefits of the technology cannot be demonstrated to relevant audiences like potential adopters, investors, incumbent firms etc.

In addition to the above discussed contributions, this thesis questions the attackers' advantage positions postulated by different theories of innovation and firms' competition. Most well-known theories of innovation and firms' competition, postulate the creative destruction of incumbent firms and industries as a consequence of discontinuous technological change (Anderson & Tushman, 1990; Christensen, 1997). They argue that "competence-destroying" or disruptive innovations give an attacker's advantage to entrant firms and leave incumbents vulnerable to these attacks. This thesis, aligned to Bergek et al. (2013) findings, evidences that these theories: "*overestimate the ability of new entrants to destroy and disrupt established industries and underestimate the capacity of incumbents to perceive the potential of new technologies and integrate them with existing capabilities.*" (Berget et al., 2013, p. 1210). In particular, as discussed in the previous sections, this thesis finds that incumbent firms simultaneously compete and collaborate with entrants during the formative phase of the TIS. Moreover, incumbents become critical for the legitimation of the TIS in complex institutional contexts.

Table 6-1 Main theoretical contributions. Developed by the author

Theory/studies	Contribution	Extent of contribution
Technological innovation systems **(Carlsson and Stankiewicz, 1991; Bergek et al. 2008b; Bergek et al., 2015; Markard et al., 2016)**	Legitimation as a contextual process	This study confirms and extends the understanding of legitimation as a critical contextual process for the transition of formative to growth phase in a TIS.
	Pragmatic legitimation dimension	This research adds important insights to TIS legitimation by evidencing the criticality of pragmatic legitimacy and incorporating it into the TIS analysis.
	Mechanisms of legitimation	This study adds new insights to existing literature on TIS legitimation dynamics by proposing a framework on the mechanisms that contribute to build legitimacy.
Sociotechnical transitions **(Geels, 2005a; Markard, 2016)**	Influence of landscape pressures (societal and public debates)	This study adds new insights to the influence of societal and public debates in technological transitions, by suggesting that landscape pressures might not be sufficient to build legitimacy.
Theories of firm competition **(Anderson and Tushman, 1990; Christensen, 1997)**	Role of incumbent firms Competition and collaboration	This study suggests new insights to theories of firm competition, by evidencing the coexistence of collaboration and competition dynamics led by incumbent firms. It confirms the analysis done on this respect by Bergek et al. (2013).

6.5.2 Contribution to methodology

This thesis has explored the operationalisation of different TIS constructs such as, the analytical framework by Bergek et al.(2008a), the motor of innovations approach (Hekkert et al., 2007), and the framework proposed by Hellsmark and Jacobson (2009). The findings in the operationalisation of these frameworks, generate a number of contributions to the methodology of TIS that are discussed over the next paragraphs.

The first contribution relates to the validity of TIS constructs beyond the field of the energy sector. With probably the only exception of Kukk (2016), Kukk's et al. (2016) studies on Herceptin[30] and personalised cancer medicines, empirical studies in the TIS field relate to technologies in the energy sector. This thesis validates the principles of TIS for technologies outside of the energy sector, through the exhaustive operationalisation of TIS constructs for two very different technologies: CFD and mHealth.

As discussed in the literature review chapter, TIS analysis has traditionally taken a meso-level perspective in the analysis of system functions, as a way to explain innovation failure and draw policy recommendations (Hekkert et al., 2007; Bergek et al., 2008a; Bergek et al., 2008b). However, more recent TIS research has also incorporated micro-level analysis, to study the influence of the actions of system builders in the development of TIS structures and institutional alignment. See for example the studies of Hellsmark and Jacobsson (2009), Hellsmark (2010), Musiolik and Markard (2011) or Kukk et al. (2016). This research evidences that an analysis centred on system builders provides richer results to unfold TIS dynamics, particularly when looking at the dynamics surrounding different institutional contexts. Therefore, this thesis suggests the inclusion of system builders' perspectives into TIS analysis and concur with recent criticisms of TIS scholars on the limitations of analysis purely based on functions' frameworks (Bergek et al., 2015).

This research finds that the identification of system builders might present difficulties, particularly in non-retrospective studies like the mHealth case study (chapter 4). This thesis

[30] Herceptin is an antitumoral drug developed by Hoffman la Roche group and initially targeted at aggressive breast cancer.

points to this aspect as a limitation of current TIS methodology and suggests further empirical research to elaborate new methodologies in the identification of TIS system builders.

Finally, this research agrees with Bergek et al.(2015) in considering the setting of TIS boundaries as a potential analytical problem in TIS studies. This particularly applies to the identification of what remains inside the TIS and what is part of the external context structures. Moreover, this research suggests that TIS frameworks, like Bergek et al. (2008a) and Hellsmark and Jacobsson (2009), should be updated to include the analysis of context structures, currently only covered in part by the function "Development of positive externalities".

6.5.3 Contribution to practice

This thesis explores the dynamics and mechanisms leading to innovation legitimation. The topic is of central relevance not only to innovation scholars, but also to involved practitioners like policy makers, system builders and firms. They can benefit from a set of propositions and a framework that can be of practical value in the development of strategies and policy actions towards the development of BTIs.

An important practical benefit of the framework is its focus on the interactions between the TIS and its contexts. As Bergek et al. (2015) contend, providing a framework based on contexts improves TIS as a policy tool and increases the awareness among practitioners that technologies develop differently in different contexts. As a consequence, it allows the identification of more favourable opportunities for the development of new technologies.

As an example, system builders can optimise the entrepreneurial experimentation function by selecting favourable institutional contexts with lower levels of competition or institutionalisation. Moreover, this thesis provides a set of actions that contribute to developing pragmatic, moral and cognitive legitimacy. Chief among them is co-creation of knowledge. Should system builders develop knowledge following the precepts of co-creation of knowledge, they will have more chances to legitimate in a larger number of institutional contexts.

Additionally, this research provides insights on the factors that contribute to the development of system builders' transformative capacity. As shown in figure 4-5 in section 4.3.3, in addition to co-creation of knowledge, organisational, institutional and leadership factors influence their ability to develop TIS institutional processes and institutional alignment.

Policy makers, on the other hand, can also benefit from the insights and results of this thesis. They are, together with system builders, key actors during the formative phase of technological innovations. Their role is critical to mobilise resources and facilitate the creation of collaborative spaces where knowledge can be developed and actors' visions aligned in a similar manner to the initiatives led by the European Commission during the elaboration of the Code of Conduct. The proposed framework will help policy makers to identify frictions and misalignment in involved contexts and provide them with a set of tools that will contribute to reducing misalignment.

6.6 Limitations and future research

This thesis has explored important non-studied areas on innovation legitimation that, as discussed in the previous section, offer significant contributions to theory, methodology and practice. Moreover, they pave the way for further research pointing to the same central topic. However, this study, as most research in the social science domain, entails certain limitations. The most important ones, are highlighted below.

The first limitation relates to the scope of this research. The results and conclusions of this thesis are valid only for BTI's developed by system builders or entrant firms. As in the majority of co-evolutionary studies of innovation, this research presents certain *Schumpeterian bias* in placing entrepreneurs at the core of the innovation process. However, this bias doesn't necessarily imply that this thesis neglects the role of large incumbent firms as potential creators of BTIs. As discussed in sections 5.2.3 and 5.5.1, this research acknowledges, in alignment with

Bergek et al. (2013), that incumbent firms operating in well-established sectors can also develop BTI's as a result of their internal capabilities.

From a methodological perspective, the main limitation of this research relates to the reliability and validity of the obtained results and in particular, to the *external validity* and the generalisation of the results beyond the context of each presented case study (Bryman, 2012). As discussed in section 3.7 of the methodology chapter, whereas some scholars have criticised the use of case studies to generate theory (Tellis, 1997), others like Yin (2003), Williams (2000) or Eisenhardt (2007), consider case study a valid methodology, as the aim is to engage in a theoretical analysis from rich and in-depth data examination. In any case, this research has accomplished a number of countermeasures to minimise potential reliability and external validity weaknesses.

Firstly, during the research design phase, case studies were carefully selected to represent two opposing poles with respect to legitimation: whereas for CFD technology legitimation occurred smoothly, mHealth for clinical use was well known for being a field full of market and regulatory constraints that prevented acceptance and further adoption. Moreover, CFD represents a unique case to analyse and compare two different organisational and institutional contexts, Los Alamos National Laboratory and Imperial College, that despite having developed the same technology at the same time, took very different trajectories in the transformation of scientific knowledge into commercial innovation.

Secondly, in addition to the selection of case studies, validity and reliability weaknesses have been countered by using TIS theory and TIS analytical frameworks as a starting point for data analysis, as well as by binding emergent themes to most recent research in the field and additional literature in other related fields (Eisenhardt, 1989).

Thirdly, the interpretative nature of qualitative analysis, poses the question of whether researcher's preconceptions, experiences, values or relationships with participants represent a bias to research results. To minimise author's bias, the researcher has followed a number of best practices to maximise trustworthiness and credibility, in line with those proposed by Lincoln and Guba (1985). These include clear and robust research design and case selection, as previously discussed, triangulation of interviews with document analysis and participant observation, the supervision and counselling by an experienced researcher as well as member check techniques both during the interviews and also in further post-interview communications. Therefore, although researcher bias represents one of the potential major pitfalls in qualitative research, the author has made every effort to preserve the integrity of the research, and to produce outputs based on evidence that merit credibility among academy and practitioners.

Despite its potential limitations, an important consequence of exploratory qualitative research is the opportunities that open up to extend research. The most immediate opportunity for future research in relation to this thesis, is the testing and refinement of the proposed framework and developed propositions. Such testing should be performed in both similar and different contexts to keep deepening the understanding on innovation dynamics and legitimation mechanisms. In particular, future studies could look in the following directions:

i. Refined definition of institutionalisation constraints. This thesis highlights a number of institutional constraints that influence the legitimation of TISs, like the existence of substitutive products or the clash between innovation producers and innovation adopters' institutional contexts. However, a more specific map of constraints would be highly beneficial to theory and practice. In particular, further empirical research exploring the dynamics in the creation of new business models would be very relevant.

ii. Impact of the alliances between system builders and incumbent firms on innovation trajectories. As discussed, this thesis evidences that alliances between system builders and incumbents contributes to the legitimation of TISs in complex institutional contexts. However, at the same time, these alliances form an asymmetric relationship that often strengthens the power of the larger partner (Kukk, 2016). Different experts participating in this thesis acknowledged that market takeovers by incumbent firms as a consequence of these alliances, blocked the development of further innovations in the field. Further research could take this track to analyse the impact of alliances on later innovation trajectories.

iii. Further insights of co-creation of knowledge. Due to the relevance of the co-creation of knowledge revealed by this study, the researcher suggests additional research on the co-creation of knowledge paradigm (Lusch et al., 2007; Kristensson et al., 2008) with the aim of identifying best practices and limitations, particularly for BTIs where direct involvement of potential adopters might not be plausible.

iv. Finally, as previously discussed in this section, comparative research on the legitimation mechanisms of TISs initiated by incumbent firms would contribute to extend the scope of the framework proposed in this thesis.

6.7 Conclusions

This chapter has summarised the main findings of the research, its contribution and limitations, and has presented a set of developed propositions and a framework illustrating the mechanisms that enable TIS legitimation. With this, the author brings this thesis to its conclusion. The researcher hopes that the contributions made can help to broaden knowledge in the area of systems of innovation and technological transitions, as well as improving the decision-making process of innovation practitioners and policy makers seeking for BTIs' successful diffusion trajectories.

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