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Individual versus collective strategies in system building - The case of point-of-care diagnostics in Germany

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ABSTRACT

Innovative entrepreneurs often need to engage in different system building activities in order to overcome the barriers to successful market introduction of an innovative technology. There is a large body of literature on individual system building strategies by single actors, as well as on the collective nature of system building by different actors. Yet, only limited research has been done into what type of system building activities innovative entrepreneurs undertake individually or collectively, how it depends on their size and resources, and what the trade-off between these different strategies is. This paper shows how firms', choice between individual and collective strategies depends on the availability of resources and the type of system building activity in the point-of-care testing (POCT) sector in Germany. Furthermore, we highlight the role of hospitals as end-user, whose specific needs influence the collaboration strategies of entrepreneurs along the whole value chain of POCT technology development.

1. Introduction

The distinction in the literature between radical and incremental innovations is often related to the knowledge base that is required for the development of the innovation. When a fundamentally new type of knowledge is necessary for the development of an innovation, it is labelled as radical (Freeman, 1994). However, it is not just the large shift in knowledge base that makes it so difficult to develop and diffuse radical innovations, as unlike incremental ones, the producers of radical innovations have to "build an entire system" (Musiolik et al., 2012), i.e. contribute to the build-up of an entire innovation system around new technologies.

On modern industrial markets, the development of new technologies is increasingly taking place in collaboration with external actors (Abrahamsen, 2019). Collaborative alliances are formed between firms from the same industry, including direct rivals that compete in the same markets, and indirect rivals that operate in different market niches (Amir et al., 2019).

Since both – collective and individual system building activities – have their advantages and disadvantages, the trade-off between them is complex. In this study, we will focus on the trade-off between these system building activities and analyse how it depends on the availability of resources and the type of system building activity in question. We have chosen to focus on two variables: first - the availability of resources, and second - type of system building activity.

The literature is not univocal about the effects of resources and skills on firms' system building strategies (Carnes et al., 2016). We know from earlier literature that individual system building can be a major challenge for SMEs as opposed to for large companies (Carnes et al., 2016), which makes collaboration especially important for SMEs (Bengtsson and Johansson, 2014). However, at the same time, collaboration for SMEs with larger firms is often an asymmetric relationship that is difficult to balance and gives the larger partner a power advantage (Gulati and Sytch, 2007; Holmlund and Kock, 1996). Also, as firms choose their collaboration partners, they seem to prefer companies of a comparable or larger size as they are associated with a smaller risk of loss (Bengtsson and Johansson, 2014; Gnyawali and Park, 2009; Zakrzewska-Bielawska, 2015). The coopetition literature suggests that large companies are most capable of individual system building due to their size, availability of financial resources and capabilities and good market presence (Gnyawali and Park, 2011).

Therefore, since SMEs are less able to pursue individual system building activities because of their scarce resources, they have a greater need to do it collectively. The large firms, because of their resources,

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have in parallel the best capabilities (but also fewest needs) to do system building collectively.

Next to size, the second variable that influences whether companies decide to pursue collective or individual strategies depends on the type of system building. Based on the categorisation by Van de Ven (1993) we focus on (i) proprietary activities of firms who carry out R&D activities in areas related to technological innovation, (ii) institutional arrangements that include legitimation (i.e. creation of trust) and governance (i.e. norms, rules and regulations) and (iii) market formation and consumer demand.

In order to study collective versus individual system building strategies, we chose to focus on healthcare sector. The healthcare system faces lengthy and expensive product development times and experiences a call for reducing healthcare costs while improving patient care. These developments, not to mention the global Covid-19 outbreak, have increased the demand for faster development of innovative technologies that would enable medical specialists in hospitals to increase the efficiency and quality of diagnostics. Point-of-care testing (POCT) is "*rapid diagnostic assay that can be performed close to a patient, with the results used to facilitate management of that patient*" (Moore, 2013, pp.1) by significantly reducing the time taken for diagnostics compared to laboratory based testing (Bissonnette and Bergeron, 2010; Larsson et al., 2015). However, there are a number of difficulties in introducing POCT to the market: POCT has very long and resource intensive development trajectories; POCT suffers from a lack of legitimacy amongst users (amongst medical staff); users experience integration difficulties of POCT in the existing infrastructure; It is difficult to provide large complex POCT solutions to hospitals (Bissonnette and Bergeron, 2010; Larsson et al., 2015; Luppa et al., 2011; Palamountain et al., 2012).

Therefore, it is an interesting case to study system building activities by POCT developers and producers. We want to understand how companies operate in such an innovation system in order to overcome the systemic hurdles they face when developing and introducing POCT technologies to hospitals. We specifically focus on POCT in German hospitals, as Germany has the biggest POCT market in Europe of about € 0.9 billion (Junker et al., 2010). This means that POCT companies in Germany have had a good uptake of their products, they have been successful in their system building work and have overcome many of the above-mentioned barriers.

This work leads to new insights in the understanding of collective versus individual system building from the viewpoint of large firms and SMEs and will answer the following research questions:

What kind of collective versus *individual system building strategies can we identify in innovation systems around point-of-care testing innovations? How and why do these strategies differ between large firms and SMEs in different types of system building activities?*

The paper is structured as follows. In Section 2, we review different theories of collective and individual system building. Section 3 addresses the methodology. Section 4 elaborates on the features of POCT and the case description of POCT in German hospitals. Section 5 covers the results of the empirical analysis. Section 6 concludes.

2. Theoretical background

The commitment by innovative entrepreneurs as they dedicate themselves to building up the innovation system around a new technology is called "system building" (Musiolik et al., 2012; Planko et al., 2016). It emphasises the important role of agency and can be defined as: "*the deliberate creation or modification of broader institutional or organisational structures in a technological innovation system carried out by innovative actors. It includes the creation or reconfiguration of value chains as well as the creation of a supportive environment for an emerging technology in a more general way*" (Musiolik et al., 2012, p. 1035) in order to "*address system weaknesses, to reduce further uncertainties and to strengthen the Technological Innovation System (TIS)*" (Hellsmark, 2010a, 2010b, p. 48).

System building can take place either individually or in collaboration. Last one, however, has its risks and disadvantages (Mellewigt et al., 2017). A fast-growing body of literature on coopetition (i.e. simultaneous pursuit of cooperation and competition) (Gnyawali and Charleton, 2018) emphasizes the presence of so called "coopetition losses" that make cooperation undesirable in certain cases (Zakrzewska-Bielawska, 2015). These include, for example, a high degree of interdependence with other firms and the loss of the opportunity to cooperate with other companies due to exclusivity clauses and potential conflicts of interest (Zakrzewska-Bielawska, 2015). Also, in relation to R&D, the risk of knowledge leakage can lead to a loss of control over novel technology (Zakrzewska-Bielawska, 2015). Alternatively, firms can have individual business incentives that can lead to opportunistic behaviour (Ritala and Hurmelinna-Laukkanen, 2009). Therefore, firms often struggle with a dilemma: collaborate and create collective value that is also beneficial for the firm itself, or be opportunistic in order to introduce innovative products to market before other companies and to gain market dominance (Garud, 1994; Gnyawali and Park, 2011). Since both – collective and individual system building activities – have their advantages and disadvantages, the trade-off between these alternatives is complex.

This section elaborates the different theoretical fields relevant to individual and collective strategies of large firms and SMEs in relation to different system building types: (i) knowledge creation and product development; (ii) shaping institutions according to the interests of their technologies and (iii) market formation for novel products.

2.1. Knowledge creation and product development

Innovation and R&D activities in different industries are traditionally viewed in the literature as taking place in-house within a single firm as a strategic asset (Abrahamsen, 2019).

However, during the last decade, the collective nature of R&D and knowledge creation has been emphasized by open innovation scholars (Brunswicker and Vanhaverbeke, 2015; West et al., 2014). As pointed out by Zobel et al. (2017), the main advantage of implementing open innovation would derive from the capability of the company to transform any external resource into a technology-related capability. Positive correlation has been reported between open innovation uptake and industries that are characterised by globalisation, innovativeness, technology intensity and knowledge leveraging (Amir et al., 2019). This also applies to the biotechnology and healthcare industry (encompassing POCT) (Michelino et al., 2015). Open innovation theory emphasizes the importance of cooperation for SMEs as a relevant source of innovation (Brunswicker and Vanhaverbeke, 2015).

However, this approach also has risks for SMEs, as collaboration with larger firms can often be an asymmetric relationship, which gives the larger firm a power advantage over the smaller partner (Gulati and Sytch, 2007; Holmlund and Kock, 1996). Combining resources and know-how enables firms, regardless of their size, to extend their technical competences and to bring new products to market at a faster pace. Despite of potential risks, collaboration in the R&D phase seems to be a vital collective system building activity – especially for SMEs with their inability to fulfil all necessary R&D activities internally.

2.2. Creation of legitimacy

The lack of supporting institutions is another major hurdle for an innovation system's development, because established institutional structures are not always aligned with the needs of novel technologies.

For companies behind novel technologies, the lack of legitimacy (i.e. under-developed cognitive institutions) is especially crucial, (Aldrich and Fiol, 1994) and legitimating strategies undertaken by innovative entrepreneurs take on great importance as established institutional structures cannot be relied upon (Aldrich and Fiol, 1994). The institutional entrepreneurship theory offers a useful tool to provide endogenous explanations as to how these different institutional changes are

carried out in an innovation system (Leca et al., 2008). This suggests that larger firms are more likely to act as institutional entrepreneurs than SMEs (Greenwood et al., 2002).The theory, however, also pays attention to the collective activities of institutional entrepreneurs and considers the process of institutional change as the outcome of activities by a number of *different* actors via collective action (Jolly and Raven, 2015; Leca et al., 2008). Therefore, it is not only one agency with interests (e.g. a large resourceful company), which is associated with changing different institutions, rather it can be the collective action of many different entrepreneurs with different availability of resources (i.e. SMEs).

Literature suggests that a positive image of a new technology (i.e. legitimacy) can be created when collective action is also coordinated – i.e. companies work through associations and networks (Aldrich and Fiol, 1994). In earlier empirical work, Konrad et al. (2012) demonstrated how firms successfully collaborate in networks and industry clusters to increase expectations (i.e. cognitive institutions) regarding emerging clean technologies. These kinds of initial collaborations in an emerging industry often start informally and later on develop into formal networks or industry associations (Powell, 1990). Often these kinds of industry organisations are located in the offices of larger member companies who cover the running costs of associations. Typically, this is done by large, resource-rich firms who are also well represented in association leadership (Aldrich and Fiol, 1994). Consequently, literature suggests that individual action towards institutional change is more likely to occur amongst large companies, due to their availability of skills and resources while SMEs are more likely to be involved in collective action.

2.3. Market creation

For a novel (radical) technology, markets may often not exist or be underdeveloped. Market formation refers to strategies aimed at strengthening the factors driving the diffusion of new technologies (Hellsmark, 2010a, 2010b). The coopetition literature suggests that the choice between individual and collective strategies in a value chain depends on the degree of closeness to customers. Competitors collaborate in activities when they are far from the customer – in the so-called input or pre-competitive activities, such as R&D and production (Walley, 2007; Zakrzewska-Bielawska, 2015).This limits the risks and costs of developing a new technology. At the same time, firms are pursuing more individual strategies closer to customer interaction – for example so-called output activities such as market creation, sales, distribution, and marketing. This distinguishes their products from each other (Walley, 2007; Zakrzewska-Bielawska, 2015). For that reason, regardless of the size of the companies, the market formation process is likely to be the most individual activity of the different system building types. However, SMEs might have an incentive to pursue more collective types of activities in market formation compared to large firms, as they have limited market presence themselves and could consequently benefit from the well-developed distribution networks of large companies (BarNir and Smith, 2002; Kossyva et al., 2014).

3. Methodology

3.1. Case selection

Since system building by innovative entrepreneurs is a complex process, and the literature is not univocal in terms of expected patterns, an exploratory case study methodology was used in this research (Yin, 2003). A single case study enables to test well formulated theories in a specific, often critical case. Therefore, this methodology provides a useful tool to deliver an improved understanding of the strategies and circumstances in which large firms and SMEs engage in system building strategies, either in collaboration or individually.

We chose to focus on POCT companies as an exemplary case regarding the uptake of POCT in German hospitals in the time period from 2005 – when many new POCT technologies entered the market – until 2014, for the following reasons. First, POCT is an example of an important healthcare innovation that presents new practices and testing routines for medical specialists in hospitals (Swan et al., 2007). Second, POCT's innovative features and importance lie in enabling faster diagnostics and therefore faster treatment decisions (Larsson et al., 2015). It is especially important in infectious diseases and in life threatening situations – such as sepsis or blood coagulation – where the speed of medical action in treating the patient is especially important (Bissonnette and Bergeron, 2010).

Hospitals are the fastest growing market of POCT technologies – in comparison to home self-testing or physician's office testing (TriMark, 2013). POCT is mostly used in hospitals' critical care units, emergency rooms, intensive care and operating rooms and cardiac units. German hospitals have been chosen for this analysis, because many factors have supported the general uptake and diffusion of POCT in hospitals in Germany. The overall market size of POCT in Europe was € 3.4 billion (in 2012) (TriMark, 2013). Germany has the biggest POCT market in Europe and has a market value of around € 0.9 billion, corresponding to about 30% of the total German *in vitro* diagnostic market (Junker et al., 2010). Additionally, a large share of Germany's total GDP - around 11.3%, is spent on health (The World Bank, 2014), the country has a strong interest in technologies and establishment on the German market also eases access to Germany's German speaking neighbours – Austria, for example. Additionally, particularly smaller hospitals with only a few hundred beds are under pressure to economise their processes – these hospitals have economic incentives not to run in-house laboratories, but to either outsource laboratory testing, and/or implement POCT (Moore, 2013; John and Price, 2014).

Progress towards realizing the potential of POCT in the hospital setting has, however, been hampered by a number of issues which can serve as disincentives for POCT firms to develop and market innovative POCT technologies (Palamountain et al., 2012). Amongst these barriers are cost and regulation of POCT (Bissonnette and Bergeron, 2010). Moreover, in order to implement this novel technology, changes in cognitive institutions – for example, user practices, habits and routines – are needed in hospitals as POCT tests are used next to patients by nurses and samples do not need to be sent to central laboratories. Since overcoming these barriers requires a lot of resources and skills, we assumed that some kind of cooperation between different POCT companies is taking place to create a market for POCT products. However, POCT companies are at the same time competitors, as they target the same market segments with similar products – for example, all large diagnostic companies like Roche Diagnostics, Abbott and Siemens Healthcare Diagnostics have POCT products on the market for glucose, blood gas, coagulation and cardiac biomarkers testing (TriMark, 2013).

3.2. Data collection

The first step of our analysis was to identify all the relevant structural elements: actors, networks and the institutions of the POCT sector in Germany. To do this we relied primarily on secondary data. Data were collected from 2005 to 2014 by *ex post* facto (i.e. the investigation starts after the fact has occurred) literature review. We were making use of scientific articles - for example professional journals in Medline/PubMed/ISI Web of Science, as well as "grey" literature (diagnostic industry reports, market studies, press releases, policy papers) and various websites – amongst others – online databases[1] (please see Annex 3 for a complete overview), the internet sites of government bodies (BMBF, BfArM),[2] POCT companies, professional groups (diagnostic industry

[1] Examples of databases: LexisNexis database, Funding Database of the Federal Government (http://www.foerderdatenbank.de/).

[2] BMBF (Federal Ministry of Education and Research), BfArM (Federal Institute for Drugs and Medical Devices).

networks and associations, such as: VDGH, DGKL, BVMed)[3] and patient organisations (DDK)[4] in Germany. The search terms were: 'Germany', 'hospital', 'point-of-care/bedside/near patient testing', in combination with different medical indication areas – for example cardiac markers, coagulation, faecal occult, fertility, haematology, infectious diseases.

In order to investigate the role of actor strategies in innovation systems build-up, we conducted semi-structured interviews with carefully selected 13 experts (i.e. persons in manager and senior positions, with a profound knowledge and experience on/in the POCT sector) from German POCT companies, diagnostic industry associations and networks (Annex 1). In total, we identified around 50 POCT companies on the German market, out of which around 90 per cent were SMEs. Our interview sample was purposefully selected, as these interviewees are the key informants in the German POCT innovation system. The majority of interviewees (9) were identified from internet searches of German POCT companies – both large multinationals (4) and SMEs (5). These companies all had a strong presence in the POCT hospital market in Germany and had different POCT products on the market. The remaining four experts were identified through snowball sampling through the criteria of being involved in, or having profound knowledge of, the actor strategies towards diffusion and/or deployment processes of POCT in German hospital settings. The interviewees were either people from the management, marketing or R&D departments of firms developing POCT technologies, coordinators of the industry networks or researchers in an academic organisation. The interviews were conducted in person ($n = 3$) or over the phone ($n = 10$). Interviews lasted on average one hour. To explore the different actor strategies and to understand their actual behaviour and underlying motivation towards individual or collective system building, the interview guide comprised the following sections:

(1) General uptake and market situation of POCT in Germany in general and hospitals in particular;
(2) Collaboration strategies in R&D and marketing activities as they relate to the overall development of the POCT market (including opportunities for new entrants, supportive policy initiatives, technological challenges);
(3) Market approval and regulation of POCT;
(4) Reimbursement;
(5) Identification of the main firms, collaborations and other types of stakeholders involved in the POCT diffusion process; the problems they had encountered while introducing POCT onto the German hospital market and how they overcome these hindrances.

We personalised the interview guide for each interviewee based on their company POCT profile and area of expertise. Information gathered from the interviews was anonymised and was referred to as interview A, B, C, etc. to protect the identities of the interviewees. The interviewed experts were offered the possibility to check the interview transcript for possible amendments and corrections.

3.3. Data analysis

A qualitative event history analysis was carried out to systematically analyse key market creation, R&D and creation of legitimacy processes, essential for POCT sector development in Germany over time and to gain insights into the dynamics of these processes in the German healthcare context.

The event history analysis method has been initially developed by Poole et al. (2000) and Van de Ven (1990) to analyse in a structured way complex data by gathering information as a sequence of different activities that take place over time. An activity can be defined as "the smallest meaningful unit in which change can be detected. Hence development and change can be studied in the sequence of events an entity participates in or experiences" (Poole et al. 2000: p5). In an event history analysis, system-level events were identified that were influential for market creation, R&D and creation of legitimacy of POCT in Germany , and systematically allocated to one of the three system building categories.

4. System building for POCT in German hospitals

The case study concerns system building strategies employed by large POCT firms and SMEs towards a better uptake of POCT in German hospitals. First, we give an overview of the POCT hospital sector in Germany. Consequently, we describe the different collective and individual strategies of POCT entrepreneurs, which fall under different system building types: R&D, creation of legitimacy and market formation.

Laboratory analyses are widely established normative institutions in health care. These analyses are highly used in German hospitals (Luppa et al., 2011), and take place in central laboratories (Goldenberg et al., 2014; John and Price, 2014). Due to the medical need for faster analytical results, there has been a tendency in the German medical community towards utilizing more decentralised diagnostic analysis – POCT (Luppa et al., 2011). Currently in Western countries, almost 70% of hospitals have POCT devices in use for coagulation testing, 38% for blood gases and 24% for haematology (TriMark, 2013). In the future, almost half of all diagnostics could be done through POCT, especially diagnosis of cardiac, coagulation and infectious diseases markers (TriMark, 2013).

The European POCT market is dominated by a few large diagnostic companies (i.e. Alere Inc., Beckman Coulter, Johnson & Johnson, Radiometer, Roche Diagnostics, Siemens Healthcare Diagnostics), who together had a share of more than half of the European POCT market revenue in 2012 (Frost and Sullivan, 2013). The rest of the POCT market is fragmented amongst smaller manufacturers with equally small market shares (TriMark, 2013). A similar pattern can be observed in Germany: approximately 50 companies are active in the POCT market with the majority being high technology SMEs (Interview I): there are approximately 30 companies which have either *in vitro* diagnostic (i.e. carrying out diagnostic testing outside of a living organism in a laboratory) technologies or which are dedicated to POCT, and there are 20 POCT device technology or service providers. In addition, the leading large European diagnostic companies are also active in the German POCT market.

4.1. R&D activities

As POCT devices and assays are knowledge-intensive high-technology products and services, which target the highly regulated health care market, the R&D process is resource and time intensive. It comprises, amongst other things, discovery of new biomarkers, technology development of POCT devices, assay development, integration into hospital data management systems and validation. Since POCT SMEs are often focussed around specific scientific-technical expertise, they face considerable challenges to individually achieve the following prerequisites for successful commercialisation: (i) conformity with the European *in vitro* diagnostic testing Directive and obtaining a CE mark; (ii) compatibility with implemented diagnostic platforms and hospital information management systems; (iii) satisfying customers' demands – for example with respect to performance, usability, and cost-benefit-ratio (John and Price, 2014; Junker et al., 2010). Therefore, POCT SMEs need to collaborate in order to acquire additional skills and resources to develop and introduce novel technologies successfully into

[3] VDGH (Diagnostic Industry Association), DGKL (German Society of Clinical Chemistry and Laboratory Medicine), BVMEd (German Medical technology Association).
[4] DDK (German Diabetes Association).

the market. According to data from the German Public Funding Catalogue (in German: *Förderkatalog*), which lists publicly funded R&D projects in the POCT field, we found that from 2005 until 2014, 26 POCT related R&D collaboration projects have been funded with more than € 50 million (Table 1). As part of this funding, in 2012, the German Federal Ministry of Education and Research initiated the funding programme "Mobile Diagnostic Systems" with a budget of € 17.3 million (BMBF, 2013). POCT SMEs benefit a great deal from public funding: the majority of German POCT SMEs (n= 42) have actively participated in publicly funded projects – receiving around 60% of total funding (Table 1) – and have intensively collaborated with German research organisations (17 out of 26 projects) (Table 2). On the other hand, collaboration between SMEs seems to be a much rarer event. Only 4 out of 26 publicly funded projects were collaborations between SMEs (Table 2). Our search yielded only very few examples of privately funded R&D collaboration in knowledge creation between different smaller POCT companies. One typical example is the collaboration between Abaxis and LambdaGen: these two companies joined forces and shared innovation related risks in developing immunoassays to be detected on Abaxis's POCT device Piccolo Xpress® (PR Newswire, 2013). The public funding programmes offer a good opportunity for SMEs to acquire additional resources and skills for their R&D activities. However, for SMEs, R&D collaboration with large diagnostic firms would be even more beneficial to benefit from the latter's broad skills, resources and know-how (Interview A, C). However, our searches for publicly or privately funded collaborations between large POCT firms and SMEs showed that such collaborations are rare (e.g. multinational diagnostic firms participated only in 4 publicly funded R&D collaboration projects (Table 2)). The search of press releases and market reports gave similar results. We observed that large POCT companies pursue R&D and product validation activities predominantly in-house. According to one of the interviewed company representatives, a large POCT company would never collaborate on assay development, as this is commonly considered in-house knowledge (Interview H). The same person added that

"*…we would not give it to outside companies. We have in-house competence for it, if not we would rather hire someone (than collaborate)*".

It can be concluded that maintaining complete control over know-how and technologies seems to be a major driver for this behaviour. On the other hand, POCT SMEs often offer highly specialised know-how and technologies that are required by large companies but are not available in-house. In these cases, large POCT companies seem to prefer the acquisition of small POCT firms with valuable know-how over R&D collaboration projects. In the highly competitive POCT hospital market, organic growth is often not quick enough for large POCT companies. As hospitals prefer to buy a complete solution from one provider over several providers with limited solutions (Interview E), large companies follow the strategy of acquiring capabilities and products that are already close to market. This allows them to offer a larger product portfolio to their clients and thus increase their competitiveness. As a representative of one of the large POCT companies explained it:

Table 1
Overview of organisations participating in publicly funded research projects in Germany in the period 2005–2014 (data retrieved from the German Public Funding Catalogue, 2015).

	Number	Public funding € (% of the total project funding)	
Funded projects	26	52 Million (100%)	
Funded organisations	79		
	-Large POCT firms	4	1.1 Million (2%)
- POCT SMEs	42	30.6 Million (59%)	
- Research and academic organisations	33	20.3 Million (39%)	

Table 2.
Overview of collaboration activities of POCT companies participating in publicly funded research projects in Germany 2005–2014 (data retrieved from the German Public Funding Catalogue, 2015).

Participating organisations	Number of projects
Funded POCT related research projects	26
Funded project consortiums:	
- Large firms &large firms	0
- Large firms & SMEs	1
- Large firms & research and academic organisations	1
- Large firms & SMEs & research and academic organisations	3
- SMEs & SMEs	4
- SMEs & research and academic organisations	17

"*… first we think whether we can do it internally or do we need to acquire these kinds of capabilities. And then we decide what is quicker, where is time to market shorter? Is it acquisition or organic development, depending on what we already have*" (Interview I).

Alere is a very good example of a large company, which follows such a market formation strategy: in addition to internal R&D, an explicit merger and acquisition strategy has led to their leading position in the Western European market (22.3% of overall European POCT sales) (Frost and Sullivan, 2013). The company has acquired nearly 100 smaller companies over the last few years (TriMark, 2013) and offers a broad POCT product portfolio.

All in all, it can be concluded that, in comparison with POCT SMEs, large firms are less interested in engaging in R&D collaborations, even if there is a financial incentive (e.g. through public funding). Fear of know-how drain and improving their competitive market position by acquisition of SMEs outweighs the benefits of R&D collaboration.

4.2. Creation of legitimacy of POCT

Currently, POCT has several disadvantages in comparison to central laboratory testing. First, there is lack of reliability in the quality of some POCT assays (Interview E). Although POCT companies are responsible for providing the performance data for POCT – according to the German Law on Medical Devices (in German: *Medizinproduktegesetz*) and European standards – it is the responsibility of the user to calibrate the POCT device and check whether the POCT device is technologically up to date (Junker et al., 2010). Hospital laboratory directors are often sceptical about having a POCT system, because the daily calibration of the POCT systems, quality control and documentation means extra work and responsibility (Interview H). Second, POCT causes higher direct costs. However, there are no published cost-effectiveness analyses of POCT available which could show that improved patient outcomes and lower total costs may ensue (Junker et al., 2010; Luppa et al., 2011), or that deal with the regulations on reimbursement of medical services in Germany (Junker et al., 2010). Third, implementation of POCT in a hospital implies that nurses – instead of laboratory staff – will have to operate the POCT analysers. This requires specific training and qualification for ward staff, alterations in work routines in wards and overcoming possibly negative attitudes towards extra work and effort (Interview K). Consequently, evidence-based, reliable information about POCT benefits and the indirect costs of POCT implementation would be needed in order to overcome prejudices and change existing routines:

"*… often, nobody in the hospitals fully realises the whole truth about POCT systems and their potential advantages over laboratory based testing*" (Interview K).

Therefore, POCT firms are actively engaged in providing information aimed at changing cognitive institutions (i.e. testing routines and habits) and gaining legitimacy for POCT in hospitals. According to one of the interviewees:

"*… we explain that the test is much faster and that they can start intervention much faster, you need to talk to the CEO of the hospital that he or she understands that as well. This kind of educational work is always needed*

when you want to launch a POCT at the hospital level" (Interview I).

Usually, to change existing testing routines (i.e. cognitive institutions), service specialists offer face-to-face trainings to ward-staff in how to operate a company's devices and how to take measurements. Training videos for hospital staff are also provided (Interview G, H). These specific device trainings are done by the corresponding manufacturers individually, as, according to German law on medical devices (in German: *Medizinproduktegesetz* and *Medizinprodukte-Betreiberverordnung*), a company is not allowed to train staff for another producer's device (Interview C). On the other hand, a number of POCT companies are collectively involved in the provision of training courses specifically targeted at POCT coordinators/managers. These trainings focus on the management and regulatory issues of POCT implementation in a hospital (Interview H).

Also, every year there are numerous conferences and events on POCT taking place in Germany. These have the purpose of informing the medical community about new scientific developments and technologies in the POCT field and of giving an overview of the diagnostic solutions that POCT can offer (see Annex 2). One of these annual conferences, called LaborForum, is collectively organised by a group of diagnostic companies in Germany (MCS, Roche Diagnostics, Sysmex, Cepheid and Sarsted) in order to increase the legitimacy of their technologies through scientific information diffusion (Interview E). These events and conferences seem to have positively influenced medical doctors' attitudes towards POCT in hospitals. According to interviewees, medical doctors, unlike ward staff, are more pro-POCT, since, by attending different meetings and conferences, they have more in-depth knowledge about POCT and its clinical benefits, such as faster diagnostic results (Interview K, I). Against this background, a significant contribution to the creation of legitimacy and changing cultural-cognitive institutions is the Directive of the German Medical Association on the Quality Assurance of Tests in Laboratory Medicine (in German: *Richtlinie der Bundesärztekammer* (RiliBÄK)) (Bunderärztekammer, 2015). The German Medical Association represents the interests of more than 470, 000 physicians "*in matters relating to professional policy, and plays an active role in the opinion-forming processes with regard to health and social policy and in legislative procedures"* (Bunderärztekammer, 2015).

The Directive sets standards in laboratory testing and clearly differentiates between POCT and laboratory instrument calibration requirements (Bundesärztekammer, 2008). Another factor which has had a positive impact on POCT legitimacy for a specific medical indication is the recommendation by the Society of Cardiology in Germany, that a medical unit should work with a very short turn-around time (TAT) for patients with chest pain (Frost and Sullivan, 2010). Both the RiliBÄK Directive as well as this recommendation strongly favour the uptake of POCT assays in hospitals.

We know from earlier studies that formal networks and associations can play an important role in shaping innovation systems around new technologies (Musiolik et al., 2012). Therefore, we analysed the activities of POCT related networks and associations in Germany (Annex 2) with respect to the creation of legitimacy for POCT. According to the majority of the interviewed experts, the German Diagnostic Industry Association (in German: *Verband der Diagnostica-Industrie (VDGH)*) – an umbrella organisation for more than 90 *in vitro* diagnostic companies in Germany – has the most important role of all relevant networks and associations of the diagnostic sector. The VDGH organises meetings, sends information out to member companies and harmonises industry comments on different policy issues (Interview A). Examples for POCT-related VDGH activities were active involvement in political discussions on effective ways to control infections by Methicillin resistant *Staphylococcus aureus* bacteria (MRSA). In this case, very rapid POCT diagnostics could have significant health impacts. Using these cases as an opportunity to lobby for POCT in general was initially started by a large member company, and was later expanded on the association level (Interview I).

However, the industry members of VDGH have different interests, and governance structures within the association seem to give an advantage to large companies: On the one hand, small companies face difficulties in actively participating in association activities due to lack of human and financial resources and geographical distance. As one of the company representatives explained it:

"*...I'm invited to one of the groups in Berlin, but whenever they meet, it is for me a two days travel. And this time I'm more into visiting clients and customers ... we are not participating enough in these networking activities, because we do not have the manpower"* (Interview C).

As a consequence, small companies often only participate in networks and associations on regional (in German: *Bundesland*) or local level (Interview B) with less impact. Even if SMEs want to engage in the work of association, they find that:

"... it is not that easy to find a success story for a smaller company regarding (a name of a large association), because it is above all a network of diagnostic industry and it is dominated by few very big players...therefore it is complicated for a smaller company to convince the association in their novel technologies" (Interview L).

All in all, we observe that creation of legitimacy aims at overcoming the perceived and real disadvantages of POCT compared to laboratory testing. While device- and assay-specific education and training is done individually in order to improve skills and change testing routines, companies join forces in order to inform different target groups (hospital decision makers and management staff, companies, medical doctors, policy and administration) about POCT advantages in general, POCT performance und useful applications. However, small POCT companies and their interests are not as well represented in different associations and networks as large firms.

4.3. Market formation

Companies with a strong position on the POCT hospital market are characterised by a broad product/assay portfolio, and by well-established diagnostic platforms on which the different assays are run and which can be integrated into hospital management information systems. Further, they have broad distribution networks with a well-trained sales force able to explain the knowledge-intensive POCT products to customers. The strategic focus on a broad assay portfolio and versatile diagnostic platforms is due to the fact that hospitals prefer to obtain full service from only a few providers.

"*There is a trend towards a single system that almost can do "everything". So, it can do clinical chemistry as well as immunology. The customer does not want 5 different systems, he rather wants 2 systems that cover 90% of his need and has the same interface and then you would not have to train someone for all 5 different devices separately*" (Interview E).

On average, a menu of 70 routine tests is required to cover more than 60% of the needs of hospitals (TriMark, 2013). Therefore, POCT companies try to cover as many different diagnostic fields as possible. For example, Roche Diagnostics offers POCT for cardiac markers, blood gas, coagulation, urine, and glucose testing (see Table 3). In order to also cover haematology testing, Roche has a distribution, sales and service agreement with Sysmex (Roche, 2012). This shows that large diagnostic companies, in addition to the merger and acquisition strategy followed in R&D, are interested in collaboration with other companies if they can broaden their product portfolio. Another option is the acquisition of distribution rights. For example, Axis-Shield bought the distribution rights for POCT from Progen Biotechnik. This deal was part of a comprehensive strategy to set up a distribution network in large POCT markets, such as in Germany (Pharmaceutical Business Review, 2009). Collaboration in market formation can also be a win-win for small companies with an interesting product, but without a strong sales force – if they can distribute their product via the well-reputed marketing network of a large company (Interview E). For example, since 2010, Abbott has an exclusive distribution agreement with Celera to market Celera's KIF6 diagnostic test, in addition to its Viroseq™ HIV system (Celera, 2010; TriMark, 2013). Additionally, Sysmex has distribution

Table 3.
Important POCT companies and their main market segments (Frost and Sullivan, 2013; TriMark, 2013, company websites).

	Cardiac markers	Blood glucose	Infectious diseases	Blood gas	Coagulation	Haematology	Urine analysis
Abbott Laboratories	X	X		X	X		
Alere	X	X	X	X	X	X	
Axis Shield		X	X				
Beckman Coulter						X	
Haemonetics					X	X	
Johnson & Johnson		X					
Orasure			X				
Quidel			X				
Radiometer	X			X			
Roche Diagnostics	X	X		X	X		X
Siemens Healthcare Diagnostics	X	X		X	X		X
Sysmex Corporation						X	X

collaborations with Abaxis, where they either undertake joint visits to clients or distribute each other's POCT products (Piccolo Xpress and pocH-1000i) (Interview C; Sysmex, 2013), and with Eurolyser Diagnostica in distributing the latter's blood gas POCT devices (Eurolyser, 2007).

Central IT systems that gather information from all decentralised POCT devices in a hospital are considered a key factor in successful POCT implementation and market formation in hospitals (Luppa et al., 2005). Therefore, software for POCT devices must be compatible with hospital management IT systems. This requires collective system building activities in reaching a common standard. In response to market demand, there has been a strategic shift amongst IT system providers – from closed systems to opening them up for devices from other companies (Interview G). Examples are Roche's Cobas IT 1000 System and Radiometer's Acquire POC Data Management System (Interview E).

It can be concluded that, in market formation activities, there is a high degree of collaboration between POCT companies that is driven by different needs and interests. Smaller companies with an interesting product, but without a strong sales force are interested in collaboration to distribute their product via the well-reputed marketing network of a large company. At the same time, large firms are interested in collaboration with other companies if they can broaden their product portfolio. This is due to the specific demands of hospitals as a customer group – hospitals are interested in one complete testing system from one provider to simplify the management of diagnostic processes.

5. Analysis

We will now take a closer look at our empirical and theoretical findings to answer the research questions: *What kind of collective* versus *individual system building strategies can we identify in innovation systems around point-of-care testing innovations? How and why do these strategies differ between large firms and SMEs in different types of system building activities?*

5.1. Market formation

We observed that strong collective system building activities of POCT companies are present in the market creation phase (Table 4) – even though, based on the earlier works, it was initially assumed that collaborative efforts are fewer in the marketing phase in comparison to the R&D phase or even that the market formation process is likely to be the most individual activity of the different system building types, regardless of their size (Walley, 2007; Zakrzewska-Bielawska, 2015) (Table 5). A very strong collaborative trend in the marketing phase can be explained by the specific characteristics of hospitals as customers for POCT products: Unlike individual customers, hospitals require full solutions from their providers. Currently companies are not able to provide such service alone. This forces them to collaborate in a system building category, that is usually characterised by its individual nature. This is strongly in line with the innovation ecosystems literature, but contradicts the coopetition literature (see also Table 5).

Table 4.
Overview of individual and collective strategies of POCT companies in Germany.

System building activity	SMEs	Large firms
R&D	Collective knowledge creation would be highly desirable for SMEs, especially in collaboration with large companies, as SMEs themselves do not have the resources to carry out it on their own.	Individual system building is dominant amongst large resourceful companies who prefer to acquire SMEs with a specific product in the pipeline or buy in the competence to R&D collaboration.
Creation of legitimacy	High interest in collective strategy, legitimacy on single POCT products has a very strong individual character.	High interest in collective strategy, legitimacy on POCT technologies in general is a collective effort via networks and associations, dominated by large companies.
Market formation	High interest in collective strategy, since individual activities are unlikely to occur due to the market conditions and customer needs (i.e. hospitals requiring complete solutions). SMEs, with low sales force, are trying to combine their products to offer complete systems for customers	High interest in collective strategy, larger companies are cooperating to complete their portfolio. Also very strong collaboration regarding software solutions exists between software developers and device manufacturers.

We observed very strong collaboration patterns between companies with different product portfolios aimed at offering complete solutions to clients (i.e. hospitals) and gaining a larger market share by combining their products. This applies also to large POCT firms (e.g. Roche Diagnostics). Additionally, collaboration is also present between smaller POCT firms with fewer products (e.g. Abaxis and Sysmex), suggesting that SMEs are collaborating more in market formation activities due to their limited market presence and limited financial resources (BarNir and Smith, 2002; Kossyva et al., 2014). Additionally, there is also a lot of cooperation between companies regarding software implementation, which is necessary in successful POCT uptake in hospitals.

To conclude, collective market formation emerges between different actors, as, through collaboration, they can reap additional benefits (increased sales). Our empirical material shows that it is the type of market and customers' needs that influence firms' collaboration strategies to create value that no firm could have created alone (Tables 6–8).

5.2. R&D

The open innovation literature tis univocal regarding high level of R&D collaboration in high technology sectors. i (see Table 5). Even though the POCT sector fulfils all criteria of open innovation, our results

Table 5.
Comparison of used literature strands.

Theory/Literature	Individual versus collective strategies
Institutional Entrepreneurship & Institutional Work	The theory claims that larger firms are more likely to act as institutional entrepreneurs than SMEs. However, collective institutional entrepreneurship or 'running in packs' enables firms take collective action to achieve their goals faster than acting alone. In current work, legitimacy on POCT technologies in general is a collective effort, dominated by large companies, and few evidence is available on institutional entrepreneurship type of activities.
System Building (SB)	Based on SB theory, for individual companies it is hard to achieve successful SB as they lack necessary resources, power and legitimacy. Companies should collaborate to achieve a desired change in the system. In the current work, collective SB is present in the POCT market formation and creation of legitimacy, but not in knowledge creation activities.
Open Innovation	Open innovation thinking is that the innovation landscape has moved towards increased technological and product complexity and firms cannot rely only on their internal resources anymore. Little evidence is found in the POCT sector, as individual strategies dominate POCT knowledge creation activities. Acquisitions are more common than R&D collaboration.
Coopetition	The literature argues that large companies are most capable of individual SB, especially in market formation processes. Coopetition losses make cooperation undesirable in certain cases. Based on our findings, we can see that individual activities are least likely to occur in the POCT sector, due to the specific customer needs (i.e. hospitals requiring complete solutions).

Table 6
List of interviewees.

ID	Type of actor	Role in the organisation
a	SME representative	Marketing manager
b	Industry network representative	Cooperation manager
c	Large international company representative	Sales director EMEA region
d	Large international company representative	Head of POCT
e	Large international company representative	Project manager
f	SME representative	CEO
g	Large international company representative	Head of R&D
h	Large international company representative	Head of marketing
i	Industry association executive, large international company representative	Vice president
j	Researcher	Senior researcher & project manager
k	Medium size company representative	Service manager
l	Large international company representative	Head of marketing
m	Large company representative	Director POCT Management

illustrate the exact opposite, regardless all the fulfilled preconditions. We detected in the POCT sector very few collaboration patterns in the R&D phase. This is especially true for large POCT companies. This low collaboration could be explained on the one hand by the strong presence of a few large multinational diagnostic companies with plenty of in-house resources for R&D that do not need to collaborate with competitors to carry out successful innovations. In case other firmshave any valuable input into their R&D processes, the tendency seems to be more towards acquiring these smaller firms – which have already developed the necessary know-how. To obtain a large product portfolio – which is of key importance in the hospital market – acquisition is a faster and administratively easier than R&D collaboration.

Additionally, through an acquisition strategy, large firms can remain in control of a new technology. In the open innovation literature, some

Table 7.
Examples of important POCT-related events and networks in Germany (adapted from Rau, 2014).

Events		
Name of the event	**Type of the event**	**Description**
Biotechnica	Trade Fair	International biennial medical and biotechnology fair in Hannover.
DGBMT: Mobile Diagnostik am Point-of-Care	Conference	Single event in 2013 in Düsseldorf. Organised by the Association for Electrical, Electronic & Information Technologies (VDE) together with Cluster Medical Technology North Rhine westphalia.
Lab-on-Chip European Congress	Conference	International annual conference, since 2009.
LaborForum	Conference	Annual diagnostic industry event in different locations in Germany. Organised by a group of diagnostic companies.
MEDICA	Trade Fair and Conference	International annual medical fair in Düsseldorf.
Medtech	Trade Fair	International annual medical technology fair in Stuttgart.
POCT Symposium	Conference	Biennial conference in Munich. Organised by theTechnical University of Munich in collaboration with The German Society for Clinical Chemistry and Laboratory Medicine.
Roche Days	Conference	Annual event, organised by Roche Diagnostics.
Networks		
Name of the network	**Type of network**	
Verband der Diagnostik Industrie (VDGH)	National level diagnostic industry association	
Deutsche Gesellschaft für Biomedizinische Technik (DGBMT)	National level knowledge transfer, networking	
LifeScienceNet Düsseldorf	Regional network of public and private actors (North Rhine-Westphalia state)	
Netzwerk Diagnostik Berlin-Brandenburg e. V.	Regional network of public and private actors (Berlin & Brandenburg states)	
BioLago	Regional network of public and private actors (regions from Germany, Switzerland, Lichtenstein and Austria around lake Constance)	
BioPro Baden-Württemberg	State funded agency (Baden-Württemberg state)	
Mannheim Medical Technology Cluster	Regional network of public and private actors (area around the city of Mannheim)	
Munich Biotech Cluster M4	Regional network of public and private actors (Bavaria state, around Munich)	
Medical Valley Nurnberg	Regional network of public and private actors (Bavaria state, around Nurnberg)	

Table 8.
Overview of used data sources.

Used Data Sources	
Scientific articles from professional journals	Medline, PubMed, ISI Web of Science
"Grey" literature	Policy papers, market studies, press releases
Online databases	LexisNexis, Funding Database of the German Federal Government
Internet sites of government bodies	BMBF (Federal Ministry of Education and Research), BfArM (Federal Institute for Drugs and Medical Devices)
Internet sites of professional groups	Diagnostic industry networks and associations, such as VDGH (Diagnostic Industry Association), DGKL (German Society of Clinical Chemistry and Laboratory Medicine), BVMEd (German Medical technology Association) and patient organisations DDK (German Diabetes Association) .

authors consider this kind of strategy as inbound open innovation by a large company (Bianchi et al., 2011). However, in the current study these types of activities are not considered as collaboration activities. The reasons behind the lack of collaboration of large POCT companies might also be true regarding other intellectual property (IP)-rich technology areas outside the POCT industry. These kinds of high-tech technology areas are traditionally accustomed to "closed innovation" – where protecting IP and control of knowledge dominate collaborative innovation activities. This does not provide large POCT companies with a motivating incentive to collaborate with others, and the risks clearly outweigh the potential benefits of R&D collaboration.

At the same time, since POCT SMEs often have specific technical competences and limited resources, they do not have all the necessary resources and skills to single-handedly develop and produce their products. Therefore, different R&D collaborations are highly important for POCT SMEs. Our empirical material indicated an active engagement of SME's in publicly funded R&D programs in Germany. This is in line with earlier work that reported high levels of collaboration by SMEs engaged in knowledge-intensive industries to decrease the time and resources needed for R&D (Kossyva et al., 2014; McCutchen & Swamidass, 2004). Smaller POCT firms are also looking for opportunities to acquire external competences related to transforming fundamental knowledge into concrete products and bringing them to the market. However, as stated before, the larger companies are not interested in this kind of collaboration and prefer to acquire the necessary know-how through acquisition of SMEs. This creates a picture where a division of labour is visible between large and small firms. Small firms are important for developing new knowledge and technologies and they do so in collaboration with (public) research institutes. When it comes to the market introduction of this type of knowledge large players dominate the game.

5.3. Creation of legitimacy

Lack of legitimacy is a common problem that POCT companies face, as radical innovators. We witnessed strong individual system building activities towards cognitive institutional change by both SMEs and large companies, in creating further legitimacy amongst medical specialists for specific POCT technologies and devices. At the same time, these individual strategies towards higher legitimacy of specific products indirectly also contribute to overall legitimacy of POCT technologies (Table 4).

Individual strategies are complemented by collective action: Creation of legitimacy for POCT in general frequently takes place via different industry associations. However, required resources for active participation in networks and associations and governance structures within these networks and associations favour larger firms whereas SMEs have more difficulties to shape these collective activities according to their interests. As an alternative, we have witnessed the emergence of a number of regional level networks and clusters (see Annex 2 for examples). These serve as a platform for smaller companies to cooperate in order to increase legitimacy of their products, but are less powerful and influential than national associations and networks.

Therefore, in creating higher legitimacy for POCT technologies in general, large POCT companies seem to be pursuing both collective and individual strategies. This collaborative strategy is highly dependent on resources, which explains the somewhat lower involvement in collective activities by SMEs.

We have added new insights to institutional entrepreneurship theory (Table 5), by showing, how creation of legitimacy has been developing in a POCT diagnostic industry that is dominated by large multinational companies, but also has a strong presence of SMEs.

6. Conclusions

We have shown that the choice of entrepreneurs between individual and collective strategies depends on the availability of resources and the type of system building activity. SMEs and large firms pursue different system building strategies. Large firms with a lot of resources hold a dominant position over SMEs and undertake collective system building activities (i) in creation of legitimacy for the whole technology via industry associations and (ii) market formation in order to offer complete technological solutions to the customers. In the R&D phase the large firms prefer individual and in-house activities. SMEs are interested in collective strategies in all system building activities – unless prohibited by regulation (i.e. knowledge diffusion and creation of legitimacy for their specific products) (see also Table 4). However, due to their lack of resources and skills, SMEs are often not capable to engage themselves in a collective strategy (i.e. participation in industry associations). Thus, the availability of resources determines the potential to pursue individual strategies but also collective ones.

We have also witnessed that it is not only the availability of resources (i.e. typical case for SMEs) but also product characteristics (i.e. many complementary products, technologies and services that are needed for the final diagnostic service) and customer needs that are important in determining whether firms collaborate or act individually. Collaboration in market formation by large firms takes place, because of specific customer needs (i.e. hospitals) that require as complete technological solutions from companies as possible. Therefore, large companies, having a very dominant position, take the role of the integrator and combine the individual solutions to the overall POCT system, which is sold to customers. Market conditions and customer needs also impact R&D strategies - in the POCT sector few collaboration patterns in the knowledge creation (R&D) and product development phase exist, as the risks of knowledge leakage and lengthy contract negotiations or the settlement of IP issues outweigh the potential benefits of R&D collaboration for large companies and they prefer business acquisitions instead. In this sense, our findings meet innovation ecosystems thinking that emphasises how firms have to combine their individual offerings in one integrated solution to create added value for customers.

Our research results can contribute to a higher awareness of these requirements, and to a higher awareness of individual versus collective strategies in different dimensions of system building, and support decisions in which cases individual or collective strategies seem most promising. Certain aspects of key importance are not unique to the POCT sector, but seem to apply to (radically) innovative fields in general, e.g. the need to include the user needs and the regulatory requirements already very early in product development and to acquire the required skills and competences in time, be it in-house, through partners or by forming alliances for collective system building activities. On the other hand, certain aspects seem unique to the POCT sector, especially the need to integrate novel solutions into the system structure of diagnostic platforms and clinical IT systems, predominantly governed by large companies, and the need to accompany the technological innovation by innovations in practical routines, division of work and responsibilities in

clinical wards, i.e. by creating legitimacy. As large POCT companies often have the role of gatekeepers, which govern the access of innovative solutions to the POCT market, there is a need that they actively and continuously scout the SMEs for truly innovative solutions.

Limitation of this work is that it focused only on one case, the German POCT sector. To generalise the findings of this research, more work needs to be done to focus on further operationalisation and quantitative studies of these three system building activities in different geographical delineation, to analyse whether typical patterns emerge.

When broadening the geographical scope, it would be most interesting to choose countries for comparative studies where the national health care system has different features (e.g. not so strong division between inpatient and outpatient sector), followed by doing similar studies in other technological fields, and compare them with the POCT findings. It would be especially interesting to find out if and how the specifics of the POCT sector (e.g. high importance of regulations for market approval, strict division of responsibilities amongst staff members (e.g. doctors, nurses, laboratory specialists) affect the collective versus individual system building activities of system building.

Furthermore, future research should also consider additional relevant dimensions, such as timing, organisational structures, and analyse how they affect system building strategies of companies within and outside of POCT sector. This exploratory study took place at one moment in time, and it was not possible to observe the development of and dynamics between the key system building activities over time.

The dynamics between different system building activities from an entrepreneurial point of view constitute an important field for future research. This work could be seen as a starting point for a number of other interesting research projects on strategic individual and collective system building around innovative technologies in different sectors.

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CRediT authorship contribution statement

Piret Kukk Fischer: Writing – original draft, Conceptualization, Methodology, Software. **M.P. Hekkert:** Writing – review & editing. **B. Hüsing:** Data curation, Writing – original draft. **E.H.M. Moors:** Writing – review & editing.

References

Abrahamsen, M.H, 2019. The role of innovation partnerships in healthcare innovations. Paper submitted to. In: Proceedings of the 35th IMP Conference, pp. 28–30. August.

Aldrich, H.E., Fiol, M.E., 1994. Fools rush in? The institutional context of industry creation. Acad. Manag. Rev. 19 (4), 645–670.

Amir, Y., Lavie, D., Hashai, N. (2019). Multimarket competition and alliance formation: negotiating, structuring and governing partnerships. 10.1017/9781108236188.019.

BarNir, A., Smith, K.A., 2002. Inter-firm alliances in the small business: the role of social networks. J. Small Bus. Manag. 40 (3), 219–232.

Bengtsson, M., Johansson, M., 2014. Managing coopetition to create opportunities for small firms. Int. Small Bus. J. 32 (4), 401–427.

Bianchi, M., Cavaliere, A., Chiaroni, D., 2011. Organisational models for open innovation in the bio-pharmaceutical industry: an exploratory analysis. Technovation 31 (1), 22–33.

Bissonette, L., Bergeron, M.G., 2010. Diagnosing Infections – current and anticipated technologies for point-of-care diagnostics and home based testing. Clin. Microbiol. Infect. 16 (8), 1044–1053.

Brunswicker, S., Vanhaverbreke, W., 2015. Open innovation in small and medium-sized enterprises (SMEs): external knowledge sourcing strategies and internal organisational facilitators. J. Small Bus. Manag. 53 (4), 1241–1263.

Bundesärztekammer, 2008. Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen. Deutsche Arzteblatt 105 (7), 341–355. A.

Bundesärztekammer, 2015. About the German medical association (data retrieved on 1st September 2015: http://www.bundesaerztekammer.de/weitere-sprachen/english/german-medical-association/).

Carnes, C.M., Chirico, F., Hitt, M.A., Huh, D.W., Pisano, V., 2016. Resource orchestration for innovation: structuring and bundling resources in growth-and maturity-stage firms. Long Range Plan. 50 (4), 472–486.

Celera, 2010. Celera signs agreement with Abbott for distribution of CE-marked KIF6 test to identify patients at risk of coronary heart disease. (Data retrieved on 1st April 2015: https://www.celera.com/celera/pr_1284760729).

Eurolyser, 2007. Eurolyser Diagnostica and Sysmex Europe Sign Cooperation Contract. Press release 14.09.2007.

Freeman, C., 1994. Critical survey: the economics of technical change. Camb. J. Econ. 18 (5), 463–514.

Frost & Sullivan 2010. European point of care testing market. M59F-55.

Frost & Sullivan 2013. Global point-of-care testing (POCT) market. M8FD-52.

Garud, R., 1994. Cooperative and competitive behaviours during the process of creative destruction. Res. Policy 23 (4), 385–394.

Gnyawali, D.R., Park, R., 2009. Co-opetition and technological innovation in small and medium-sized enterprises: a multilevel conceptual model. J. Small Bus. Manag. 47 (3), 308–330.

Gnyawali, D.R., Park, R., 2011. Co-opetition between giants: collaboration with competitors for technological innovation. Res. Policy 40 (5), 650–663.

Gnyawali, D.R., Ryan Charleton, T., 2018. Nuances in the interplay of competition and cooperation: towards a theory of coopetition. J. Manag. 44 (7), 2511–2534.

Goldenberg, S.D., Bisnauthsing, K.N., Patel, A., et al., 2014. Point-of care testing for clostridium difficile infection: a real-world feasibility study of a rapid molecular test in two hospital setting. Infect. Dis. Ther. 3 (2), 295–306.

Greenwood, R., Suddaby, R., Hinings, C.R., 2002. Theorizing change: the role of professional associations in the transformation of institutionalized fields. Acad. Manag. J. 45 (1), 58–80.

Gulati, R., Sytch, M., 2007. Dependence asymmetry and joint dependence in interorganizational relationships. Adm. Sci. Q. 52 (1), 32–69.

Hellsmark, H., 2010a. Unfolding of the Formative Phase of Gasified Biomass in the European Union: The Role of System Builders in Releasing the Potential of Second-Generation Transportation Fuels from Biomass. Department of Energy and Environment, Chalmers University of Technology, Göteborg. PhD Thesis.
Holmlund, M., Kock, S., 1996. Customer dominated relationships in a supply chain: a case study of four small-sized suppliers. Int. Small Bus. J. 33 (1), 26–41.
St John, A., Price, P.C., 2014. Existing and emerging technologies for point-of care testing. Clin. Biochem. Rev. 35 (3), 155–167.
Jolly, S., Raven, R.P.J.M., 2015. Collective institutional entrepreneurship and contestations in wind energy in India. Renew. Sustain. Energy Rev. 42, 999–1011.
Junker, R., Schlebusch, H., Luppa, B.P., 2010. Point-of-care testing in hospitals and primary care. Dtsch. Ärzteblatt Int. 107 (33), 561–567.
Konrad, K., Markard, J., Ruef, A., Truffer, B., 2012. Strategic responses to fuel cell hype & disappointment. Technol. Forecast. Soc. Chang. 79 (6), 1084–1098.
Kossyva, D., Sarri, K., Georgopoulos, N., 2014. Co-opetition: a business strategy for SMEs in times of economic crisis. South East. Eur. J. Econ. 1, 89–106.
Larsson, A., Greig-Pylypczuk, R., Huisman, A., 2015. The state of point-of-care testing: a European perspective. Upsala J. Med. Sci. 120, 1–10.
Leca, B., Battilana, J., Boxenbaum, E., 2008. Agency and Institutions: A Review of Institutional Entrepreneurship. Harvard Business School Press, Boston, Massachusetts.
Luppa, P.B., Gässler, N., Haeckel, R., et al., 2005. Stellungnahme der Arbeitsgemeinschaft„Point-of-care Testing“ der DGKL zum Thema Vernetzung von POCT-Geräten im Krankenhaus mit Zentrallabor. J. Lab. Med. 29 (4), 241–245.
Luppa, P.B., Müller, C., Schlichtiger, A., Schlebusch, H., 2011. Point-of-care testing (POCT): current techniques and future perspectives. Trends Anal. Chem. 30 (6), 887–898.
McCutchen, W.W., Swamidass, P.M., 2004. Motivations for strategic alliances in the pharmaceutical/biotech industry: some new findings. J. High Technol. Manag. Res. 15 (2), 197–214.
Mellewigt, T., Thomas, A., Weller, I., Zajac, E.J., 2017. c. Strateg. Manag. J. 38, 2353–2369.
Michelino, F., Lamberti, E., Cammarano, A., Caputo, M., 2015. Measuring open innovation in the bio-pharmaceutical industry. Creat. Innov. Manag. 25 (1), 4–28.
Moore, C., 2013. Point-of-care tests for infection control: should rapid testing be in the laboratory or at the front line? J. Hosp. Infect. 85 (1), 1–7.
Musiolik, J., Markard, J., Hekkert, M.P., 2012. Networks and network resources in technological innovation systems: towards a conceptual framework for system building. Technol. Forecast. Soc. Chang. 79 (6), 1032–1048.
Palamountain, K.M., Baker, J., Cowan, E.P, 2012. Perspectives on introduction and implementation of new point-of-care diagnostic tests. J. Infect. Dis. 205 (2), 181–190.
Pharmaceutical Business Review, 2009. Axis-shield buys point-of-care distribution business in Germany. (Data Retrieved On 3rd April 2014: http://www.pharmaceutical-business-review.com/news/a24a7axisshield_buys_pointofcare_distribution_business_in_ge).
Planko, J., Cramer, J.M., Chappin, M., Hekkert, M., 2016. Strategic collective system building to commercialize sustainability innovations. J. Clean. Prod. 112 (4), 2328–2341.
Powell, W.W., Cummings, L.L., Staw, B.M., 1990. Neither market nor hierarchy: network forms of organization. In: Research in Organizational Behaviour, 12. JAI Press, pp. 295–336. Greenwich, CT.
PR Newswire, 2013. “Abaxis and LamdaGen corporation enter into R&D diagnostic collaboration”. PR Newswire 25 October 2013.
Rau, L., 2014. Treiber Und Hemmnisse im Innovationssystem „Mobile Diagnostik“ in Deutschland. Fakultät für Wirtschaftswissenschaften, Karlsruhe Institute of Technology, Karlsruhe. MSc Thesis.
Hellsmark, H., 2010b. Unfolding of the Formative Phase of Gasified Biomass in the European Union: The role of System Builders in Releasing the Potential of Second-Generation Transportation Fuels from Biomass. Department of Energy and Environment, Chalmers University of Technology, Göteborg. PhD Thesis.
Ritala, P., Hurmelinna-Laukkanen, P., 2009. What’s in it for me? Creating and appropriating value in innovation-related coopetition. Technovation 29 (12), 819–828.
Roche, 2012. Sysmex and Roche renew successful alliance in the hematology business. Press Release 13th April 2012.
Swan, J., Goussevskaia, A., Newell, S., et al., 2007. Modes of organizing biomedical innovation in the UK and US and the role of integrative and relational capabilities. Res. Policy 36 (4), 529–547.
Sysmex, 2013. Abaxis Piccolo Xpress (Data Retrieved On 1st February 2015: http://de.sysmex-europe.com/index.asp?id=19280).
Zakrzewska-Bielawska, A., 2015. Coopetition? Yes, but who with? The selection of coopetition partners by high-tech firms. J. Am. Acad. Bus. 20 (2), 159–166.
The World Bank, 2014. Health Expenditure (Data retrieved on 1st December 2014. The World Bank http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS).
TriMark, 2013. Point of Care Diagnostic Testing World Markets. TriMark Publications, LLC.
Van de Ven, A.H., 1993. The development of an infrastructure for entrepreneurship. J. Bus. Ventur. 8, 212–230.
Walley, K., 2007. Coopetition: an introduction to the subject and an agenda for research. Int. Stud. Manag. Organ. 37 (2), 11–31.
West, J., Salter, A., Vanhaverbeke, W., Chesbrough, H., 2014. Open innovation: the next decade. Res. Policy 43 (5), 805–811.
Yin, K.R., 2003. Case Study Research. Sage Publications, Thousand Oaks.
Zobel, A.K., Lokshin, B., Hagedoorn, J., 2017. Formal and informal appropriation mechanisms: The role of openness and innovativeness. Technovation (59), 44–54.