Exploring the emergence and shifting of new and radical product concepts in the context of In-vitro Diagnostics industry

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Abstract

This thesis explores how new radical product concepts emerge under uncertainty in the context of the In-vitro Diagnostics (IVD) industry. Specifically, it studies how new product concepts that build on fundamentally new technology are elaborated, defined and modified in an early development stage within a globally operating corporation. An inductive single-case study design with two embedded cases within an IVD corporation is employed, building on a wide range of primary and secondary data to study this phenomenon. Data collection and analysis within and across the embedded cases were informed by Grounded Theory methods and techniques. Theory building led to the development of *Scoping* as a core-variable to explain the emergence of new product concepts under uncertainty. It is further characterised by a temporal as well as capability dimension, each building on two interlinked concepts, respectively: exploring and normalising for the temporal dimension, and substantive as well as dynamic organisational abilities from a capability perspective. This thesis sheds light on the dynamics of new, radical product development in complex market and corporate environments, contributing to our understanding of constant adaptation processes (concept shifts) during early development phases; suggesting that well-established exploration and exploitation phases of NPD are connected through an additional normalising phase that is bridging these two.

Keywords: New Radical Product Development, Front-end of Innovation, In-vitro Diagnostics, Concept Shifting, Scoping

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Declaration of Original Content

I declare that the work in this thesis was carried out in accordance with the regulations of the University of Gloucestershire and is original except where indicated by specific reference in the text. No part of the thesis has been submitted as part of any other academic award. The thesis has not been presented to any other education institution in the United Kingdom or overseas.

Any views expressed in the thesis are those of the author and in no way represent those of the University.

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Abbreviations

B2C	Business-to-Consumer
BA	Business Area
BD	Business Development
CAGR	Compound Annual Growth Rate
COGS	Costs of Goods Sold
CP1 review	Concept progression 1 review
CTO	Chief Technology Office
DCC	Design Control and Commercialisation
DPC	Divisional Portfolio Committee
EU	European Union
Fin	Finance
FTO	Freedom-to-Operate
GT	Grounded Theory
HIS	Hospital Information System
HR	Human Resources
HW	Hardware
I/C	Idea & Concept
IP	Intellectual Property
IPM	International Product Manager
IT	Information Technology
IVD	In-vitro Diagnostics
IVDR	In-vitro Diagnostic Device Regulation
LC	Life Cycle
LIS	Laboratory Information System
M&A	Mergers and Acquisitions
MSA	Medical and Scientific Affairs
NA	North America
NASA	National Aeronautics and Space Administration
NPD	New Product Development
PhD	Doctor of Philosophy

PMI	Project Management Institute®
PoC	Point-of-Care
pre-DCC	pre-Design Control and Commercialisation
QDA	Qualitative Data Analysis
R&D	Research and Development
RPV	Resources Processes & Values
SME	Subject Matter Expert
TA	Technology Assessment
TMB	Technology and Marker Board
TSG	Technology Stage-Gate
UoG	University of Gloucestershire

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1 Introduction

This thesis aims to explore how new, radical product concepts emerge under uncertainty and how organisations in the In-vitro-Diagnostics (IVD) industry adapt newly emerging product concepts in radical, new technology contexts. Therefore, this empirical research study and its pursued research objectives can be framed in the following way:

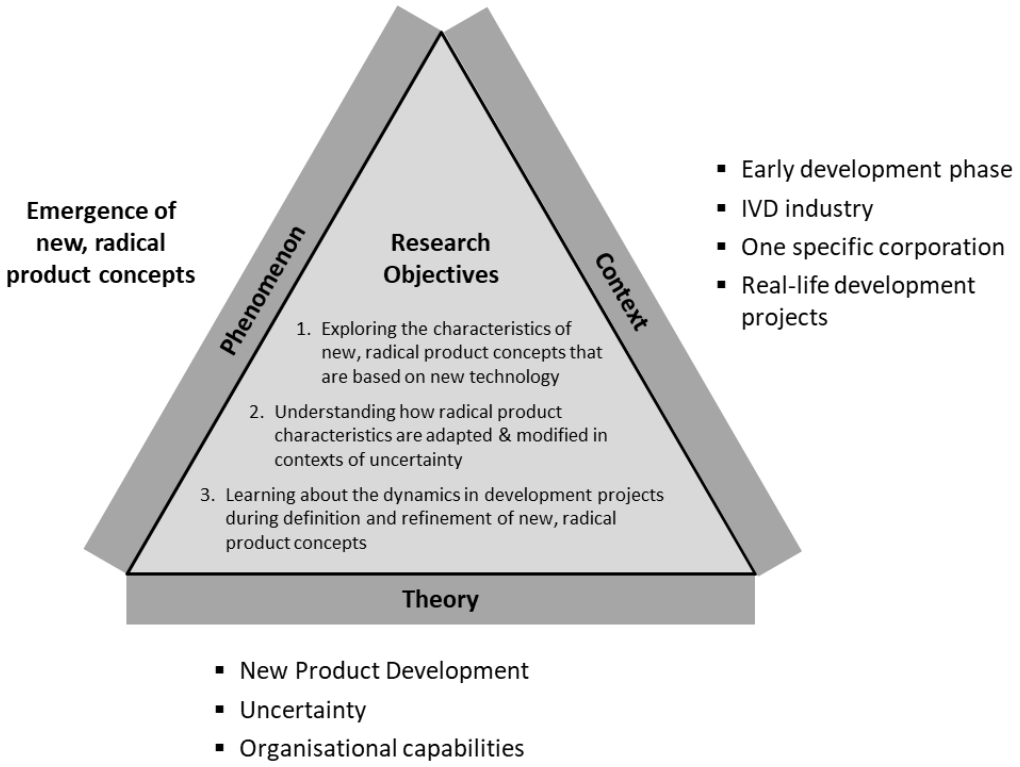

Figure 1. Aim of research / defining research study

On a higher level of abstraction, the study explores the **emergence of newness**, building on Damanpour (1991), a key scholar in this domain, who defined such emergence and implementation of innovation as "the generation, development and adaptation of novel ideas". In a corporate context, these ideas and drivers for newness could cover several types of newness, such as service innovation, method innovation or, like in this case, product innovation (Johannessen, Olsen, & Lumpkin, 2001). Such newness in respect of novelty of a product or technology may arise from within or outside an organisation. Internal novelty refers to the technology that is new to the organisation and external novelty means that the technology is new to the market/industry (Cooper, 2006; O'Connor, 1998). Besides the newness

aspect, the phenomenon is also characterised by an **uncertainty** component. In this context, uncertainty can be seen as an inability to assign a certain likelihood to an outcome (Gifford, Bobbit, & Slocum Jr, 1979). This uncertainty at an early stage is amongst other factors mostly driven by a lack of information about the subject as well as an unclear relationship between cause and effect (Lawrence & Lorsch, 1967). Risk, in contrast, would allow probabilities to be assigned to certain outcomes based on past experiences.

To fully frame the phenomenon, one needs to recognise the IVD context. Medical devices and IVD products as related groups of products, have significantly contributed to the continuous improvement of modern healthcare (Pietzsch, Shluzas, Paté-Cornell, Yock, & Linehan, 2009). This improvement was driven by a high degree of product innovation. New technological developments play a key role in this context as they build the basis for new radical innovation that introduced and created new diagnostic paradigms in healthcare (Dosi, 1982).

These above mentioned innovation and uncertainty aspects of the research phenomenon have received great attention amongst researchers in the past decades as innovation was seen as a key driver to create and maintain competitive advantage in the long run (Danneels & Kleinschmidt, 2001; Drazin & Schoonhoven, 1996). In this sense, the development of novel products was, and still is, vital for the long-term success of a company and has, therefore, been the focus of academia as well as management practice in recent decades (Johannessen et al., 2001; Pietzsch et al., 2009).

Robert Cooper, as the originator of the **stage-gate process**, was a key contributor to the successful management of new product development (NPD). His widely applied approach consists of a multi-stage process with predetermined stages (Cooper, 1990). This approach helped to improve R&D performance on a portfolio as well as project level. But it may be critiqued for its **lack of flexibility and insufficient** consideration of the early phase of new product development. Consequently, in recent years even Cooper himself recognised the need for an adaptation of his methodology to the new reality, which is characterised by a fast-changing business environment and the emergence of new technologies (Cooper, 2014).

In this context of newly emerging product concepts, the early development phase of new product development is of particular interest to practitioners, regulators and researchers (Gassmann & Schweitzer, 2014; Kim & Wilemon, 2002; Reinertsen, 1999) as during this phase, the key concepts and features of a new product are defined and the strategic directions for the following development activities are set. This particularly applies to IVD product development, as development cycle times are quite long (>5 years) and regulatory requirements require decisive steps to be taken about the product concept scope early in the process.

Research to date has investigated, amongst other aspects, the definition of product concepts (Bacon, Beckman, Mowery, & Wilson, 1994; Crawford & Di Benedetto, 2010; Krieg, 2004). The focus was either on the overall process nature of new product development (Cooper, 1990; Cooper & Kleinschmidt, 1991; Högman & Johannesson, 2013), on single process steps such as the front-end (Gassmann & Schweitzer, 2014; Koen et al., 2001; Reinertsen, 1999), or concept shifting, a model considering the changes of new product concepts after its initial definition (Seidel, 2007).

Yet, little is known about how new product concepts emerge and **how their radical characteristics change** at the front end of innovation (Florén & Frishammar, 2012; O'Connor & Rice, 2001) or in uncertainty decision-making contexts (Herstatt, Verworn, & Nagahira, 2004; Zhang & Doll, 2001). On this, the extant body of knowledge requires further insights about how organisations and project teams try to ensure project progressions (Seidel, 2007), as such organisations frequently struggle to properly define product concepts particularly when they emerge from radical innovation in novel technology contexts (Cooper, Edgett, & Kleinschmidt, 2002).

To achieve the aim mentioned above, an inductive single-case study design with two embedded cases within a globally operating IVD corporation is employed, allowing for close engagement with real-life development projects of a leading IVD corporation. Data collection is built on a wide range of primary and secondary data such as in-depth interviews or project artefacts. For confidentiality purposes, the names of companies, projects and research participants names are disguised

throughout this thesis. Methodology-wise data collection and analysis within and across the two embedded cases were informed by grounded theory methods and techniques (Glaser, 1978, 2005; Glaser & Strauss, 2010). As a result, the analysis led to the emergence of "*Scoping*" as core-variable that explains the emergence of new product concepts under uncertainty. This full access to real-life development projects provided the basis for valuable empirical insights into new product development both from a theoretical as well as a practical perspective.

In the following paragraphs the above described research topic will be specified in more detail with regards to the aim of the research, the applied research design as well as its industry context. Finally, it is reflected upon the role of the researcher and the overall structure of this doctoral research study will be presented.

1.1 Research aim and objectives

The IVD industry is known for its high degree of innovation (Shields & Sale, 2014); nevertheless, organisations are frequently struggling to properly define new product concepts. While exploring the phenomenon of newly emerging product concepts, this research study is leveraging already existing theory on new product development. However, knowledge in the interdisciplinary fields of early product development is very fragmented and is particularly lacking empirical research in the context of radical, real-life IVD development projects (Medina, Kremer, & Wysk, 2013; Millson & Wilemon, 1998).

The research objectives addressed by this empirical study are:

- …to explore how new, radical product concepts based on new technologies are defined.
- …to learn about how radical product concepts are adapted and modified in contexts of uncertainty.
- …to understand how organisational capabilities influence the emergence of a new, radical product concept during its definition and refinement.

In doing so, this study builds on past calls for more research to better understand this phenomenon in radical product development contexts (Cooper, 2006; Herstatt et al., 2004; Högman & Johannesson, 2013). Furthermore, this empirical research study is considering the cross-functional nature of organisations, as IVD product development requires an integration of various disciplines/backgrounds such as biology, medicine, software, electronics and hardware development.

Driven by the nature of the research objectives, the following qualitative, case-study research design was adopted to build new theory on this phenomenon.

1.2 Research methodology at a glance

To reflect the exploratory nature of this research study, a single-case study design that builds on two embedded cases (Yin, 2013) within a globally operating IVD corporation was adopted. To ensure comparability between the cases with regards to novelty of product concept as well as technology and to control for the effect of internal and external factors on the selected cases, a sampling strategy based on the following comparable sampling criteria was applied: governance structures, project phase, project size and scope, as well as the early stage in which a new product concept is emerging.

As a result of deploying the sampling criteria, **two comparable but distinct cases** were identified. The first embedded case (Case A) covers the emergence of a new product concept that builds on a novel detection technology for near patient testing. The second embedded case (Case B) is making the emergence of a new lab technology its main subject of exploration.

During data collection, a broad range of primary and secondary data was collected for the purpose of **data triangulation** as well as to identify additional research participants. Primary data was collected via semi-structured face-to-face interviews and supplemented by artefacts such as emails, meeting minutes, use case-diagrams as well as further general project documentation (Bryman & Bell, 2011; Creswell, 2013). In total ten participants per case were purposively selected for the interviews. The interviews lasted on average sixty minutes and were recorded and

transcribed verbatim (Brinkmann & Kvale, 2015). In this process of semi-structured interviewing the aim was to discover critical events and incidents that contributed to the early innovation phase of new product development in the context of a globally operating IVD corporation. A total of twenty-two interviews, including follow-ups were conducted. For confidentiality reasons, the respondents' names as well as the company's name are disguised throughout the thesis.

Data collection and **data analysis within and across the two cases** was informed by grounded theory methods and tools (Glaser, 1978, 2005; Glaser & Strauss, 2010). Initially texts and artefacts were coded substantively, meaning that the substantive codes were emerging from the data and were developed spontaneously rather than a priori in the form of critical events, activities, issues or contextual aspects. The substantive codes formed the basis for a second cycle of theoretical pattern coding and a constant iteration between within- and cross-case data. This circling between substantive / theoretical codes and theory led to the discovery of *Scoping* that contributes to the explanation of the emergence of new, radical product concepts.

1.3 A snapshot of the IVD industry and corporate context

The case company examined is a key provider of medical diagnostic solutions for the IVD industry. In-vitro diagnostics products are defined by the Food and Drug Administration (FDA) as "those reagents, instruments and systems intended for use in the diagnosis of disease, or other conditions, including a determination of the state of health, in order to cure, mitigate, treat or prevent disease or its sequelae. Such products are intended for use in the collection, preparation and examination of specimens taken from the human body." (U.S. Food and Drug Administration, 2014a). Therefore, they comprise products such as laboratory instruments, test kits or reagent systems (Patterson, 1998).

With a global market size of approximately $53 billion in 2013 (Shields & Sale, 2014) the IVD-industry represents a relatively small share of the global public health sector but due to its broad application, it plays an important role in this field. This impact also comprises a more effective and efficient use of healthcare resources in

the future. This is of particular importance in the developed healthcare systems, such as the US or EU, which are struggling with a cost increase due to an aging population (Dall et al., 2013).

Besides the above-mentioned cost aspect the IVD industry is also recognised for a high degree of innovation e.g. as it provides high medical value diagnostic tests for personalised healthcare treatment (Medina, Kremer, & Wysk, 2013).

Through the medical application area and the related risks for patients, the industry is also characterised by strict regulation, which leads to constraints regarding new development, manufacturing, marketing and application of IVD solutions.

As outlined, certain industry characteristics make IVD a unique industry. To further understand the context of the planned doctoral research study, a detailed understanding of the IVD industry is of importance. Therefore, the subsequent sections will illustrate the following characteristics in more detail:

- Broad application in the healthcare system leveraging multiple technologies
- Complex product architecture
- Broad stakeholder / customer coverage
- Extensive regulatory requirements

Broad application in the healthcare system leveraging multiple technologies

IVD testing is widely applied in the healthcare system, for example in the diagnosis, prevention, monitoring, treatment or alleviation of an injury, disease or handicap (European Parliament and Council of the European Union, 1998). Furthermore, the application can also be differentiated by the type of disease, the specimen or the location where the testing and analysis is executed (Day, 2013).

As a result of the various combinations of diseases, types of specimen and test locations, a broad spectrum of technologies are available to best fit the requirements of the specific setting (e.g. chemical conversion, photometry, electro-/chemo-luminescence, antigen-antibody reactions). These design aspects need to be considered when developing an IVD product.

Complex product architecture

IVD products are multipartite products; typically an IVD system consists of a measurement device with a measurement cell, a sample feeding system, chemical or biological consumables and software that is calculating/processing the test results (European Parliament and Council of the European Union, 1998). Furthermore, an IVD device needs to offer a broad range of IT interfaces to collect, integrate and process data as it is usually embedded in an information network e.g. within a hospital or a network of laboratories. This leads to a high degree of integrating different disciplines in new product development. Firstly, an instrument and its components build heavily on engineering and physics. Secondly, the chemical and biological consumables require expertise in chemical, biological and biotechnological sciences. Lastly, the IT component of IVD products calls for broad capabilities in software development and data analytics.

Broad stakeholder / customer coverage

When developing an IVD product, the individual requirements of multiple stakeholders need to be considered and weighed up against each other. Being more complex than classical business-to-consumer (B2C) product development, in retail for example the following key stakeholders are typically involved in product design as the decision power for purchase, payment and usage of a product is distributed among different interest groups (Shields & Sale, 2014). Amongst others, key stakeholders such as patients, device operators, physicians, regulatory bodies or payers need to be reflected upon.

Extensive regulatory requirements

IVD products have to comply with a broad range of regulatory requirements (Casteels & Rohde, 2013). There are medical device- / IVD-specific regulations on the one hand and general regulations for the marketed product in a certain country / region on the other hand.

Its “hurdles” for approval depend on the risk assessment of the specific solution. In the European Union for example, the IVD market is regulated via the EU directive 98/79/EC which is incorporated accordingly into local legislation e.g. in the UK via the Medical Devices Regulations (European Parliament and Council of the European Union, 1998; "Medical Devices Regulations 2002," 2002). A more detailed description of the industry-specific IVD regulation, the regulatory landscape of the key markets, European Union and United States of America, can be found in paragraph 4.1.1.

In general, it must be noted that the regulatory landscape is, on a global scale, very fragmented which means that the regulatory framework is mostly country-/region-specific and varies considerably.

Besides the industry specific regulations, general country-specific regulations for marketed products apply. These general regulations range for example from regulations for labelling of hazardous materials up to low-voltage electronic requirements for small handheld devices.

When integrating the above-mentioned remarks, the IVD industry may be characterised as a complex environment for product development. Manifold aspects such as stakeholder structure and regulations have an impact on NPD (Pietzsch et al., 2009; Casteels & Rohde, 2013). In this context, over the past decade, the case company became a leading provider of IVD solutions. With an above industry-average R&D spend (which is approximately 5-10% of revenue depending on business area), the case company is committed to its strategic focus of innovation leadership. Driven by a strong innovation culture, the case company has proven that it is able to engage in incremental and radical innovation, which in turn contributed to strong, above industry-average, levels of commercial development.

1.4 Ethical considerations related to qualitative case study research

Ethical considerations were addressed early on in the research design, before actually starting to collect data, choosing a research design, which was outlined beforehand, that is in line with the University of Gloucestershire's code of conduct, meaning that ethical principles were considered during the design and execution of the research study. A key guiding document in this context is the University of Gloucestershire's code of ethics "Research Ethics: A Handbook of Principles and Procedures". As no deceptive or covert methods, no special group of participants such as young children or sick people were involved, no pre-authorisation of the research project by the University of Gloucestershire Research Ethics Committee was necessary. Furthermore, a cross-checking of the University's Code of Ethics with the code of conduct of the researched corporation did not reveal any contradicting positions.

The overall guiding principle was to protect any research participant from harm and to ensure the integrity of the planned research study. This was necessary as research participants were for example critically reflecting on the organisation and processes of the company they were working for. As a consequence, ethical considerations needed to be considered for qualitative research at all stages throughout the research process ranging from specifying the research questions to making data and analysing as well as composing the findings of the data set (Creswell, 2013).

Highlighted by the University of Gloucestershire Code of Ethics (University of Gloucestershire - University Research Committee, 2008) as well as Miles, Huberman, and Saldaña (2014) and Brinkmann and Kvale (2015) four ethical areas were anticipated early on in the process; (a) informed consent, (b) confidentiality, (c) consequences and (d) role of the researcher (see Table 1):

Table 1. Ethical considerations

Element	Guiding principles	Measures taken
General aspects	▪ Relationship shall be characterised by mutual respect and trust ▪ Telling the truth and going beyond concerns like keeping a promise ▪ Facing participants with openness ▪ Avoiding putting any research participants at risk	▪ Ethical protocol treating ethical issues that can be anticipated in a qualitative case study investigation
Informed consent	▪ Informing participants about overall purpose of investigation ▪ Ensuring voluntary nature of participation ▪ Agreeing on which data will be made and how it will be used ▪ Granting the right to refuse participation at any time ▪ Clearing identification of the sponsoring institution	▪ Providing general information about research study & methods applied: (a) briefing before encounter (b) information sheet sent via email (c) introduction of encounter (d) debriefing after interview ▪ Two step approval of participation creates sense of trust
Confidentiality	▪ Defining what information is available to whom ▪ Not disclosing any personal data allowing identification of participants ▪ Restricting access to interview data / other research materials	▪ Data is stored on a personal drive which can only be accessed by the researcher ▪ Confidential hardcopies are shredded before disposal ▪ Raw data will be deleted after completion of research study
Consequences	▪ Anticipating and avoiding possible harmful consequences for participants	▪ Ensuring that participants maintain ownership of their data e.g. participants confirm and approve transcripts ▪ Published data is not containing any identifiers that allow inference to an individual
Role of researcher	▪ Researcher's integrity is magnified because he himself is the main instrument for obtaining knowledge ▪ No dependent relationship to research participants	▪ Transparency of procedures through briefings and information sheet ▪ Publishing only finding that are as accurate and representative to the field of inquiry as possible ▪ Balancing tension between a professional distance and a personal relationship

It must be noted that the responsibility of ethical topics lies with the researcher who plans and undertakes the research. This is not merely necessary for qualitative case study research but also for other types such as quantitative research. Therefore, as outlined previously, I as the researcher was well aware of the potential ethical issues related to this research study and these were addressed in advance through a set of mitigating measures that were part of a dedicated ethical research protocol.

Further ethical aspects are related to my role as researcher within the researched organisation which are outlined in more detail in section 1.5. I myself am part of the global research and development organization of the same corporation but there is no dependent relationship between the research participants and myself (like for example a direct reporting line). Furthermore, there was no operational involvement into any activities of the respective technology projects.

1.5 Role of the researcher

In the context of the chosen qualitative case-study research design the role of the researcher as well as his pre-understanding require specific consideration. This is particularly due to the exploratory nature of this research which utilises interpretative reasoning. My **subjective, interpretative perceptions are evident in almost all research steps,** ranging from interviewing to creating data to analysis of data. This again "introduces" a couple of ethical, personal as well as strategic issues alongside the research process (Creswell, 2013). Having these concerns in mind, the research study needs to be framed against my personal background and beliefs, the skills required to conduct such an exploratory study as well as detailed remarks about the context of the research study.

My **personal background and beliefs** can be best characterised when looking at the past experiences and profound knowledge in the field of new product development. This expertise was built up in the past years through university education on the one hand and practical work experience on the other. During academic studies I gained in depth knowledge in the field of pharmaceutical process engineering (Diploma degree) as well as business knowledge through a Master's degree in European Business.

Afterwards I gained work experience in the medical and life sciences industry as strategy consultant in the fields of R&D Management, business strategy and post-merger integration. When starting in a new position a focus was set on innovation management in the diagnostics industry. In both jobs I had access to ready-made research settings of business and technology driven development pipelines, experiencing that teams were particularly struggling to properly define the product concept in the early phase which as a consequence triggered my genuine interest in that research domain.

The broad experience in this field is of particular importance as only this allows me as the researcher to have **conversations with research participants at eye-level** and to recognise connections in that complex topic area. These intense interactions with the research topic and subjects of enquiry are a solid basis for my constructivist research approach.

Furthermore, I reflected on the specific requirements of a constructivist research methodology on a skill level. Consequently, I needed to approach the topic in an open and empathic manner. On the one hand openness supports the recognition of new emerging concepts and explanations and on the other hand **empathy allows an understanding and feeling** of what research participants are experiencing in their professional as well as personal lives. This means for example that throughout an interview I needed to **listen actively and maintain a sensitive interest in the participant** to elicit precious information (Brinkmann & Kvale, 2015). These deep insights lie at the bottom of every constructivist social scientist.

This openness and empathy turned out to be challenging as it implies a certain **balance between a professional distance and a personal relationship.** This circumstance and potentially related conflicts raised a further required skill around "neutrality". Neutrality in the sense of value free is a means of success for the research project as it is conducted in a field of manifold personal, functional as well as local interests which results in a complex field of tension. For example, the superordinate clash of R&D which is often seen as a detailed, technology-driven function whereas the marketing function is often seen as customer-oriented and visionary well illustrate the **complex context** of this research study. Therefore, keeping neutrality in the two roles of an employee and a researcher in that field was crucial. This neutrality was also supported by me not being actively involved in the NPD projects when they were initiated and therefore no dependent relationship, such as manager/employee, existed.

1.6 Dissertation structure

Following the introduction to the doctoral research study, this thesis is structured in five key building blocks, with individual sections on **literature review**, **research methodology**, **case studies**, the **core- variable *Scoping*** and a **conclusion**.

At first, a **literature review** section (section 2) is providing an overview of the current state of research in this domain. After explaining the literature review approach the current state of knowledge in related research fields is depicted. Moreover, key constructs, such as concept shifting, are critically reflected upon and the need for this and further research is illustrated.

Subsequently, chapter 3 depicts the **research methodology** by marking out the underlying philosophical stance of the researcher before describing the data collection approaches. In addition, data analysis procedures are presented and a critical reflection on theory building is performed.

Chapter 4 aims to further deepen the understanding of the **research context** and the **case study** by outlining the context of the research study with regards to specific industry and corporate characteristics. This section is followed by a thick description of the two embedded cases (Case A & Case B).

Following this, chapter 5 introduces the **core-variable *Scoping*** and outlines research findings in detail, meaning that the temporal as well as capability dimensions are mapped out individually. Furthermore, the findings are discussed in the context of existing NPD research to either confirm the current body of knowledge or to identify deficiencies, omissions or inadequacies in existing theoretical knowledge about the phenomenon.

To **conclude**, the contribution of this research study concerning theory, but also managerial practices is demonstrated as part of chapter 6. This includes a critical reflection on the limitations of the study as well as suggestions for further research.

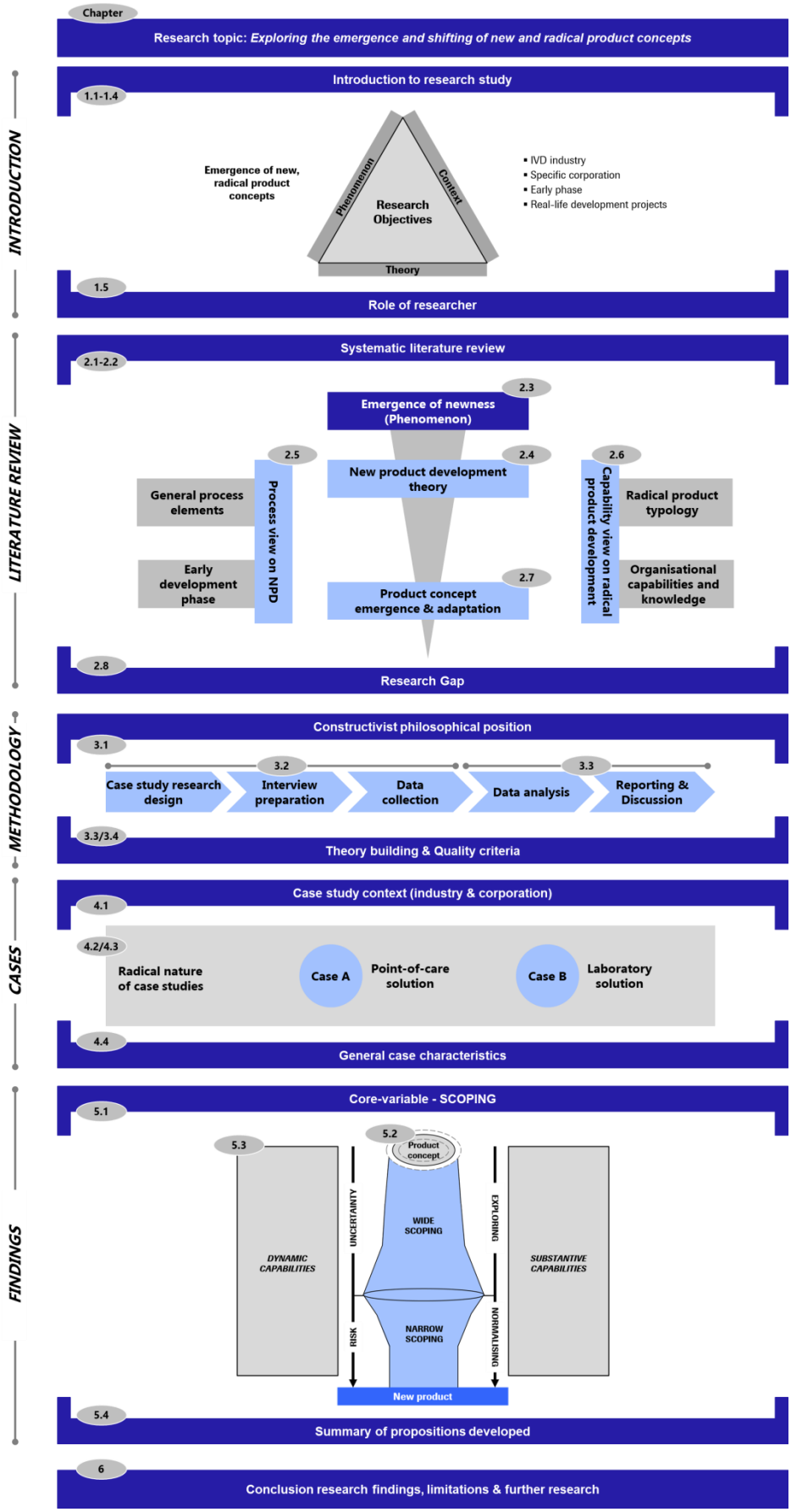

Figure 2. Dissertation structure

2 Literature review

The following systematic literature review was performed to investigate the state of knowledge in the research field of newly emerging product concepts that build on new technology. Therefore, this section looks at the existing body of knowledge in the field of emerging radical product concepts under uncertainty, building on existing theoretical and empirical studies in this research domain. As this research phenomenon is highly complex and existing studies cut across a broad variety of disciplines which include amongst others organisation theory, R&D management and marketing the theoretical framework is drawn from a rich and cross-disciplinary theoretical base.

As part of this literature review section, at first, the procedure of the systematic literature search is mapped out before outlining the overarching research phenomenon, i.e. the emergence of newness. Next, the research study is positioned in the broader domain of new product development theory and prior research on the front-end of innovation as well as radical product innovation are presented. Finally, key publications in the context of the definition and adaptation of new product concepts are discussed.

2.1 Aim of literature review

The aim of this literature review is to disclose the current state of knowledge in the field of new product concepts emerging in the context of the IVD industry. Consequentially the literature review will pursue the following objectives:

- **Objective 1:** *Exploring to what extent the field of emerging new product concepts under uncertainty has already been researched.*
- **Objective 2:** *Documenting the current state of knowledge on this phenomenon, particularly in the context of IVD.*
- **Objective 3:** *Identifying and reflecting upon key constructs that form the theoretical as well as managerial basis of this research.*

2.2 Literature review procedure

This section will discuss the systematic literature review approach adopted in this research. Thereby the key elements of the literature review such as search design, inclusion/exclusion criteria as well as the systematic analysis of the current state of knowledge on this phenomenon will be outlined. Figure 3 provides an overview of key steps in the process of a systematic literature review:

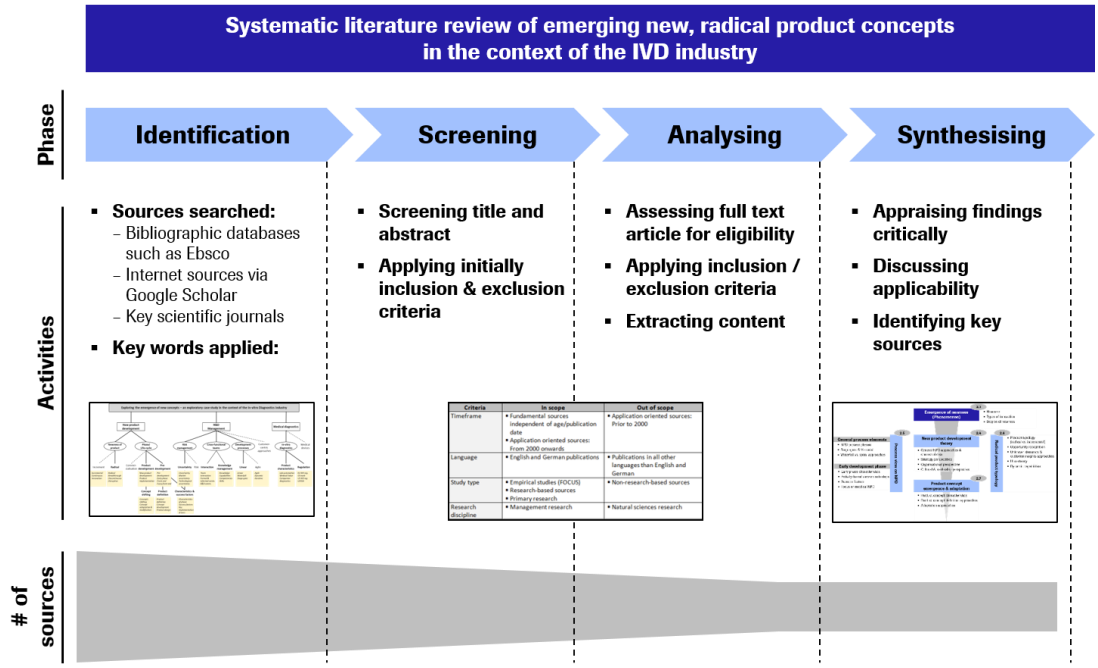

Figure 3: Systematic literature review approach

2.2.1 Applying a systematic literature review approach

The systematic literature review approach is seen as one of the most reliable styles of reviewing research (Clarke and Oxman inTranfield, Denyer, & Smart, 2003). This approach is used when a transparent, structured and therefore reproducible process is needed as is the case in the intersection of research areas such as new product concepts, uncertainty, technology development and In-vitro diagnostics. This contrasts with the **narrative review** technique which is the most usual form in management research.

This technique is critiqued for its subjectivity when it comes to the selection and appraisal of studies (Denyer & Tranfield, 2006). Taking this into consideration this

step was executed with great care, thereby highlighting the criticality of the review of existing research in the process of the overall doctoral research as it allows the researcher to position his research in the domain of NPD theory and to outline the expected contribution to knowledge.

Tranfield et al. (2003) propose the following three stages within a systematic review, which were also applied in this review:

- **Planning the review** and developing a review protocol (paragraph 2.2.2)
- **Conducting the review** and extracting data (paragraph 2.2.3)
- **Reporting and disseminating** the current state of research in the context of this study (paragraphs 2.3 -2.7)

2.2.2 Search design

As proposed by Tranfield et al. (2003), the comprehensive review covers published and unpublished sources. In the context of this analysis this means that published sources from published journals or bibliographic databases were used as well as unpublished sources like internet pages and conference documentation.

The detailed search comprised five main sources:

- Bibliographic databases focusing on business/management:
  The following databases, which cover published sources like journal articles, cases as well as dissertations, were searched: Ebsco, Business Source Complete, Emerald Insights and EThOS.
- Internet sources via Google Scholar
- Conference proceedings: Zetoc
- Library catalogues: Searching OPAC Bayerische Staatsbibliothek (Bavarian state library, Munich)
- Key scientific journals – identified through review of the ABS ranking: e.g. R&D Management, Journal of Marketing, Management Science, Journal of Product Innovation Management, Creativity and Innovation Management

To identify relevant sources a list of key words was compiled. This list was developed during several iterations of brainstorming and was reviewed during the data analysis phase (Figure 4). The key words can primarily be divided into four categories:

- **General terms** related to product development and the early development phase: e.g. new product development, early development phase, fuzzy front-end or product concept.
- **Method-specific terms** like product definition or stage-gate.
- **Theory-specific terms** such as new product development theory or concept shifting theory that primarily emerged during the data analysis phase.
- **Industry-specific terms** referring to medical devices or In-vitro Diagnostics.

The defined key words were combined in manifold ways when searching different sources of information. For the screening of the search results the titles and abstracts were scanned, and a set of inclusion/exclusion criteria applied. Through the strict application of the following inclusion and exclusion criteria (Table 2), a large set of more than 500 sources was compiled.

Table 2. Definition of inclusion and exclusion criteria

Criteria	In scope	Out of scope
Timeframe	▪ Fundamental sources independent of age/publication date ▪ Application oriented sources: From 2000 onwards	▪ Application oriented sources: Prior to 2000
Language	▪ English and German publications	▪ Publications in languages other than English and German
Study type	▪ Empirical studies (Focus) ▪ Research-based sources ▪ Primary research	▪ Non-research-based sources
Research discipline	▪ Management research	▪ Natural sciences research

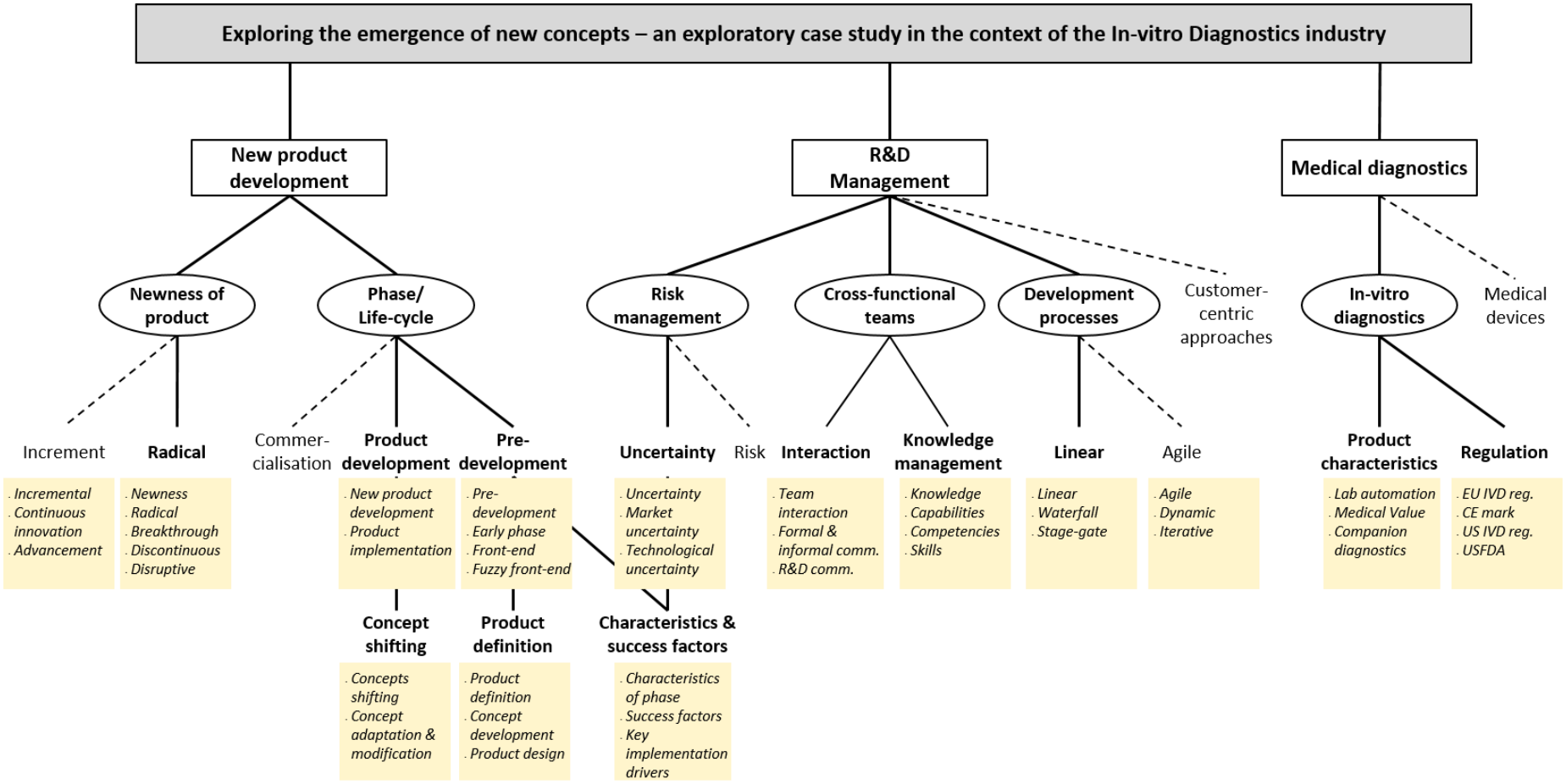

Figure 4: Mind map of key words applied – relevance tree

To legitimise the exclusion of certain research studies from the identified portfolio of sources each criterion shall be explained in more detail.

Timeframe

The search covered a broad time horizon with no cut-off date for seminal works in the respective domains. This is because early seminal works on new product development go back in time far before the 1980s. These fundamental works needed to be considered to better position the research. A stricter cut-off limit was applied for application-oriented sources. The used sources did primarily cover recent publications from 2000 to ensure that the impact of the latest developments and trends, such as digitalisation and globalisation, are considered.

Language

Publications in English and German language were included in this review. Further publications in other languages were not considered due to the fact that in the area of new product development it is common practice to publish in English and it is also taking into account that the researcher involved in this review is English and German speaking.

Study type

The focus of this literature review was set on research-based publications and primary research, as such excluding non-research-based sources. This decision can be justified as research publications generally provided details on the research approach and methods, which is a set of information that is essential when evaluating and critically reflecting on the results presented.

Research discipline

Only publications in the area of management and business research were considered for the analysis and synthesis phase. Publications from the research area of natural sciences were not relevant for this specific research topic in the context of the highly regulated in vitro diagnostics industry. This category was added to the list of inclusion and exclusion criteria after a preliminary test of the search design. The test showed that otherwise the scope would have been extended to the wide

space of natural sciences, which was not relevant for the purpose of this research study.

To also ensure a reasonable quality standard of sources, **three main indicators for the quality assessment were applied**. Firstly, wherever possible original sources like legislative texts, in the case of regulatory requirements, were used. Secondly, the grading of the respective journal the article was published in was considered and thirdly, the sources were checked with regards to signs of bias by authors.

It has to be noted that when just considering a research-based source, no empirical study or article was identified that was addressing the topic of emerging product concepts in the context of In-vitro diagnostics, medical devices, pharma or life sciences holistically. This can be seen as a first indication of the need for an empirical research study focusing on this particular phenomenon.

2.2.3 Overview of thematic areas identified during systematic literature review

As a result of the systematic literature review (see chapters 2.1-2.2), a broad variety of relevant sources was identified and analysed. These sources can be clustered in five broader themes that also provide the overall structure for presenting and discussing the literature review outcome.

The first, more abstract theme addresses the research phenomenon which is at the centre of this research study, namely the emergence of newness (chapter 2.3). This general theme is subsequently translated into the more specific product innovation field through the theory on new product development (chapter 2.4). Building on that, the final chapter 2.7 discusses the specific research topic of the emergence and adaptation of new product concepts.

Additionally, to provide a comprehensive picture of the research domain, the process nature of NPD and the emerging product concept, which received great attention from key scholars in that research domain, are outlined. This overarching theme is discussed within chapter 2.5. Furthermore, the specific nature of the product with regards to newness and radicalness requires particular attention

(product typology). The key aspects of this research stream are summarised in the context of organisational capabilities and knowledge as part of chapter 2.6.

Figure 5 provides a comprehensive overview of the overall literature review chapter including the five thematic clusters:

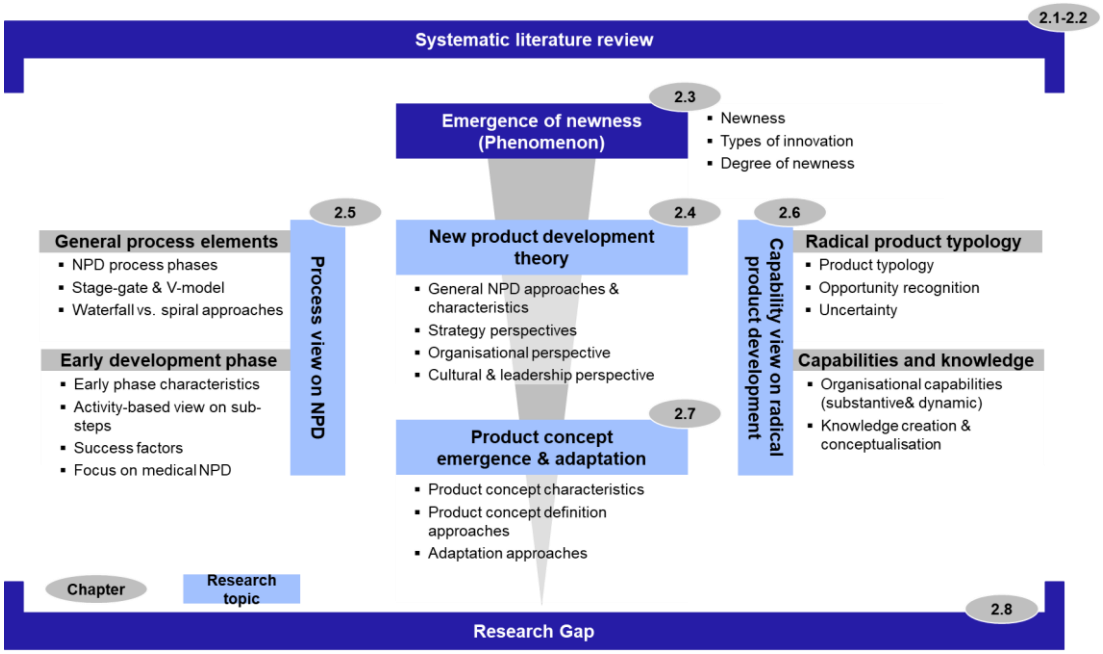

Figure 5. Overview of literature review chapters including thematic clusters

Before outlining these five thematic clusters, Table 3 provides a comprehensive overview of key publications for each of the clusters:

Table 3. Key publications identified during systematic literature review

Research topic	Themes	Author / Year	Type of research	Thematic focus
Emergence of newness (Phenomenon)	**Newness**	Johannessen et al. (2001)	▪ Empirical research ▪ Field studies	▪ Dimensions of newness
		Schumpeter and Fels (1939)	▪ Theoretical research	▪ Circular flows of economics ▪ Phenomenon of economic development
	Types of innovation	Dosi (1982)	▪ Theoretical research	▪ Technological innovation/paradigms ▪ Interplay between scientific advances, economic factors and institutional variables
		Johannessen et al. (2001)	▪ Empirical study ▪ Field studies	▪ Dimensions of newness
		Slappendel (1996)	▪ Theoretical research ▪ Literature review	▪ Organisational view on innovation ▪ Individualist, structural and interactive process perspectives
	Degree of newness	Damanpour (1991)	▪ Meta-analysis	▪ Determinants' and moderators' effect on organisational innovation ▪ Type of innovation, scope of adoption and innovation
		Garcia and Calantone (2002)&	▪ Theoretical research ▪ Literature review	▪ Meta-analysis on innovativeness with focus on radicalness ▪ Newness factors
		Reid and De Brentani (2004)	▪ Theoretical research	▪ Early phase of radical, discontinuous innovation ▪ Information flow and decision making process
New product development theory	**General NPD approaches & characteristics**	Rüegg-Stürm and Grand (2015) Rüegg-Stürm (2003)	▪ Book	▪ "St. Gallen Management-Model" ▪ Holistic management theory ▪ Integrating aspects like key stakeholders, categories, processes, resources, etc.
		Trott (2016)	▪ Book	▪ New product development characteristics such as organisation, strategy, processes
	Strategy perspectives	Booz, Allen, and Hamilton (1968)	▪ Empirical research	▪ Management practices with focus on NPD strategy
		Schilling (2015)	▪ Book	▪ Strategic management with focus on technological innovation
		Moenaert, De Meyer, Souder, and Deschoolmeester (1995)	▪ Empirical research ▪ Ex post facto design	▪ Strategic impact of R&D as well as marketing activities ▪ Uncertainty reduction

Research topic	Themes	Author / Year	Type of research	Thematic focus
	Organisational perspective	Griffin, Price, Vojak, and Hoffman (2014)	▪ Empirical research	▪ Role of organisation structures as well as individuals on innovation
		Jones (2013)	▪ Book	▪ Organisational models incl. design implications and influencing factors for structural options
		Eisenhardt (1985)	▪ Empirical research ▪ Questionnaire	▪ Control mechanisms for innovation with focus on reward systems
	Cultural & leadership perspective	Dobni (2008)	▪ Empirical research ▪ Survey	▪ Innovation culture as source for competitive differentiation ▪ Model for measuring an organization's innovation culture
		Van de Ven (2017)	▪ Empirical research ▪	▪ Managerial role and control mechanisms in leading, relating, and cycling through NPD
		Vojak, Price, and Griffin (2012)	▪ Empirical research	▪ Innovation culture ▪ Role of management in leading serial innovators
		Zien and Buckler (1997)	▪ Empirical research ▪ Interviewing	▪ Innovation spirit in multi-national corporations
Process view on NPD – General process elements	**General NPD process phases**	Cooper (1988)	▪ Empirical research ▪ Retrospective case-study	▪ New product development process ▪ Role of formal new product process
		Smith and Reinertsen (1991)	▪ Empirical research ▪ Case studies	▪ Product life cycle and development cycle ▪ Practical tools for development cycle reduction
	Stage-gate & V-model	Alexander and Clarkson (2002)	▪ Theoretical research	▪ Design for validation v-model in medical context
		Arrighi, Le Masson, and Weil (2015)	▪ Case study	▪ Connecting NPD process phases with design processes
		Cooper (1990)	▪ Empirical research ▪ Case-study	▪ Stage-gate system and implications for managing NPD ▪ Stage-gate system from idea to post-implementation review
		Cooper and Kleinschmidt (1991)	▪ Empirical research ▪ Case-study	▪ Strategic importance of new product development processes
	Spiral approaches	Edwards, Cooper, Vedsmand, and Nardelli (2019)	▪ Empirical research	▪ Hybrid model of agile and stage-gate development approaches ▪ Focus on small-medium-sized enterprises
		Gonzalez (2014)	▪ Theoretical research	▪ Advancing agile approaches in the context of front-end ▪ Agile project management, management innovation

Research topic	Themes	Author / Year	Type of research	Thematic focus
		Probhaker (2006)	▪ Conceptual research ▪ Practical implication	▪ Dynamic solutions delivery model
		Schwaber and Sutherland (2011)	▪ Empirical research	▪ Agile / SCRUM guide incl. process and tools for application
Early development phase	**Early phase characteristics**	Koen et al. (2001)	▪ Empirical research ▪ Testing theoretical model based on survey	▪ Theoretical model - New Concept Development ▪ Key elements such as opportunity identification/analysis, ideas genesis, ideas selection, technology development
		Moenaert et al. (1995)	▪ Empirical research ▪ Ex post facto design	▪ Front-end, fuzzy front-end characteristics incl. uncertainty ▪ Integration of R&D as well as marketing activities
	Activity-based view on sub-steps	Cooper (1988); (Cooper, 1994)	▪ Empirical research	▪ Role and activities of a formal NPD process e.g. screening, market research, product testing, financial analysis
		Pietzsch et al. (2009)	▪ Empirical research ▪ Best practice analysis & interviews	▪ Process characteristics for medical devices ▪ Impact of regulatory authorities such as US FDA on development activities
	Success factors	Bacon et al. (1994)	▪ Empirical research ▪ Case study design	▪ Influence of factors such as development cycle times, decision making, senior management involvement, etc.
		Florén, Frishammar, Parida, and Wincent (2018)	▪ Conceptualising based on literature review	▪ Framework building on 2 types of success factors, foundational factors and project specific factors
		Verworn, Herstatt, and Nagahira (2008) (Verworn, 2009)	▪ Empirical research ▪ Testing conceptual model based on survey data	▪ Key variables of front-end impacting project execution and project success ▪ Influence of uncertainty over course of project
	Focus on medical NPD	Brown, Dixon, Eatock, Meenan, and Young (2008)	▪ Empirical research ▪ Survey design	▪ Success factors for medical device development ▪ Focus on company and product factors
		Eatock, Dixon, and Young (2009)	▪ Empirical research ▪ Survey design	▪ Evaluating in medical context the adoption and impact on success of development tools and methods such as quality function deployment, lean development, design of experiment
		Medina et al. (2013)	▪ Empirical research ▪ Mostly document analysis	▪ Development model and process based on clusters such as regulatory and medical specialties, patents, development, etc.
		Pietzsch et al. (2009)(Jan B. Pietzsch & Paté-Cornell, 2008)	▪ Empirical research ▪ Best practices / interviews	▪ Process characteristics for medical devices ▪ Impact of regulatory authorities such as US FDA on NPD

Research topic	Themes	Author / Year	Type of research	Thematic focus
Capability view on radical product development	**Product typology (radical vs. incremental)**	Eling and Herstatt (2017)	▪ Empirical research	▪ Approaches to manage the front end of radical as well as incremental innovation projects ▪ Elements such as uncertainty triggering fuzziness
		Garcia and Calantone (2002)	▪ Literature review	▪ Terminological differences between incremental and discontinuous/radical innovation
		Gassmann and Schweitzer (2014)	▪ Book	▪ Management of front-end of innovation, focus on radical type ▪ Dealing with uncertainty, focus on management of people
		Reid and De Brentani (2004)	▪ Theoretical research	▪ Role of individuals and organisations for radical innovation
		Veryzer Jr (1998)	▪ Empirical research ▪ Case study design	▪ Exploratory nature of discontinuous NPD processes, reflecting convergence of developing technologies & contextual factors
	Opportunity recognition	Christensen (2013)	▪ Book	▪ Challenges to recognise opportunity of new technology
		O'Connor and Rice (2001)	▪ Empirical research ▪ Case study design	▪ Events of opportunity recognition during idea generation but also during further development activities
	Unknown demands & customer insights approaches	Griffin and Hauser (1993)	▪ Empirical research	▪ Voice of customer in new product development e.g. via structured approaches such as quality function deployment
		O'Connor (1998)	▪ Empirical research ▪ Case study design	▪ Balancing a vision of a product based on a technology and a customer-driven perspective
		Verworn et al. (2008)	▪ Empirical research ▪ Survey design	▪ Differences between incremental and radical NPD highlighting challenge to estimate market and customer demands
	Uncertainty	Gifford et al. (1979)	▪ Empirical study	▪ Definitions and measures of uncertainty particularly in context of decision-making settings
		O'Connor and Rice (2013)	▪ Empirical research ▪ Longitudinal case study	▪ Model of uncertainties comprising technological, market, organisational as well as resource aspects
		Zhang and Doll (2001)	▪ Theoretical research ▪ Conceptualisation based on literature review	▪ -Applying uncertainty theory in context of front.end fuzziness, leading to definition of fuzziness in terms of environmental uncertainty
	Organisational knowledge conceptualisation	Akbar and Tzokas (2013)	▪ Empirical research	▪ Organisational knowledge conceptualisation at front-end of new radical product development ▪ Integrating steps of conceptualisation in terms of overlaps, outcomes, contributors, interactions and volatility

Research topic	Themes	Author / Year	Type of research	Thematic focus
		Nonaka and Von Krogh (2009)	▪ Theoretical research	▪ Role of tacit knowledge and knowledge conversion in organisational knowledge creation
		Nonaka and Takeuchi (1995)	▪ Empirical research	▪ Development of SECI model ▪ Conversion between tacit and explicit knowledge
		Pérez-Luño, Alegre, and Valle-Cabrera (2019)	▪ Empirical research	▪ Connecting knowledge management (e.g. role of tacit knowledge) with product innovation
	Organisational capabilities	Easterby-Smith and Prieto (2008) & Easterby-Smith, Lyles, and Peteraf (2009)	▪ Theoretical research	▪ Nature of dynamic capabilities and their consequences ▪ Applied in the context of knowledge management
		Eisenhardt and Martin (2000)	▪ Theoretical research	▪ Characteristics of dynamic capabilities ▪ Resource-based view of a firm on dynamic capabilities and its processes
		Turcan and Juho (2016)	▪ Empirical research ▪ Multiple-case study	▪ Dynamic capabilities in context of early stage ventures
		Winter (2003)	▪ Theoretical research	▪ Comparing substantive, lower-order capabilities with dynamic, higher-order capabilities
Product concept emergence & adaptation	**Product concept characteristics**	Hooge, Chen, and Laousse (2019)	▪ Empirical research ▪ Case study design	▪ Innovation capability management in front-end ▪ Developing a typology of emerging concepts incl. structured process and patterns of emergence
		Koen et al. (2001)	▪ Empirical research ▪ Testing theoretical model based on survey	▪ Theoretical model - New Concept Development ▪ Key elements such as opportunity identification/analysis, ideas genesis/selection, concept and technology development
		Kotler, Armstrong, Wong, and Saunders (2011)	▪ Book	▪ Definition and delineation of key terms such as products, product concept, etc. from a marketing perspective
		Krishnan and Ulrich (2001)	▪ Theoretical research ▪ Literature review	▪ Interconnecting aspects such as concept development, product strategy, product design, performance testing and validation in a decision-making framework
		Montoya-Weiss and O'Driscoll (2000)	▪ Empirical research ▪ Case study design	▪ Multi-stage process to transform an initial idea into a robust product concept
	Adaptation	Bacon et al. (1994)	▪ Empirical research ▪ Case study design	▪ Managing product definition at early point in time ▪ Investigating influence of factors such as development cycle

Research topic	Themes	Author / Year	Type of research	Thematic focus
	approaches			times, decision making, senior management involvement
		Florén and Frishammar (2012)	▪ Theoretical research	▪ Theoretical framework covering several early stage adaptations to allow for a corroborated product definition
		Griffin et al. (2014)	▪ Empirical research ▪ Case study design	▪ Role of individuals and leadership to overcome barriers to develop radical product concepts, bringing them to market
		O'Connor and Rice (2001)	▪ Empirical research ▪ Case study design	▪ Later stage events of opportunity recognition triggering adaptation of product concept
		Seidel (2007)	▪ Empirical research ▪ Case study design	▪ Concept shifting to conceptualise changes to novel, radical product concepts after initial generation ▪ Events triggering changes to specific concept components to ensure project progression

Next, all five thematic clusters and their key publications will be discussed in a comprehensive way.

2.3 Emergence of Newness – Phenomenon

When researching the phenomenon of the emergence of new product concepts that builds on new technology it is all about the degree of innovation for NPD. The description of the phenomenon and the use of the expression "new" implies that new product innovation comes along with "newness" (Johannessen et al., 2001). This aspect of newness has received much attention amongst researchers in the past decades as innovation was seen as a key driver to create and maintain competitive advantage in the long run (Danneels & Kleinschmidt, 2001; Drazin & Schoonhoven, 1996).

Literature on innovation can be classified into various research streams, ranging from specific research domains that look at innovation from specific angles such as technology development and business models to holistic innovation approaches such as the "St. Gallen Business Innovation Model".

Following Johannessen et al. (2001), the more specific innovation approaches comprise orientations such as:

- **Individual-oriented perspective**: focusing on the role of individuals and the influence of related aspects such as gender, age, educational training or creativity on innovation.
- **Structure-oriented perspective**: highlighting the importance of organisational factors to foster or limit an organisation's ability to innovate.
- **Interactive-oriented perspective**: putting the interaction of individuals and groups as well as their actions (e.g. decision making) at the centre of research enquiries.
- **Systems of innovation-oriented perspective**: paying great attention to the effect of local, regional or trans-regional innovation systems on innovation (i.e. ecosystems comprising various stakeholders such as research institutions, customers, suppliers, etc.).

All these research streams have two aspects in common, they build on the concept of (a) a process of emergence and (b) newness as a basis for innovation (Johannessen et al., 2001; Schumpeter & Fels, 1939; Slappendel, 1996). With

regards to the aspect of *newness*, leading researchers such as Johannessen et al. (2001) classified six types of innovation:

- New products
- New services
- New methods of manufacturing
- Opening new markets
- New sources of supply
- New ways of working

What these types of innovation have in common, is that they build on the same key concept of *newness* as a source of innovation, which allows for differentiating between true innovation on the one hand and mere change on the other (Slappendel, 1996).

To further outline the core concept of *newness*, Johannessen et al. (2001) suggest reflecting upon the three questions: What is new? How new is it? To whom is it new?

The first question "**What is new?**" refers to the substance of the innovation, be it a new service, a new technology or eventually a new administrative system (What's) (Damanpour, 1991). As a result, it is possible to differentiate between mere change and newness that allows for real innovation (Damanpour, 1991; Slappendel, 1996).

The second question "**How new?**" focuses on the degree of newness. Several empirical as well as theoretical research studies have paid attention to the extent of newness that determines the degree of innovativeness. In this context Garcia and Calantone (2002) and Dosi (1982) have for example debated the distinction between two types of newness, i.e. radical and incremental innovation. By this, newness is characterised through the indicator of whether the newly developed solution/item/subject stays within an already existing innovation paradigm (incremental) or whether it is associated with more "revolutionary" or "discontinuous" innovation outside an existing innovation paradigm (radical) (Dosi, 1982; Reid & De Brentani, 2004; Veryzer Jr, 1998).

This basic definition of the degree of newness ("How new?") and the idea of staying within or moving outside an innovation paradigm directly leads to the aspect of perspectives on newness. By asking the question "**New to whom?**" one raises the awareness for the unit of analysis in respect of the perspective on newness, meaning that when evaluating the extent of newness ("What is new?" and "How new?") one needs to take the unit of analysis into account. To cover both new product and services as well as processes, Kotabe and Scott Swan (1995) and Johannessen et al. (2001) argue for assessing newness from an industry-/firm-based perspective.

These three questions can also be integrated (Jin, Shu, & Zhou, 2019) and used to classify the degree of newness in a 3x3 matrix (Figure 6) along the two dimensions of technological and market newness:

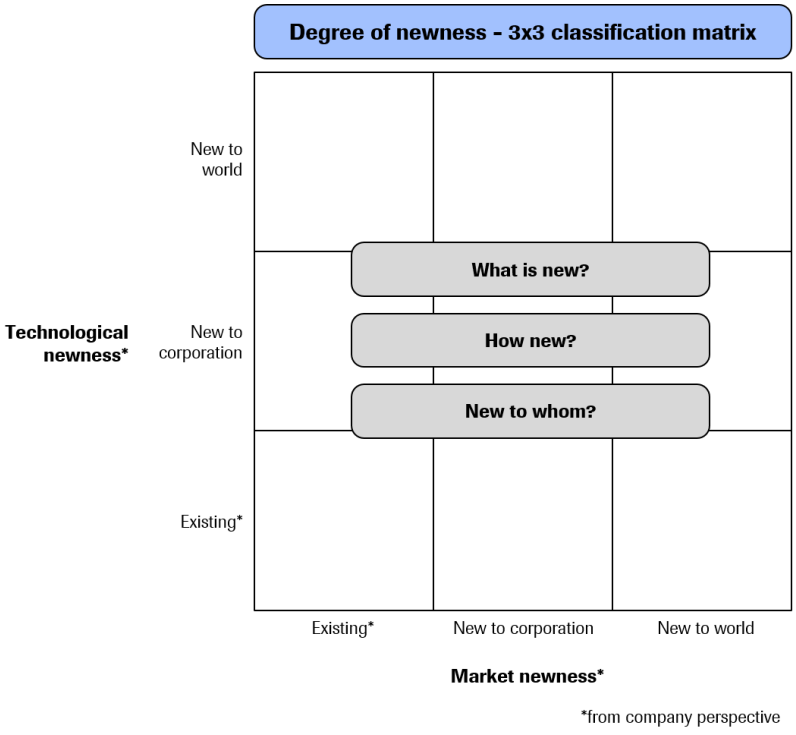

Figure 6. 3x3 matrix to classify degree of newness

These questions as well as the resulting 3x3 classification matrix will later on be used to characterise the two sampled within-cases in more detail (see section 4.2).

As mentioned above, *newness* can be observed in several areas such as product/service but also process developments. However, when it comes to a successful realisation of newness it is rather about an emergence and adaptation

process of the innovation than about the degree of advancement (Johannessen et al., 2001).

Damanpour (1991), a key scholar in this domain, defined the emergence and implementation of innovation as “the generation, development and adaptation of novel ideas” (Damanpour, 1991). This emergence of new product developments can be seen as the initial phase of a two-stage conceptualisation which starts with an initiation stage and concludes with the implementation stage (Duncan, 1976; Johannessen et al., 2001). In the context of the initiation phase, the early emergence process comprises steps such as “problem perception, information gathering, attitude formation and evaluation” (Damanpour, 1991) which lead to the decision of whether to adopt new developments or not.

Following Dosi (1982), such emergence can be triggered by two contrary developments. Thereby he is opposing one-directional explanations of innovation that primarily recognise market-driven stimuli. In fact, the key driver for the emergence of new product concepts can either be traced back to technological factors (“technology push”), market forces (“demand-pull”) or a combination of both (Dosi, 1982). Technology push approaches on the one hand highlight the causal determination of new technological developments that manage to advance from science and technology development to the market. Demand-pull approaches on the other hand recognise market dynamics as the key trigger for new product development and technological change.

After this primary initiation, the emerging product concept is implemented during new product development, a phase in which the new product concept as well as the implementing organisation are adopted to allow for an initial utilisation as well as continued use of that new product (Damanpour, 1991).

The two stages described above have received much attention by researchers in the past decades as the organisational characteristics that foster the initiation of new product development differ considerably from those that facilitate its successful implementation (Agostini, Nosella, & Filippini, 2016; Duncan, 1976). In this context, a whole new research domain in the field of innovation models emerged that focussed on the contradicting requirements of organisational characteristics to

either foster successful initiation (exploration) or implementation (exploitation) of innovation. In the context of newly emerging product concepts, this refers to the fact that, for example, low organisational formalisation as well as low centralisation promote the initiation of new product concepts whereas a successful implementation favours, in turn, a high formalisation and low structural complexity (Awojide, Hodgkinson, & Ravishankar, 2018; Damanpour & Aravind, 2012).

Taking the above into consideration one can summarise that this research phenomenon has received great attention, particularly when conceiving the emergence of newness as innovation in general and new product innovation in particular. This aspect will become even more important in the future as the speed of change in the market place is constantly rising, driven by an exponential development of technological advancement, increasing global competition or faster cycles of shifting customer needs (Johannessen et al., 2001). Next, the general phenomenon is transferred into the specific context of new product development.

2.4 New product development embedded in general management research

Providing the market with new products is critical for the long-term commercial success of a corporation, hence the management of new product development is of strategic importance (Van Oorschot, Eling, & Langerak, 2018). NPD has been subject to many research studies that have focused on major areas of interest, such as the strategic perspective, the organizational aspects, their process nature or the cultural/leadership view (Cooper, 2019; Schilling, 2015; Trott, 2016). All these areas also represent key focus areas of general management theory like the St. Gallen Management-Model (Rüegg-Stürm, 2003; Rüegg-Stürm & Grand, 2015).

From a strategic perspective, new product development is part of the product strategy which can be seen as a **sub-strategy of the overall corporation or business area strategy** (Booz et al., 1968; Krishnan & Ulrich, 2001; Schilling, 2015). It concerns the transformation of market insights into a market opportunity and ultimately a product available for sale, considering aspects such as target market,

project prioritisation, technology fit, by answering questions like (Moenaert et al., 1995; Trott, 2016):

- What is the firm's target market?
- Which portfolio of product opportunities will be pursued?
- What are the timing and resource requirements of NPD projects?
- Which technologies will be employed?

This finally results in consolidated product and technology roadmaps to illustrate the strategic NPD portfolio perspective.

From the perspective of organizational theory, research has either focused on the impact of the **organizational structures** on NPD (Griffin, 1997; Jones, 2013), such as matrix or decentralized organizations, or on **process planning**, which led to concepts such as the stage-gate process (Cooper, 1988, 2006). This process view helped to structure development activities within globally operating organisations, improving their operational performance through faster development and stricter cost controlling. Due to the significance of the process perspective to the general research domain of NPD but also to this particular research study, the process nature as well as the specific characteristics of the early process phase shall be characterised in more detail in separate paragraphs of this literature review (2.5).

As part of organisational theory, NPD research has also addressed specific aspects such as R&D decision making and control mechanisms like performance evaluation and rewards (Eisenhardt, 1985; Krishnan & Ulrich, 2001; Martinsuo & Poskela, 2011; Van de Ven, 2017).

These control mechanisms are also closely linked to the broader fields of leadership and innovation culture. Research has shown a strong link between innovativeness of an organisation and its organisational culture and spirit (Dobni, 2008; Zien & Buckler, 1997). It has for instance been found that the innovative strengths of an organization are associated with a culture that emphasises learning development but also strong market and customer centricity (Hurley & Hult, 1998; Zien & Buckler, 1997). Furthermore (senior) leadership aspects like participative decision making, reward system or monitoring performance are recognised to have a significant

impact on an organisation's innovation capacity (Dobni, 2008; Van de Ven, 2017). This also led to a reframing of the development of novel, innovative products and solutions by exploring a people perspective. In this context, Vojak et al. (2012) introduced and focused on the role of serial innovators who have repeatedly proven their crucial role in delivering innovation. The subsequent graph outlines the essential features/characteristics of serial innovators as well as associated managerial implications on how to best lead such kind of people, fostering an innovation culture.

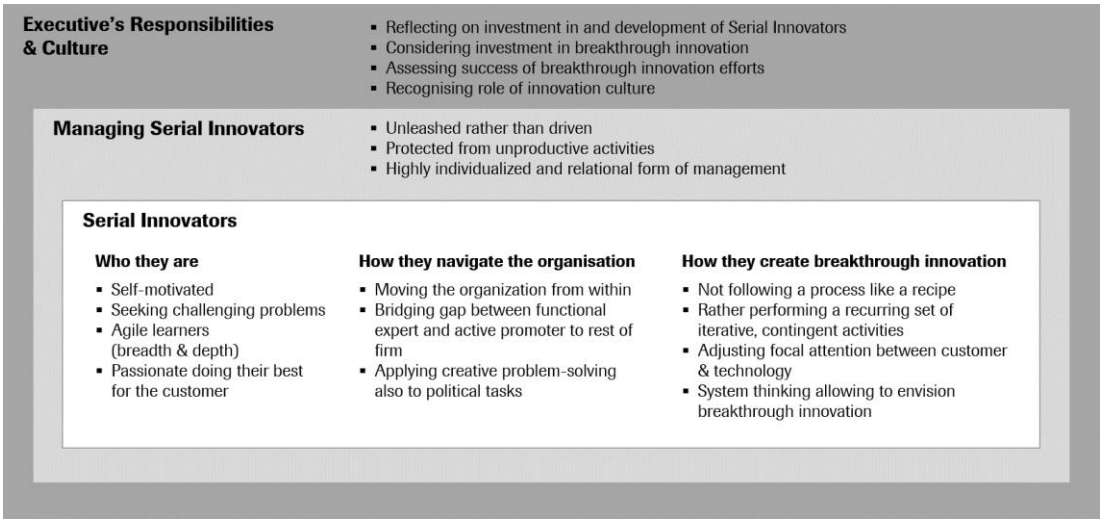

Figure 7. People perspective on breakthrough innovation (adapted from Vojak et al. (2012))

Considering the above stated, one can summarise that new product development is a highly interdisciplinary research field integrating various strategy, process, organizational, cultural and leadership theories which therefore triggers a holistic assessment of the emergence of new product concepts in the early NPD phase.

2.5 Process view on new product development

With the aim of learning about and improving new product development one key research stream within this domain focuses on its process-nature (Cooper & Kleinschmidt, 1991). At first, section 2.5.1 provides an overview of general process aspects such as the overall new product development phases and basic approaches like the stage-gate model. Afterwards, the specific characteristics of the early

development phase in which product concepts typically emerge are discussed as part of section 2.5.2.

2.5.1 General perspectives on NPD processes

The new product development process usually comprises three phases (a) pre-development, (b) development and (c) marketing (see also Figure 8).

Pre-development which is addressed in more detail in section 2.5.2, is also called front-end of innovation or fuzzy front end and it comprises the initial steps from idea creation/collection, idea incubation, idea assessment through to release to development (Smith & Reinertsen, 1991). The associated selection decisions are taken on a portfolio level as well as on a single project-level. In the subsequent formal **development** phase, an authorised and funded project is initiated and a new product is developed and manufacturing is set up. Finally, in the **marketing** phase the new product is launched and marketed (Russell & Tippett, 2008).

Figure 8: New Product Development Phases

In the past decades many leading firms have applied a formal, phased product development process, such as the stage-gate approach, to their development activities (Cooper, 1994). The aim of the formalisation was to improve product development with regards to both effectiveness and efficiency (Cooper & Kleinschmidt, 1991). Consequently, this had a major impact on a firm's design of management and controlling procedures.

The stage-gate process put forward by Cooper (1994) is a formal blueprint that steers an idea from its creation through to and beyond the market launch. The process consists of a set of information gathering and analysis stages (Figure 9). Each stage is followed by a gate at which, based on specific criteria, a go-/no-go decision is taken. In that sense, gates are defined as quality control mechanisms.

For illustration, the individual stages and gates of a five-stage process following Cooper and Kleinschmidt (1991) are shown and outlined below.

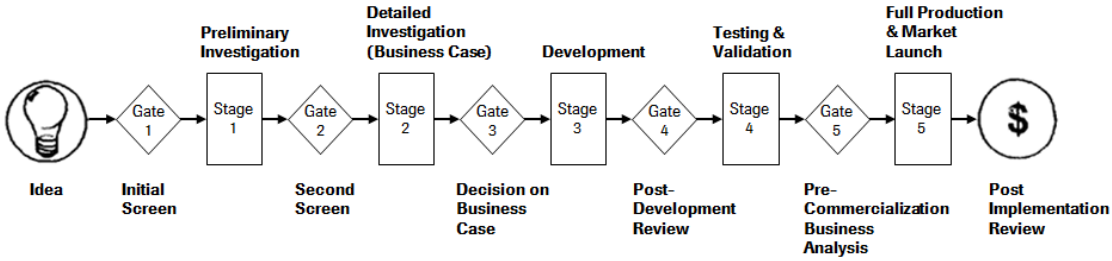

Figure 9: Stage-gate process (Cooper & Kleinschmidt, 1991)

The new product development process is initiated by a new product idea which is moving on the **Gate 1 "Initial Screen"** with a set of deliverables, respectively inputs. In this case, the input may consist of a detailed description of the product idea including a first draft of the value proposition. These inputs are submitted to the first gate where a review board applies a set of exit criteria. The criteria can be seen as a hurdle to decide upon for moving the product idea and hence the project to the next stage "Preliminary Investigation". The criteria at this early gate deal for example with strategic alignment, opportunity assessment, market attractiveness but also technical feasibility. Based on these criteria a first go-/no-go-decision is taken on two levels. On the one hand, each product idea is initially screened at a project level. On the other hand, multiple product ideas may be screened and prioritised at a portfolio level.

Subsequently, a positively screened project moves on to **"Preliminary Investigation" (Stage 1).** During that phase, potential market and technological benefits are assessed by performing a broad variety of actions such as market research, user feedback or technical assessments. As a result of Stage 1, a first overview of relevant market and technological information is available at relatively low costs. This data forms the input for a "**Second Screen" (Gate 2)** which is very similar to Gate 1 but this time it builds upon a much broader and more detailed set of information. At this gate, as well as at all other gates, a checklist of quality criteria is applied. These gate checklists comprise a gate-specific set of judgement criteria that can either be categorised as optional "should meet" or mandatory "must meet" criteria.

In the case of a positive decision the project proceeds to the **"Detailed Investigation" stage (Stage 2)**, the last phase before actually entering into formal product development. This stage is composed of market activities such as research on customer needs or analysis of the competitive environment but also technological aspects such as showing technological feasibility or a proof-of-concept. As a final step in pre-development, the development team needs to verify the overall attractiveness of the project before making major resource/financial commitments.

This critical decision is taken at **Gate 3 "Decision on Business Case"**, a milestone which can also be seen as the entry gate for product development. At the same time, it is the last decision point before typically entering heavy spending. Therefore, the product idea is assessed on two levels: firstly, on a product concept level (i.e. target market, product positioning, product features, product specifications, etc.) and secondly on a project level, meaning that the project itself is assessed with regards to project plans, financials, etc. This ultimately leads to a formal product development decision and entry into the **"Development" stage (Stage 3)**.

This decision marks the transition from a pre-/early development into product development; a stage in which the product concept is implemented, marketing plans are developed and amongst others technical, manufacturing, patents or legal issues are resolved. During product development an intermediate **"Post-Development Review" is suggested (Gate 4)**, where the progress of the development activities is assessed, and the continued financial attractiveness of the project is reviewed. In addition, the remaining implementation activities are updated and detailed for project implementation until project launch. During that stage **(Stage 4 – "Testing & Validation")**, a broad variety of implementation activities are performed such as customer tests in the marketplace to demonstrate customer acceptance, or trial production runs to show robustness of manufacturing processes and confirmation of so far estimated production costs. All these testing and validation activities are required before approaching **Gate 5 – "Pre-Commercialization Business Analysis"**. This final gate is the last review and hence a

quality control checkpoint before releasing the product to the market. A focus of the assessment is set on a successful implementation and validation of product development activities. In addition, financial considerations play an important role in deciding on the product launch as well as the implementation of production and marketing plans. If the review is successful and a positive commercialisation decision is taken, the product is released for market launch and enters into **Stage 5 "Full Production & Market Launch"**.

After a certain product- and industry-specific period of time, when launch activities are completed and the new product is managed as a "regular" product, a final **"Post Implementation Review"** is conducted before officially terminating the project organisation. This last review of the project execution and also the product performance in the marketplace typically marks the end-point of the stage-gate process.

Even though in corporations customised stage-gate processes might consist of a different number of gates and stages and perhaps not every project will pass through all stages of such a process, all systems have in common that they try to increase R&D efficiency by managing NPD risks e.g. through addressing key challenges in each phase (Veryzer Jr, 1998).

Cooper's process flow must be seen as a second generation and evolution from the early beginnings of new product development processes established by National Aeronautics and Space Administration (NASA) and the waterfall model which Royce (1970) created for software development. The so-called NASA phased project planning was a first attempt to systematically manage the development process by breaking the development into specific phases. At that time, the process was engineering-driven and mostly a control methodology to check every development element for progress and completeness (Cooper, 1994). Therefore, the model was later questioned for its research focus and the primary consideration of technical risks with no marketing, finance or other function being involved. In addition, the business aspect had not yet been considered (Cooper, 1994). This was because the model was purely addressing development activities of government-funded projects and no business aspects. Subsequently, the second generation stage-gate

process originated by Robert G. Cooper evolved to an “end-to-end” process which ranges from idea creation to post-launch activities (for details see Figure 9). Furthermore, it advanced in its degree of functional integration through an involvement of further business functions like marketing and manufacturing.

Besides Cooper, a growing number of researchers have investigated the process nature of new product development throughout the 1980s and 1990s. Many works tried to generally determine which process elements are most likely to associate with new product success and others tried to adapt the process to specific contexts such as specific industries, product or project types (Cooper, 1990; Cooper, 1994; Leonard-Barton, 1992; Smith & Reinertsen, 1991).

Based on an empirical study, Cooper and Kleinschmidt (1991) postulate that a variety of leading firms have established a rigorous stage-gate process and that this is becoming the state-of-the-art process. At first sight, these results may be questioned as the survey was performed by the originator of the stage-gate process and it comprised only 29 in-depth interviews from five different companies, which is a relatively small sample size to claim generalisability. However, the importance and relevance of the stage-gate process needs to be acknowledged as various other studies such as Pietzsch et al. (2009) and Eatock et al. (2009) underpin the positive impact and broad application of this methodology in general and also in the context of medical device development.

A common concept, building on this approach, is the development of a product concept and ultimately a product according to the so-called “**V-model**” (see Figure 10) that was adopted to fit the regulatory validation requirements of the IVD industry. As a result, the validation V-model which is compliant with the change control regulations was introduced (Alexander & Clarkson, 2002). This model starts its product definition with determining the customer and product requirements a new product shall fulfil. Subsequently, it interlinks a sequence of development steps with each other and with the associated stages of testing. The vertical axis of the figure indicates the level of detail whereas the horizontal axis represents the temporal dimension meaning the project progress.

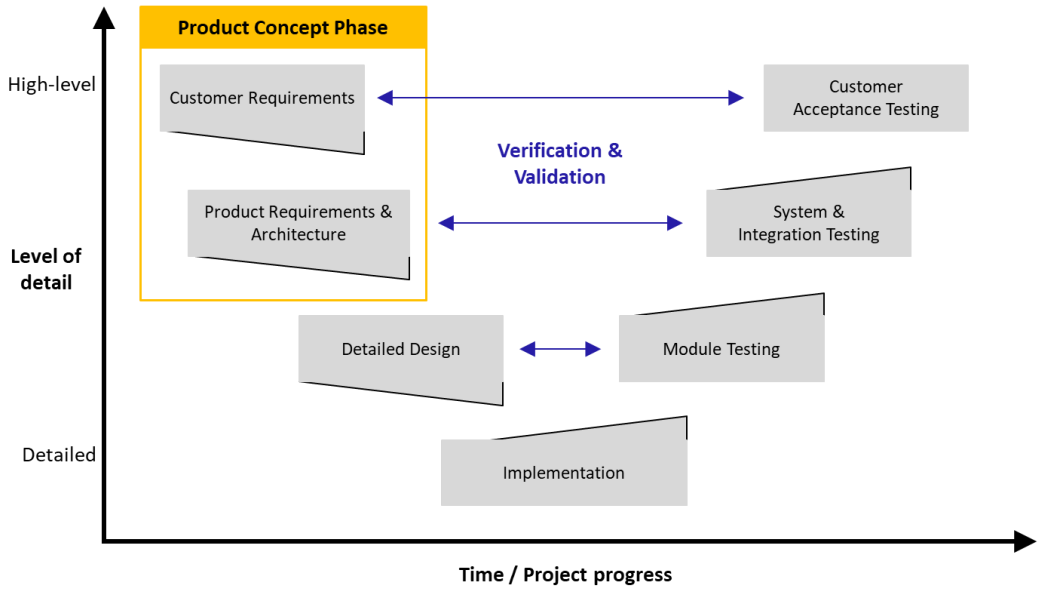

Figure 10. Key process steps of the V-Model (adapted from Alexander and Clarkson, 2002; Day, 2013)

During concept development and selection these early defined customer as well as product requirements are used as a basis for developing individual product concept components. To sufficiently describe the product and to demonstrate the product's performance in a **medical context**, a set of information needs to be provided which includes for example a detailed description of the intended use as well as a clinical investigation or summary of clinical data to show the safety and effectiveness of the new product (U.S. Food and Drug Administration, 2014b). From a quality standpoint, this **V-model makes sure that a device fits its intended use**. The process comprises all steps from the initial definition of the product concept through to the implementation of the manufacturing process and thereby ensures completeness throughout the process. On an operational level, the V-model approach is often linked to a stage-gate process and a classical, linear project management approach which was for example developed and formalised by the Project Management Institute (PMI). This is due to the fact that at the beginning the model asks to think ahead of all steps for the final device validation stage (Alexander & Clarkson, 2002).

Linear project management can be characterised as a control-oriented, phased approach that was institutionalised through the foundation of the Project

Management Institute in 1969 (Project Management Institute, 2008). This approach focuses on the elimination of uncertainty by planning ahead for various elements such as project time, project costs, project quality and communication based on a clear mission (Project Management Institute, 2008). Trial and error iterations for example are mostly excluded (Lenfle & Loch, 2010). Therefore, it must be critically noted that this is only possible if two preconditions are fulfilled. Firstly, project goals are clearly defined from the beginning and secondly the means of reaching the target are identified and plannable (Lenfle & Loch, 2010). This can be questioned in the context of novel projects with high uncertainty due to external and internal influencing factors.

Consequently, the stage-gate process has been critiqued for its lack of flexibility and inertia and even Cooper himself recognised the need for an adaptation of his methodology to the new reality which is characterised by a fast changing business environment and the emergence of new technologies (Cooper, 2009, 2014; Cooper & Sommer, 2016).

Alternative approaches exist which rather focus on dynamic capabilities such as an organisation's ability to react to external changes in a timely manner (Easterby-Smith et al., 2009; Edwards, Cooper, Vedsmand, & Nardelli, 2019; Helfat & Peteraf, 2003). Most approaches build on the spiral model, which stems from Barry Boehm's elaborations in the mid-1980s. It can be seen as a first attempt for a more agile and flexible development approach. New, modified spiral models such as the Dynamic Solution Delivery Model (Probhaker, 2006) and the SCRUM approach (Schwaber & Sutherland, 2011) have emerged in software development. These dynamic approaches, that are sometimes referred to as agile approaches, have specific characteristics in common that will subsequently be outlined based on the SCRUM approach as one of the most popular and widely used methodologies.

- **Iterative development**: Instead of one long development cycle, the development activities are split into several cycles. The number of cycles depends on the complexity of the product and the progress that is made during each iteration.

- **Time boxing**: Each development cycle, which is two to four weeks long, focuses on the delivery of certain requirements. During this so called sprint, requirements are not changed.
- **Focus on customer and fit for use**: Every requirement is prioritised, based on customer needs, and the "product owner" as proxy represents the customer in each iteration and throughout the development process.
- **Running system**: Furthermore, each iteration has the goal to deliver a running system that fulfils a set of customer requirements. This focus on functional capabilities allows frequent testing and therefore a constant feedback loop.
- **Cross-functionality**: All the above-mentioned aspects build up on open communication and collaboration across all functions involved. Frequent interaction such as the daily SCRUM and planning- & review-meetings in the beginning and at the end of each sprint facilitate intensive collaboration.

A more detailed overview of agile principles can be found in the agile manifesto which was published by 17 leading researchers and practitioners in the area of agile and dynamic development (Beck et al., 2001). Gonzalez (2014) particularly focused on the application of agile approaches in the early stages of innovation.

To sum up, the process-nature of new product development has been investigated intensively (Cooper & Kleinschmidt, 1991; Crawford & Di Benedetto, 2010). Highly structured process-driven approaches such as the seven- or five-stage process from Cooper (1988) have been formed to manage new product development. In a systematic, linear way individual stages are worked through and so-called gates act as quality control checkpoints. In early process phases, topics like preliminary market assessment, business analysis and technology reviews are addressed (Cooper, 1990). Later on, during product development and validation, various activities are recommended to implement the product concept, develop marketing plans and to resolve amongst others technical, manufacturing, patents or legal issues (Cooper & Kleinschmidt, 1991).

As a result, development processes have successfully been implemented in many corporations and have contributed significantly to a more efficient but also effective use of resources in new product development. However, particularly the stage-gate system as one of the most prominent process-driven development approaches is frequently critiqued for its inefficiency and high degree of formalisation. This means that for example certain project streams might wait at a gate until all required tasks are successfully completed and project progression is granted (Arrighi et al., 2015). In addition, the evaluation of stage-gate decision criteria in the front-end of new product development revealed that criteria mostly address technical, marketing as well as strategic alignment aspects but few criteria are available to assess the business potential of high-complexity and -novelty projects (Martinsuo & Poskela, 2011).

Therefore, specific attention needs to be paid to the sub-process steps at the front-end of innovation. During this phase, product concepts typically start to emerge, meaning that the key features of the new product are defined and the strategic directions for the following development activities are set (Eling & Herstatt, 2017; Koen et al., 2001). That is why the specific characteristics of this early phase will be examined and outlined in more detail in the subsequent section 2.5.2.

Furthermore, the current state of literature on development processes suggests that radical product development significantly deviates from incremental product development. Veryzer Jr (1998) for example found out that in the context of radical, technology-driven developments, organisations usually deviate from classical, linear development processes. Thus, the special aspects of radical innovation projects need to be analysed in more detail in a dedicated section (for further details see section 2.6).

2.5.2 Deep-dive into the early development phase

Pre- and early-development describe the stages of an emerging product before it enters formal product development (Markham, 2013). These phases have gained **broad attention** by researchers in the past decades, as several research studies

provided evidence of a positive impact of up-front activities on the overall success of new product development (Cooper & Kleinschmidt, 1995; Florén et al., 2018; Trotter, 2011). As a consequence, various concepts and terms arose (Moenaert et al., 1995) and the **early development phase** is now for example called Fuzzy Front-End, Front-End of Innovation, Pre-Development or Early Development (Koen et al., 2001; Smith & Reinertsen, 1991).

Initially Reinertsen (1985) introduced the term Fuzzy Front-End in 1985 to take the specific, fuzzy nature of the early development phase into consideration. Consequently, in the 1990s this project phase as well as the expression attracted a broad interest in the research field of NPD. Later on, more value-free terms such as "front-end of innovation" introduced by Koen et al. (2001) were also covering common elements prior to formal new product development, but provided an alternative expression to the so far predominantly used and more expressionistic term "fuzzy front-end" (Reinertsen, 1985).

In general, the pre- and early development phases comprise the steps in which an **organisation formulates the concept of a product** that needs to be developed and it determines whether or not resources will be invested in the development of the concrete product idea (Moenaert et al., 1995) (**outcome-based view**). Consecutively, the development project is initiated. Besides an outcome-based view on the front-end of innovation, an increasing number of publications have investigated this project phase from different angles such as a process- or activity-based view.

Looking at it from a **process perspective**, the concept of the Fuzzy front-end, promoted by Smith and Reinertsen (1991), is seen as the first phase of the NPD which covers the initial steps from the generation of an idea to its formal approval for development (respectively its termination). Further researchers such as Cooper (1988), Murphy and Kumar (1997) and Verworn et al. (2008) additionally subdivided this stage into individual sub-steps such as (a) generation of idea, (b) initial screening, (c) preliminary evaluation and (d) concept evaluation and thereby emphasise the importance of the two market-related & technology-related tasks.

From an **activity-based perspective,** different approaches exist regarding the sequence, wording, interrelation and formality of tasks but ultimately, they all have a similar scope in common. Overarching activities include the identification and assessment of an opportunity, generation of an idea, formulation and communication of a product strategy, definition of a product concept, planning of an NPD project as well as reviews through the management/decision body (Khurana & Rosenthal, 1998).

One research study by Pietzsch et al (2009) even focused on this development phase in the specific context of the medical device industry. As a result, they were able to adapt the list of most common activities in the early phase specifically for the development of medical devices as follows:

Phase 0 – Pre-development aspects:

- Company strategy fit
- Identification of clinical needs
- Preliminary market assessment
- Preliminary regulatory considerations
- Reimbursement strategy
- Intellectual property assessment

Phase 1 – Initiation / opportunity and risk analysis (Pre-development):

- Verification of clinical needs
- Early stage technology risk assessment
- Draft product concept
- Competitive product assessment
- Review and refinement of phase 0 activities
- Initial R&D planning

Phase 2 – Development - Formulation concept and feasibility

- Initiating development project
- Beginning of development activities

A more detailed description of early technology assessment and the overall new product development process in the context of new medical devices can be found in

the research studies of Pietzsch and Paté-Cornell (2008) as well as Pietzsch et al. (2009).

Independent of the outcome-, process- or activity-based perspective on the front-end of innovation, all definitions have in common that the approval and investment decision, whether positive or negative, typically marks the end-point of the front-end phase as well as at the very same moment also the initiation of formal product development (Kim & Wilemon, 2002).

The early phase has gained broad attention by researchers; several studies have provided evidence for a **positive impact of up-front activities and front-loading** on the overall success of new product development (Cooper & Kleinschmidt, 1995; Florén et al., 2018; Trotter, 2011). These connections were also supported by research studies that showed that front-end issues such as a non-properly defined product concept often causes project failure at later stages resulting in higher costs (Bacon et al., 1994). Due to these direct relationships between front-end activities and project success, several research studies have looked at identifying successful management practices (Brown, Dixon, Eatock, Meenan, & Young, 2008; Gassmann & Schweitzer, 2014; Hooge et al., 2019; Trotter, 2011). Bacon et al. (1994) narrowed down the list of factors for successful early product development to the following ten key capabilities/elements:

- **Strategic alignment**: product alignment with corporate or business unit strategy.
- **Customer/user needs assessment**: clear vision of needs (both performance & cost expectations).
- **Competitive analysis**: analysis of existing and prospective solutions of competitors.
- **Regulatory assessment**: consider regulatory requirements as well as IP matters.
- **Product positioning**: consider positioning towards customer and competitors.
- **Priority criteria list**: rank and prioritise key product features.

- **Risk assessment**: assess market, technology, manufacturing and design risks incl. mitigation measures.
- **Selection of market channel(s)**: identify appropriate market channels.
- **Guidance from management**: management guidance regarding objectives and trade-offs.
- **Project resources**: provide sufficient resources (financial & non-financial).

This list shows that the identified success factors not only cover a broad range of thematic areas such as organisation, strategy, resources, culture and leadership; the individual elements also take effect on different levels. Following Florén et al. (2018), these levels can be classified as **foundational or project-specific. Foundational factors** on the one hand are relevant for all a firm's projects and comprise aspects such as senior management support or the alignment of a new product concept with the corporate strategy. **Project-specific factors** on the other hand are just applicable to individual projects of a corporation. These factors may include the analysis of the competitive landscape, specific regulatory requirements or a clear project-specific set of product criteria to make trade-off decisions among product features.

Besides the identification of success factors, research studies have derived clear **operational practices and managerial implications to solve front-end problems** (Kim & Wilemon, 2002). In this context, Kim and Wilemon (2002) for example call for a consideration of multiple technological and/or commercial alternatives as part of risk management to cope with the sometimes fuzzy nature of a product idea. Moreover, the crucial role of a product champion is acknowledged when it comes to combining technical competence and market knowledge to achieve a high technical performance or to maintain the momentum despite setbacks: circumstances that frequently come along with the development of major innovations.

Besides general research on successful practices in the front-end phase, as stated above, multiple research studies have addressed single, more specific topics, ranging from **organisational and process to cultural** aspects.

In the context of **organisational** research, Moenaert et al. (1995) looked at the front-end from an interaction and cross-functionality perspective and suggested

fostering a close communication between R&D and marketing functions. That way, uncertainties should be reduced which in return has a positive impact on front-end performance.

Another research stream is focused on **control mechanisms** in the context of project organisations and processes (Poskela & Martinsuo, 2009; Simons, 1995). This is seen as an integral part of a company's organisational design as a multitude of managerial actions are pursued with the target to maintain or alter patterns in organisational activities (Simons, 1995). In the context of the front-end of product development, management control was particularly investigated with regards to **balancing the two opposing tendencies of creativity and control** (Poskela & Martinsuo, 2009; Simons, 1995). Up to now, research findings in this regard have been conflicting. This conflict on the role of management control goes back to two opposing perspectives on the issue; that on the one hand people working in the front end require a certain independence and freedom to deal with the associated uncertainty and to leverage the creativity elements of this phase (Blauth, Mauer, & Brettel, 2014). Whilst on the other hand, further researchers argue that behavioural control improves communication and coordination which is vital for using resources effectively and to achieve the company's long-term objectives (Poskela & Martinsuo, 2009).

In the context of **medical product development**, an additional aspect comes into play. As summarised by Brown et al. (2008) in their analysis of various studies on the success factors in NPD for medical devices, particularly the pre-development activities of preliminary market assessment and preliminary technical assessment have an impact on new product success. As also outlined in section 1.2, especially the technical assessment plays a key role in the context of the IVD industry as a large proportion of product innovation is linked to the development and introduction of new technologies. Technology development can therefore be seen as a precursor and facilitator of new product innovation.

According to Högman and Johannesson (2013) technology development is characterised by a rather diffuse goal of building up technological knowledge or demonstrating feasibility. The increasing technological knowledge comes along with

reduced technology risks even if uncertainty remains due to further unknowns (Cooper, 2006). On the contrary, new product development has the sharp goal of coming up with a commercial product in the end.

In practice, it is therefore common to separate technology and product development but at the same time to also closely interlink both streams (Cooper et al., 2002; Högman & Johannesson, 2013) as, often, a new product development is initiated as soon as technology development has shown a certain technological maturity and suitability for the product application.

This means that technological basic research is performed separately but it serves as a basis and a trigger for new product ideas. For this reason, technological development that is initially carried out separately, might transition to new product development and might then be executed and carried on as part of early product development. Consequently, in an early development phase the new product development project is **exposed to uncertainties in different dimensions** such as technological uncertainty but also associated regulatory or market uncertainties (Högman & Johannesson, 2013; van Oorschot, Sengupta, Akkermans, & van Wassenhove, 2010). In this regard, uncertainty is characterised by an inability to assign a certain likelihood to a specific outcome (Gifford et al., 1979). Risk in comparison is rather defined as an ability to ascribe a probability of occurrence to a specific incident. These patterns of uncertainty in the respective phases shall be analysed in more detail in the context of radical product typology, which forms the main topic of section 2.6.

To sum up, the early development phase comprises the steps in which an organisation formulates the concept of a product that needs to be developed and it determines whether or not resources will be invested in the development of the product idea (Moenaert et al., 1995). It can either be described by the process it follows, the activities that are carried out in this phase or the final outcome at the end of the front-end phase.

As multiple studies have provided evidence for a positive impact of front-end activities on the overall success of new product development (Cooper & Kleinschmidt, 1995; Florén et al., 2018; Trotter, 2011) this phase has received

noticeable attention by researcher. Several successful practices in managing this unique development phase were identified in areas such as organisation, strategy, resources, culture and leadership.

However, it has to be noted that the complexity of development activities is heavily dependent on the innovation type (radical vs. incremental) (Frishammar, Dahlskog, Krumlinde, & Yazgan, 2016; McDermott & O'Connor, 2002; Reid & De Brentani, 2004). The early development of radical new products poses considerable challenges to organisations and requires different approaches with regards to NPD activities such as strategic planning or market opportunity assessment (Eling & Herstatt, 2017; Poskela & Martinsuo, 2009; Verworn, 2009). Amongst others, Gassmann and Schweitzer (2014), Veryzer Jr (1998) and Reid and De Brentani (2004) suggest that significant differences between an incremental and radical development project can be traced back to the early development stage. Therefore, the next section will focus on the specific characteristics of radical innovation projects particularly in the front-end phase but also in the more general context of NPD.

2.6 A capability view on radical product development

Within the great variety of existing studies on new product development, different typologies of products are used, such as incremental and radical products (Eling & Herstatt, 2017; Garcia & Calantone, 2002; Gassmann & Schweitzer, 2014). Next, the specific characteristics of new radical product development are outlined, followed by a discussion of the capability and knowledge perspective on new product development of this innovation type.

2.6.1 Radical product typology

Radical product innovation, as described in this present study, triggered by new technology, has been described in different ways. For example the terms radical innovation (Garcia & Calantone, 2002) and discontinuous innovation (Reid & De Brentani, 2004; Veryzer Jr, 1998) have been used interchangeably for settings in

which new product concepts were new from internal as well as external perspectives (Holahan, Sullivan, & Markham, 2014; O'Connor, 1998). Internal novelty refers to the technology that is new to the organisation or corporation and external novelty points to technology that is new to the market or industry.

In their more specific definition of "technological innovation" the Organisation for Economic Co-operation and Development (OECD) (1991), highlighted that technological innovation depends on a combination of technological development in respect of invention with commercialisation. Innovation in that context is not purely about basic or applied research but also about introducing the product to the market (Garcia & Calantone, 2002). Otherwise, a technological novelty will just remain an invention with no or only very limited economic value.

A broad variety of research studies have investigated this specific product type with its unique characteristics (see also Table 4 below) regarding the novelty of the product, its customer needs as well as the uncertainty related to such projects. Consequently, development activities need attention concerning the required expertise, the development process that is followed and the corporate culture.

Table 4. Characteristics of radical NPD projects (derived from Garcia and Calantone (2002))

Characteristics	Radical	Incremental
Newness	Rather revolutionary	Rather evolutionary
Demand/ customer need	Creating a so far unrecognised demand	Satisfying known, unmet needs
Uncertainty/risk	Uncertainty settings	Risk management
Process nature	Different focus of activities and sequence of process steps	Often classical sequence of stage-gate systems
Expertise	Building up new knowledge & capabilities	Building mostly on existing knowledge & capabilities
Culture / mindset	Rather creative and forward-looking	Rather efficiency-and improvement-driven

The radical nature of the product typically also goes back to the degree of **newness**. However, this newness can be viewed from different perspectives: from a company's (O'Connor & Rice, 2001), a customer's (Garcia & Calantone, 2002) or a market/industry's (Kleinschmidt & Cooper, 1991).

Garcia and Calantone (2002), bundle these different perspectives into a macro and a micro perspective on product innovation. The macro view on the one hand sees innovativeness as the capacity of a new product to trigger a **paradigm shift in global science and/or the structure of a market or even of a whole industry**. The micro view on the other hand just looks at the innovativeness of a new product or service from a customer's/user's as well as the company's perspective (Garcia & Calantone, 2002). Particularly the micro-level view is heavily influenced by the perception of individuals that are part of the organisation and hence depends significantly on the available experience with the technology that is developed (Veryzer Jr, 1998).

Following Garcia and Calantone (2002) radical innovation comprises a new technology element that leads to discontinuities on both a micro as well as a macro level. Veryzer Jr (1998) adds to this definition the opposing word pair of "evolutionary innovation" versus "revolutionary innovation" to explain the differences between incremental and radical innovation. In essence, most researchers have chosen a macro perspective (i.e. exogenous factors such as newness of technology to the world) to define radical innovation products, whereas incremental innovation products are predominantly defined on a micro-level (i.e. existing technology targeting existing markets).

A further aspect of newness in the context of radical development projects is the consilience of a novel business opportunity (solution) that is addressing newly identified or newly created and so far, unrecognised needs (problem). In his books "Seeing What's Next" and "The Innovator's Dilemma", Clayton Christensen provides numerous cases of established firms that are **lacking opportunity recognition** capabilities, meaning that they for example fail to envision unrecognised demands (problem/need) and the subsequent transformations of their own industry based on new technology (solution) (Christensen, 2013; Christensen, Anthony, & Roth, 2004).

Compared to incremental innovation which usually focuses on an improvement of existing products, e.g. through satisfaction of known customer needs, radical innovation often does not directly address a known need but rather creates a so far **unknown demand** (Garcia & Calantone, 2002). This in turn changes the role of the

customer in the early development phase as it is more exploratory and less customer-driven, meaning that many customers experience difficulties in envisioning the potential of a new technology product.

Well-known customer research methods to obtain and make use of customer information seem to be **less expedient in radical innovation contexts** than in incremental innovation contexts (Moon, Johnson, Mariadoss, & Cullen, 2018; O'Connor, 1998). O'Connor (1998), who has conducted research in this field for more than 20 years, identified significant changes in the way market learnings are generated and utilised. Changes occur for example in (a) the nature and point in time of a market-related inquiry, (b) the applied market learning techniques and/or (c) the confidence in the generated insights. Potential reasons for limited insights from classical approaches may originate from a more vague and fuzzier customer input as these usually have only little to compare the novel product to. Additionally, they may lack the ability to envision the associated new technological as well as market potential of the novel product (Veryzer Jr, 1998; Wang, Jin, Zhou, Li, & Yin, 2020).

But even if the customer requirements are fairly understood this doesn't necessarily mean that they are properly integrated into a radical product concept, for example via product specifications (Verworn et al., 2008). In their empirical research Verworn et al. (2008) suggested that this is particularly distinct for NPD projects where for example a lack of communication between technical and marketing functions or simply issues in translating customer insights into technical features frequently occur.

Even though the market and the customer are well understood, the nature of uncertainty that comes with radical innovation projects may pose considerable challenges to development teams. This was re-confirmed by O'Connor and Rice (2013) when assessing existing but also developing new managerial practices for radical innovation projects.

In this context, **uncertainty** is defined as the inability to assign likelihood to a certain outcome (Gifford et al., 1979). Risk in contrast, is regarded as the ability to assign such probabilities based on the perception of an existing relationship or pattern.

Thereby, Gifford et al. (1979) build their definition of uncertainty on two general characteristics, the available information load and potentially existing patterns (vs. randomness). This implies that uncertainty is rather low in situations if adequate data is timely available and if one in addition can discern a certain pattern of regularity (Zhang & Doll, 2001). Similarly Lawrence and Lorsch (1967) suggest that uncertainty, particularly environmental uncertainty, typically embraces three elements: (a) a lack of clarity regarding information, (b) a general ambiguity about the causal relationship between decisions and corresponding results and (c) a time lag between decision and feedback about the result.

Looking at **uncertainty from a project-level perspective**, O'Connor and Rice (2013) have compiled a comprehensive overview of four key categories of uncertainty: technical, market, organisational and resource; providing a framework in the context of radical innovation. These four key categories can be best described by outlining some of the potential discontinuities that might occur:

- **Technical**: major setback in technology or application development.
- **Market**: market test of prototype fails; assumptions about attractiveness turn out to be false.
- **Organisational**: loss of champion; change in senior management or project management.
- **Resource**: major loss or gain of funding; failure to close alliance deal.

Even if O'Connor and Rice (2013) are not proposing any clear recommendations for action, it is suggested that this broad variety of uncertainties can be reduced by developing new project management competencies as well as deploying adapted processes on a corporate-level to support radical innovation projects (O'Connor & Rice, 2013).

To cope with the unique challenges of radical product development, research on development practices in the context of **project uncertainty and risks** proposes different approaches **in the field of development processes** for example than for incremental product development (Qazi, Dikmen, & Birgonul, 2020). Veryzer Jr (1998) for instance focused on potential differences in the process space as classical

stage-gate approaches turned out not to be conducive to implementing radical development projects. In fact front-end activities ask for a higher degree of flexibility as rigorous processes might be destructive (Nobelius & Trygg, 2002; Verganti, 1999). The radical sample cases involved in the study of Veryzer Jr (1998) revealed that the process for discontinuous NPD significantly differed with regards to the focus of activities and the sequence of process steps for both the technological as well as the marketing streams. Examples for areas of difference comprise amongst others (a) the exploration of various technologies in parallel, (b) the role of a determined champion or "visionary", (c) the history of failed or discontinued projects within a company or organisational unit and (d) the impact of existing alliances with partners and suppliers (Veryzer Jr, 1998).

These differences in the development process were also confirmed by the empirical study of Herstatt et al. (2004) who in addition emphasised that R&D effectiveness as well as efficiency can be achieved if technological as well as market uncertainties are reduced through **initial planning**. Thereby, they highlighted the positive impact of initial planning during the front-end phase on mitigating the impact of uncertainties.

Additionally, decision making was identified as a process element that requires special attention. Such control mechanisms that need to be adapted for radical contexts have been investigated intensively (Frishammar et al., 2016; Reid & De Brentani, 2004; Zhang & Doll, 2001). Reid and De Brentani (2004) for example propose new ways of decision making at the front end of discontinuous innovation to cope with the complex frame conditions. By creating new roles and interfaces such as the gate-keeper, the boundary spanner or the project interface they try to better connect the individual decision making level (Reid & De Brentani, 2004).

Besides the specific process characteristics, a further important aspect of radical innovation is associated with the management of domain knowledge and capabilities. In the context of **knowledge management** which was intensively researched by scholars such as Nonaka, Von Krogh, and Voelpel (2006) and Schulze and Hoegl (2006) particularly the process of knowledge conceptualisation is of high relevance: a process that is leading to newly generated knowledge (Nonaka et al.,

2006). The second research stream in that context received great attention in the late 1990s and early 2000s as it addressed **organisational capabilities** in general and **dynamic capabilities** with a particular focus on changing, discontinuous environments. The capability and knowledge perspective on new radical product is outlined in more detail in section 2.6.2.

Finally, **cultural and mind-set elements** were highlighted in the context of early and radical development projects. Zien and Buckler (1997) amongst others identified innovation culture as a key factor that has an influence on sustaining and promoting radical innovation within a corporation (Cooper, Edgett, & Kleinschmidt, 2004; Reid, de Brentani, & Kleinschmidt, 2014). In that context, multiple influencing factors arose such as the influence of management support on innovation culture or the promotion of a "try and learn" mind-set to foster the exploration piece of radical innovation (Sommer and Loch (2004). O'Connor and Rice (2001) also suggest that the act of opportunity recognition involves a certain creative element that comes into force on an individual level rather than on an organisational one. Therefore, individuals and their ability to see and champion opportunities play an important role in this step when imagining for example new markets that currently do not exist yet. In addition, the track record of successfully developed radical products as well as the potential history of failed or discontinued projects are of relevance (Veryzer Jr, 1998).

In essence the unique radical product development type can be characterised by its degree of newness, the kind of customer needs addressed, and the level of uncertainty related to product development. Influencing factors such as the required expertise, particularities in the development process as well as corporate culture elements were highlighted as mentioned above.

Most research findings are so far attained by qualitative studies applying case study methodology; however, the few research studies that approach the topic in a quantitative way (Holahan et al., 2014) mostly confirm qualitative findings of major best practice studies (Cooper et al., 2002, 2004; Cooper & Kleinschmidt, 1995; Griffin, 1997). Only a few aspects of the quantitative findings are challenging respectively augmenting current practices (Holahan et al., 2014):

- **Development processes**: research showed that against expectations radical projects are managed within a less flexible framework. This is no surprise as the studies were not differentiating between front end and formal product development practices. It appears reasonable that more radical and hence riskier product development is monitored more strictly from the point in time they enter formal procedures. This is not seen as a contradiction with most front-end specific research as it is likely the case that purely the product concept development in the front end is managed in a more flexible way.
- **Organisation of product development activities**: findings are consistent with literature as mostly dedicated project leaders are entrusted with the task of running the radical product development project from an early point in time onwards.
- **Senior management commitment**: confirming the critical role of senior leadership in the development of radical innovation products yet recognising that such support might be expressed formally but also informally.
- **Organisational culture**: research is recognising that radical product concepts also build on informal structures from within but specifically also from outside the company.

These key aspects are also adopted in the *Resources, Processes and Values* (**RPV**) theory of Christensen et al. (2004) that tries to holistically explain why established companies frequently struggle to come up with radical but also disruptive products. The theory claims that the organisation's strengths and weaknesses to innovate can be traced back to its resources, processes and values.

In this context, **resources** stand for the assets a firm has or has direct access to, representing the foundation to fully exploit a new, disruptive business opportunity. This means that an organisation needs to capitalise on a set of tangible (e.g. technology, existing products, financial resources) as well as intangible assets (e.g. people/human capital, technological know-how) to successfully approach new product development.

In addition, corporate **processes** represent a second important influencing factor to new disruptive product development. When capitalising on available resources it is crucial how an organisation is putting certain procedures such as product development process, market research approaches and project planning into practice. When such activities are carried out, the way of working might differ with regards to patterns of interaction, communication or decision making.

Lastly, the **values** of an organisation affect the transformation of available inputs (i.e. resources) into disruptive outputs (i.e. products). In this context, values are primarily defined as the priorities an organisation is following, meaning that a clear idea of what the organisation wants to bring to the market is available. In this context Christensen et al. (2004) particularly highlight the role of how an organisation is prioritising and making decisions on a portfolio-level, i.e. the meta-level view of all innovation projects an organisation is running (e.g. at company-/divisional-level). Therefore, the question arises: Do corporate values allow for a prioritisation of a disruptive opportunity over other alternatives? If so, the set of criteria that is typically applied for resource allocation needs to reflect this in areas such as (a) expectations regarding size of opportunity, (b) existing cost structures, (c) profitability expectations but also (d) business model constraints. Concerning this matter, the positive/negative track record of past investments in innovation projects also has an impact on corporate values such as courage/risk-taking, curiosity or trust in people.

Taking the three above stated key aspects of the R*esources, Processes and Values (RPV)* theory into account, corporations may successfully approach new opportunities if they have the right resources available to succeed, if processes facilitate innovation and if the organisation's values allow for supporting disruptive innovation. At the same time identifying and analysing a company's resources, processes and values allows deep insights to be gained into its ability to innovate (strengths & weaknesses). A review of several innovation projects highlighted that incumbent firms, even if they have the right resources at hand, frequently fail in disruptive innovation because their values and processes do not appreciate working on these topics (Christensen et al., 2004).

2.6.2 A capability and knowledge perspective on radical new product development

Besides the specific process characteristics, a further important aspect of radical innovation is associated with the management of organisational domain knowledge and capabilities. The research stream of organisational capabilities received great attention in the late 1990s and early 2000s by addressing **organisational capabilities** in general and dynamic capabilities with a particular focus on changing, discontinuous environments. In this context, capabilities can be further characterised as either an ability or a high-level routine. With regards to the ability-perspective Helfat and Peteraf (2003) defined a capability as an organisation's ability to implement a set of tasks in a coordinated way with the aim of reaching a particular end-result by building on organisational resources. For example, Winter (2003) added a routine element to this ability-based definition by characterising capabilities as a high-level routine (or set of routines) that have reached a certain threshold of practiced activity. In addition, it brings a management team of an organisation in a position to decide upon a set collection of options to create a certain output.

In this regard literature differentiates two types of capabilities, i.e. substantive and dynamic capabilities (Winter, 2003). **Substantive capabilities** on the one hand are defined as an organisation's ability to solve a specific problem or to achieve a specific outcome (Winter, 2003). **Dynamic capabilities** on the other hand refer to an organisational ability to integrate, build and reconfigure operational and *substantive capabilities* through adaptation of internal as well as external competencies to deal with rapidly changing, discontinuous environments (Teece, Pisano, & Shuen, 1997). Taking this into consideration, dynamic capabilities do not directly affect a desired outcome, they rather contribute indirectly to a specific outcome through affecting the operational capabilities and hence the operational procedures (Helfat & Peteraf, 2003). Therefore, dynamic capabilities by default imply a certain change as they try to build, integrate or reconfigure further resources or abilities (Zahra, Sapienza, & Davidsson, 2006).

Following Eisenhardt and Martin (2000) as well as Zahra et al. (2006) literature showed that organisations may benefit from dynamic capabilities in manifold areas such as (a) entering new markets (King & Tucci, 2002), (b) utilising existing resources and building new skills (Bowman & Ambrosini, 2003), (c) crafting value-creating strategies (Turcan & Juho, 2016) or (d) leveraging new technology for commercialisation (Marsh & Stock, 2003). These benefits may come into play if an organisation manages to integrate dynamic capabilities into their strategic and organisational processes (K. M. Eisenhardt & Martin, 2000), be it new product development, partnering or strategic decision-making. In this context, strategic decision-making is building on dynamic capabilities by consolidating various business, functional and personal expertise to create value (particularly in dynamic market environments) (Easterby-Smith et al., 2009; Winter, 2003).

Likewise, dynamic capabilities regarding new product development refer to routines that allow for instance managers and development teams to integrate diverse sets of skills, knowledge and functional backgrounds to develop innovative solutions (Eisenhardt & Martin, 2000). In this specific context, Tushman and Anderson (1986) for example investigated the dynamic adjustment of capabilities depending on the product type. They firstly identified that during radical product development, existing capabilities are **enhanced**, meaning that they are extended to further strengthen a leading position; but secondly certain competencies are also destroyed, meaning that new competencies actually **replace** existing ones. This perspective on expertise in radical innovation projects was later on extended by introducing a third dimension. Besides the original categories of enhancing capabilities and destroying competencies, McDermott and O'Connor (2002) added **stretching** as a third category in the context of radical innovation. Stretching in that sense implies that new capabilities are developed that allow the organisation to tap into new fields without replacing already existing expertise.

As a result, the highly dynamic, unpredictable environments found in new product development or strategic decision-making require organisations to constantly challenge and revise their own routines. Key approaches to further develop

capabilities are for example improvisation, creativity or trial-and-error (Turcan & Juho, 2016; Zahra et al., 2006).

However, these approaches are not just relevant in the context of dynamic capabilities and dynamic NPD environments, they also play a crucial role in the related research domain of organisational knowledge management in general and knowledge creation/conceptualisation in particular. Knowledge creation can be seen as the starting point of new radical product development that is triggered by new radical product ideas (Cooper, 2009; Florén & Frishammar, 2012; Montoya-Weiss & O'Driscoll, 2000). This domain has been intensively researched by scholars such as Nonaka (1994), Nonaka et al. (2006) and Schulze and Hoegl (2006) and comprises multiple dimensions.

The process dimension covers several evolutionary steps from knowledge creation to knowledge expansion, refinement and crystallisation (Nonaka, Toyama, & Hirata, 2008) which ultimately lead to newly generated organisational knowledge (Nonaka et al., 2006). Along this path, new knowledge is generated, assessed, refined and aligned with organisational resources to finally make it concrete and explicit within an organisation (Schulze & Hoegl, 2006).

This conceptualisation of organisational knowledge can be characterised by (a) a dynamic nature, (b) an integration of knowledge that is distributed across the organisation and its surrounding as well as (c) the interactions of several stakeholders. The dynamic nature refers to the evolutionary process (Shadbolt & Milton, 1999) of building knowledge when integrating different types of knowledge that might be vested in internal and external stakeholders (Kogut & Zander, 1992; Tsoukas & Mylonopoulos, 2004). These types of knowledge are also developed in an iterative, theoretical and empirical process (Gassmann, 2018). Furthermore, the dynamic nature is driven by the diverse set of interactions involved for instance in the context of new product development, being it the dialogue of functional experts when synthesising new knowledge or disagreements when trying to balance explorative and exploitative tendencies within an organisation (Nonaka & Toyama, 2002; Nonaka et al., 2006). Research on the interactive nature of organisational knowledge conceptualisation also shed light on the role of individuals respectively

teams in this process. Nonaka and Takeuchi (1995) for example argue that individuals can rather be seen as generators of new ideas while teams subsequently develop and implement them (West, 2002).

A further important research stream investigates the interactive/dynamic nature of the process in terms of the type of knowledge created. Research differentiates between **tacit knowledge** that is highly personal and typically hard to articulate and **explicit knowledge** that is more tangible and more easily shared within an organisation (Goffin, Koners, Baxter, & Van der Hoven, 2010). In this context, interactions are seen to facilitate the transition in-between tacit and explicit states in both directions (Nonaka & Von Krogh, 2009; Pérez-Luño et al., 2019). Moreover, studies such as that of Popadiuk and Choo (2006) and conceptual papers such as that by Venkitachalam and Willmott (2017) suggest that tacit knowledge is more expedient when it comes to exploring new things (and the inverse also holds).

Even though the consideration of knowledge types is highly complex and contested, its link to the exploring and exploiting dynamics, that are also a key part of this research study, marks a key element as it tries to interconnect the concepts of knowledge conceptualisation and knowledge management with (product) innovation (Akbar & Tzokas, 2013). Considering the specific focus of this research on the emergence of new, radical product concepts, the studies of Schulze and Hoegl (2006) (front-end of NPD) and Akbar and Tzokas (2013) (radical NPD) need to be highlighted in particular.

Firstly, Schulze and Hoegl (2006) investigated organisational knowledge creation at the front-end of new product development, thereby assessing the impact of Nonaka's SECI model (Nonaka & Takeuchi, 1995) on product concept emergence. As a result, Socialisation (tacit >> tacit) and Internalisation (explicit >> tacit) were found to positively affect idea and concept generation, whereas Externalisation (tacit >> explicit) and Combination (explicit >> explicit) were seen to be negatively related in the context of this early process step. Even though this research omitted aspects such as the role of individuals/teams and the interactive nature of the knowledge conceptualisation process, it provided significant contribution in the context of knowledge types and their conversions across the early phase of NPD.

Secondly, in radical contexts, only a few research studies address the phenomenon of knowledge conceptualisation. The study by Akbar and Tzokas (2013) is one of the few that tried to provide a holistic review of the topic by analysing aspects such as the outcome of the knowledge conceptualisation stages, its major contributors, the nature of knowledge, patterns of interaction as well as its volatility. This enabled the researchers for example to characterise the contributors as well as the nature of knowledge in the knowledge conceptualisation stage. Typically during initial knowledge generation, deep and conceptual tacit knowledge is explored and generated by individuals rather than teams. However, during the subsequent evaluation and expansion of knowledge, tacit knowledge is rather brought to a team level where it is further developed. Finally, during refinement and crystallisation phase, knowledge is increasingly expressed in an explicit form making it available to a broader range of operational and managerial individuals (practical team members and managers/leaders) (Akbar & Tzokas, 2013).

2.6.3 Conclusion on radical NPD and the role of knowledge and capabilities

To sum up, the broad range of publications in the field of radical product development, a first set of studies in radical contexts mostly from the 1990's, focused primarily on classical process-related approaches of how to manage radical innovation projects; primarily through improved planning, decision making, etc. (Arrighi et al., 2015; Cooper & Kleinschmidt, 1995). However, further successful practices have been identified early on. Sommer and Loch (2004) for example focus on the exploration of radical innovation and promote a mind-set of "try & learn". In this context, Nonaka and Takeuchi (1995), Christiansen, Hansen, Varnes, and Mikkola (2005) as well as Akbar and Tzokas (2013) add the perspective of knowledge management to the early phase of new, radical product development, meaning that the exploration of newness is often based on a process of building up new knowledge and competencies. More recent publications also recognise the need for flexibility and creativity (Badke-Schaub, Goldschmidt, & Meijer, 2010; Griffiths-Hemans & Grover, 2006) to build "exploring", dynamic capabilities (Boehm & Turner, 2004; Högman & Johannesson, 2013). These refer to the ability of an

organisation to integrate, build and reconfigure its operational capabilities through adaptation of internal as well as external competencies to for example deal with rapidly changing, discontinuous environments (Teece et al., 1997). Therefore, dynamic capabilities by default imply a certain change as they try to build, integrate or reconfigure further organisational resources or abilities (Zahra et al., 2006) which are for example beneficial when leveraging new technology for commercialisation (Marsh & Stock, 2003).The subsequent section will outline the role of creativity and flexibility as part of new product development with a particular focus on the emergence of new product concepts.

2.7 Product concept emergence and adaptation

At first, this section will outline the different views of research domains such as marketing and engineering on the definition of a new product concept. Afterwards the process of defining a new product concept is explored including a review of key factors that influence these activities. Finally, as changes to the inputs of a product definition suggest certain flexibility with respect to the need for shifting a product concept, the final paragraph will introduce approaches that take this adaptive nature of product concepts during but also after its initial definition into account.

The emergence of a new product concept typically starts with a **new product idea** that is afterwards further developed to a holistic product concept. In that sense a new product idea can be characterised as a kind of **mental picture** of a possible and also feasible solution to a specific problem (Griffiths-Hemans & Grover, 2006).

In research this early transition process is also called **opportunity recognition**:, a step that bridges the gap between the emergence of an idea and the initial evaluation of the innovation idea (O'Connor & Rice, 2001). In the particular context of technology-driven radical innovation projects, its main goal is to make the cognitive leap from the technical idea to an imagined and fully expressed business opportunity (O'Connor & Rice, 2001). This is even the case if, despite the radical nature of the business opportunity, the market needs to undergo a significant transformation or may not exist yet.

Later on, when converting such an idea into a product concept, additional elements such as key product features as well as addressed customer benefits are specified (Parish & Moore, 1996). According to Montoya-Weiss and O'Driscoll (2000), a product concept is even characterised on a broader scale for example by a clear definition of the underlying technology as well as an estimation of market opportunities. In addition, it includes an evaluation of market segments and positioning, competitive landscape as well as an internal alignment with strategic aspects such as technology and product roadmaps (Cooper & Kleinschmidt, 1991; Khurana & Rosenthal, 1998).

The extant research on front-end innovation investigated the emergence of various characteristics of a product concept and its definition from different research streams such as marketing, organisations or engineering/manufacturing (Krishnan & Ulrich, 2001).

From a **marketing** perspective on the one hand, research focuses on the business perspective of product concept features by defining a product concept as a detailed description of the product idea and as a bundle of attributes that are tailored to a specific potential customer group. Moreover, the product concept expresses significant product properties regarding quality, performance or design from a customer viewpoint (Kotler, Keller, & Bliemel, 2007).

From an **organisational** perspective on the other hand, a product concept can be characterised as an artefact that is resulting from a product definition process performed within an organisation (Krishnan & Ulrich, 2001).

Looking at it from a different angle, the **engineering** domain rather sees a product concept as a complex assembly of interacting product components that need to fulfil a set of customer/product requirements. Therefore, the focus of product definition is rather set on the specification of customer and product requirements as part of engineering tasks that shall be met by the future product (International Institute of Business Analysis, 2015).

All these various definitions of a product concept have in common that the primary sources of input to the process are customer needs, ideas from R&D and market

assessments. Moreover, they are trying to answer a set of common questions that are equally relevant to customers as well as the corporation. Krishnan and Ulrich (2001) identified in their meta-study on product development case studies a list of key questions that are typically raised and answered during product concept development:

- What are the target values of the product attributes, including customer needs and price?
- What is the core product concept?
- What is the product architecture?
- What variants of the product will be offered?
- What will be the overall physical form of the product?

The last question about the physical form of the product points to the interlinked research stream of product design. This subject is clearly related to product concept development but also distinct as it is rather focusing on aesthetic aspects resulting in geometric models of components, whole instruments and bills of materials than taking a holistic view of a product concept (Eppinger & Ulrich, 2015; Ullman, 2009)

Building on the above considered questions of what a product concept constitutes, a further research stream addresses the process nature of newly emerging product concepts, thereby focusing on the **sequence of activities** as well as dedicated **techniques in sequencing divergent and convergent** steps that support defining the scope of a new product concept (Gordon, 1961; Krieg, 2004). In that context, divergent thinking means to come up with multiple potential options (Reid et al., 2014) whereas the transition to convergent thinking means to select among these options to define a single (final) product concept (Seidel, 2007)

In this regard, Koen et al. (2001) created one of the most well-known holistic frameworks for product definition, the so called “New Concept Development Model”. The empirically based process model gained considerable attention as it

turned away from a pure linear view on front-end activities by adopting a circular approach to make clear that ideas in the early phase rather flow and circulate.

For that reason, he also chose the visual imagery of a wheel consisting of the three integral parts (a) wheel, (b) engine and (c) rims (for details see Figure 11 and below explanation).

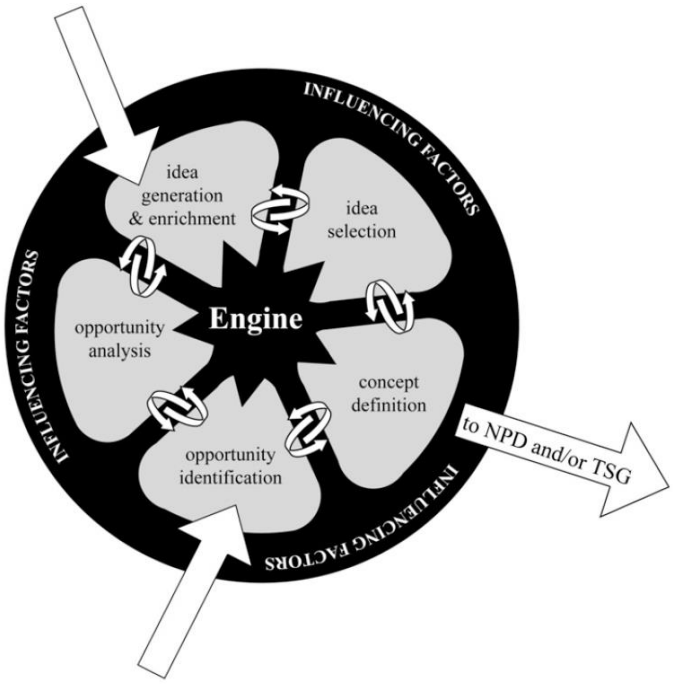

Figure 11. New Concept Development Model (Koen, 2001)

In the inner part of the model, the **wheel covers the five key activities** of the front end (a) opportunity identification, (b) idea generation, (c) opportunity analysis, (d) idea selection and finally (e) concept definition. In addition, the engine, which is located at the centre, comprises organisational attributes as well as team and collaboration aspects. The third integral part, the rim, consists of various environmental influencing factors impacting the organisational attributes as well as the five activities in the inner part of the model. These environmental factors include amongst others customer and industry trends, competitive aspects, regulatory shifts as well as the strength to enable science and technology (Koen et al., 2001).

In this model, as well as in general, innovation projects typically start with the generation of a new idea or the recognition of a new opportunity (see arrows in

graph). However, unlike linear approaches the models of Cooper (2010), Pietzsch et al. (2009) and Koen et al. (2001) suggest that new ideas and opportunities circulate and flow across the five inner elements until they enter into a new product development or a technology stage-gate (TSG) process.

Even if successfully managed, **product definition appears not to be linear**. Although a product concept might have reached a relatively stable and mature state towards the completion of an initial product definition, Bacon et al. (1994) already emphasise in their early works that changes in the inputs to the product definition, be they competitive offerings, technological aspects or regulatory interpretations, may occur at all times. Therefore, suggesting that during but also after the initial product definition in product development, trade-off decisions and adaptations of the product concept might be necessary.

This view thereby contrasts with early research studies that tended to focus on practices of how to manage and monitor the convergent definition process of a new radical product concept, for example in the areas of decision making or idea selection processes (Cooper, 1988, 2009; Krishnan & Ulrich, 2001). In fact, it appears like an early study of a new generation of research that looks at the phenomenon more holistically by recognising the importance of both divergent and convergent dynamics in the front end of innovation.

Bacon et al. (1994) and Vojak et al. (2012) started the development of a new product concept rather with an alternating **sequence of divergent and convergent dynamics**, pointing out the role of exploratory elements in radical innovation projects. In that context, divergent thinking on the one hand considers multiple potential options (Reid et al., 2014) whereas convergent thinking covers practices that are used to prioritise among these options to define a product concept (Seidel, 2007), Following Reid et al. (2014) both dynamics may come into force on an individual as well as organisational level. As a result, both dynamics have a shaping effect on the scope of a new product concept.

With regards to this **shaping process and the consequential adaptive nature** of the product concept definition, literature differentiates between the point in time the adaptation is happening (pre-/product development) and two functional research

streams. One functional stream approaches the topic with a **structural perspective** on flexibility (i.e. size and configuration of organisation) while the other one focuses on the more **organisational/leadership view** (Arrighi et al., 2015).

The **structural perspective** suggests modular process models such as product platforms or product architectures to frame new product development. With this modular approach a concept can flexibly be adapted on the level of module components while at the same time the underlying platform or architecture remains stable and sets the boundaries of the exploration (MacCormack, Verganti, & Iansiti, 2001).

The **organisational/leadership view** recognises the crucial role of individuals as well as development teams in defining and adapting a radical product concept to make it a success. In this organisational context, Griffin, Price, and Vojak (2012) for example introduced the construct of the "serial innovator", characterising a personality of an individual as well as a way of working that allows individuals to overcome organisational barriers of innovation (for details see section 2.4 which contains a review of the serial innovators concept).

Time wise, researchers were either focusing on an initial product concept definition during pre-development or on a later-stage adaptation of product concepts during formal product development. To provide a comprehensive overview of the most prominent research concepts in that context, two empirical concepts for the later-stage adaptation (opportunity recognition & concept shifting) as well as one theoretical attempt for early-stage adaptations (corroborated product definition) shall subsequently be outlined in more detail. The theoretical concept for early stage adaptations is chosen as no empirical research study in this context is known.

A **first later-stage adaptation** concept recognises the adjustments that are made in the process of constant opportunity recognition (O'Connor & Rice, 2001) (see also Figure 12). In doing so, O'Connor and Rice (2001) acknowledge that after an initial product definition phase as part of which an opportunity is recognised, certain events of discontinuities may trigger a reconsideration and hence potential recurring adaptation of the opportunity.

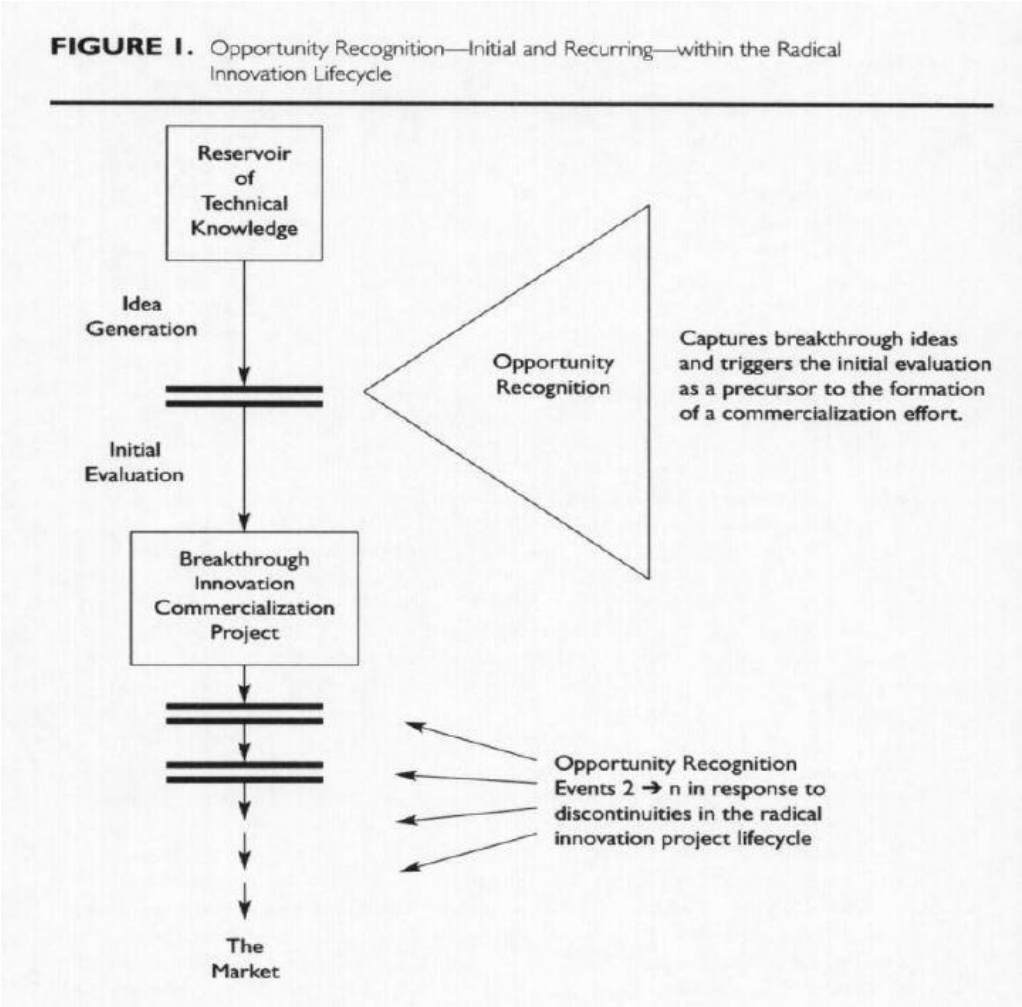

Figure 12. Opportunity Recognition - Initial and recurring evaluations (O'Connor and Rice, 2001)

As illustrated above, O'Connor and Rice (2001) indicate an initial opportunity recognition in the transition from a newly generated idea to an initial evaluation of an opportunity and start of a formal product development project, but at the same time emphasise a recurring "re-recognition" of an opportunity throughout the product development process. Accordingly, this means that as a response to potential discontinuities in the lifecycle of a radical product, the business opportunity, which marks an important element of the product concept, is frequently reassessed and adapted.

A second major concept in the context of later-stage adaptations concerns the organisational approach of ***concept shifting*** (Seidel, 2007). Seidel (2007) introduced *concept shifting* to appreciate that an adaptation of product concepts also takes place following the front-end phase, during the implementation of new product concepts. That way he addressed later stage shifting of key concept components,

meaning that following an initial definition of a product concept, certain concept components may be changed over time by the project team/leadership team with the goal of ensuring project continuation, implementation and ultimately go-to-market product readiness.

Triggered for example by new technical or market information, the development team sees the need for a reconsideration of the product concept. However, instead of questioning the overall concept through an iteration back to an earlier stage of product development, the teams prefer to just adapt single concept components. In his empirical study which comprised six research projects (radical nature) across different industries, Seidel (2007) was able to point out that this concept adaptation did not just occur sporadically but rather on a larger scale. Across the six case studies more than half of the finally implemented concept components were specified by later elaboration or shifting. Such significant changes to an initial product concept were not expected prior to this research study.

When investigating this practice of shifting concepts, Seidel (2007) identified four common practices development teams were generally following in the context of radical development projects.

Firstly, teams **identify inconsistencies** of components, a mismatch between the product concept and what is desirable from a market, customer or corporate perspective. This inconsistency indicates that an adaptation, in the way of eliminating or upgrading concept components, is required.

Secondly, a product concept is **not adapted entirely** and not throughout the whole development process. Instead of questioning the entire product concept, selected components are frozen while allowing for a search of new solutions for other, shifting components. This means that while allowing for flexibility in one area the fixation of other key concept components ensures a certain stability of the overall product concept.

Thirdly, a shift of the product concept occurs by **substituting concept components**, meaning that an existing concept component is replaced by a new one with a similar “descriptive form” as Seidel (2007) calls it.

A fourth and last practice is dealing with **maintaining dual concepts** instead of just a single adapted one. This means that the new, revised concept is not just carried forward, rather it refers back to the initial concept, which is preserved as a deferred one. In doing so, the project lead and the whole team try to maintain a momentum and commitment to the original product vision even if it is not implemented in the first place.

As a whole, these identified practices also reflect the organisational nature of the concept shifting model as they illustrate the team's and team leader's power to control and change a product concept to ensure project continuation and ultimately implementation.

Besides the two approaches that recognise concept adaptations such as shifts at a later development stage, it is suggested that this process of constant changes might already commence in an earlier phase. However only one empirical research study by Hooge et al. (2019) (conference paper stage) and one theoretical model on "corroborated product definitions" by Florén and Frishammar (2012) were found that address the emergence process of new radical product concepts and recognises the adaptive nature of the product definition.

The empirical research study by Hooge et al. (2019) was carried out as a single case study within a large mobility corporation. It tried to shed light on the coherence of "new concept development", as Hooge et al. (2019) called the emergence process of a new product concept.

Even though the study was able to classify new product concepts into stand-alone concepts and interrelated concepts (more complex ones) and identify key influencing factors, such as design approaches, cognitive generative powers and process elements that have an impact on corporate innovation goals, it predominantly focused on the creativity and design perspectives of NPD. Thereby it omitted a more holistic view on new concept development which is recognised as a highly complex phenomenon (particularly for interrelated concepts).

Furthermore, on the basis of theoretical considerations, Florén and Frishammar (2012) approach the topic of defining a product concept and adapting it based on an **alignment process model** (for details see Figure 13). This means that when *Scoping* an emerging product concept, it needs to meet external needs but also internal requirements at the same time. In that sense, it can be seen as an integrative framework for the front-end of NPD to sense, recognise and shape a new opportunity, also suggesting that the outcome of the front-end phase is rather a corroborated product definition that has passed through a process of repetitive adaptation than a linear, one-time definition.

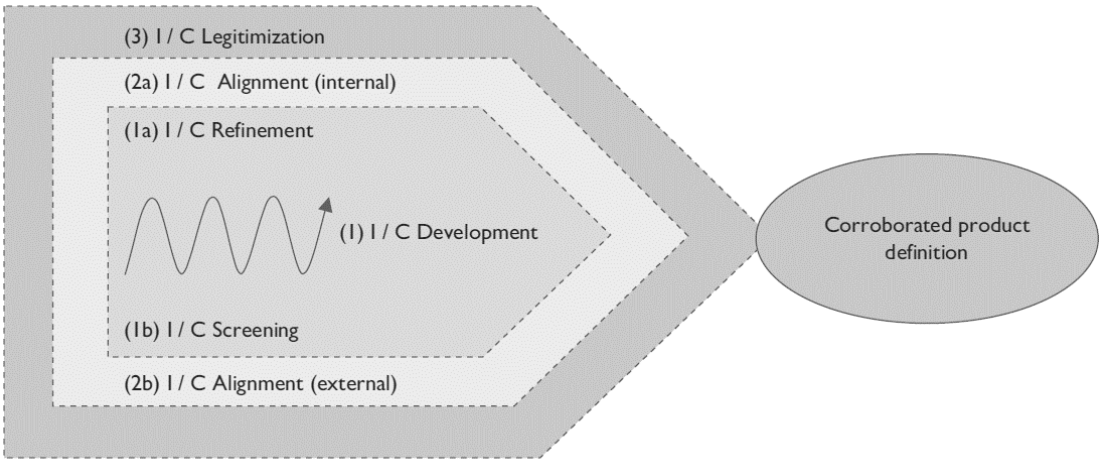

Figure 13. Corroborated product definition (Florén & Frishammar, 2012)

Key steps of the adaptation process shall now be outlined:

Idea and concept (I/C) development (1) refers to the transformation process of converting inputs, i.e. product ideas which represent recognised business opportunities, into output elements in the form of a product concept (Khurana & Rosenthal, 1998).

The curvy trajectory at the centre of the graph above already implies that this process is not linear; it rather forges ahead iteratively in-between the two sub-actions, I/C refinement and screening (steps 1a / 1b). In this phase, development teams are trying to balance exploratory and exploitative dynamics by switching in-between **screening** and **refinement** of a product concept, meaning that a concept is scoped based on two opposing actions that are characterised by creativity and experimentation (screening) on the one hand and ensuring relevance regarding

valuable customer benefits or technological feasibility (refinement) on the other hand. In that sense refinement must be seen as a team member's or management/leader's ability to identify and address certain "generative constraints" as Arrighi et al. (2015) put it.

As a result of these initial idea and concept development steps, a preliminary product idea is refined into an initial product concept that requires further internal/external alignment before determining whether it should be carried forward. The internal perspective (step 2a) on the one hand focuses primarily on a strategic fit between the envisioned product concept and the firm's overall strategy and product portfolio. The external alignment (step 2b) on the other hand concerns aspects such as competitive product offerings, technological developments or the regulatory framework. As a result, during idea and concept **alignment,** an adjustment to internal as well as external environments takes place.

Finally, idea and concept **legitimation** (step 3) as a third key activity concern the socio-political context and acknowledge the need for a broad organisational commitment and objectivation. In this regard, legitimation can be referred to as a first-order objectivation of meaning. In this first step of objectivation, a new product concept which is characterised by a high degree of newness and uncertainty in decision-making, needs to be legitimised before it can be further objectivised through institutionalisation (Turcan, 2018).

This initial step of objectivation affects all corporate levels ranging from legitimisation on a project team level to steering committees as well as top management commitment. A lack of internal legitimisation might either delay or even discontinue development activities despite a potentially high-value product concept. Because of the recurring steps of refinement, alignment and legitimation, a radical new product concept might receive wide acceptance amongst a broad range of key stakeholders before entering into formal product development.

Even though the publication of Florén and Frishammar (2012) is just of theoretical nature, it is the only known conceptual model that could be identified in the course of this systematic literature review that tries to integrate front-end exploratory and exploitative dynamics in a process of refinement, alignment and legitimation to

ensure project continuation; thereby recognising that the scope of a product concept is shaped by internal as well as external factors and that its implementation is heavily dependent on a legitimisation, ideally on a corporate level.

Taking the above into account, it can be noted that regardless of the functional perspective or the varying number and sequence of activities, the emergence of new radical product concepts is fundamentally about recognising a new product idea and consequently developing a commercial product concept that is an answer to this aspiration. As structured approaches of product definition are recognised to have a positive impact on market success (Krieg, 2004), the above reviewed concepts try to shed light on this phenomenon from a structural (MacCormack et al., 2001) but also more organisational (Griffin et al., 2012; Seidel, 2007) perspective. In addition, the literature search tried to provide a comprehensive overview of approaches to early (Florén & Frishammar, 2012) but also later stage (O'Connor & Rice, 2001; Seidel, 2007) adaptation of product concepts.

2.8 Conclusion on systematic literature review

As part of this empirical research study, a comprehensive systematic literature review was performed on the emergence of new, radical product concepts under uncertainty. Based on the review, this thesis looked at the research phenomenon from multiple perspectives, which led to the identification of five main themes. These were presented in the previous chapters with an increasing thematic focus, along-side a decreasing level of abstraction, starting with (a) the general phenomenon, the emergence of newness, then (b) NPD theory in general but also with a focus on (c) the process nature. Furthermore, light was shed on the specific innovation type of (d) radical product innovation and the role of organisational capabilities. Finally, the current state of research with regards to (e) the emergence of product concepts as well as their adaptation was examined.

Despite some researchers already addressing this research phenomenon, one can summarise that this domain is particularly lacking empirical research that sheds light on controversially discussed or open questions such as:

- To what extent do product concepts change during an adaptation process in an early development phase?
- Does the emergence process differ for radical/incremental product concepts?
- What influence does the alignment and legitimisation process in pre-development have on a product concept (as proposed by Florén and Frishammar (2012))?

3 Research Design/Methodology

This section outlines the methodological design of this empirical research study to provide an answer to key research questions like what characteristics new, radical product concepts are based on and which dynamics in development teams occur within projects during definition and refinement of new, radical product concepts.

To address these questions, the methodological characterisation of the research study is subsequently illustrated on an ontological, epistemological as well as methodology level (Figure 14).

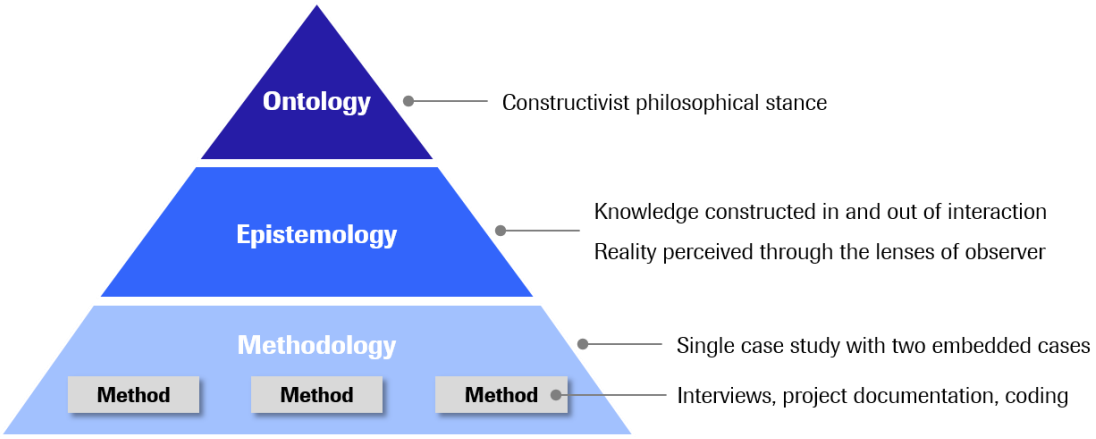

Figure 14. Three levels of methodological discourse – Ontology, Epistemology & Methodology

In this context, the research study is investigating this phenomenon holistically, i.e. taking into account that it is not a mere process topic. In fact, it is rather building on further aspects such as tacit and explicit knowledge that are utilised in product definition. Due to these facts about the research phenomenon as well as the personal beliefs of the researcher, the research study is approached based on a constructivist ontological and epistemological position.

In line with **constructivism**, a qualitative, exploratory single-case study design with two embedded cases is deployed that is **informed by Grounded Theory methods** (Yin, 2013). Both within-cases were comparable with regards to novelty of product concept and technology as they were selected based on similar sampling criteria such as corporate/governance structures, project phase, project size and scope, as well as early stage in which the product concept is emerging.

A broad range of primary and secondary data was collected; primary data was mainly collected via semi-structured face-to-face interviews and supplemented by artefacts such as emails, use case-diagrams and general project documentation such as meeting minutes and progress reports. Ten participants per case were purposively selected for the interviews which lasted on average sixty minutes and were recorded and transcribed verbatim. The interview style can be characterised as an interview traveller as Brinkmann and Kvale (2015) describe the approach, motivating the interviewee to tell his individual stories, using his own terminology. This process aimed at discovering critical events and incidents that contributed to the early innovation phase of new product development under uncertainty in the context of a globally operating IVD corporation.

Data collection and data analysis within and across the two cases was informed by grounded theory methods and tools (Glaser, 1978, 2005; Glaser & Strauss, 2010). Following an **initial substantive coding cycle**, which formed the basis for a **second cycle of theoretical pattern coding**, potential influencing factors for the emergence of new theory were identified. Constant iteration between within- and cross-case data, substantive and theoretical codes, and theory led to the discovery of *Scoping*. The core-variable that contributes to the explanation of the emergence of new product concepts under uncertainty.

Figure 15 provides an overview of the key methodological elements.

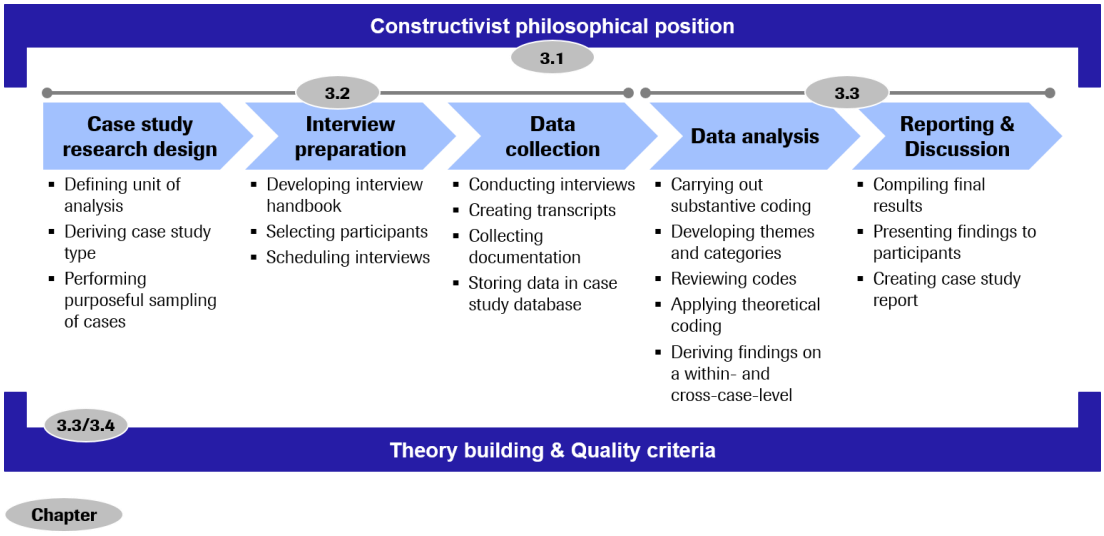

Figure 15. Overview of research methodology

In the following paragraphs the above described research topic will be contemplated from three different perspectives. At first, the philosophical position of the empirical study is described in more detail and first implications and considerations on the actual research design and methods used will be drawn. Afterwards the case study research design is introduced by elaborating on the unit of analysis and the sampling strategy. Furthermore, the data collection and data analysis approaches are illustrated. Finally, the concluding sections make the overall design and execution of this empirical study the subject of discussion.

3.1 Research philosophy

This section describes the constructivist philosophical current this research is following and discusses the eligibility of this philosophical stance to explore the phenomenon of emerging product concepts. To debate this philosophical stance, potential differences and commonalities with further research streams such as realism & active interventionism are outlined on three philosophical levels, an ontological, an epistemological and a methodological level (Moses & Knutsen, 2007).

Ontology on the one hand represents the most abstract philosophical level and is concerned with the nature of reality. A key question in this context is how society is constructed and how this affects everything around us (Easterby-Smith, Thorpe, & Jackson, 2012). **Epistemology** on the other hand constitutes the philosophical study of knowledge and is concerned with questions about what knowledge actually is and also what is regarded as reasonable, acceptable knowledge (Bryman & Bell, 2011). A further key aspect in that context brought up by Guba (1990) is the **relationship between the knower and the known.**

The third level, the **methodological**, denotes the different ways knowledge is acquired (Moses & Knutsen, 2007). It is directly deduced from the ontological and epistemological view of the researcher and can be seen as a framework of how to collect and analyse data (selection of research methods). As a synonym for research design it basically deals with the use of research methods that are located one level

below methodologies. Moses and Knutsen (2007) use the metaphor of "tools" for methods as problem-specific techniques, whereas a methodology can be seen as a well-equipped "toolbox". To get to the heart, a research methodology is deduced from the researcher's ontological and epistemological view and comprises the selection of appropriate methods to generate reliable knowledge. These (three) layers are also set into relation as illustrated in Figure 16.

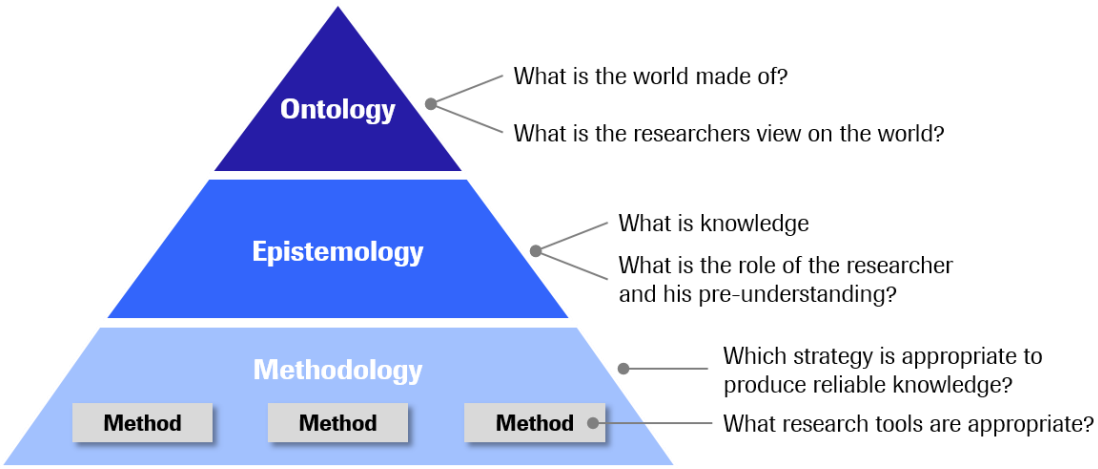

Figure 16. Structuring philosophical considerations

Next, a focus is set on the constructivist philosophical paradigm this research is following.

3.1.1 Following a constructivist philosophical stance

This research study is heavily influenced by my constructivist worldview, which shall be described in more detail. On an ontological level, constructivists generally claim that **reality is socially constructed** and that researchers only have access to the real world through their own senses (Bryman & Bell, 2011). With this in mind, social phenomena and, importantly, their meanings are created through social interactions and are therefore in a state of constant revision (Bryman & Bell, 2011). Furthermore, the researcher himself plays a key role in creating this reality. Consequently, constructivists like myself recognise the **subjective nature of knowledge creation** and stand therefore in opposition to more objectivistic paradigms such as naturalism.

It has to be noted that constructivists consciously apply their way of thinking to understand social phenomena such as the emergence of new product concepts within organisations, recognising the big gap between the natural and social world which make different approaches necessary for both worlds (Moses & Knutsen, 2007). As a result, I acknowledge that the real world cannot exist independently from human beings and their observers.

To some extent, constructivism is similar to realism, representing an answer to the critique on positivist approaches in social sciences by turning away from naturalist philosophical ideas. The only commonalities naturalists and constructivists still share are the **diversity of currents** in both camps and their shared perception to explain social patterns of the world (Moses & Knutsen, 2007). This diversity of philosophers and their ideas makes it also hard to unify basic beliefs in a single philosophical stance within this thesis. Therefore it has to be noted that the following remarks on the basic concept of the constructivist paradigm may certainly be discussed critically building on diverse constructivist thinkers such as Kant, Kristeva or Kuhn (Moses & Knutsen, 2007).

From an **epistemological point** of view, which is directly deduced from the ontological position, constructivists believe that knowledge is constructed in and out of human interactions and that the observer plays a key role in this regard as they perceive reality through their lens. Whewell (1869) goes one step further arguing that the sense perception of the observer is just the first step followed by the processing of perceptions.

According to Moses and Knutsen (2007) the sense perception and the subsequent processing are influenced by the following four elements that are by no means comprehensive but do cover key aspects:

- **History** shows manifold changes in perspective and worldview that lead to paradigm shifts in research. This is in line with the basic belief that human knowledge has evolved over the years through rapid shifts and bounds instead of a mere accumulation of single pieces. This development is characterised by periods of rapid progress followed by stagnation incl. going back and forth. In the context of IVD, for example, the role of new

technologies such as biotechnology has tremendously shifted innovation paradigms over the years.

- **Society** plays a key role in knowledge creation and preservation. In this context, constructivists perceive knowledge on the one hand on an individual level where humans act as "knowledge-carrier" and on a social level with societies as "knowledge-pools" on the other. Thus, the social aspects and the context of scientific knowledge do matter (Moses & Knutsen, 2007).
- **Ideas** are the drivers that allow us to make sense of the subjects our senses unveil. This includes the evaluation and interpretation of such facts.
- **Language** is not just a tool through which observations and knowledge are expressed in a neutral and instrumental way. For constructivists, language often expresses the relationship between the observed subject and the observer. In addition, it is seen as a vehicle to create the above described societies, respectively "knowledge pools", out of individuals that act as "knowledge-carriers" (Moses & Knutsen, 2007).

The elements mentioned above are heavily influenced by the observed subject as well as the observer, their background and their belief and can thus be characterised with a high degree of subjectivity. In fact, this subjectivity is the main criticism and reason why naturalists and realists reject the constructivist philosophy not complying with positivistic scientific quality standards (Easterby-Smith et al., 2012).

These **basic beliefs heavily influenced this research design**. To approach the world and its social constructions, constructivists track down those social constructions and understand their meanings in a real life setting (Yin, 2013). As a consequence, this research study principally utilises **qualitative methods** such as interviewing (Easterby-Smith et al., 2012); generally speaking, methods that allow a small sample of subjects studied in depth rather than a large sample (Bryman & Bell, 2011). Therefore, the phenomenon of new product concept emergence is investigated in a single case-study framework, which will allow getting an idea of a phenomenon in a deep and holistic way. In the context of this research study, the focus on depth

becomes apparent in the specific application of **in-depth interviewing** of project team members in the environment of IVD and a specific company-/project-setting. This specific setting will reflect the IVD industry that is characterised by a high degree of regulation and product complexity as well as the company setting of an international corporation with more than 20.000 employees and a specific organisational structure.

As the **researcher plays a key role** in a constructivist research process, my role, values and involvement in the case need to be considered (Yin, 2013). For this study this includes e.g. my personal background, my past experiences with the product definition phase, my position in the company as well as my actual role in the product definition process that will be subject to this exploration. The above mentioned aspects are extremely important to overcome some of the naturalist critiques such as bias (Moses & Knutsen, 2007), a key aspect that this research study is taking into consideration. In fact, constructivists in general are **well aware of this criticism** and they in turn try to reduce these weak points by e.g. describing the context and potential areas of bias transparently. This transparency was created through a dedicated introductory section on the role of myself as the researcher (1.5) as well as annotations throughout the case study making every piece of information available so that the reader can make their own personal assessment whether on the knowledge created from data is of relevance.

In line with the research phenomenon and my constructivist view, this research study follows an inductive reasoning (Figure 17) with a tendency to start with observation and data creation considering its context (Easterby-Smith et al., 2012).

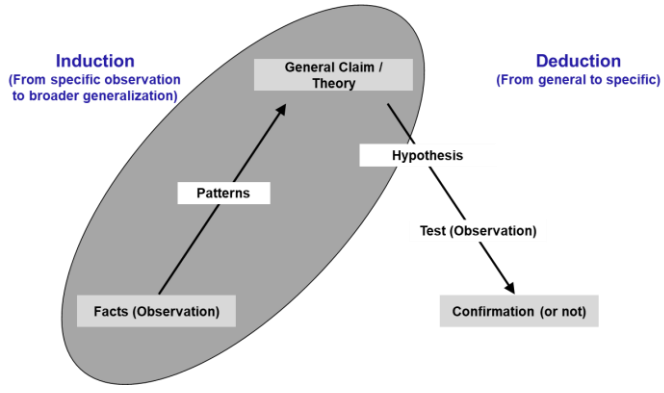

Figure 17. General approach of inductive reasoning (Moses & Knutsen, 2007)

3.1.2 Contrasting philosophies of a realist/active-interventionist paradigm

In contrast to the pursued constructivist research philosophy, the research objectives could theoretically also have been approached from a realist or active-interventionist perspective. To illustrate why these related but distinct paradigms do not fully match the envisioned research approach, they shall be described and contrasted in the following paragraphs.

Outlining and contrasting Realism with the constructivism paradigm

The realist paradigm can similarly to constructivism be seen as a response to the continuing critique that social phenomena cannot be approached in the same manner as phenomena in natural sciences (Moses & Knutsen, 2007). Therefore, realism is positioned in-between naturalism and constructivism, combining perceptions from both philosophies. Scientific realism emancipated as an independent school over the years and due to the **plurality of conceptions, various sub-paradigms**, such as transcendental realism, critical realism and empirical realism, emerged (Moses & Knutsen, 2007). The following explanation will primarily focus on the popular sub-paradigm of critical realism.

The realist ontology assumes that an **object of scientific enquiry exists and acts independently from the researcher**. The underlying assumption is that a physical and social world exist independently from any observation made about them (Easterby-Smith et al., 2012). At the same time a realist recognises that the studied reality is embedded in a social environment and may therefore have several layers (Moses & Knutsen, 2007). A major difference to naturalism, which is also known as positivism, is that in particular critical realists believe that general laws might exist but are also exposed to modifications in the course of time (Bryman & Bell, 2011). This property of realism has an analogy with constructivism that also believes in a state of **constant revision of the meaning** of social phenomena as they are created through social interactions.

As a result, when exploring the emergence of new product concepts in the product definition phase, a realist would recognise that this product definition process is

based upon a large set of interactions. These take place in a social environment e.g. in the context of the In-vitro diagnostics industry and a cross-functional organisational set-up of a corporation. Consequently, following Bhaskar (2011) remarks and the critical realist perspective, this emergence must also be investigated in the context of social structures and relations. Furthermore, critical realists admit that in the process of knowledge creation objectivity has its limits, but remains an ideal and a major trigger for the design of the research project when, for example, determining the sampling strategy.

These ontological and epistemological beliefs would have directly affected the selection of methodology as well as methods used. In contrast to constructivists, realist researchers would use a wider range of rather qualitative or quantitative research techniques (e.g. known as mixed-methods) as long as they are in line with the nature of the studied object (Moses & Knutsen, 2007). In this regard, a particular phenomenon would be approached from various angles with various methods. The goal would be to generate a manifold data set, which allows compensating the weaknesses of a specific approach by the strengths of another technique. This approach as well as triangulation play an important role to ensure rigorous research (Bryman & Bell, 2011). Due to their strong belief in objectivity, realists would commonly select quantitative methods such as surveys or standardised questionnaires for data collection (Easterby-Smith et al., 2012) and additionally make use of further quantitative methods to eliminate some of the naturalist's objections. Furthermore, supplementary **qualitative methods can increase depth** when examining a social phenomenon (Bhaskar, 2011).

In the context of the emergence of new product concepts, quantitative methods could be applied to test certain hypotheses, such as an improved cross-functional interaction, through quantifying the number of interactions or a more efficient product definition through investigating the number of identified product features in a certain timeframe. However, that way the research would be bound to a primarily deductive research approach, meaning that the empirical study is based on and limited to already existing new product development theory that requires exploration with a basic hypothesis that will for example be tested quantitatively

(Moses & Knutsen, 2007). As a result, a hypothesis could be confirmed or disproved but a new exploration of the emergence and shifting of new product concepts would only be possible to a limited extent. Such a procedure would contradict with my envisioned inductive way of thinking which rather starts with observation and generation of data as an initial point (Easterby-Smith et al., 2012).

Concerning the type of knowledge generated, realists **focus on causality** and try to explain phenomena regarding cause and effect, whereas constructivists aspire to understand the social relationships of a particular phenomenon (Moses & Knutsen, 2007). In the context of this research study and the investigated phenomenon of emerging product concepts, realists would rather focus on a specific influencing factor such as the cross-functional composition of development teams, trying to explain its dynamics with regards to cause and effect. The generated knowledge would likely confirm or disprove the assumed constructs on product definition in the context of the IVD industry but would only to a limited extent allow for creating new theory in that field.

Outlining and contrasting active-interventionism with the constructivism paradigm

Active-interventionism is a further philosophical stance that can be seen as a counter movement to constructivism, naturalism and realism. It is a paradigm that embraces several research approaches enabling the researched subject to play a more influencing role in the research design and its outcomes (Bryman & Bell, 2011). Following Bryman and Bell (2011), approaches like action research, feminism or participative forms fall into this category.

In the following remarks, the action research approach shall be reviewed exemplarily for an active interventionist methodology. This decision can be justified as action research is a key approach within the interventionist stance (Easterby-Smith et al., 2012) and particularly with regards to its practical orientation, action research and such doctoral programmes have a lot in common. However, it has to be noted that action research cannot fully be designated as a philosophical stance

but **rather as a pragmatic problem-solving technique** for practitioners that are research affine.

Nonetheless, this paradigm is of particular importance as it highlights the role of the research subject and changes the relationship between the researcher and the research subject(s) compared to many other philosophical currents (Bryman & Bell, 2011). Easterby-Smith et al. (2012) for example characterised the action research approach by assuming that:

- Social phenomena are constantly under revision rather than static.
- The researcher becomes part of the change process.
- Learning about an organisation can best be achieved by trying to change it.
- People affected by the changes should be involved.

This way of thinking goes back to Kurt Lewin who is seen as the founder of action research (McNiff, 2013). His research approach tries to generate knowledge by changing the situation under exploration and has so far reached its peak with the community development movement in the second half of the last century (Easterby-Smith et al., 2012).

Fully in line with my constructivist research philosophy, action research from an ontological perspective also recognises the comprehensive involvement of people and the focus on their inclusion implies that reality is socially constructed. Furthermore, from an epistemological perspective the researcher is in general heavily **building on the explicit and tacit knowledge of the involved people** when generating new knowledge.

However, theory building will rather be incremental as action research is building upon an **iterative research approach** starting with the diagnosis of the problem, followed by the development of a solution and bringing this solution into action with the involvement of members of the organisation in a real life environment (McNiff, 2013). Finally the results are reviewed and these results again build the basis for the next action research cycle (Bryman & Bell, 2011). This cycle will be passed through several times until a satisfactory level of maturity is reached (Jönsson & Lukka, 2006).

As a result of the iterative procedure of integrating observation, preparation, action as well as analysis and review, this approach will not allow for a pure inductive or deductive mode of action and reasoning (McNiff, 2013). The approach is in fact rather following a sequence respectively cyclic logic, combining inductive elements such as starting with observation to build theory with deductive elements like testing new theory in a set sequence of research steps.

Against the background of a real life organisational setting and that the emergence of new product concepts will be explored together with employees being involved in the development of new IVD products, the interventionist approach might theoretically also have been a feasible option for this research study. It would even have been tempting as it might have maximised the practical outcomes of the research and potential process improvements might have created awareness of upper management within the company. Notwithstanding these advantages of very deep insights, this approach also entails severe drawbacks such as conflict of interest or bias towards the researcher and the "clients" (Bryman & Bell, 2011). Therefore, it was not pursued in this research study.

In conclusion, active-interventionists would rather focus on the product definition process, trying to improve the overall process within the framework of a specific industry / corporation. The generated knowledge would in addition primarily touch upon the practical and application-oriented side of emerging product concepts in the specific context of the IVD industry and one corporation, neglecting the creation of new theory on that phenomenon.

3.1.3 Impact of constructivist paradigm on research study and outcomes

The starting point of this research study has been the question of, how new, radical product concepts emerge that are based on new technologies. In this context, the research study is investigating this phenomenon holistically, e.g. taking into account that it is not a mere process topic. In fact, it is rather building on further aspects such as tacit and explicit knowledge that are utilised in product definition. Due to these facts about the research phenomenon as well as my personal beliefs as

researcher, the research study was approached from a **constructivist ontological and epistemological position**.

In line with the constructivist methodology, a qualitative, exploratory case study design is deployed that is informed by Grounded Theory methods such as in-depth interviewing for data making. As a result, this research study follows an **inductive reasoning** which starts with observation and data creation considering its context (Easterby-Smith et al., 2012). The generated data is then used during data analysis to work up to identifying potential general social patterns. These **social patterns** can subsequently form the basis for a broader generalisation, transcending time and space.

Although more objectivistic approaches, such as realism, might allow for more generalisable theory confirmation, the insights gained through this constructivist methodology will allow for creating meaningful findings for instance on the social aspects of product development in international corporations, reflecting e.g. the impact of people's experiences and capabilities. Even if this might make it difficult for me as a researcher to induce broad generalisable knowledge, it might however form the basis for future deductive research that then applies a realist or even naturalist research approach. That way, confirming the newly generated theory by testing hypotheses that are being developed and tested based on the specific findings of the case study.

This particular example shows that when talking about research philosophies, there is no right or wrong. It seems to be more a question of suitability and sequence, when and which approach to apply to a specific research phenomenon (Easterby-Smith et al., 2012). **Suitability** on the one hand refers to approaching the right research questions with the right way of thinking and the right research methods. **Sequence** on the other hand means to apply inductive approaches first to create new theory and to draft hypotheses that will afterwards be tested in a more deductive fashion based on naturalist, realist approaches.

The envisioned suitability of the constructivist paradigm to explore the emergence of a new radical product concept under uncertainty is well in line with my basic beliefs (paragraph 1.5) as well as leading researchers in the field such as Yin (2017)

for case study research or Seidel (2007), Koen, Bertels, and Kleinschmidt (2014) and O'Connor & Rice (2001) for product concept adaptation (for details see chapter 2.7)

3.1.4 Conclusion on research philosophy

During this part of the methodological discourse, the motivation and rationale for the constructivist philosophical stance were presented, highlighting that key methodological decisions were based on the researcher's beliefs and their overall fit with the research phenomenon.

In addition, the specific ontological as well as epistemological considerations were presented which formed the basis for the research design of a single-case study methodology. In the second part of the methodology chapter the main pillars of the research design, i.e. data making techniques and applied analysis methods, will be outlined.

3.2 Characteristics of data collection/creation

The constructivist world view of the researcher led to the application of a qualitative case study research design. In that context, case study research must be seen as a holistic method not just a data collection approach. This means that the following questions brought up by Philliber, Schwab, and Samsloss (1980) are considered early on:

- What questions are to be studied?
- What data are relevant?
- What data needs to be collected?
- How are results analysed?

To answer these questions, the following section outlines the chosen research design by defining the **unit of analysis,** outlining the **case study type** as well as introducing the **data sources** used for data collection. Finally, a summary of the **data collection procedures** is presented.

3.2.1 Defining a case study research design

The aim of this section is to present the characteristics of the case study research design. Shaped by the nature of the research phenomenon and the research objectives, the case study typology, the unit of analysis as well as the sampling strategy are outlined in the next paragraphs.

3.2.1.1 Case study typology - Single-case study research with two embedded cases

This research study employs a case study research design to investigate the emergence of new product concepts in the context of the In-vitro diagnostics industry. That way it tries to close the gap in empirical research on this phenomenon that became evident during the literature review. In addition, the approach to investigate a small sample in its context and in depth rather than to aim for large numbers of cases seeking statistical significance, like most quantitative

researchers do, appears to be an appropriate path from a methodological perspective (Mason, 2010; Miles et al., 2014).

According to Yin (2017), case study research is a suitable method if the **nature of the research** is rather explanatory or exploratory. By addressing mainly "how" and "why" questions the cases allow for investigating how new product concepts emerge in the context of the IVD industry in detail. Furthermore, this **contemporary nature** of the events suits a case study design (Dul & Hak, 2007). Only product concepts that emerged recently are examined. Therefore, only people who were recently or still are involved in the definition of new product concepts, are approached to examine this contemporary incident in its real-life context. A further characteristic that favours case study research is that the researcher himself has no impact on the course or outcome of the cases or any of the **behavioural events** related to these. The projects are initiated and executed independently from this research study.

With regards to the case type, this study consists of a single case, looking at emerging product concepts within a specific corporation that is active in the IVD market. These characteristics form the framework and context of the overall case study. Within this single case the research examines the emergence of two separate, not interlinked product concepts that represent the two within-cases (Figure 18) (Baxter & Jack, 2008).

The first within-case addresses the emergence of a new point-of-care product concept whereas the second within-case makes the emergence of a new lab technology its main subject of investigation. The purposeful selection of these two within-cases is further detailed below in section 3.2.1.3.

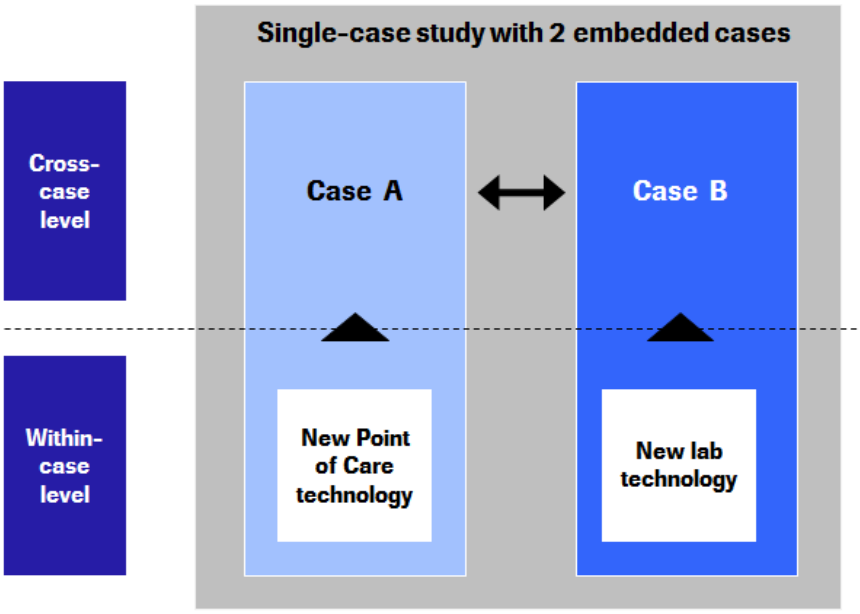

Figure 18. Schematic overview of single-case study with two embedded cases

This case study is based on theoretical sampling, positioned as a specific case, designed to focus on strategic commonalities and differences to maximise the reach and scope of the developed theory.

3.2.1.2 Unit of analysis

According to Yin (2017) a first important step when conducting case study research is to reflect upon the research phenomenon under investigation and to clarify the unit of analysis as these two elements have a major impact on the research design. In this context the **emergence process of new product concepts represents the phenomenon** under investigation. According to that and in line with the research objectives, the **unit of analysis shall be the newly emerging product concepts**, with the analysis taking place at the level of project teams involved in the definition of new product concepts, consisting of individuals from Marketing, Sales, R&D as well as other functional areas.

To extend the view on the unit of analysis, the unit of analysis is not only defined but also bound as part of the overall case study approach (Yin, 2017). Bounding in that sense stands for characterising what is part of the phenomenon and what is part of the context. In this particular case, the study is bound through:

- The **case environment** such as the IVD industry or the context of a specific corporation.
- The **specific development projects,** addressing the development of product concepts in the context of a new point of care and lab technology.
- The **timing,** locating the research study in the early phase of a project in-between initiation of product concept definition and design-freeze milestones.

3.2.1.3 Sampling strategy on a case-level

The single-case study design builds on two embedded cases within a globally operating IVD-corporation. Its aim is to build theory from the case study rather than to test existing theory (Dul & Hak, 2007). The cases are **purposively selected**, based on theoretical considerations instead of external circumstances or a purely statistical basis (Glaser & Strauss, 2010). These considerations are the guiding principle for any sampling decision that needs to be taken when preparing for or collecting data (Miles et al., 2014). Furthermore, this logic applies for sampling on two levels. Firstly, the two within-cases are purposively selected on a case-level. Secondly, on a lower level, a number of participants have to be selected for each within-case as well. This paragraph is solely focusing on the sampling strategy on a case-level; for details on participant selection please see paragraph 3.2.3.1.

In practical terms, Miles et al. (2014) suggest different strategies for a purposeful sampling of cases. The spectrum ranges from maximum variation cases, critical cases to typical cases. In that sense, maximum variation sampling focuses on so-called “outlier cases” to check whether general patterns still apply to those maxima. The second type, bringing critical cases into focus, may be a good strategy to confirm or disconfirm specific findings. However, as both prior characterised strategies tend to confirm or check the applicability of already established theories in extreme situations, this **research study employs typical cases** instead. This strategy is adopted to build new theory based on data generated from typical,

representative cases in this domain, which also helps to increase the fit and transferability of potential findings.

Therefore, both cases consist of a specific, real-life project that aims to define a new product concept. They are selected based on common criteria such as uniformity in corporate governance structure, project phase, project size and scope. This means that they are comparable with regards to:

- **Novelty of product concept**: Developing new product concepts from scratch which means that a new product and not an update of an existing product is developed.
- **Technology development**: Introducing a new technology to the IVD field. This technology may already have been applied in the basic research field but is not yet made available to IVD. Furthermore, technology development in this context comprises elements of combining different technologies, automating and integrating them into one product.
- **Maturity of new product concepts**: Focusing on an early stage in which a new product concept is emerging.
- **Timeframe**: Both initiations occurred close together in 2012/2013 and lasted until 2015/2016. This is important to ensure that the two projects are executed within the same strategic framework and with certain stability and consistency on a management level.

Besides all the alluded to commonalities, the two cases can be differentiated with regards to the way the teams are documenting customer requirements.

- **Case A** employs, after in-depth training, the customer-centric use case approach to structure and facilitate this product definition process.
- **Case B** develops a new product concept following the corporate guidelines for new product development by defining and documenting customer requirements in the classical way of “X should allow for…”.

As the reach of a developed substantive theory is heavily influenced by decisions about the group under investigation (Miles et al., 2014), the contrasts between the

two embedded cases were minimised through common selection criteria that were outlined above (Glaser & Strauss, 2010; Miles et al., 2014). At the same time, particular differences between the cases allowed for a focus on strategic commonalities and differences (Glaser & Strauss, 2010; Patton, 2015).

In conclusion, this purposeful sampling strategy is chosen to lay the basis for a broader generalisability and to **maximise the reach and scope of the developed theory**. However, it must be noted that the sampling is not just limited to the selection of adequate cases but also covers the selection of research participants within each case. This "lower-level" sampling is detailed in section 3.2.3.1.

3.2.2 Data sources utilised

The selection of data sources is influenced by the overall philosophical constructivist position of this research study. As a consequence, this research study seeks **to have a clear problem in mind** and to be open respectively **receptive to the emergent** at the same time (Glaser, 1978). This receptiveness is expressed in a broad use of different types of data that will be integrated into this study.

According to Yin (2017), qualitative research can be based on a broad range of data sources. In his seminal work "Case Study Research", Yin (2013) generally refers to six important **sources of evidence**:

- **Documentation,** such as emails or meeting minutes.
- **Archival records** comprising data such as stored files or records.
- **Interviews** representing guided conversations.
- **Direct observations,** meaning passively observed social, environmental conditions.
- **Participant observations** as a sub-category of observation additionally containing an active role of the researcher in the fieldwork.
- **Physical artefacts** comprising physical items such as a prototype of a technical device.

To finally decide upon the selection of appropriate sources of evidence, one needs to keep the different data types in mind that are analysed when investigating the emergence of new product concepts. Holliday (2016) proposes four main types: (a) behaviours, (b) events, (c) institutions and (d) relations.

In the context of this research study firstly, the description of **behaviours and relations** is essential when trying to understand the cross-functional team dynamics during the emergence of new product concepts. Secondly, the description of **events** allows for identifying critical events that affect the course of the cases. Finally, descriptions regarding the **institution** provide details on the processes, structures, regulations and tacit rules within the organisation. This data is essential when trying to understand the industry and company context this case study is embedded in.

After having considered a broad range of sources of evidence as well as the different data types, the **scope of sources is limited to interviews and documentation**. At first, available project and general company documentation is collected throughout the data collection process. Secondly, semi-structured in-depth interviews will serve as the basis to further explore the research phenomenon.

At the same time, observation will not be utilised as it bears the risk of an influence, respectively manipulation of the course of such a project. Furthermore, this would require a massive effort to capture the overall process of an emerging product concept which lasts roughly two to three years. Particularly in the case of a participant observation, an active role in the project would have an impact on the natural setting of the real-life projects. Furthermore, physical artefacts will also not be collected as sources of evidence. In the context of the development of new diagnostic tests this appears not to be feasible as for example a prototype of a biochemical test which consists of 30-50 microliters of reagents in a reaction tube would not be meaningful. However, it must be noted that these physical artefacts are indirectly included in the data set in the form of illustrations, diagrams and graphs of the measuring principle which are part of the project documentation.

Next, the two sources of evidence, interview encounters and documentation, are further outlined.

3.2.2.1 Interview encounters

Historically, this technique goes back to the Chicago School of Sociology that had a pioneering role in applying what is today known as research interviewing (Brinkmann & Kvale, 2015). These encounters represent a research technique to generate primary data.

The general purpose of **research interviewing** is to generate data out of the interaction of an interviewer with an interviewee. Through this source of evidence qualitative researchers try to understand the world and the meaning of certain experiences from a **subjective point of view** to create knowledge out of this socially constructed data (Brinkmann & Kvale, 2015; Morris, 2015).

As the subject and the context of the conversation will be business related and held within a corporate setting everybody is working in, the interviews can be classified as **professional conversations** (Brinkmann & Kvale, 2015). Furthermore, the interviews can, according to Brinkmann and Kvale (2015), be characterised as elite interviews because the interviewees either are elite due to their hierarchical position (e.g. project leader, head of department, etc.) or due to their expert position within the organisation. This aspect and the potentially resulting power asymmetry between me as the interviewer and the interviewee are reflected on in section 3.2.3.2 which covers the interview style. This imbalance may be reduced or even offset by a well-informed interviewer who is for example knowledgeable about the topic and has mastered the technical language.

Such **semi-structured in-depth conversations** lasted approximately one hour and can be classified as in-depth due to the level of detail rather than its actual length. If the time was not sufficient to extensively explore the phenomenon, an additional inquiry was scheduled to follow-up on selected topics. To closely engage with the interviewees, the interviews were held face to face. This allows for maintaining a certain control over the scope of interviewing.

A further aspect that needs to be considered is that this interview data arises in a very specific setting. Brinkmann and Kvale (2015) characterise the data with specific attributes such as:

- **Produced**: Data is socially constructed in the interaction of an interviewer and an interviewee but also through its documentation, e.g. in the format of a transcript. This way it is also in line with the constructivist philosophical position.
- **Linguistic**: Spoken language is the medium of interview research even if it is later on documented and converted into written form.
- **Narrative**: Interviewees tell stories about their experiences which must be seen as a powerful way to gain deep insights.
- **Conversational**: Meaning of narrative descriptions can be discussed to make sense out of them.
- **Contextual**: Interview data is located in its particular context so that the knowledge that is obtained within one situation is not automatically transferable. Therefore, an extensive description of the cases and their context is crucial during analysis.

Particularly, the narrative attribute is important to keep in mind when creating interview data. By asking different kinds of questions during the interview a lively discussion with practical experiences shall be encouraged. Furthermore, the contextual aspect is considered when analysing and theorising from the cases.

In the following section (3.2.3), more detailed information about the interview design and its implications for data analysis are provided by describing (a) the interview type, (b) the selection process of interview participants, (c) the style of the encounter and finally (d) an approach for how to document the conversations.

3.2.2.2 Documentation

As a second, complementary source of evidence, documentation was chosen, including items like emails, meeting minutes and photographs as well as general project documentation such as progress reports. An aim associated with this data type is to have the opportunity to add to and cross-check the spoken word of

respondents with more formal project documentation. Additionally, it was a useful way to identify potential research participants.

This source of evidence was **generated independent of this research** study and can therefore be classified as secondary data. It is rather collected unobtrusively and its stable nature is highly appreciated particularly in the context of perennial projects. These characteristics of the data sources allow for looking back at different stages of the emerging product concept and allow for revisiting the data several times during the analysis process.

Additionally, it helps obtain the language and terminology used by research participants (Yin, 2017). This is also illustrated by the two subsequent examples of documentation that exemplify the detailed results of a patient journey workshop (Figure 19) on the one hand and the terminology used on a management level on the other hand (Figure 20).

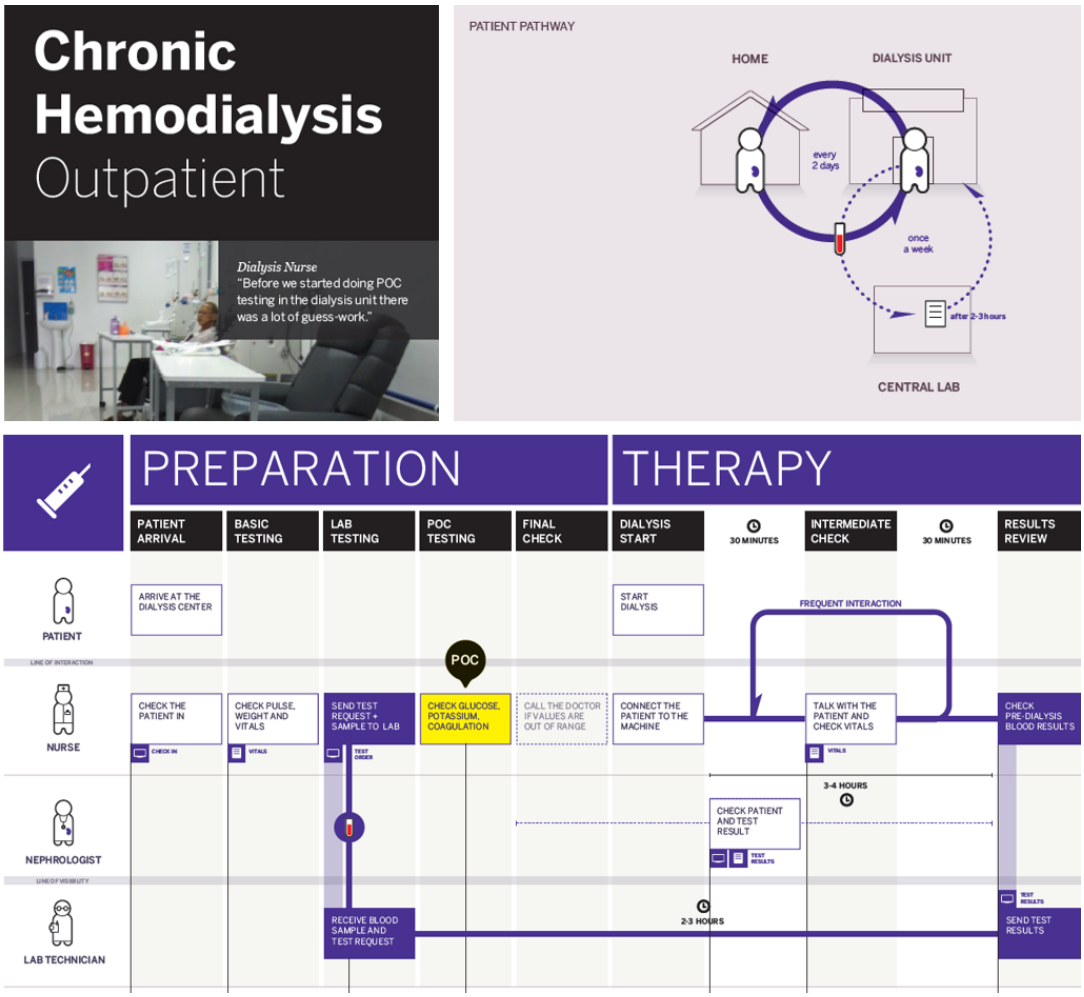

Figure 19. Example of documentation as data source – Patient-centric workflow analysis (Case A)

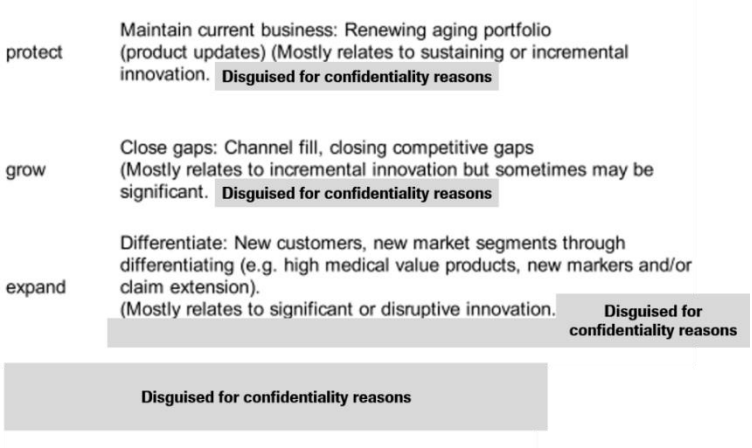

Figure 20. Example of documentation as data source - Strategic portfolio options (Case B)

Besides the mentioned benefits of this data source, a drawback clearly is that confidentiality aspects might restrict sub-sequent disclosure or publishing of the research. Quantitative researchers also frequently critique this source of evidence for its potential biases. Yin (2017) for example highlights the **risk of bias involved in the creation and reporting of documentation** as well as the bias in the selection process of documentation. To reduce this risk, the author of the documents as well as the distribution list are considered during selection and analysis.

With regards to the data collection procedure, documentation was either collected during the interviews or independent of the encounters through screening of the corporate intranet and the confidential "project teambase" (i.e. cloud-based data platform to store and exchange documents) that the researcher was granted access to. This data collection process resulted in more than 300 documents that were screened and more than 40 documents that were in the end included in the data analysis. The list of documents comprises sources that can be classified into three different categories:

- "**Public, internal" documentation** such as project descriptions or project timelines openly available to every employee. A channel to access this data was for example the corporate intranet.
- **General project-specific documentation** such as organisational charts of the team available to the whole project team. A channel to access this data was for example through the "project teambase".

- **Confidential documentation** such as strategic assessments or business plans that are just accessible for selected individuals. This data which is not to be published was provided in confidence mostly via personal emails.

To mitigate the risk of bias in the collection, the screening and selection process of the most relevant documents was guided by a set of principles such as:

- **Thematic fit**: The content of the documentation needed to be interlinked with the research phenomenon of newly emerging product concepts. That way for example mere organisational topics like scheduling of team meetings were not textually considered.
- **Dynamic updates**: Documentation like organisational charts or project timelines that are frequently updated were only included once to their full extent, when changes in-between different versions occurred.
- **Recurrence**: Duplicates were excluded.

In the end all relevant documentation was consolidated and stored in a case study database along with the interview data (Baxter & Jack, 2008).

3.2.3 Adaptive data collection approach

In line with the constructivist research philosophy and the exploratory nature of this research study, data collection followed an adaptive design (Yin, 2017), meaning that key elements such as the selection of research participants or the style of interviews allow for a certain flexibility to take newly emerging insights into account. These elements of data collection are now specified in more detail.

3.2.3.1 Selecting participants - Sampling on a participant-level

As part of a qualitative, data driven research design, the participants were **purposively selected,** following a snowball sampling approach. This means that only at the start of the interview process was a small **initial group of interviewees** "pre-selected" in alignment with the respective project leaders. Thereupon all further research participants are identified in the course of interviewing and data analysis.

During that process a set of criteria was applied to decide upon the eligibility of the candidate:

- Each person was or still is involved in the development of the new product concept in the respective case.
- The selection was not triggered by the researcher but by the functional expertise which made a person associated with or part of the project team.

As a result, the research participants themselves and the emerging topics (theoretical sampling) guided the selection process of further interview partners as well as the focus of topics discussed. Due to these characteristics, the course of interviewing and data collection was only predictable to a limited extent (Glaser & Strauss, 2010) and needed to be adapted continuously (Miles et al., 2014).

To ensure consent of participation, an agreement was achieved in a **two-step approach**. In a first step line managers were informed about the research project including information on the timing and resources that are needed. After a general agreement about a potential participation of employees from various functional departments, the respective individuals were approached and asked about their willingness to participate.

This two-step approach carried the risk that a prior agreement with the line manager might dilute the right to refuse participation; but in a corporate setting, senior management had to be informed about such a research enquiry first, to comply with hierarchical approval procedures. The potential pressure on employees was reduced by providing detailed information on the research procedure and by stressing the voluntary nature of participation at multiple points of the encounter.

These pieces of information as well as further details on aspects such as confidentiality and anonymity, were also incorporated and highlighted in the invitation letter that was sent to all potential participants in the beginning. This information package was sent as an email, contacting potential interview partners, and then included in meeting invitations when scheduling the interviews. An example of the invitation letter is enclosed in appendix A.

Following a snowball sampling strategy, the research started with five pre-selected interviewees. Thereafter, following the principles of theoretical sampling (Glaser, 2005) that demand a selection of participants based on the emerging topics identified during data collection and analysis, the list grew to ten people per case who were chosen from the development project teams.

Table 5 provides a full picture of the 20 people that were interviewed during this research project:

Table 5. List of research participants incl. functional role and unique identifier

#	Participant code	Functional role	Follow-up (yes/no)	Case
1	S5	Project Management	yes	Case A
2	S3	R&D Instruments		Case A
3	S6	Marketing – Product Manager		Case A
4	M1	R&D Applications		Case B
5	M5	Business Development	yes	Case B
6	S9	International Liaison Manager	yes	Case A
7	S2	R&D Technology		Case A
8	S10	Requirements Engineering		Case A
9	S7	International Marketing		Case A
10	M9	Requirements Engineering	yes	Case B
11	M10	Business Liaison Manager	yes	Case B
12	M8	International Marketing		Case B
13	S8	Marketing / Regional Sales		Case A
14	M2	Instrumental Analytics		Case B
15	M7	International Marketing		Case B
16	S1	Development Lead	yes	Case A
17	M4	Project Management	yes	Case B
18	S4	Software Development		Case A
19	M3	Development Lead	yes	Case B
20	M6	Project Management		Case B
-	R	Researcher	-	-

A more detailed list of participants and their functional roles at the time of enquiry cannot be disclosed for confidentiality and anonymity reasons. If the head of a certain department is involved, this functional description would in some cases directly identify the respective person.

The sequence of interviews was alternating between the two cases and different functional areas. The following figure provides a full picture of all interviews conducted including information on the sequence of interviews, arising recommendations by interviewees for further interview partners and key topics discussed (Figure 21). Furthermore, the graph points out individual topics that were followed-up after the initial interview e.g. through further interview sessions, emails or documents that were shared after the interview.

New **interviews were conducted until a point of saturation** was reached, meaning a point where the interviews began to yield little to no new insights (Brinkmann & Kvale, 2015). In terms of Grounded Theory, this point may also be called **theoretical saturation** (Glaser, 2005) as further research encounters add little to no additional value**.** This level can only be achieved through simultaneous collecting and analysing of data (Glaser, 2005). This is also the reason for approaching two cases in parallel and why the above interview process lasted a period of more than nine months.

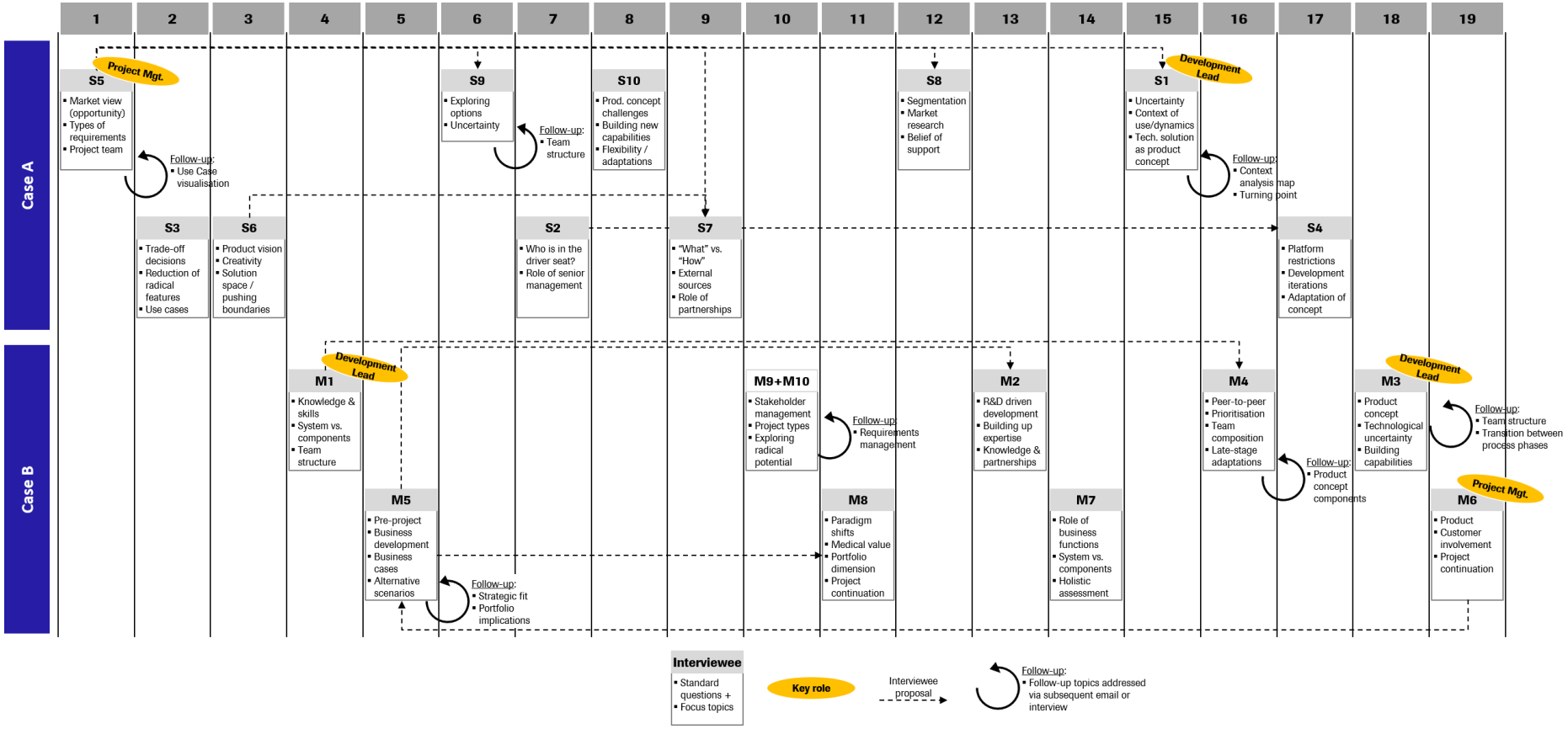

Figure 21. Sequence of interviews including focus topics

To provide a solid overview of the research participants, personal data such as the gender, work experience, educational background as well as their functional role were collected. Key characteristics are summarised below in Figure 22:

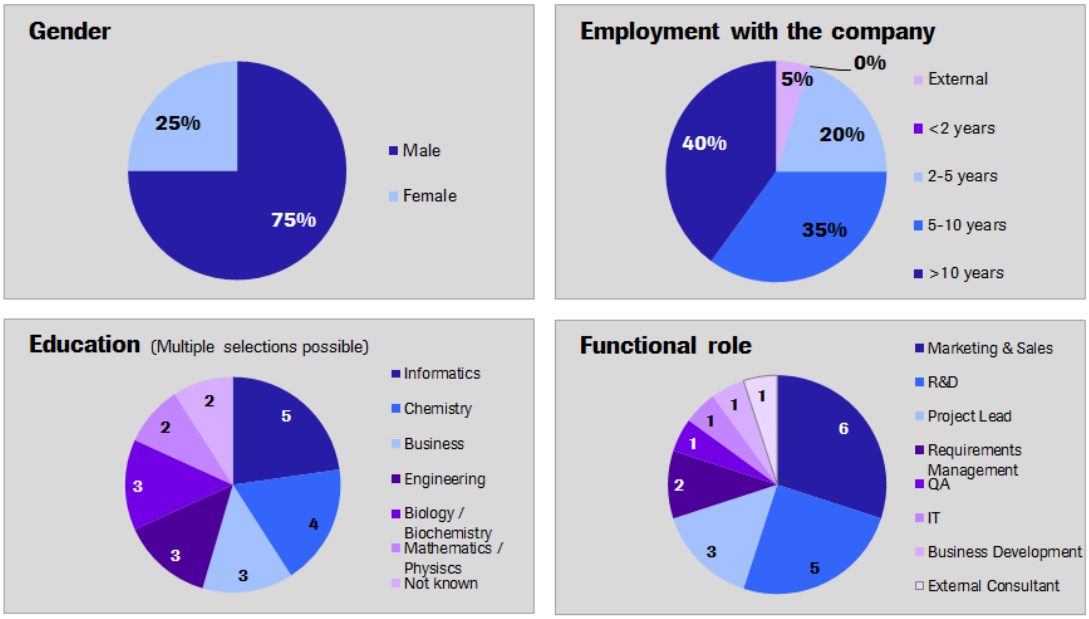

Figure 22. Interviewee statistics

Except for one person from Latin America, all interview partners were European and located in Europe at the time of interviewing. Furthermore, there were interviewees from both genders involved in the data collection phase; however, with a ratio of 75% it was dominated by male participants. This could have been expected a priori as this ratio is in line with the overall company's gender distribution in most functional areas involved in new product development.

Participants were mostly working for the company for more than five years and 40% longer than ten years. Furthermore, a wide range of educational backgrounds is represented, ranging from business to various disciplines in natural sciences. Some of the interviewees even hold double degrees in business and natural sciences.

A further characteristic of the interviewee group is their broad mix of functional backgrounds. Most people descend from Marketing, Sales or Research & Development functions but further functional backgrounds such as IT, QA or Requirements Management complement the group of people involved in an early phase of new product development.

3.2.3.2 Interview procedure & interview style

The purpose of the aspired qualitative in-depth interviewing was to closely engage with the project team members of the two cases to explore their views, experiences and individual perceptions of the phenomenon under investigation. To do so, the one-on-one interviews were held employing a semi-structured in-depth interviewing protocol. This means that an interview protocol assured a certain similarity of discussion but the semi-structured nature of the interview allowed for an open, conversation-like enquiry. This facilitated staying flexible during the interviews and getting to the bottom of participant responses (Morris, 2015).

Brinkmann and Kvale (2015) also describe this interview style as the "Interview traveller" which expresses that the researcher starts a conversation with a person by asking open questions, motivating them to **tell individual stories, using their own terminology**, instead of directing the course of the conversations by direct or leading questions. This also highlighted the descriptive nature of interviews where research participants were encouraged to precisely describe what their experience is and how they acted in the context of emerging product concepts (Brinkmann & Kvale, 2015; Morris, 2015). At the same time, the explicit topic of the conversation provided a clear focus of the discussion and indicated that it was not entirely non-directive.

These characteristics of the interview style lead to a point where the expressions "encounter" or "enquiry" appear to be more appropriate and thus will be used interchangeably with the term "interview".

Following a referral or an emerging theme, the identified potential respondent was contacted prior to the encounter via phone, email or personal meeting. This way in a first introduction to the topic, relevant information such as the following was provided:

- Personal introduction, in case the participant was not known yet.
- Description of the research topic in general.
- Introduction to the purpose and aim of the research.

- Illustration of the overall research procedure, from first contact to completion of research study.
- Elaboration on ethical principles.

As I already knew some of the participants from my previous professional life within the company, easy access to potential candidates was assured.

If a candidate accepted to take part in the research study a 60-minute one-on-one meeting was scheduled. This formal invitation again contained the invitation letter including essential information referred to earlier on; for details see appendix A (Morris, 2015).

During the encounter, an **interview protocol** ensures a certain standardisation of proceedings. This protocol consisted of five sections; an introduction, a personal background section, a main part as well as a summary and finally a section on next steps. It was designed in a way that it included a broad spectrum of questions to introduce, prove, test or detail a topic that was discussed. This variety was particularly important as during a semi-structured conversation many methodological decisions had to be taken on the spot (Morris, 2015). This required a **proper preparation** as well as a **skilled interviewer** who needs to be knowledgeable about the methodological options available when producing knowledge through conversation (Brinkmann & Kvale, 2015; Creswell, 2013; Miles et al., 2014).

As a result of the previously outlined enquiry style, the conversations tended to be a hybrid of a conceptual and a narrative interview. This means that on the one hand questions aimed to explore the meaning and conceptual dimensions of a central issue such as the emergence of a product concept in the context of the IVD industry. On the other hand, the interviews clearly focused on the real life experiences the team members had in the course of the initiation and execution of an early development project. As a consequence, to say it in Brinkmann and Kvale (2015) words, there needed to be a balance between the “miner” in conceptual phases and the “traveller” who just listens and obtains information from interruptions in narrative phases of the conversation (Brinkmann & Kvale, 2015).

To prepare for this complex dialogue the interview guide contained a broad range of potential questions to stay flexible. Informed by Brinkmann and Kvale (2015) and Yin (2017) a selection of key question types is outlined:

- **Introductory questions**: Mostly open questions setting the stage for a specific topic. Allowing the respondent to explain broadly what he/she has experienced.
  Example: "From your perspective, what are the major concerns in that respect?"
- **Follow-up question**: Extension of answer through curious/critical attitude. *Example critical follow-up: "To what extent is that from your perspective unique?"*
- **Probing questions**: Pursuing with the answer and probing their content; however, without stating potential dimensions that may be taken to account.
  Example: "I understood ..., why did you actually do that?" (incl. interpretative)
- **Specifying question**: Asking for a more precise description/explanation. *Example: "Could you please describe that in more detail?"*
- **Direct question**: Introducing a topic or a specific dimension; preferably at later stage of the conversation when initial topics had already been discussed.
  Example: "Which additional topic were you not satisfied with?"
- **Structuring question**: Directing the course of the conversation to a new topic for example in case a specific topic has been discussed exhaustively. *Example: "Were you also experiencing challenges with …?"*
- **Interpreting question**: Interpretation of participant responses to clarify its meaning; for example, through rephrasing the original statements. E*xample: "If I understood you correctly, …?" or "Can I summarise this by …?"*

- **Silence**: Conscious use of silence as a stylistic element. Allowing for pauses to stimulate the interviewee for new aspects or to give time for thought or reflection.

The complete documentation of the interview protocol can be found in appendix B.

The main part of the encounter is introduced with the open question "*In my thesis I'm exploring the specific characteristics of the emergence of new product concepts. From your perspective, what are the major concerns in that respect?" (part of interview protocol).* The respondents are that way very openly asked to reflect upon their personal view on the phenomenon. In this early narrative phase of the enquiry, a few follow-up questions are used to extend certain answers and to keep the flow of the conversation going. In addition, probing and specifying questions are utilised to gain more precise and properly understood descriptions. However, a strong emphasis is set on purely listening to respondents' statements and explanations.

At the end of the research conversation the participants were again asked whether there are any further topics they would like to address. If not, the conversation was ended by thanking the participants for their participation and their valuable insights into the project. Finally, the conversation was concluded by outlining the next steps of the research project. A focus in that respect was set on the timeline of the study, the analysis phase and a potential follow-up on a particular topic that may emerge during future inquiries.

The particular **encounters were undertaken with individuals only** to gain insights into their personal views and opinions. A group setting like in a focus group with 6-10 people appeared not to be desirable, as firstly, in a group, certain individuals may not speak openly. Secondly, the cross-functional nature of such a group might inhibit politically sensitive topics or conflicts from being addressed. Thirdly, a group setting might also bear the risk that single individuals dominate the discussion or even overwhelm other team members. A more confidential one-on-one setting appears to be more promising to encourage participants to precisely describe what their experiences are and how they act in the context of emerging product concepts. It must be noted that one conversation is carried out with two

participants. In that particular case, a participant proposed during the introduction of the topic to spontaneously invite a further colleague, who is a subject matter expert in his team, to join the interview.

With regards to the language of the conversation, the research participants are free to choose between German or English, depending on what they feel more comfortable with. This limitation to just these two languages was adequate as all respondents in the business context were either fluent or native speakers in German or English. This is important to highlight as language was the main medium and a high proficiency is crucial to be able to verbalise one's own view (Brinkmann & Kvale, 2015).

A further characteristic of the **encounters** is that they were **primarily conducted face-to-face** and the setting was carefully chosen. The personal meetings were held in a separate neutral meeting room and not an open space office. Furthermore, the room needs to be closed to ensure a private, confidential conversation. This is also in line with Brinkmann and Kvale (2015), who highlight the setting as a key element to speak openly and for the interviewer to get to a point where the respondent is free and safe to talk openly. However, it must be noted that two conversations were held via phone due to sickness and long-term parental leave.

Further deviations from the enquiry protocol took place in two regards. On the one hand a few personal introductions actually started outside the meeting room and were therefore not possible to be recorded. This occurred for example when getting a coffee in the kitchen first or when meeting at the office space and then walking jointly to the meeting room. On the other hand, it was not necessary to ask for a detailed description of the role and position of some of the interviewees as they were already known. These deviations are consciously accepted as otherwise the encounters would have turned into an artificial conversation, not following the goal that they should be as natural as a research interview can be.

The research procedure described above was developed in the design phase of the research study; however, to prepare for the practical part of the research conversations, two pilot interviews were conducted before the actual start of the data collection process.

This was primarily to practice the interview procedure and interviewing skills as recommended for example by Brinkmann and Kvale (2015) as well as Morris (2015). Although I was already a quite experienced interviewer, mostly through my four-year professional consulting career, the pilot inquiries allowed a focus on being an "interview traveller" instead of "miner" (Brinkmann & Kvale, 2015). In addition, it was an excellent way to test tools such as the interview protocol. Based on these practical experiences some questions were reworded and the decision was taken not to carry any print-out material to the conversations. Instead, key questions were copied into the notepad so as not to distract the respondents with any pieces of paper. Furthermore, the purpose of the pilot enquiries was to practise the overall procedure ranging from the general introduction to the final closing. This reemphasised the need to reserve dedicated time for additional topics brought up by conversation partners towards the end of the meeting.

3.2.3.3 Documenting & storing gathered data

The documentation of gathered data was specifically adapted to the respective data types. On the one hand there were **artefacts**, such as workshop minutes, pictures, organisational charts or further project documentation, that were already documented, mostly in the form of Microsoft PowerPoint® presentations, Word® documents or photographs. As these documents were created by project team members in the context of the progressing projects and not for the purpose of this research study, this data type can be classified as secondary data.

On the other hand, **direct, personal encounters** with the research participants **were documented in a transcript**. To do so the conversations were audio recorded and a transcript created. A transcript in this context can be seen as a written document that captures the verbal, conversational interaction between the research participant(s) and the researcher (Brinkmann & Kvale, 2015; Morris, 2015)).

Each conversation was transcribed word-by-word but filler words or sounds like "hmm" were not documented literally. However, to **capture the atmosphere** of the interviews, stylistic oral characteristics like pauses, emotional expressions such as

laughter or sighing were additionally documented as annotations (Brinkmann & Kvale, 2015). Otherwise, this rich dimension of the conversation would have been lost through the transcription process step. Table 6 provides an exemplary overview of transcript conventions that are applied to integrate key stylistic verbal characteristics:

Table 6. Transcript conventions to capture stylistic elements

Subject	Symbol	Details	Example
Speech break	(pause)	▪ Indicating a pause or speech break	▪ What we did (pause); we tried to…
Simultaneous speaking	…	▪ Indicating an onset of people talking at once	▪ Participant A: We were absolutely clear about… ▪ Participant B: Why that? ▪ Participant A: …the future direction of the project.
Emotions	(laughing) (anger)	▪ Documenting non-verbal expressions like facial expressions ▪ Documenting emotions that were e.g. transmitted through the pitch of the voice	▪ Nobody had a clue (laughing). Anyway we just… ▪ …had developed to a major issue which caused a lot of trouble (anger).
Highlighting	CAPITAL LETTERS	▪ Indicating a text segment that was stressed	▪ …a REAL issue…
Ambiguous phrases	(Annotation)	▪ Detailing the meaning of ambiguous expressions	▪ "hmm" is specified as "hmm (affirmative)".

In two cases where research participants refused the recording of the conversation; detailed notes were taken, and meeting minutes were created during and closely after the encounter.

The transcription as well as the composition of meeting minutes were carried out by myself, which fosters a close engagement with the gathered data right from the start. This is particularly important as the **first cycle of coding was performed simultaneously** to noting down the research conversation. Hence the direct transcription must not be seen as a pure documentation step but rather as the **starting point of data analysis** which was also an instrument to improve data reliability.

Further measures to ensure reliability of the transcribed data and overall documentation procedures include firstly, that two professional audio recorders were used at the same time to ensure a high audio quality. Secondly, the initial transcripts were once again proof-read while listening to the audio recording. The full set of transcripts is not included in the thesis but available upon request as only extracts from transcripts are used in the analysis and findings sections.

Finally, all documents, both artefacts as well as transcripts, are consolidated and stored in a secured research database with restricted access rights. The data structure also served as a blueprint for the data directory in the qualitative data analysis software NVivo® that was used during data analysis. A list and preliminary structure of pooled data can be found in appendix C.

3.2.4 Conclusion on data collection approach

Building on a constructivist philosophical stance, this part of the methodological discourse presented the key characteristics of the research design in the context of data collection. In addition, the data making process was outlined by elaborating for example on interviews and documentation as data sources, associated sampling strategies and the use of interviewing to collect data. Finally, the approach to document and store data in a research database was depicted.

In the third part of the methodological chapter, the key building blocks of data analysis, i.e. analysis techniques (e.g. substantive coding) and theory building are illustrated in more detail.

3.3 Data analysis and interpretation of case study findings

Following the remarks on data collection procedures in the context of a single-case study methodology, this section will look at the data analysis approach in more detail. This comprises applied data analysis techniques such as memoing, substantive and theoretical coding that are informed by Grounded Theory methodology. In addition, the two levels of analysis, namely within-case and cross-case, are described and their interplay is illustrated to demonstrate the contrasts and differences between the two individual cases in detail. Finally, the process of conceptualisation respectively theory building is outlined.

3.3.1 Data analysis procedure

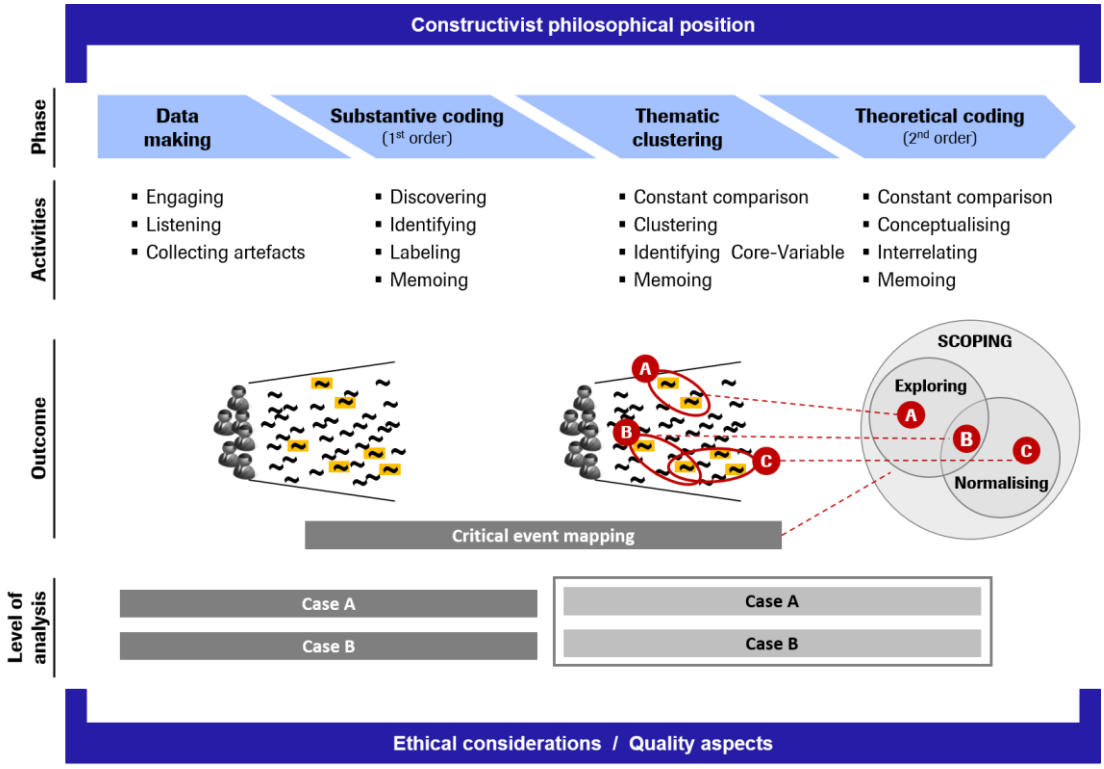

Figure 23. Data analysis procedure

Data analysis was conducted in **several subsequent and iterative steps** which also reflects the process nature of theory building (Glaser, 1978; Glaser & Strauss, 2010). As outlined in chapter 3.2, characteristics of data collection, the analysis had already started during data creation. In parallel, the **substantive coding technique** was applied to identify and label first key sections of research encounters and

project documentation. This formed the basis for identifying critical events of Case A and Case B which were mapped on a **critical event matrix**. During that time, the first rough ideas of the core-variable *Scoping* emerged. To better characterise and detail this core-variable a final cycle of **theoretical coding** was initiated. In that step, the research findings were interrelated and **conceptualised on a cross-case level**. Appendix D provides an illustration of these individual analysis steps based on the example of dynamic capabilities.

These initial data analysis steps, which ranged from data making and substantive coding to selective coding, did span a period of more than 18 months and were supported by the qualitative data analysis software NVivo®. This is quite a long time span but it was seen as the most vital step in the overall research process which requires time in the exploration phase to ensure high quality of work (Glaser, 1978)

3.3.2 Data analysis techniques

To explore the characteristics of new, radical product concepts that are based on new technology, the data analysis phase was characterised by a deep-dive into the generated data and a process of discovery (Glaser, 1978). This process was supported by a **set of dedicated techniques to facilitate the transition from separated, unclassified pieces of data to the emerging theory of *Scoping***.

The subsequent paragraphs individually outline all key techniques that were applied to give data meaning; here the span ranges from procedures like substantive coding, annotating and memoing to conceptualising ideas and thoughts, up to theoretical coding to underpin and structure the newly developed core-variable *Scoping*.

Figure 24 below illustrates the **flow of analysis steps** and applied techniques from the generated data to the interpretation of meaning. Following a constant comparative approach to build new theory, data analysis was not linear but rather interactive, interconnected and iterative (Bazeley & Jackson, 2013) going back and forth between generated data on a within-case level and cross-case findings:

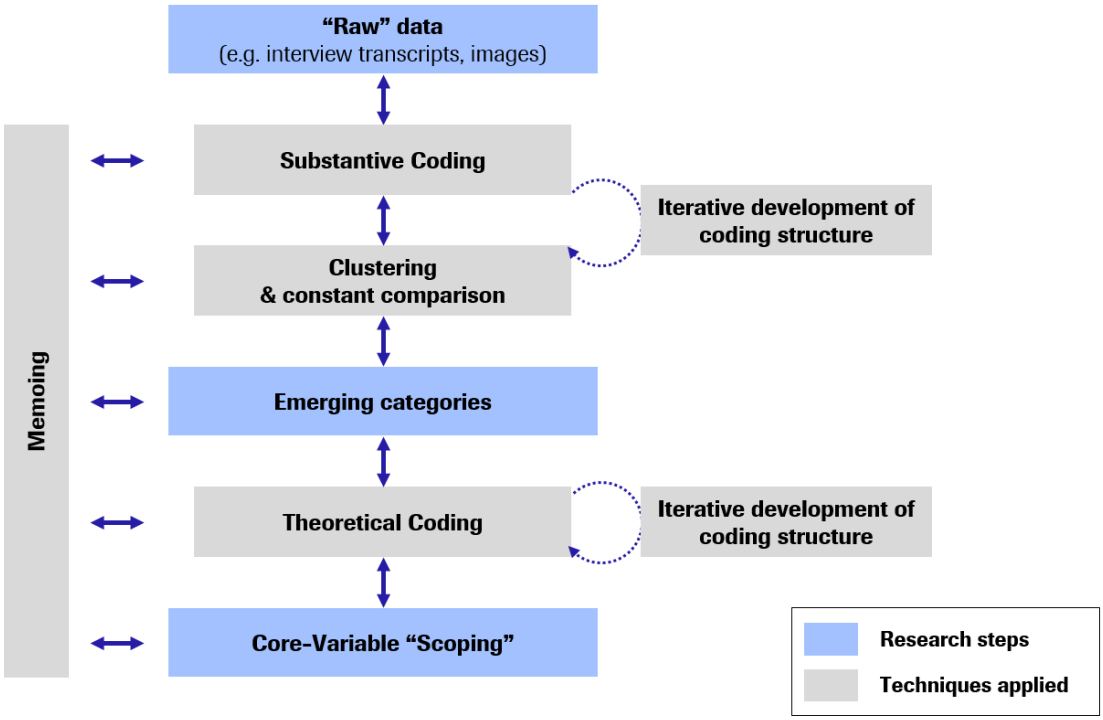

Figure 24. Data analysis flow - iterative, cyclic data analysis process (Creswell, 2013)

Initially, texts and artefacts were coded substantively, meaning that codes were emerging from data and were developed spontaneously rather than a priori. During that step, substantive codes were iteratively developed and constantly clustered into a set of predominant substantive themes. Substantively coded data formed the basis for a second cycle of theoretical pattern coding, which led to the discovery of potential influencing factors for the emergence of new product concepts. Constant iteration between within- and cross-case data, substantive and theoretical codes, and emergent theory led to the discovery of *Scoping* that contributes to the explanation of the emergence of new product concepts. As part of Appendix D, this iterative analysis process is illustrated using the example of dynamic capability, which builds a key concept of *Scoping*.

Next, key data analysis techniques deployed will be described in more detail.

3.3.2.1 Substantive coding

In general, coding describes the **process of attaching one or more labels to a piece of data** (e.g. text segment) in order to assign meaning to a descriptive piece of information and to allow later identification of these statements (Bazeley &

Jackson, 2013; Miles et al., 2014). In this context, one differentiates two kinds of codes: lower-level substantive codes on the one hand and higher-level theoretical codes on the other. Initially, this section will focus on substantive codes whereas section 3.3.2.3 will elaborate on theoretical coding.

Due to the exploratory nature of this research study, the coding process was initiated with no pre-set list of codes. Such a list rather emerged on the fly in the course of data analysis (Creswell, 2013; Glaser, 1978).

The emerging codes were labelled in a descriptive way, which means that the code summarised the general topic in a single word or short phrase with a basic descriptive tag or a more complex metaphor (see also Figure 25). If possible and suitable, the created expressions referred to the actual language that was used during the research encounter. One could argue that the substantive coding was following an "in-vivo" approach but this is not the case due to the clear focus on the descriptive and summarising nature of the codes (Saldaña, 2012).

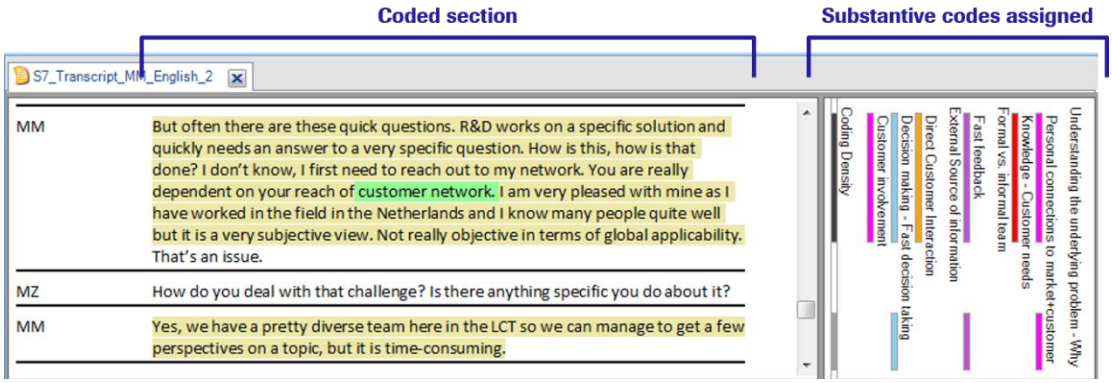

Figure 25. Exemplar substantive coding in NVivo® incl. annotation

The newly created substantive codes were associated with the data in a manual fashion which refers to labelling the data while listening to audio recordings and reading through the transcripts or the different sources of data carefully. The identified codes were created in the QDA software NVivo® and respective pieces of data were tagged while transcribing or going through the whole set of data sources line-by-line (Charmaz, 2014). A further key characteristic of the substantive coding process was that, in the case of coded text, the codes comprised small text sections or whole sentences rather than just single words or whole paragraphs. This way it

was possible to capture a necessary amount of context and detail which hence gave the statement meaning.

Furthermore, this labelling helped to structure the data and to identify the first emerging themes. All this evolved over time into a so called codebook (example Figure 26), a comprehensive overview of all arising and applied substantive codes including a description of the meaning as well as examples to illustrate the scope of its application (Holliday, 2016; Saldaña, 2012)

Themes	Substantive Code	Description	Coding Example	Memo
Business case	**Business case development – Financial assessment**	Development of holistic business case, covering commercial as well as financial perspective of the product concept	**Case B:** M4: "The assessment of business opportunities is demanding as the product is addressing a partially existing market but in a different customer segment and established competitors are applying a different business model (equipment sale & test kits vs. reagent leasing)."	- **Holistic assessment of product concept** - **Uncertainty**
Communication	**Continuous communication**	Communication aspects related to the frequency and intensity of communication flows.	**Case B:** M8: "We need a high degree of cross-functional integration particularly within R&D. We try to achieve this through a close collaboration and co-location of interlinked units such as System Technology, Analytics, etc. They need to communicate with a high cycle rate, you know."	- **Information flow** - **Team dynamics**
	Cross-functional exchange	Aspects covering the communication between different functional units.	**Case A:** S7: "We can articulate the customer needs but for instance not the technical aspects. For me technical folks and marketing need to find a language to talk with each other. Sometimes a requirement was defined in a way that I wouldn't understand it if I read it. You don't know what was meant with that."	- **Information flow** - **Team dynamics** - **Knowledge & capabilities**
	Flow of information	Elements related to the flow of information between different parties involved.	**Case A:** S7: "…maybe as an addition, I'm not a friend of Chinese whispers, that only works rarely, you lose so much information, I prefer to be involved myself.".	- **Flow of information** - **Knowledge & capabilities**

Figure 26. Exemplar codebook section - substantive coding

The developed codes cover different kinds of data/elements such as (Bazeley & Jackson, 2013; Lofland & Lofland, 2006):

- **Events**: incidents happening throughout the emergence of new product concepts.
- **Activities**: behaviours or actions that are carried out.
- **Participations**: which people are involved in certain activities or events.
- **Issues**: controversial topics that are debated.
- **Strategies**: activities to achieve a certain goal.
- **Contexts**: settings in which an action, event, etc. occurred.

These elements just represent one way of classifying certain data points. Glaser (2005) and Glaser and Strauss (2010) have adopted further types of data but in the end all exploratory researchers try to understand basic social processes by addressing questions like: Who is involved? How are people interacting? What are the consequences of action? Which role does the context of the enquiry play?

A further characteristic of the substantive coding approach was the simultaneous nature of coding, meaning that frequently two or more codes were assigned to a single piece of data (Saldaña, 2012).

Even though new codes emerged throughout the coding process, generally all previously coded data sources were not revisited. A new code was applied from the point it was identified; only if a higher-level category was not "theoretically saturated", were previous research encounters analysed again (Glaser & Strauss, 2010). A higher-level category in that context is a set of recurring themes that are discovered while sifting through various sources of data. Each theme that emerged in the substantive coding process was coded as a separate node and was used to generate theory that is grounded in data later on in the process (Saldaña, 2012).

While diving deeply into the generated data, one has to highlight that the main goal of substantive coding is not just labelling data but interlinking themes and correlating dimensions to understand its meaning (Saldaña, 2012). In classical GT this process is called "constant comparison" or "constant comparative method".

As a result of substantive coding as well as constant comparison of identified codes and themes, a **node tree was developed** that comprises a list of more than 170 codes (see also example in Figure 27 below). As part of the codebook the node tree helped to organise the randomness of emerging nodes and themes (Bazeley & Jackson, 2013). A first draft of the node tree was refined during a second cycle of reading through selected transcripts and listening to specific audio recordings. The substantive codes were either:

- **Specified**, e.g. rewording "team work" into "team collaboration".
- **Subdivided**, e.g. splitting communication into multiple sub-codes.

- **Merged**, e.g. bringing together two types of market knowledge under one node.
- **Maintained**, i.e. staying as initially drafted.

53	**Conflicting mindsets**	Big picture vs. Detailed view
54	**Conflicting mindsets**	Mindset - Habits-Thinking patterns-Paradigms
55	**Conflicting mindsets**	Mindset - Implementation Focus
56	**Conflicting mindsets**	Mindset - Visionary Thinking
57	**Conflicting mindsets**	Short-term vs. Long-term thinking
58	**Customer insights**	Customer involvement
59	**Customer insights**	Direct Customer Interaction
60	**Customer insights**	Focusing on specific customer segments
61	**Customer insights**	Market potential vs. Tech performance (chicken or egg dilemma)
62	**Customer insights**	No direct customer involvement in concept phase - Maketing and Regions as intermediate
63	**Customer insights**	Personal connections to market+customer
64	**Customer insights**	Understanding the underlying problem of a customer - (Why?)
65	**Customer insights**	Unmet customer needs
66	**Customer insights**	External Source of information
67	**Development process**	Feasibility
68	**Development process**	Formalisation through use of tools
69	**Development process**	Formalisation through use of tools - Access to tools
70	**Development process**	Formalisation through use of tools - Documentation Style
71	**Development process**	Formalisation through use of tools - Tool Breaks
72	**Development process**	Formalisation through use of tools - Usage of Tools
73	**Development process**	Interdependencies between long term-strategic planning and short term project planning
74	**Development process**	Low level of standardisation
75	**Development process**	Milestones and handover points

Figure 27. Exemplary node tree - substantive coding

This overall substantive coding step with its intense exposure to research data formed the basis for developing a first conceptual clarity. Assigning codes to data represents the “critical link” between data making and their explanation of meaning (Dul & Hak, 2007). Furthermore, it marked the start of a more detailed theoretical analysis step (Bazeley & Jackson, 2013).

3.3.2.2 Memoing

A second important technique used throughout data analysis is memoing. Memoing depicts the composition of a memo which can be characterised as a **place to store and accumulate information**, thoughts but also conjectures on a specific topic (Glaser, 2005). In practice, different forms of memos exist e.g. “journal” memos to document the doctoral research journey, “to-do” or “administrative” memos to manage a variety of open tasks but most importantly “analytical” or “theoretical” memos to conceptualise thoughts and to hypothesise about newly developed propositions. Such analytical or theoretical memos allow for reflecting upon

different elements in the process of coding and conceptualising by covering aspects like (Saldaña, 2012):

- **Observations** or thoughts allowing for reflection upon these.
- **Arising questions** and even conjectures that can be captured and interlinked with arising ideas and emerging themes or patterns.
- **Links** to further codes, memos or research encounters.
- **Follow-up topics** for further research encounters as well as future directions of the study.
- **Discussions** of theoretical constructs as part of a theoretical memo.

The following example of a memo on informal team structures (Figure 28) illustrates the **reflective thinking process** when beginning to analyse specific expressions on the one hand but also continued to think about further coherences on the other (Glaser, 2005; Glaser & Strauss, 2010).

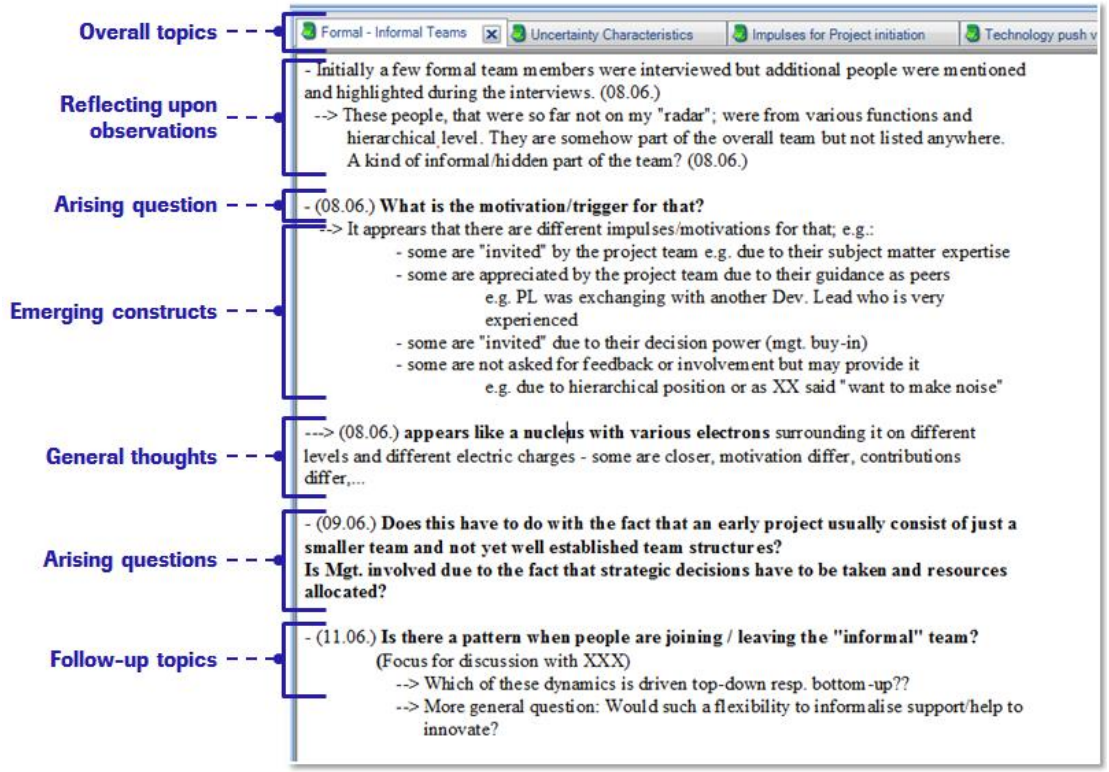

Figure 28. Exemplar memo from qualitative data analysis software

A further characteristic of memos is that they are not restricted to codes. Following the earlier described method of constant comparison, memoing is a key technique

to support this process by interlinking different codes, revealing gaps or highlighting practical implications.

This detailed and reflective nature of memos also sketches out the main contrasts to annotations, a further technique of taking research notes. Therefore, an **annotation** can rather be seen as a short comment on a piece of data that is similar to a short, written, note. It is an additional, widely spread way to integrate additional information to a source which might become useful (Bazeley & Jackson, 2013). Figure 29 provides an example of an annotation, which is covering the definition of a technical term, explaining what the expression actually stands for. A further characteristic of an annotation is that it has a rather limited field of application that does not include reflective elements.

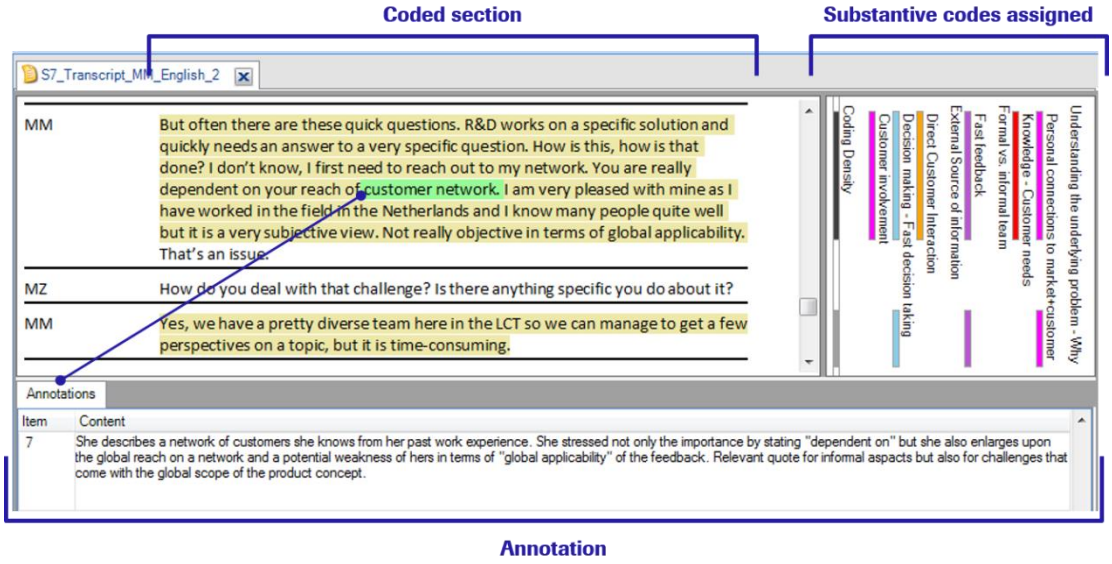

Figure 29. Examplar annotation

From an operational perspective, when starting to write a memo the coding process is interrupted. Taking a break from the constant input resulting from listening or reading was crucial so as not to lose any arising idea or not to miss documenting thoughts properly (Glaser, 1978).

In that context, memoing must be seen as a key technique to support the process of reflective thinking as well as creative development of new ideas by documenting and structuring the researcher's thoughts.

3.3.2.3 Theoretical coding and constant comparative method

Theoretical coding comprises the **process of conceptualising** how the identified substantive codes relate to each other. Its goal is to understand the context and correlations of emerging themes and in that sense it can be defined as a set of modelled, interrelated and multivariate hypotheses (Glaser, 2005). This correlation of dimensions allows for better understanding of the specific characteristics and interrelations that lower or increase meaning. During this part of the doctoral research, the analysis is constantly comparing incidents and emerging concepts of the same kind within but also across the two cases (Glaser, 1978). Grounded Theory researchers describe this proceeding as a **constant comparative approach**, meaning that substantive as well as theoretical codes that are grounded in data are constantly compared with each other to extract meaning; comparing e.g. (a) incidents to incidents, (b) incidents to emerging concepts, or (c) emerging concepts to emerging concepts) (Glaser, 1978, 2005).

Based on these systematic connections and derived hypotheses, the theoretical codes are linked to a core-variable, a central construct that appears to have the greatest explanatory relevance for the phenomenon (Saldaña, 2012). In the context of this research study, the **core-variable *Scoping* has emerged** to best describe the emergence and constant adaptation of a new product concept during its process of emergence.

During this phase of theoretical coding, the technique of memoing played a key role as memos accumulated key information and thoughts on a specific topic. Therefore, it was an important vehicle and intermediate step in conceptualising and moving from a substantive, descriptive level to a more abstract one. Appendix D provides an example of this conceptualisation in the context of dynamic capabilities.

In the same way as substantive codes, theoretical codes are also grounded in data but in contrast, they represent more **general phenomena on a higher level of abstraction**. This abstraction may for example become apparent through the detaching of time, place or people (Glaser, 2005). In terms of the two embedded cases, this means that the theoretical codes are detached from the contexts of a specific industry, corporation and/or development team.

The perceptible progress with initial codifying, i.e. the application and reapplication of codes to qualitative data (Saldaña, 2012), varied a lot as this process was influenced by multiple factors. First, the richness of data or relevance of material as Glaser and Strauss (2010) call it, had a huge impact. Sometimes it took an hour to code half a page of transcript which was rich in substance but at other times it was possible to go through two pages in just 30 minutes. Second, the maturity of the coding structure affected the process massively. The emergence of new codes took time and effort to include into the coding manual and to properly define their meaning. Third, the timing in the research process did influence the coding progress. Particularly in the early phase of data making and analysis, it took some time to become familiarised with the data and to phrase all codes in an appropriate way. Finally, my overall mood and openness as researcher towards the data and potentially new emerging codes did affect the coding process. Glaser (1978) also calls this circumstance "**personal sensitivity**", an aspect which is involved in qualitative research influenced by Grounded Theory methodology. To maintain an open mindset, it helped to learn about the already existing diversity and richness of theoretical codes. This was for example achieved through studying Grounded Theory literature to get familiar with a broad range of theoretical codes that repeatedly emerge in social sciences. This list comprised potential codes such as: "processing" (i.e. stages, phases, steps, transitions) or "cycling" (i.e. going over the same path over and over again, spiralling upwards or downwards) (Glaser, 1978). This knowledge and the resulting awareness of already existing concepts formed the basis for staying open to all kinds of new codes that emerged throughout the data analysis phase.

As a result, all the factors mentioned above had an impact on the overall theoretical coding process that supported the identification and definition of the newly emerging core-variable. The most challenging part of the research journey was characterised sometimes by a fuzzy way of working, meaning that there was a risk of drifting in focus and persisting with substantive relevance only.

3.3.3 Theory building

When elaborating on the theory building approach of this research study, one needs to take the inductive research nature as well as the research context into consideration, meaning that this research study is adopting a case-study research methodology to build new theory rather than to test pre-existing theory (Eisenhardt & Graebner, 2007). The newly constructed theory is in the end directly emerging from data and is developed through patterns that are recognised within and across the two embedded cases (Sato, 2016; Weick, 2003, 2007). Subsequently, the theory building process shall be described in more detail by highlighting (a) the type of theory developed, (b) the key elements of theory and (c) the process steps involved in theory building. Finally, specific advantages of theory building from case-studies are presented before also referring to key quality indicators of "good theory" (Eisenhardt & Graebner, 2007).

In general, in social sciences there exist two types of theory: grand social theory and mid-range social theory (Denzin, 1970; Weick, 2007). Following Denzin (1970), **grand theory** can be characterised as a highly abstract form of theorising in which theory is highly detached from specific contexts or concrete concerns. In contrast to grand theory, **middle-range theory** is an approach to construct theory that is trying to **bridge between grand theory and empirical research** (Merton & Merton, 1968). That way it is providing specific, sometimes context-bound, theory from which it is possible to derive empirically testable research propositions and hypotheses (Eisenhardt, 1989).

In the context of case-study research, the general applicability of theory is rendered secondary (Yin, 2017) as case study theorising has different goals and comprises further advantages (Sato, 2016). Firstly, it is seen as a promising way to generate new theory even if "just" mid-range, not relying on previous literature or prior empirical evidence. Secondly, it originates directly from data and evidence, thereby recognising that detailed knowledge on the research phenomenon needs to be obtained first before trying to answer complex social questions.

The developed middle-range theory typically contains several theory elements that are similar to grand theory:

- **Variables/constructs:** Theory delineates single factors that are used to explain the phenomenon under investigation (Dubin, 1969). (What?)
- **Interrelations/dynamics:** Theory represents the relation between identified variables, depicting for example a social pattern and the dynamics that justify the proposed causal relationship of the developed theory perceived by (a) the persons involved (in-vivo) and (b) the researcher/sociologist themselves. The researched people may perceive single events without noticing the overall process (Whetten, 1989). These patterns and dynamics often build the basis for propositions that are developed throughout the research study. (How? & Why?)
- **Process nature:** Theory builds on a social process that involves two or more clear stages that are perceived by the persons involved (in-vivo) or the researchers themselves as the researched people may just perceive single events without noticing the overall process. In addition, theory typically comprises breaking points such as critical junctures (Glaser, 1978). (How?)
- **Pervasiveness**: Theory is trying to either explain or give rise to variations in the process as elements might change over time. Concepts unrelated to the core-variable are not included in the emerging theory and hence excluded from the research study (Glaser, 1978). (How?)
- **Temporal & contextual aspects:** Temporal and contextual aspects serve as cornerstones to bound the degree of generalisability and reach of the newly developed theory (Dubin, 1969; Glaser, 1978). (Where? Who? & When?)

The essential elements of theory result from a theory building process intensively researched and discussed in literature from different angles. On the one hand, Glaser (1978) as well as Glaser and Strauss (2010) elaborated as outlined in the previous section on the **constant comparative method** to develop Grounded Theory, thereby building on an iterative data generation and analysis approach that is transcending between data generation, within-case and cross-case analysis to develop a so-called “core-variable”. The core-variable tries to conceptualise the

main concerns and explains most of the variations of behaviours that could be observed in the context of the research phenomenon.

On the other hand, Eisenhardt (1989) as well as Eisenhardt and Graebner (2007) focused on the **process nature of theory building** or theory construction as they call it; delineating a specific process in the context of case study research. A set of theory building steps that can be followed to produce novel, testable and empirically valid theory comprises the overall process from selecting cases and crafting protocols to analysing data, shaping hypotheses and reaching theoretical saturation.

Besides a process view on theory building, a further key research stream highlights the need for appropriate procedures. Miles et al. (2014) focus for example on a set of procedures and methods for analysing qualitative data to build theory.

In general, all scholars mentioned above may focus on different aspects of theory building but they pursue a common goal i.e. to come up with high quality theory or as Eisenhardt (1989) phrased it "good theory" that is parsimonious, testable and logically coherent. To assess its quality, a set of criteria can be applied. Whetten (1989) argues that it is about the value added contributions e.g. of proposed changes to an existing theoretical model and that it is not sufficient to just add or subtract certain factors from existing models to come up with new high quality theory. Sato (2016) adds to this, that high quality theory is not just about the outcome of the research but also about the selection of appropriate methods and their professional execution. Like in any other empirical research study, this can for example be supported by providing additional information on the use of employed methods, the context in which the research study takes place as well as a clear link to the evidence created.

As a result of a rigorous use of methods from the qualitative toolbox and a constant comparison of substantive and theoretical findings on a within- as well as cross-case level, new insights can be created that result in new, high quality theory.

3.3.4 Conclusion on data analysis approach

The detailed description of the data analysis procedure provided an overview of how the phenomenon of newly emerging product concepts was approached to understand how radical product characteristics are adapted and modified during a development project.

At first, this section outlined how methods like substantive coding, memoing and theoretical coding were applied to the comprehensive data set that was generated. In line with the exploratory nature of this research study and the process nature of theory building (Glaser, 1978; Glaser & Strauss, 2010) this research was following a constant comparative approach to build new theory. Therefore, data analysis was rather interconnected and iterative going back and forth between generated data on a within-case level and cross-case findings. With the development of a core-variable, findings from a within-case level were integrated on a cross-case level to the emerging theory of *Scoping*.

3.4 Quality criteria

When designing and implementing a research study it is important to consider quality aspects from the outset. To evaluate the quality of data collected and analysed, findings generated as well as theory developed, a broad set of criteria is discussed in research. Scholars such as Yin (2017), Guba and Lincoln (1994) and Glaser (2005) propose different elements that might be relevant in the context of qualitative, exploratory case study research.

Yin (2017) refers to several reliability- and validity-related aspects particularly when designing and executing **case study research**. In this regard, **validity** (construct, internal and external) elaborates on the basic principle of integrity in implementing research. Validity is sub-divided into (a) construct validity, that addresses the correct operational procedures to build and test new concepts, (b) internal validity, that is concerned with the causal relationship and explanations of a new concept (e.g. by considering rival explanations) and (c) external validity, that is about generalisability of findings beyond the specific research (Dul & Hak, 2007; Yin, 2017). The second category of case-study-specific quality criteria refers to **reliability**, which has the objective to set up the research process in a way so that further researchers can arrive at the same findings and conclusions (Bryman & Bell, 2011). A detailed description of the cases, case-study protocol and generated findings may support transparency, but it must be critically noted that the unique cases and research settings of this research study limit reproducibility. Due to this exploratory GT-driven nature of the research, quality criteria proposed by Yin (2013) are only suitable to a limited extent.

Guba and Lincoln (1994) proposed an alternative approach and terminology for qualitative research to ensure high quality, differentiating between credibility, transferability, dependability and confirmability. In this regard, **credibility** addresses the suitability of operational procedures as well as the consideration of credibly constructed results (similar to construct and internal validity). **Transferability** parallels external validity and covers the application and fit of findings in other contexts. **Dependability** is similar to reliability, addressing the underlying issue of consistency throughout the overall research process from data collection/analysis,

generation of findings through to development of theory. Lastly, **confirmability** deals with the inevitable biases associated with qualitative research (e.g. researcher bias, participant biases).

Even though this terminology raised by Guba and Lincoln (1994) might be suitable to evaluate the integrity and quality of exploratory, qualitative research, this study will apply four criteria brought up by Glaser (2005): fit, work, relevance and workability. This terminology best fits the Grounded Theory and exploratory nature of the research as GT is never right or wrong. In fact, GT should **fit** the issue, be of **relevance** to the domain, be **workable** in this context as well as **modifiable** to reflect new insights grounded in data.

More specifically, **fit** refers to an appropriateness of research techniques used from a methodological perspective as well as appropriateness of theory developed. This quality criterion supports the suitability of new theory throughout the whole research process from data collection to generation of findings and emergence of theory. With regards to data collection and analysis, theoretical sampling was applied on a within-case and cross-case level to ensure fitness. Additionally, during analysis, conceptual codes emerged directly from the data rather than building on existing, pre-conceived codes/theory. This means that data categories were not "forced" as Glaser (1978) calls it. Instead, a dense theory emerged in the substantive area based on emergent codes and categories.

Taking this discussion of fitness into consideration, one can conclude that this GT criterion is crucial for high quality research. One could even point to this criterion being the most important one to evaluate the quality and integrity of GT research as it is the basis for the three following criteria. In addition, it shares similar characteristics with the previously mentioned criteria construct validity (Yin, 2017) and credibility (Guba, 1990; Guba & Lincoln, 1994).

The second criterion **work** refers to the ability of GT to explain and even predict future behaviour in the substantive area it was emerging from (Glaser, 1978). Work or workability therefore is related to how well a theory accounts for the way a specific concern is addressed (Glaser & Strauss, 2010). To fulfil this requirement, the research study is building on data from real-life development projects, considering

the substantive context of large organisations in the IVD industry. In addition, it is sufficiently multi-dimensional, taking for example variations in capabilities, development processes, resources or the industry context into account.

Furthermore, the developed GT, namely core variable *Scoping*, is trying to balance the level of abstraction with regards to real-life issues in a specific corporate, industry context but at the same time allowing for broader **generalisability or transferability** as GLASER calls this aspect. This means that the developed theory is not tied to a specific location, occasion or person/organisation: in fact, it is providing conceptual generalisability and relevance (Glaser, 2005). From a methodological perspective, this balance of substantive/theoretical relevance is supported through theoretical sampling and a thick description of the cases and the research context. In the terminology proposed by Yin (2017) respectively Guba and Lincoln (1994), workability as well as transferability are similar to internal validity and generalisability external validity.

The third criterion **relevance** refers to a theory's focus on a core concern (Glaser, 1978). By conceptually grounding the developed theory of *Scoping* in the data from two usual embedded cases, a certain relevance and significance is ensured. Furthermore, emerging product concepts as a major theme can be regarded as highly relevant as NPD and innovation in general are key for a corporation to maintain a long-term competitive advantage in the marketplace. Going beyond the business impact of NPD, the successful management of new technological innovation may also contribute to advancements in healthcare for the benefit of different social stakeholders (e.g. patients, healthcare providers, insurers).

The fourth and last criterion to evaluate the quality of GT is about **modifiability**, meaning that one can modify the developed GT continuously based on new insights that may for example originate from new data. Such flexibility ensures fitness and relevance for the social world it has emerged from (Glaser & Strauss, 2010). The developed theory of *Scoping* generally fulfils the criterion of modifiability as, for example, the two temporal and capability dimensions may be adapted, or supplemented by additional dimensions. These may be based on changing frame conditions of a constant adaptation process of an emerging product concept due to

regulatory, technological or further developments (concept shifts). In this regard, the temporal dimension may for example be modified to cover further process steps/sub-steps.

Taking the above described criteria into account, one can summarise that readers of GT should apply these four quality criteria strictly and ask specific questions as described below to guide the design and composition of a GT research study (Grounded Theory Institute, 2019):

- What is the substantive area of interest?
- What comprises the data sources and were they collected in accordance with Grounded Theory principles?
- Was constant comparison conducted?
- Was theoretical sampling conducted?
- What is the core category and what are the related categories?
- Is there theoretical completeness and conceptual integration? What theoretical codes structure the theory?
- Has the literature been sampled and integrated into the theory?

Going beyond the GT criteria to evaluate the quality of the developed theory, Denzin (1970), on a higher level of abstraction, fosters the use of different triangulation approaches to increase overall quality in areas such as **data, method or theory triangulation**.

Firstly, various types of data such as interviews and documentation were used and data was collected from different functional areas (e.g. R&D, Marketing, MSA, etc.) at different points in time. Secondly, methodological triangulation was applied during collection and analysis, employing on the one hand different methods to balance the strengths/weaknesses of single techniques (between-method triangulation) (Bryman & Bell, 2011). On the other hand, between-method triangulation is supplemented by within-method triangulation, meaning that for example in interviewing unstructured elements such as open questions are

combined with structured elements like direct questions to overcome the flaws of a single method. Finally, theoretical triangulation was achieved by staying open-minded during data collection and analysis, considering different theoretical perspectives and rival explanations. This led to the integration of both a temporal, process-oriented dimension of *Scoping* as well as a capability view. The fourth type of triangulation brought up by Denzin (1970), investigator triangulation, which would theoretically have been possible to apply, was deliberately excluded. Thus, this study just builds on one single investigator, considering the sensitivity of early R&D projects and the resulting restricted access to highly confidential business information.

Taking the above described criteria into account, one can summarise that a Grounded Theory is generally neither right nor wrong; it may have more, or less, fit, workability, relevance and modifiability.

3.5 Conclusion on overall research design

To explore the emergence of new product concepts in the context of the IVD industry this empirical study employed a qualitative case study research design. This design choice was heavily influenced by my social constructivist world view and belief that this phenomenon, the emergence of a new product concept, is embedded in the social environment of a cross-functional development team.

The single-case study design was built on two embedded cases within a globally operating IVD-corporation. Each case consisted of a development project that was selected based on common criteria such as corporate/governance structures, project phase, project size and scope. To engage closely with the development teams, a broad range of primary and secondary data was used, putting emphasis on semi-structured face-to-face interviews that were supplemented by project artefacts. Next, the conversation transcripts as well as the project artefacts formed the basis for an iterative within- and cross-case analysis (Yin, 2013). The respective analysis techniques that were applied (e.g. substantive/theoretical coding,

memoing) were influenced by grounded theory methods and supported by the qualitative data analysis software NVivo (Bazeley & Jackson, 2013).

As a result, substantive themes were initially identified on a within-case level before extending the analysis to the cross-case level with the aim of developing potential theoretical cross-case concepts. This process led to the emergence of *Scoping* as a core-variable.

Following this methodological review, the next section will more closely depict the research context (IVD industry & corporation) as well as the two within-cases.

4 Depicting the two embedded cases including their contexts

The previous section discussed the single case study methodology that was applied to undertake this empirical research study. To explore the characteristics of new radical product concepts that build on new technology, two development projects within an organisation that is active in the IVD industry are analysed as part of this section (structure outlined in below Figure 30). The cases are of high relevance to researchers and practitioners as the case company is a leading provider of IVD solutions with a strong focus on innovation leadership and a positive track record of bringing radical and incremental innovation to healthcare.

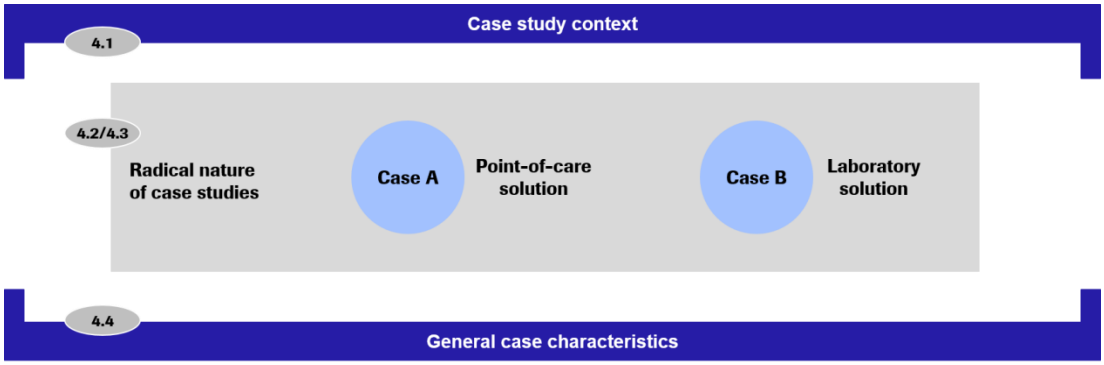

Figure 30. Depicting the case study context

The two cases address the development of new diagnostic products that build on detection technologies newly applied in the IVD industry. The new product concept that is emerging as part of Case A builds on a novel detection technology for near patient testing, a segment of IVD that is also called point of care diagnostics. The main idea of the new product concept is to integrate diagnostic testing of formerly separate instruments into one integrated testing platform. Within Case B a new lab technology that shall be introduced to the IVD sector is the main subject of exploration. In this context new lab technology refers to an application of the new product in larger, specialised commercial laboratories as well as central laboratories in hospital settings allowing for new and more accurate diagnostic testing.

The next section will begin with describing the context of this research study by characterising the IVD industry as well as the corporate contexts the two case studies are embedded in. Afterwards, the general corporate innovation process is mapped out as it builds the framework for the development of new products within

the corporation under investigation. Subsequently, the general radical nature of the two embedded cases are outlined before presenting them individually. When providing a think description of the two cases, key substantive concepts are presented that emerged during within-case analysis to map out the dynamics in development projects during definition and refinement of new radical product concepts.

As a conclusion, the two cases are critically reflected upon to illustrate the general case characteristics including commonalities and differences. For confidentiality reasons, the names of interviewees, technologies, products as well as the company are disguised throughout the thesis.

4.1 Context of single-case study research

4.1.1 The IVD industry

The **In-vitro Diagnostics industry** provides products intended for use in diagnosis of diseases or other conditions in order to cure, mitigate, treat, or prevent diseases or its late sequelae. These IVD products may range from reagents and instruments to complete test systems that are intended for use in collecting, preparing and examining specimens taken from the human body (U.S. Food and Drug Administration, 2014a).

From an **economic perspective**, In-vitro Diagnostics represent a significant market with sales expected to exceed 60 billion € in 2018 (Boston Biomedical Consultants, 2016). Furthermore, the fact that professional diagnostics will play a central role in personalising healthcare suggests that the market will continue to grow substantially in the future, with an expected annual growth rate of more than 5% (CAGR) over the next five years (Boston Biomedical Consultants, 2016). Moreover, the market can be characterised as highly consolidated and concentrated with the Top 5 companies, Roche Diagnostics, Siemens Healthineers, Abbott, Beckmann Coulter and Ortho Clinical Diagnostics (in order of market share), covering more than 60% of the market (Boston Biomedical Consultants, 2016).

In order to further understand the context of the planned doctoral research study, a detailed understanding of the IVD industry is important. Therefore, this section will provide industry insights by illustrating characteristics such as:

- Political and social environment
- Broad application in the healthcare system leveraging multiple technologies
- Complex product architecture
- Broad stakeholder / customer coverage
- Extensive regulatory requirements

Political and social environment

In the context of an aging population, in many industrialised countries the prevention of diseases and treatment of ill people plays an important role. However, societies need to ensure funding for people to access these medical treatments. In times of increasing public debt e.g. as a result of the last global financial crisis in 2007, the cost pressure increases and has led to a price erosion of many diagnostic tests in the past years (EY, 2017).

In that respect, diagnostics in general but also **IVD in particular play an integral part in advancing and developing the healthcare systems further**. Even if IVD only stand for a small portion of healthcare expenditure (<2% of worldwide healthcare spending) the information gathered with such diagnostics informs clinical decision making on a broad scale (>60% of clinical decision-making influenced) (European Diagnostic Manufacturers Association, 2015). In that sense IVD information may be one lever to allow for a personalised treatment of patients and high medical value testing to improve patient care but at the same time allow for a more effective use of healthcare resources.

Broad application in the healthcare system leveraging multiple technologies

IVD testing is widely applied in the healthcare system in the diagnosis, prevention, monitoring, treatment and alleviation of an injury, disease or handicap (European Parliament and Council of the European Union, 1998). Furthermore the application

can also be differentiated by the type of disease, the specimen or the location where the testing and analysis is performed (Day, 2013).

The **types of diseases** range from the detection of infectious diseases, identification of specific tumour markers to the determination of blood coagulation. Furthermore, the **location** of testing may vary from patient home testing, ambulatory care, to centralised, large-scale hospital or commercial laboratories and also life science research. Moreover, different **kinds of specimen** derived from the human body like blood, blood serum, urine or tissue, are employed for testing (European Parliament and Council of the European Union, 1998). It has to be noted that the application of IVD tests lies primarily in the field of professional applications and needs to be delineated for example from research applications on the one end of the spectrum and pure lifestyle applications on the other end of the spectrum (U.S. Food and Drug Administration, 2014d).

The scope of **technologies** ranges from traditional technologies such as photometry which have been established for decades to well-established technologies building for example on antibody-antigen-reactions or cutting-edge next generation sequencing technologies. Frequently, new technologies are introduced to the industry; most recently developments of digital sensors allowed for an establishment of a new product category of non-invasive digital biomarkers.

As a result of the various combinations of diseases, types of specimen and test locations, a variety of technologies are available to best fit the requirements of the specific setting/application. These design aspects need to be considered when developing an IVD product. In this context, however, IVD data must be seen as only one source of diagnostic information, which complements or competes with other types of diagnostics such as imaging techniques like magnetic resonance imaging.

Complex product architecture

IVD products are multipartite products. They usually consist of a measurement device with a measurement cell, a sample feeding system, chemical or biological reagents/consumables and software that is processing the test data and results

(European Parliament and Council of the European Union, 1998). The following example (Figure 31) shows pre-analytics units for sample preparation as well as analysis units.

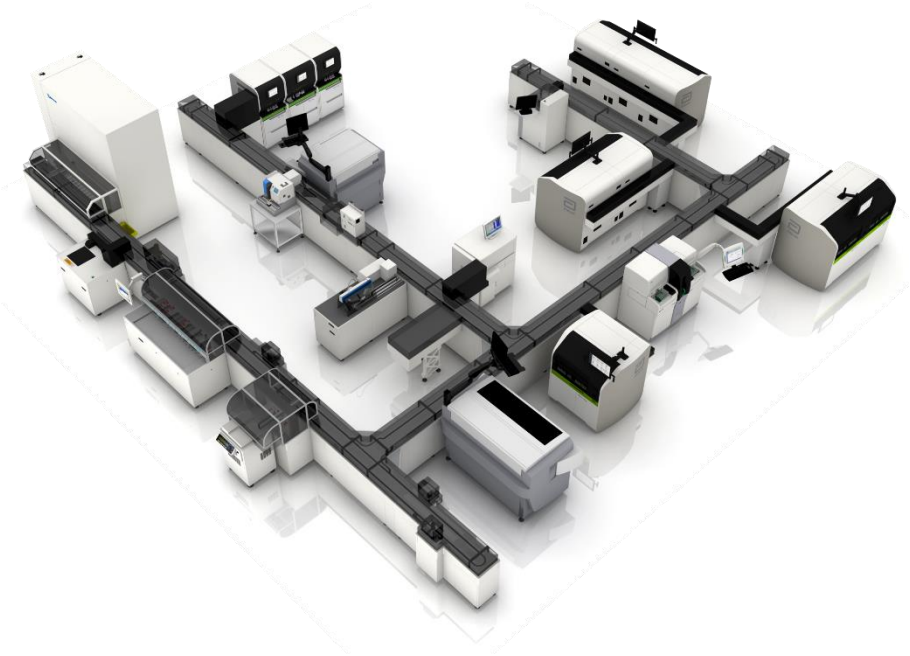

Figure 31. Illustration of a complete IVD system incl. pre- and post-analytics (Source: Abbott)

Compared to most research applications, these systems allow for an almost fully automated sample and testing workflow. When a blood sample is drawn from a patient it is brought to a lab unit where it is manually placed into a sample feeder. At first, a sample has to pass one or more preparation steps e.g. sample purification is executed. Then the sample moves on to the analyser to be tested in a measuring cell. Afterwards samples are either disposed or brought to an archive for storage. In parallel, test data is generated, calculated and analysed.

A further key characteristic of an IVD system is its **design for high performance**, meaning either test performance in terms of **quality of results or in terms of throughput**. High quality of test results may for example be expressed in a low detection limit of a certain analyte or the test result being characterised by a high level of sensitivity (few false negatives) and/or a high specificity (few false positives). Throughput, as the second element of performance, might be linked to the number of test results a system is able to determine in a certain timeframe.

Today's high throughput systems can perform more than 10,000 diagnostic tests per hour.

A further aspect that is gaining increasing importance in the digital age is the technical availability of a broad range of IT interfaces to further IT ecosystems. This means on the one hand that IVD data may be embedded into information networks such as hospital or laboratory information systems (HIS / LIS). On the other hand, connectivity may also allow an operator or lab director to access and control the instruments remotely.

Broad stakeholder / customer coverage

When developing an IVD product, the stakeholder structure is rather complex as multiple stakeholders need to be considered and weighed up against each other. There is no single "customer" as for many consumer products. Indeed, the powers of a customer are split between patients, users (instrument operators), decision makers (regulatory bodies, physicians) and payers (insurances). Therefore, amongst others, the following key stakeholders need to be reflected upon in new product development:

- **Patient**: Asking for example for product safety as well as precise and fast test results. However, may not decide on purchase of product.
- **Device operator**: Requiring for example easy and safe use of a device but unlikely to decide upon purchase.
- **Physician**: Requesting for example fast and precise test result, data availability in hospital or laboratory information system. Stakeholder group that typically makes the inquiry for diagnostic testing
- **Commercial manager**: Taking the purchase decision in many cases and in that context asking for cost efficient acquisition and operation over the life span of a diagnostics product.
- **Regulatory body**: Primarily raising requirements that try to balance time-to-market on the one hand, and product safety and effectiveness on the other.

- **Payer**: Emphasising reimbursement aspects as integral part of new product design (Pietzsch et al., 2009). Requirements vary depending on the kind of healthcare system the product is developed for (publically vs. privately funded).

Extensive regulatory requirements

IVD products have to comply with a broad range of regulatory requirements (Casteels & Rohde, 2013). There are IVD-/industry-specific regulations on the one hand and general regulations for marketed products in a certain country or region on the other.

The "hurdles" for product approval depend on the risk related to the specific IVD product (Day, 2013). In general, during the approval process a developer has to show that on the one hand a compliant and documented development process was followed and on the other hand sufficient medical evidence data can be presented. To sufficiently describe the product and to demonstrate the product's performance a set of information needs to be provided, which may include a detailed description of the intended use, clinical investigation or a summary of medical data to show safety and the effectiveness of the new device (U.S. Food and Drug Administration, 2014b). That way, authorities try to balance between fast time to market of new technologies and product safety and effectiveness (Medina et al., 2013).

It must be noted that the regulatory landscape is very fragmented which means that the regulatory framework is mostly country-/region-specific and varies considerably. Only limited governmental effort is made to harmonise regulatory standards across the IVD industry globally.

To give an impression of the industry-specific regulatory characteristics, the regulatory landscape of two key markets, USA and Europe, is exemplarily outlined in the following textboxes. A more detailed overview of US and EU regulations can for example be found in the reviews of Pietzsch, Aquino, Yock, Paté-Cornell, and Linehan (2007) and Casteels and Rohde (2013).

EU regulation

The European Union regulates the IVD market via the EU directive 98/79/EC (European Parliament and Council of the European Union, 1998) but it will be substituted by the new In-vitro diagnostic device regulation (IVDR) that was released in 2017 and will become effective as of 2022 (European Parliament and Council of the European Union, 2017). Existing regulation is incorporated into local legislation in the UK via the Medical Devices Regulation. The directive was a first attempt to harmonise the EU-legislation for IVD products (Casteels & Rohde, 2013) to establish a homogeneous market with common quality standards.

Regulatory requirements in the EU include corporate operations under a quality management system and a CE marking process which was developed for a range of product groups such as IVD or measuring devices. The common standard for an IVD quality management system is the international standard ISO 13485 that ensures that basic requirements are fulfilled. The hurdles for product approval depend on the risk related to the specific IVD product (Day, 2013). Manufacturers of most low-risk products such as clinical chemistry analysers can "self-declare" conformity with the CE marking requirements. For high-risk products such as infectious disease tests (e.g. HIV), the assessment of a regulatory authority covers quality assurance, design examination and verification of manufactured products (Day, 2013). Furthermore, the suitability of an IVD product needs to be proven by an evaluation of clinical data (Rehmann & Wagner, 2018). Given the fact that the EU directive 98/79/EC is implemented locally, the CE marking approval process is executed by local notified bodies (European Parliament and Council of the European Union, 1998).

It has to be critically noted that through the decentralisation of current regulatory authorities, so far a full, EU-wide harmonisation has not been achieved but with the new IVD regulation becoming effective in 2022 a major step will be made (European Parliament and Council of the European Union, 2017).

US regulation

In the USA, the Food and Drug Administration regulates the IVD market (U.S. Food and Drug Administration, 2014a). The level of regulation depends as in the EU on the risk related to the IVD product (Pietzsch et al., 2007). The classification ranges from low-risk class I to high-risk class III products. IVD devices are mostly classified as class II or III e.g. in the case of infectious disease diagnostics (U.S. Food and Drug Administration, 2014d).

For such products the FDA requires firstly that development, manufacturing and marketing activities run in the environment of a quality management system (U.S. Food and Drug Administration, 2014c) and secondly an approval process needs to be followed (Day, 2013). For the approval there are two possible options, the 510(k) and pre-market approval process, depending on the novelty of the product. The approval via the 510(k) process applies if one can provide evidence that the new device is substantially equivalent to a product which is already marketed in the USA (Day, 2013). Pre-marketing approval is required if the developed product has a new or modified intended use (U.S. Food and Drug Administration, 2014b).

Regulation regarding the development process primarily covers the design controls and ranges from design and development planning, design input to design validation (U.S. Food and Drug Administration, 2014c). Regulatory clearance requires a set of information such as description of the intended use, clinical investigation or a clinical data to show safety and effectiveness.

Furthermore, many US IVD products fall under the regulation of the Clinical Laboratory Improvement Amendments (CLIA) which was established to improve quality of testing; every laboratory has to obtain a certificate of compliance (Centers for Medicare & Medicaid Services, 2012) e.g. through standard operating procedures such as calibration procedures (Centers for Medicare & Medicaid Services, 2012). Of particular importance are CLIA requirements also regarding patient-self-testing products (such as for case study A).

Besides the industry specific regulations, general country-specific regulations for marketed products also apply. These general regulations range for example from regulations for radio communication units in the case of wireless local area network connectivity, labelling of hazardous materials up to low-voltage requirements for small handheld devices.

When integrating the above mentioned remarks, the IVD industry can be characterised as a complex environment for product development. Manifold, product- and context-related, aspects such as product architecture, stakeholder structure and regulations have an impact on the emergence of a new product concept in an early phase (Pietzsch et al., 2009).

4.1.2 IVD corporation examined

The emergence of new product concepts is investigated within a single corporation. To characterise this corporate context, the corporate's structure and governance as well as the predominant business model are outlined.

The corporation "under investigation" is a leading provider of IVD solutions with a strong focus on R&D, providing innovative solutions to the market. Its headquarters is located in Europe, but business operations have a global reach. Its ownership structure can be described as a stock listed corporation with still a considerable percentage of shares owned by the founding family.

The commercial activities comprise two businesses, a pharma as well as a diagnostics division. The diagnostics division holds a leading position in its industry that also has roots back to the strategic focus on "innovation leadership". Itconsists of four business areas with revenues of more than €10 billion in 2019. As a result of the strategic focus, the case company is not only significantly investing in R&D for existing but also in new technologies and products (e.g. next generation sequencing, digital solutions) to innovate within existing and to tap into new businesses. This commitment to innovation is reflected in an above average R&D spent of 5-10% of sales (depending on the business area and several major mergers and acquisitions within the past years).

Both case studies, which form the basis of this doctoral thesis, are located within one specific business area of the diagnostics division which is focusing on products/services for professional use.

The organisation is set up in a multi-layer matrix structure with several layers of business units and functional units like Human Resources (HR), R&D, Quality Assurance or Medical Scientific Affairs (for details see Figure 32). The business units are fully responsible for business performance such as profit and loss accounts whereas functional units act as service providers within the organisation.

Like most other IVD corporations in the industry, business operations of the case company under investigation are heavily influenced by the predominant **business model** which is a so called “Razor Blade” model. This means that technology platforms are provided to customers to measure a set of parameters, but main revenue streams are generated by sales of dedicated consumables. Such consumables are for example biological reagents like antibodies, internal standards or calibrators but also single-use disposables such as pipette tips or sample tubes to fulfil regulatory and quality requirements.

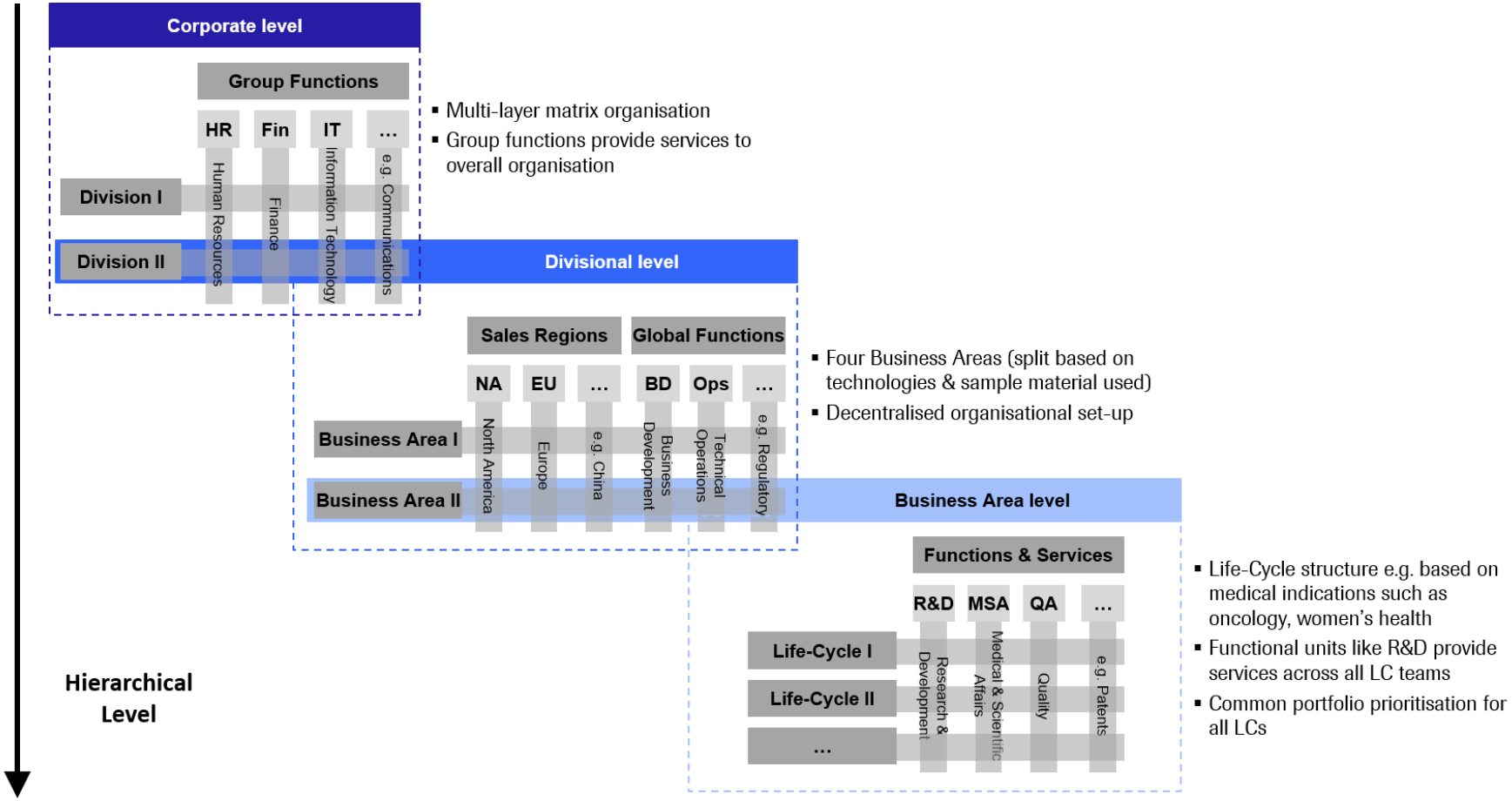

Figure 32. Multi-layer matrix structure

From an organisational perspective, **the corporate governance** structure for the R&D field comprises a broad set of processes, regulations, norms and decision bodies that are associated with new product development. The governance model is summarised in the following framework (Figure 33) highlighting characteristics of the process phases as well as the composition of the involved decision bodies.

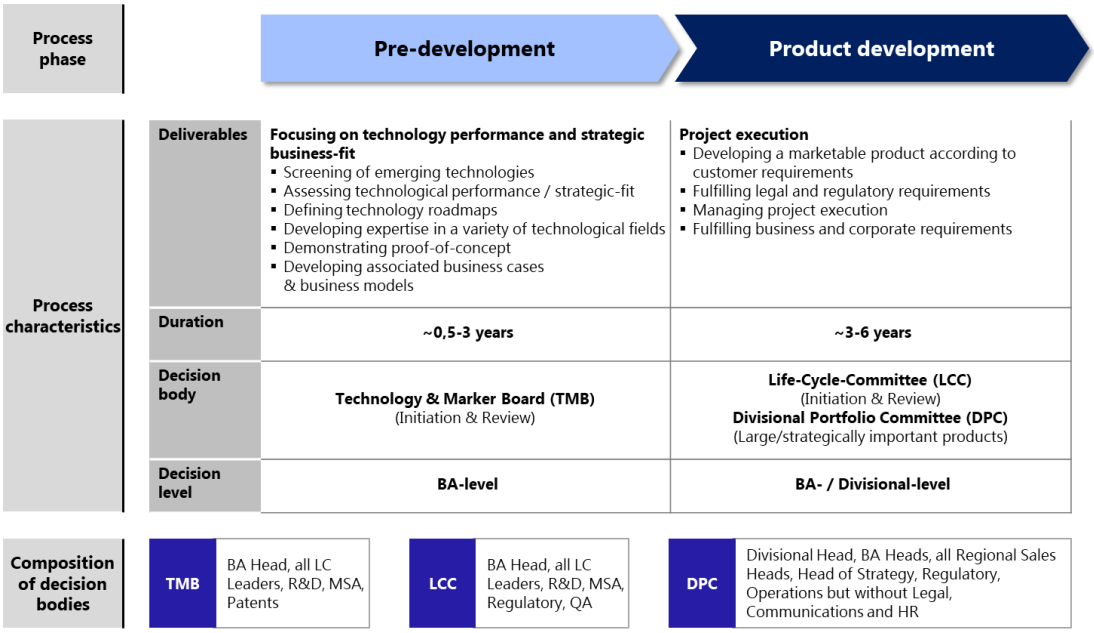

Figure 33. Governance structure and operational framework for early innovation

This structure is following a stage-gate-driven innovation approach and consists of two major phases: a pre-development phase and a product development phase. For the entire process including each of the two individual steps and sub-process steps, a clear set of deliverables, decision bodies as well as roles & responsibilities is defined.

Supported by a strong innovation culture, characterised for example by an open mindset, experimentation, cross-functional cooperation and a trial-and-error mentality, the organisation was able to successfully deliver several innovation projects in the past years. These projects inter alia successfully defined new product concepts and demonstrated a strong track record in their implementation. As a result, the case company was able to further strengthen its leading position in the industry, resulting in above-average commercial development (sales and profit).

In the next section, the corporate new product development process including its sub-process steps will be depicted in more detail as it forms a basis for NPD.

4.1.3 Corporate new product development processes

The corporate new **product development process** is shaped like an innovation funnel with a broad entry narrowing down from phase to phase. This means that initially a broad spectrum of technologies and product ideas is screened and assessed but few topics show technological and business potential as well as a fit to the business strategy so that they are carried forward to product development. From a process and temporal perspective, pre-development covers several sub-process steps that are leading towards product development and which are visualised below (Figure 34): technology assessment, technology enabling, new business development and proof of concept that are leading towards the product development phase.

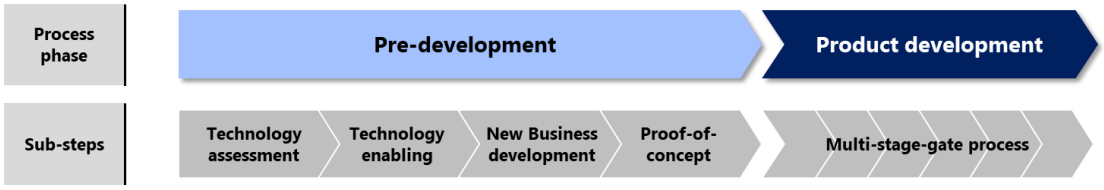

Figure 34. Corporate new product development process incl. sub-steps

Initially ***technology assessment*** (TA) deals with the evaluation of newly emerging technologies. In the context of this research study, TA can be seen as a specific type of cost-benefit analysis which focuses on the forthcoming benefits that are associated with an investment in a new detection technology. This new technology may originate from the scientific community within the IVD industry or may be put forth from another industry/field. Specifically, the TA which is performed within the case study can be characterised as an expert TA, meaning that selected groups of functional, technological experts review the newly emerging technology. To holistically evaluate such technology, experts from various internal and external stakeholder groups such as research, medical affairs, marketing and key opinion leaders are involved.

Furthermore, it has to be noted that the TA conducted in the context of this research study purely focused on internal decision making whereas other types of TAs (e.g. Health TA) also target political and/or regulatory decision makers. In

essence, TA pursues the goal of providing key internal decision makers with an evaluation of expected costs and benefits to decide on a further engagement with the technology.

If a technology is seen as promising and can add value to the IVD market and the case company, a subsequent ***technology enabling*** phase is initiated. During that mostly R&D focused phase, an early stage technology is further developed to gain insights into its applicability and level of maturity. This includes experimentation and early research of internal and/or external teams to explore the strength and weaknesses of the new technology. In this context, technology enabling should not be mixed up with the term "enabling technology", which characterises a new base technology that itself or combined with other technologies has the potential to trigger a significant technological leap in multiple fields.

Following these mostly technology- and research-driven technology assessment and enabling stages, the ***new business development*** phase gives the assessment a more holistic character by adding a customer- and marketing-centred episode. With this additional layer, it is all about the development of new growth opportunities from a business perspective. Therefore, additional stakeholders from Business Development, Marketing, Sales, Regulatory as well as Medical Affairs are included to integrate their knowledge and ideas regarding the patient, customer and business sides of the emerging product concept (that builds on new technology). This holistic assessment also includes the evaluation of partnering options as a key aspect of "make or buy" scenarios e.g. a co-development with a strong technology partner or an early consideration of a strategic partnership for later supply and manufacturing of the product (Sørensen, 2012).

Finally, the broad range of product concept ideas are presented to senior management of the business unit to decide on the path forward. These decisions focusing on key business and technological elements that will be tested in a proof-of-concept phase. Furthermore, the funding as well as the organisational set-up of internal and potential external parties that are involved is defined.

In the following ***proof-of-concept*** phase, a product concept and its components are further developed with regard e.g. to technological performance and maturity,

customer needs, strategic positioning, manufacturability and a first draft of a business plan. Its goal is to verify which new product concept components are practically feasible and strategically desirable. Such feasibility is for example demonstrated via a prototype that is used to simulate the technological complexity and may also contribute to identify the remaining technological gaps that need to be addressed in further development activities. Carrying out a proof of concept study also fulfils further purposes such as the generation of real-life test data needed in the context of intellectual property. Patent offices usually require a demonstration of key functionality prior to granting a patent.

If a successful proof-of-concept can be demonstrated and business aspects are favourable, the foundation for the subsequent investment decision to enter into formal development of the new product/solution is laid. A final review and go-decision to start product development is taken on a BA-level or on a divisional level depending on the scale and strategic importance of the product.

Following a positive investment decision, a formal, highly regulated ***new product development*** process is initiated to move the product concept to a viable product that can be commercialised in a compliant way. Compliance in that regard means that the development process as well as the product itself comply with general as well as IVD-specific regulation.

As part of the product development, multiple development activities are performed to demonstrate and document the compliance as well as performance of the new product. These required development activities are part of a formal process which consists of design controls to transition a product concept and its designs through development planning and design inputs to a design validation (U.S. Food and Drug Administration, 2014c). The U.S. Food and Drug Administration (2014b) for example requires a clear definition of an intended use, a clinical investigation and a summary of clinical data to show safety and effectiveness of the new product as part of premarket approval of a medical device. A common concept in the context of formalised development processes is the widespread validation V-model which was outlined in the literature review in section 1.2. Within this researched organisation, the validation V-model is implemented as the so-called “Design Control &

Commercialisation" (DCC) process, a stage-gate process that covers all key aspects of the V-model up to product launch and commercialisation.

As this research study explores the emergence of new product concepts, a focus is set on the first four phases (i.e. technology assessment, technology enabling, new business development & proof-of-concept) up to the go-/no-go decision to enter formal product development. During these stages, first product ideas around a new technology evolve and are further developed to a new product concept that is, later on potentially, implemented during product development.

Before outlining and analysing the two embedded case-studies in more detail, their radical nature shall be set forth.

4.2 Radical nature of embedded cases

The two R&D projects under investigation can be characterised as radical innovation projects due to their technological as well as market newness. As part of Figure 35 they are mapped into a 3x3 classification matrix for product radicalness:

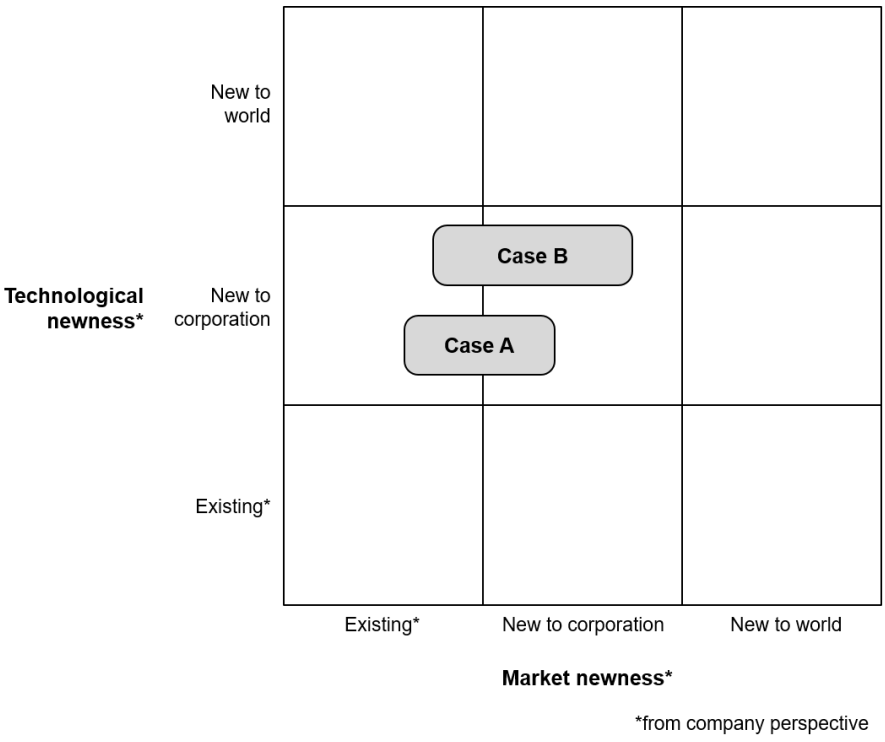

Figure 35. Radical nature of products / degree of newness

Both products that are developed within the same organisation share similar radicality characteristics as they build on a technology that is new to the organisation, meaning that the technology was not utilised in any other product before. As for Case A, a new detection technology is applied in the context of near patient testing that allows for consolidation of various test parameters like small molecules or enzymes into one test platform. As part of Case B, a new detection technology is tapped into for large scale IVD laboratories that enables new and more accurate diagnostic testing (combining lower detection limits with higher test specificity). Both technologies are not new to the world since basic research e.g. in academia, has been exploring these subjects for many years. However, as significant technological advancements are made, the organisation does not just need to build up established skills and expertise in the respective fields, it also needs **to**

constantly build up new and extend existing expertise to stay at the forefront of latest developments.

Furthermore, concerning market newness, the new products will allow the company to partially serve existing markets but at the same time create and tap into new fields. This will mainly be possible due to the envisioned new product features as well as a superior performance of the novel products. This way it will bring a competitive advantage in existing markets but at the same time build the basis to also open new markets to the company.

Beyond the business opportunities that come along with the radical product concepts, the products might have a systemic impact on healthcare as they could possibly change clinical practice in medical laboratories and for care providers such as hospitals.

To sum up, both projects can be considered as radical innovation projects and not as incremental or "medium" innovation projects that are positioned somewhere in-between the two extremes (Eling & Herstatt, 2017; Garcia & Calantone, 2002). In addition, it must be noted that from a corporate perspective, the above described technology as well as market newness also implicate a broad range of uncertainties. For that reason, both projects are compared to incremental development projects rather perceived as high-risk projects.

Next, the concrete, real-life development projects of the two embedded cases are outlined.

4.3 Exploring the two embedded cases

As a first step of analysis, the two individual embedded case studies are described in more detail. As part of a thick description, a case-specific critical event list is mapped out that includes a broad range of themes that influenced the emergence of the two new product concepts. Such critical events firstly include major incidents that happened throughout the emergence of new product concepts (being of a positive or negative nature). Secondly, they comprise key activities or actions that are carried out during product concept definition. Thirdly, they cover significant issues such as controversial topics that were debated within the development teams.

That way, the case descriptions as well as the within-case analysis provide a first idea of themes influencing the emergence of new radical product concepts. Furthermore, these descriptive case characterisations can be seen as an initial step in understanding the dynamics of this basic social process *Scoping* which is comprehensively analysed and evaluated in the findings section (cross-case level).

4.3.1 Case A – New IVD point-of-care solution

The embedded Case A covers the emergence of a new product concept that builds on a novel detection technology for **near patient testing**. This segment of IVD is also called point of care diagnostics as specimens are tested close to the patient, for example in an intensive care, emergency room or ambulatory care setting. Common application fields include settings in which a diagnostic test result is for example for time/urgency matters directly generated near the patient instead of sending a sample for analysis to a centralised lab. In addition, the product concept and its new technology allows for fulfilling the market need for a more integrated PoC-product. Integration in that sense refers to a consolidation of various test parameters like small molecules and enzymes from different application fields such as diabetes management, cardiovascular diseases or inflammation into one testing platform. So far, this multitude of IVD tests is split across multiple measuring devices and is furthermore utilising different testing technologies.

The encounters with the research participants revealed that particularly events related to the areas of business, technology development as well as project team can be identified as critical events. The following time bar shows the critical events in the course of the development project (Figure 37).

The new product concept started to emerge in the second half of 2012. Following an initial technology assessment, in September/October 2012 a market analysis was initiated based on the **unmet market need for a new, highly integrated PoC solution**. Integration in that sense refers to a consolidation of various test parameters from different application fields that were so far utilising different detection technologies into just one measuring device. A product manager summarised his view on the new product concepts as:

"…the vision was […] to provide all of the parameters that a clinician needs to make a full decision; because if they can't make a decision, they have to wait." (S6)

Furthermore, the ambition was to improve the performance of the PoC tests to a lab-like level. Therefore, multiple existing and newly emerging technologies were assessed with regards to their suitability. On the one hand, existing technologies were reviewed for whether they can be further advanced to meet the new demands. On the other hand, novel technologies were **explored** and evaluated with regards to their technological fit.

Figure 36. Examplar PoC device incl. consumables (Source: Alere GmbH)

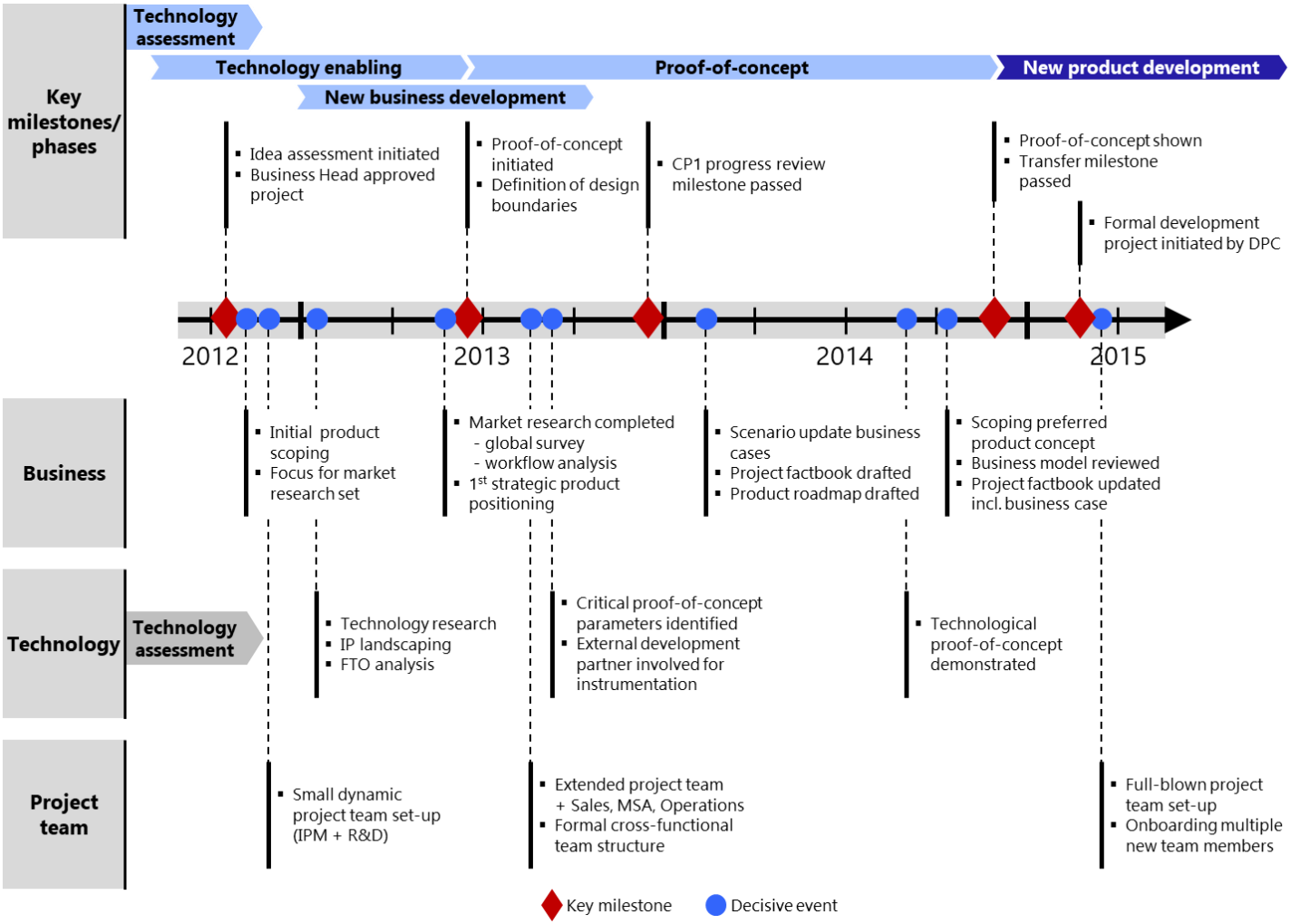

Figure 37. Critical event list Case A (Point-of-care technology)

Following approval by the Business Area Head in September 2012, a small project team started to build on the learnings from the broad technology assessment. With the **support of senior managemen**t, a group of less than 10 people, primarily from marketing and R&D functions, further evaluated several technologies to produce new product ideas. As part of this initial product *Scoping* (further elaborated on in chapter 5), the focus of activities was besides technological considerations primarily set on business aspects such as market insights or IP landscaping. By combining the technological as well as market/business view of new product development, the team was supposed to draw a first, more holistic picture of a new product concept.

The market insights were gathered through two external market studies. Firstly, a global user survey to identify market trends and secondly a complementary analysis by a consumer research and design agency that was focusing on existing but also potentially future medical workflows. As a product manager argues, the team appreciated external stimuli at this early point of exploration:

> *"…when we were working with XXX (Annotation: name of external customer research agency disguised for confidentiality purposes), they mapped out all of these workflows. […] they did the people to people interaction, of who talks to who and how the workflows look like and who does what. […] They mapped that out and that was a good starting point to say;…" (S6)*

In parallel, R&D was investigating a set of emerging, promising PoC technologies, which were identified during the initial technology assessment, with regards to their performance and applicability. Thereby, the organisation was not only able to **extend existing knowledge and capabilities** around these technologies and market applications, but to successfully build **totally new**. Interestingly, in this context it became apparent that particularly activities such as IP landscaping or freedom to operate (FTO) analysis as well as customer engagement played a significant role that allowed for tapping into the enormous **external body of knowledge**.

> *"…what I do anyway is that I have still a few customers in the Netherlands that I know really well and that I can always involve. For instance, we once had a question regarding the XXX (product name deleted for confidentiality purposes) with the ICU and the use of blood types. Why do ICUs prefer arterial blood over venous blood? This was a topic I had an idea about because of the contamination risk but didn't know it for sure so I quickly texted a message to a friend. I asked what is the reason why you prefer arterial blood over venous blood? About 15 minutes later I received his answer, that's the kind of interaction and also the kind of pace we need." (S7)*

As a result, a comparison of technologies and their potential market applications pointed out advantages and disadvantages. Additionally, potential scenarios for combining such technologies in a new testing platform were developed. Based on these detailed technological as well as marketing insights, the team was able to define an initial design space and a first draft of a strategic product positioning up to the end of the second quarter in 2013. In this regard, Figure 38 illustrates the intended use of the technology in the areas of diabetes management, cardiovascular disease as well as in inflammation and stroke. The set of diagnostic parameters that comes along with the indication fields is quite broad, ranging from small molecules, enzymes to large protein molecules.

	Focus				
Medical need / disease	**Diabetes Management, Metabolic Syndrome**	**Cardiovasuclar Diseases, Inflammation, Stroke**	**Coagulation status and monitoring**	**Acute/Critical Care Metabolic Syndrome**	**Complete Blood Count**
Diagnostic discipline and analyte target	**Clinical Chemistry**	**Heterogeneous Immunoassay**	**Coagulation**	**Blood Gas & Electrolytes**	**Hematology**
	Small molecules, Enzymes	Proteins	Clotting time	Gas, ions, small molecules	Cells
Related parameters	▪ Glucose ▪ Glycated haemoglobin (HbA1c) ▪ Creatinin ▪ Cholesterol ▪ etc.	▪ High sensistivity troponin T (hsTnT) ▪ Beta human chorionic gonadotropin (βHCG) ▪ N-terminal prohormone brain natriuretic peptide (NT-proBNP) ▪ etc.	▪ PT/INR ▪ ACT ▪ aPTT	▪ pO2 ▪ pCO2 ▪ pH ▪ Na ▪ K ▪ Cl ▪ etc.	▪ Hb ▪ Ptl ▪ Hct ▪ etc.

Figure 38. Point-of-care indication areas incl. testing parameters

During the subsequent business review which marked the end of the "technology enabling" phase and a key milestone of the new business development phase, first **trade-off decisions regarding the technological as well as product scope** were taken. The small team which comprised of **highly engaged** experts produced a new, radical product concept **(*wide scoping*)** which envisioned improving the medical value of PoC solutions in existing market segments but also new ones. Single individuals such as a development lead, were pushing for these new business opportunities even if not the whole organisation was sharing their views:

> *"…our main topic is that we are very much focused on the patient and the medical value, otherwise we don't make any money. My point is though that the market is meanwhile much more mature and there is a very good basic supply with diagnostic tests. We all don't share the same mindset yet, that we need to adequately reflect all the other customer groups." (translated)*

Technology-wise an innovative, radical test strip technology was selected to be further explored, allowing to measure various parameters from glucose, ketones to lactate and cholesterol on one test strip through an integrated electrochemical as well as optical detection technology. Along with the new technical opportunities, the business development stream of the project team was coming up with **new, creative business model options**. By addressing new customer segments or shaping new revenue models (reimbursement systems/approaches) they were exploring scenarios outside the "classical" strip-/reagent-selling model (similar to razor blade model).

> *"Usually you have the strip and then you build your revenue model around the consumables. Strip business, that's what our company is good at but then we also developed concepts that were quite different. I mean, what are we going to do in the end; providing data. Do you know what I mean? […] So then really building a data-driven model. What does this mean for us? What can something like that look like?" (S6 - translated)*

With the later taken "go-decision" to start the proof-of-concept phase, the project team was extended by now dedicated, formal representatives from MSA, technical operations and sales functions. This marked a **turning point** in the early product development phase as on the one hand the team managed to ensure funding for the next phase.

> *"…that actually was the time when, being honest, we had for the first time a real budget. I mean an official, dedicated budget for our project. Not just bits and pieces from here and there" (S8)*

On the other hand, the small, former Marketing and R&D dominated team, was now turning into a more formalised cross-functional project team; thereby **substituting the so far mostly informal involvement** of further functional experts through official functional representatives in the team.

In the subsequent phase of product concept definition, each **functional stream worked on a set of deliverables** that were mainly derived from the stage-gate process requirements or autonomously enforced by the team itself. **MSA's** main

achievement was to identify clinical needs and requirements from a medical perspective. The **R&D** team, equipped with additional funds for experiments, started to deeply analyse the measuring technology in the context of potential future application fields. They for instance identified critical technological aspects such as the most challenging test parameters with regards to sensitivity or hurdles for the miniaturisation of the PoC technology. The most critical aspect from an R&D perspective was by far the ambition to bring the test performance as close to a lab-like performance as possible. All this exploratory research and development work was just possible when additional funds were available.

In addition, the **attitude of team members as well as the explicit support of senior management** to actively reach out to external knowledge carriers, fostered a mindset of open collaboration with external partners (research partners & potential suppliers).

> *"We then had relatively quickly the opportunity to draw on a software service provider. They had teams in Germany, India, and places you cannot think of. They were really good these software guys. That way we really had enough manpower on board in a short timeframe, at least compared to our internal processes. […] There was this one person in the organisation XXX (name of department head disguised for confidentiality reasons), you might know him. He was pushing for that." (S4 - translated)*

At the same time, **Technical Operations** units were performing the first small scale production trials of the test strips to demonstrate manufacturability and to get a better feeling for associated manufacturing costs (costs of goods sold (COGS)).

Furthermore, **Marketing** advanced the business model and integrated insights from various disciplines into an updated business plan. In addition, Marketing started to engage with the global sales organisations to receive the first market feedback on the emerging product concept. This feedback was again shared across all functions within the project team to be integrated into the continuous and very iterative proof-of-concept activities. One of the international product managers pointed out the complexity of this internal alignment process by stating:

> *"…and the cross-functionality makes it so complex, particularly in the case of the XXX project (Annotation: project name disguised for confidentiality purposes). We have people from regulatory, quality, operation or even legal, basically functions from all over the company, involved in this project." (S8)*

Based on the intense team effort, about half a year after the start of proof-of-concept, the business team was able to circulate a refined update of the product concept and product roadmap in February 2014. At this highly dynamic point in time a lot of project activities were running in parallel and the team worked highly integrated across all functional streams. To establish a **shared understanding of the product vision** and a common set of requirements across multiple disciplines, the team adopted the structured Use Case approach in this early phase (to define and prioritise vague/unclear customer requirements).

> *"Saying well, the customer wants X, Y, Z but it's like ok, is that what he really wants? So, Use Cases often are a way, is that what they really need? You go, that might not actually be what they need because it is not simply been expressed in a right way." (S6)*

During the project the technological piece of the proof-of-concept was successfully completed by September 2014. The R&D team was able to demonstrate a high test performance for critical parameters as well as a preferable option for the design of test strips and the handheld device. However, even if the technological feasibility and the business opportunity were clearly underlined and regulatory authorities indicated their support, various remarks from internal functions such as Marketing, R&D, MSA and Technical Operations needed to be integrated into the holistic product concept until November 2014. That way the team tried to consider several potential risks arising to achieve an **internal and external alignment and consent to carry the project forward**.

As a result of the last nine months, the proof-of-concept phase can rather be characterised by a ***narrow scoping*** (see also chapter 5.2.3) that goes in line with a certain degree of "**de-radicalisation**" (see also chapter 5.2.3), meaning that novel, radical product concept components were either modified or sometimes even completely replaced by less radical and hence less risky alternatives. This de-radicalisation aspect was for example illustrated by a development partner:

> *"I have experienced that frequently, that this in parts also means that we are not able to deliver that; because we have our supplier / partner and they don't provide that. (translated)"*

These kinds of adaptations affect almost all product concept elements. In the business context for example the initially preferred revenue model was adopted in

favour of the already established, predominant revenue model instead of a novel approach. On the technological side, the team decided to integrate an internally available solution rather than a new, more radical option that was building on the capabilities of an external partner. As a result, the **product concept was passing through a process of constant adaptation** with dedicated phases that were exploratory to open up the scope of development in the beginning as well as specific phases later on in which the scope of the product concept was contracting.

> *"Yea, the project as it started is not the project we are working on today, very clearly. […] Probably the project when it started was ok, oh no really right at the start it was purely a handheld, when it really started. […] And then it became a platform and then instead of doing a platform now it's going back and its sort of a hybrid." (S6)*

However, following the constant adaptation of the product concept during the proof-of-concept phase, the **project managed to successfully pass the "Transfer" review milestone** and, following a presentation to the Divisional Portfolio Committee together with a project proposal to start formal product development, the recommendation to commence product development was given. With this decision being taken in the beginning of 2015 the formal approval to translate this matured and internally aligned product concept into an actual product was granted. Afterwards, a full-blown project team was set up and multiple new members were onboarded to the project team.

4.3.2 Case B – New IVD laboratory solution

The second embedded case study B has the emergence of a new lab technology as its main subject of exploration. The new product concept is **building on a novel detection technology** that shall be made available to the IVD sector. Initially this technological novelty is targeting bigger, specialised commercial laboratories as well as central laboratories in hospital settings. This measuring technology allows for new and more accurate diagnostic testing as it combines lower detection limits with higher testing specificity. Common application fields with such a requirement profile include indication areas like newborn screening or drug-of-abuse testing. In such settings blood testing is typically not done near the patient but rather in a

specialised laboratory that is analysing blood that has been drawn from a patient and is sent to the laboratory.

Research participants disclosed during the encounters that particularly events related to the areas of business, technology development as well as project team can be classified as critical events for the definition of a novel product concept. The following chronological overview illustrates the critical events during the development project (Figure 39).

The critical event list indicates that this technology has already been assessed twice in the past. A first assessment in 2002 suggested multiple business opportunities and a great alignment with the case company's strategic focus. However, the technology revealed insufficient performance and maturity, so it was not pursued further. Six years later, in 2008, the topic received attention again when a device manufacturer approached the case company to enter into a potential strategic partnership in that technological field. However, the collaboration was rejected as the second assessment still indicated insufficient performance and technological maturity as well as no strategic fit with the external party that was striving for a different business model and type of collaboration.

Now, in a final third attempt the product idea was coming up again in 2013 during an assessment of emerging technologies. But this time circumstances were different as two elements were coming together. Firstly, several external subject matter experts pointed out the future medical need and potential of new products building on this technology. Secondly, an internal team was assessing the technology independently and this time the technology showed great advancements with regards to performance, robustness and scalability since its last assessment five years ago. These simultaneous stimuli, from an internal as well as external world, triggered a discussion on a management level to reassess the whole topic again and to continue and enforce research activities in that field.

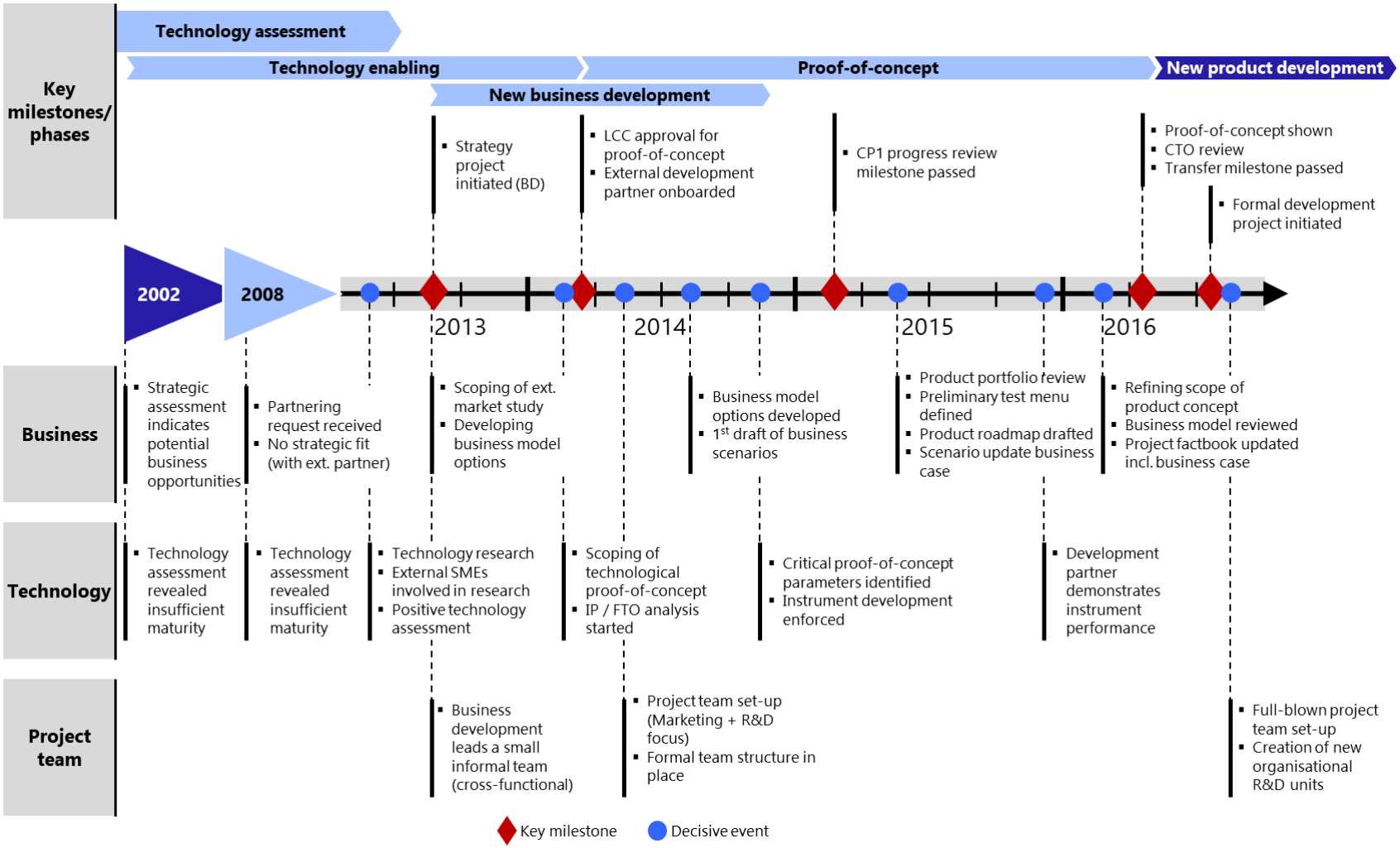

Figure 39. Critical event list Case B (Lab technology)

In addition, a new business development project was initiated in the third quarter of 2013. An involved business representative summarised this incident in the following way:

> *"…first of all we started with a strategic project, where we really concentrated on the question, what would this mean to us? Is that an interesting market? In order to decide in the next step, do we want to enter; or not?" (M5 - translated)*

The focus of this business development project, which was driven by a small team, was primarily set on the assessment of potential business opportunities and market attractiveness on the one hand. Therefore, also an external study was commissioned which identified several unmet customer needs as well as attractive application fields e.g. in the area of new born screening or drug-of-abuse testing. On the other hand, the R&D stream was in parallel further **familiarising with the technology by building up technological knowledge** as part of technology enabling. The project leader retrospectively described this highly dynamic phase of the development even as a "learning space" to explore the full potential of the technology;

> *"This goes into the direction that we indeed, from my perspective, well it is, I call it a bit overstated "learning space" for the organisation. […] Because different global organisations have to date, prior to this have not dealt with this subject before. (M6 - translated)"*

During that phase the team was furthermore preparing a proposal to explore the technology in more detail as part of a proof-of-concept study. In parallel, Business Development also brought up the strategic option to partner with a hardware manufacturer instead of developing and building up the required expertise purely internally. Several partnering options were assessed in parallel but in the end the partner of choice for this strategic question was a well-known global company this corporation had already worked with in other fields. The team was convinced that this way it is possible to leverage the existing expertise of the partner as well as to capitalise on the existing strong relationship. An experienced project lead highlighted the influence of external collaborations on knowledge and capabilities in the following way:

> *"…in our case that are for example different partnerships, if one has taken a wise decision then competencies complement each other in an optimal way and that then means that one plus one equals more than two…" (M4 - translated)*

Based on the promising outcome of the initial concept development phase (business potential because of pursuit opportunity), the Business Area initiated in early 2014 a proof-of-concept project with the goal of developing a holistic product concept. With the "go-decision" to **start the proof-of-concept** an extended project team was established that consisted of representatives from Marketing, R&D, MSA, Technical Operations and Sales functions. In this **more formalised team structure**, each functional stream worked on a specific set of deliverables, as for case study A. During that phase the R&D team **received extensive funding** to further develop the new technology as it did during the tech enabling phase to catch up with the latest technological developments:

> *"…We have initiated separate TMB projects (annotation: TMB stand for a technology board) to look at and assess different technologies. […] and one has to say, without this preparatory work that started long before the actual XXX (annotation: project name disguised for confidentiality purposes), we would not have been able to close that gap." (M2 - translated)*

Resources were spent mainly on three aspects. Firstly, the team tried to bring the technology to a performance and throughput level required for IVD applications. Secondly, a high degree of automation ranging from sample preparation, testing to analysis of results was desirable; and finally, the R&D team had to demonstrate a certain robustness of the new technology. A researcher retrospectively noted:

> *"…holistic technological assessment was performed on 3 system levels, workflow, automation and system integration […] the challenge was to identify and assess several separate technologies that have to fit into a highly integrated system configuration." (M3 - translated)*

During that phase, the development partners as well as external IP research allowed for **building up new knowledge regarding the emerging technology**. These new insights helped tap into cutting edge advancements as an experienced researcher put it:

> *"…well we now really break fresh ground and this is a combination of new, new technologies that we developed/acquired here at XXX (annotation: company name disguised for confidentiality purposes), here inhouse; combined with new technological developments/advancements from the outside world." (M2 - translated)*

From a business/marketing perspective the team was also trying to explore the radical potential of the technology with regards to elements such as novel business

models options, new customer segments or a novel interpretation of applicable regulation. For example, in the context of regulation, the **team was pushing the boundaries** by modifying the common way of doing batch-wise test calibrations. With strong **support from regulatory authorities** from two key markets an innovative way of doing calibration was developed that allowed random access and highly efficient lab testing.

> *"When we looked deeper into some of the regulatory requirements we for example identified the whole area of calibration and control measurements as really critical. […] In the end we then said, let's build two scenarios, scenario (a) the classical approach, let's stick to the rules as we apply them now and (b) let's interpret regulation in a slightly different way to make the random access possible. […] We currently don't know if it will be accepted in the end but we try to do it this way for now. […] At least we managed to get in touch with FDA to discuss our proposal and new ideas. That's already a good sign because they have been quite open so far." (M7 - translated)*

Coupled with broad management support to try out new things, the team had a **strong belief of support to challenge established ways of working and to come up with new, radical approaches to extend the scope** of the product concept (*wide scoping*). Due to the positive dynamics in the team, the project was making good progress. It was striding through the various steps of the new business development and proof-of-concept phases.

> *"Well, from the technology side one would approach that totally different, well putting a stand-alone of XXX (annotation: product name disguised for confidentiality purposes) there […] then everybody who runs lab-developed tests today would applaud and would say fantastic. So much easier. But this is far away from what we envision for XXX (annotation: product name disguised for confidentiality purposes) […] Such a solution would have been an easy access to the market, low risk and fast. […] What we have today is technology-wise by far more challenging, more difficult more expensive and riskier. Also interesting that we as XXX (annotation: company name disguised for confidentiality purposes) want to go the more dangerous paths then." (M2 - translated)*

Nonetheless, when approaching the **first review milestone a turning point** was reached as **dissenting voices continued to arise, offering resistance** to the previously developed novel ideas and product concept elements.

> *"It was then the case that we introduced a totally new technology but please somehow make it fit to our business model because otherwise we cannot cope with all that. As a consequence, this was the kind of a frame condition that we of course tried to fulfil. […] you also need support from different functions, we simply love to strive for consensus. That's simply the way our corporation works." (M5 - translated)*

For example, in the context of business model options, the so far favoured option was swinging back to the already predominant model of "reagent leasing", a razor-blade model that builds on long-term sales of consumables rather than upfront sales for the measuring instrument itself or value-based pricing approaches. Another example of **cutting down radical elements in a *narrow scoping*** was referring to the strategic positioning of the new product concept and the addressed market segments. During a review cycle of the strategic product positioning, the management team was particularly paying attention to the cannibalisation of the already existing IVD product portfolio building on other detection technologies. A project manager for example replied to the question of how the portfolio dimension impacted the product concept:

> *"… either as supplement, competing tests and expansion. Particularly those, who (pause) a lot is not perceived as supplement but rather is part of discussions to what extent a cannibalisation of X or Y (annotation: product names disguised for confidentiality purposes) exists..." (M6 - translated)*

The technological side of the product concept was only "de-radicalised" to a minor extent. Together with the development partner the R&D team demonstrated a high performance for critical test parameters as well as the feasibility to automate the overall workflow on a breadboard. These achievements ensured **continuous support and commitment** by senior management throughout the proof-of-concept phase so that this milestone could be successfully completed by May 2016 and **project continuation** was ensured.

Next the various inputs from Marketing, R&D, MSA and Technical Operations were consolidated until July 2016 into a holistic product concept together with a project proposal that was presented to the BA as well as Divisional Portfolio Committee. Due to the technological novelty and the project size (investment amount/level), an additional review by the Chief Technology Office (CTO) was performed to validate the results of the proof-of-concept phase and to also challenge the proposed product concept. After passing this milestone successfully, a formal development project was initiated.

4.4 General case characteristics

After having had a detailed look at the two individual cases, this section provides a more general view on the two development projects by highlighting their commonalities but also differences. Contrasting the two cases lays the foundation to better understand their specificities for the following exploration and cross-case analysis.

This case comparison closely looked at the key characteristics from an internal as well as external perspective as for example both products address the same IVD industry and are developed in the same corporate context. However, they are different with regards to the applied technology and the addressed customer segment.

The key characteristics of the two cases are summarised in Figure 40:

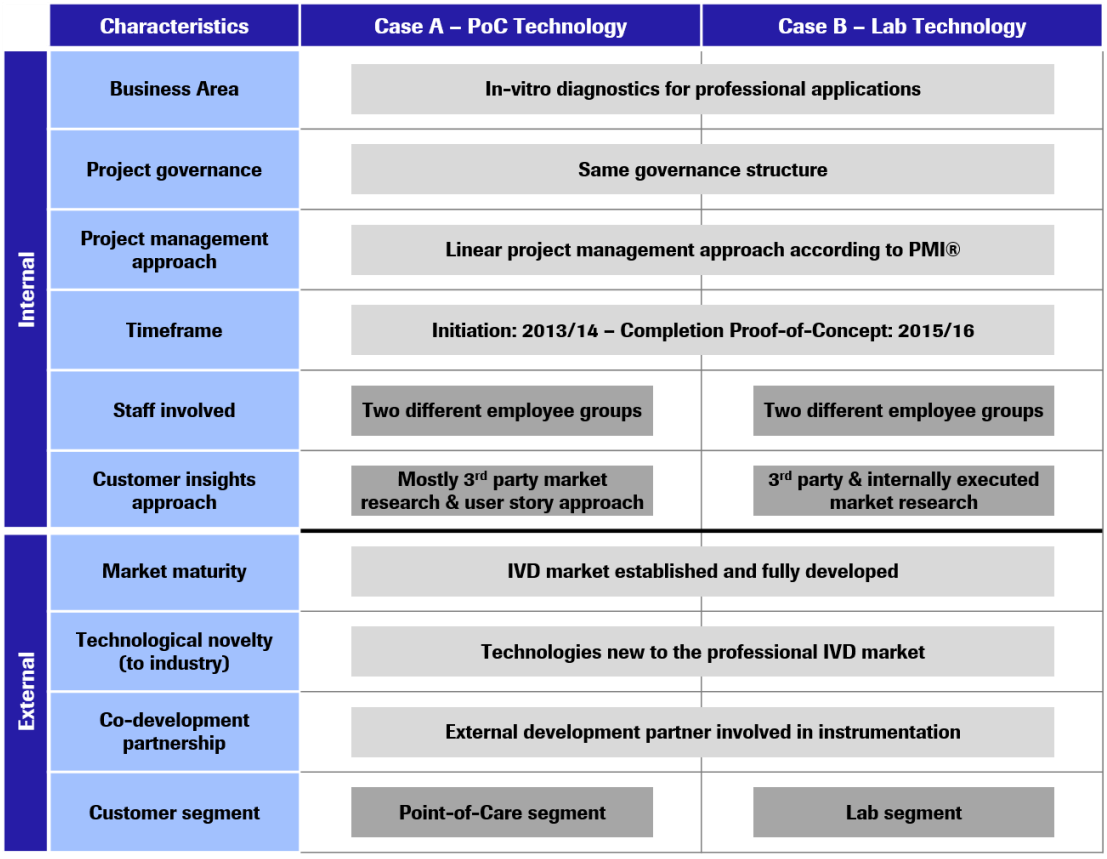

Figure 40. Comparison of both within-cases

From an **internal perspective** both cases are allocated within the **same business area** and are hence also exposed to the **same project governance** structure. This

means they have to follow the same processes with the same requirements regarding project deliverables for each project milestone. Furthermore, identical decision bodies are involved and in charge of reviewing the project progress and approving the project continuation.

A further element that showed similar characteristics was the **applied project management approach**. Both project teams followed a linear project management approach heavily influenced by the methods and techniques of the Project Management Institute®. This particularly affects the way of planning, executing and controlling a project.

In addition, the two product concepts were developed in a **similar timeframe**, meaning that the initiation was lying closely together in 2012 and 2013 and the development of product concepts lasted until 2015 respectively 2016. Therefore, the two projects were executed within the **same strategic framework** and with a certain stability and consistency on a management level. Furthermore, the slight temporal offset of roughly 9-12 months turned out to be a benefit in the sense that the two cases were never simultaneously assessed and consequently never directly competing with each other e.g. with regards to R&D funding.

However, it has to be noted that the two cases are also contrasting for example with regards to the project teams that were involved in the respective cases; meaning that there were two different groups of employees that belonged to the two case studies. Moreover, the two teams build on **different approaches to gain customer insights**. Whereas the PoC technology team (Case A) did mostly elicit customer insights from externally executed, third-party market research, the second team, the lab technology team (Case B), did supplement externally gained insights by a market study they carried out themselves. A further distinction in that context can be rooted back to the definition and documentation of customer requirements. The team of Case A adopted the so called “user story” approach to make requirements elicitation more user-centric, catchy and tangible.

Besides the outlined internal characteristics, the **external perspective** adds further essential insights to the case study descriptions. In that context for example both cases address the IVD market which is fully developed in most countries. Moreover,

the maturity of the addressed markets and the technological novelty are further similarities of the two case studies even if the technologies themselves are different. In addition, the newly applied technology(s) is an essential component of both new product concepts. A further similarity is that both cases contain an external technology partner who is directly involved in the development of hardware instrumentation.

However, it must be noted that the two product concepts also differ with regards to the market segments they are addressing. The new product of Case A is targeting the professional PoC segment whereas the newly developed product of Case B is approaching the professional laboratory market.

The above Figure 40 summarises, there do exist significant commonalities between the two cases which make them comparable to a large extent and suitable for this case-study. However, substantial differences are also indicated which needed attention particularly during the data analysis process. In that context, the preceding case descriptions and within-case analysis provided a first, descriptive idea of themes influencing the emergence of new product concepts. In addition, they can be seen as an initial step in understanding the dynamics of this basic social process which is comprehensively analysed and evaluated in the next paragraphs.

4.5 Conclusion on research context and within-cases

The description of the complex industry context, the corporate context of a leading IVD provider as well as reflection on the radical nature of the development projects under investigation formed the basis for the within-case analysis of two newly emerging product concepts. The within-case analysis was a first attempt to learn about the emergence process of new radical product concepts that build on new technologies.

Both development projects, Case A that addresses a new point-of-care technology as well as Case B which covers a new lab technology, allowed for observing certain dynamics when it came to the definition and refinement of new radical product concepts in a corporate setting.

These dynamics are summarised in *Scoping* that refers to a constant adaptation of a product concept following its initial definition in an early project phase. Thereby the core-variable is heavily building on the generated data from the two within-cases as it integrates several concepts in an early phase.

These concepts comprise aspects such as the tendency to explore new radical product concept elements when the team is leveraging dynamic capabilities like its ability to build up new knowledge and capabilities. Additionally, more *substantive capabilities* such as the ability to ensure sufficient funding or management support come into play. However, at the same time a certain tendency to "de-radicalise" and adapt the product concept to the existing corporate-/industry-context could be observed. This means that radical product features are either modified, replaced or even eliminated to favour less radical alternatives. In the end development teams seem to balance these two dynamics, exploratory and de-radicalisation, during the internal alignment to ensure project progression.

The next section will focus on these concepts by analysing data on a cross-case level to further characterise the emergent theory of *Scoping*.

5 Emerging Theory of *Scoping*

This section outlines the key findings of this research study on a cross-case level and sets forth the emergent theory of *Scoping* in more detail. First, the core-variable is introduced in general before elucidating on the findings along the temporal as well as capability dimensions of *Scoping*.

5.1 Core-variable *Scoping*

Scoping is the core variable that emerged as a key theoretical construct from the data. It refers to the process of defining and constantly adapting the scope of a new product concept in a holistic way and consists of temporal and capability dimensions.

The holistic way refers to technological and business perspectives of the new, emerging product concept. Technological view means the specification of technology(ies) the future product builds on including its key technical features. Business aspects refer for example to business model elements like value proposition, customer segmentation, delivery or revenue models. In that sense, the described product concept can be envisioned as a multidimensional space of solutions that is translated into an actual product during product development (Figure 41).

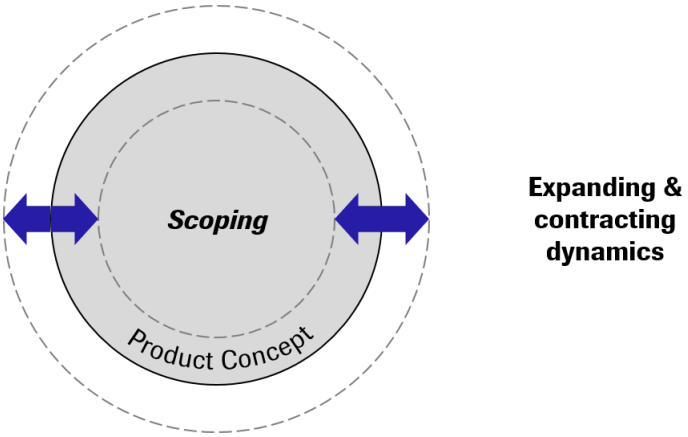

Figure 41. Core-variable - Expanding and contracting dynamics when *Scoping* a product concept

This **multidimensional space of solutions is socially constructed** and heavily vested in the individuals that define it. Each individual involved brings in his or her

subjective beliefs and over time a shared understanding of the future product is created. Based on this characterisation, *Scoping* can be seen as a social process that defines a novel product by bounding its solution space. Triggered, for example by newly emerging technologies, the status quo and its boundaries are constantly challenged due to the radical nature of the new product.

As a result of multiple influencing factors, the scope of a **product concept is changing during the early development phase**. This change represents a constant adaptation of the product concept to ensure project continuation and finally entry into formal product development to implement the product concept. In this context, the product concept is either adapted by expanding (*wide scoping*) or contracting (*narrow scoping*) its scope. *Expanding* means that the conceptual space changes to a wider scope, allowing the radical nature of the new product to be exploited. **Contracting**, means that the boundaries of the scope get tighter so that the scope is narrower.

This research study identified **two dimensions, a temporal and a capability one**, that appear to characterise *Scoping* and its expanding or contracting dynamics. The former temporal dimension relates to a change of *Scoping* over time when a product concept progresses through the research and development steps; as illustrated in Figure 42, it has two emergent concepts or phases: *exploring* and *normalising*.

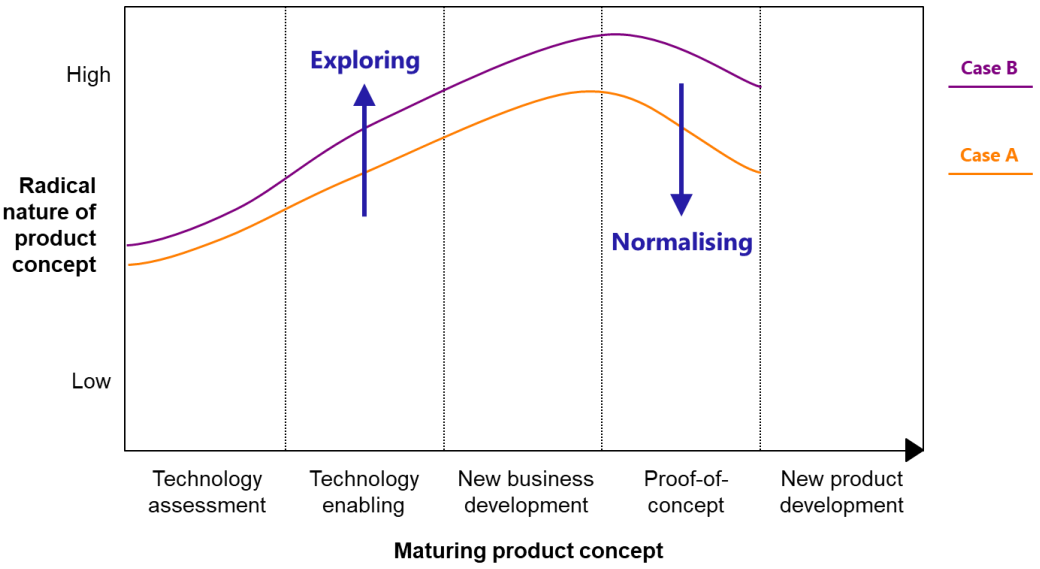

Figure 42. Temporal dimension including exploring and normalising phases

During the *exploring* phase a new technology triggers by default a questioning of the status quo and its boundaries. That is, during this phase a radical potential of a new technology is exploited in several single steps such as technology assessments or technology enabling. This is feasible if the team manages to build up knowledge and capabilities as well as ensures sufficient resources. As a consequence of *exploring*, the product scope expands in areas such as new technological features but also business model aspects which may be new to the corporation (*wide scoping*).

Normalising - in contrast to the *exploring* phase – can be observed with an increasing maturity of the product concept starting with the initiation of a proof-of-concept. This point marks a critical juncture as from that time onwards the creative, future-oriented focus as part of dealing with the associated uncertainty is gradually shifting to a more formalised, backwards-looking second phase of *normalising*. During that phase, radical concept components were either removed or modified so that the product concept was reduced and less radical (*narrow scoping*). This critical juncture is seen as a cutting point in the process of *Scoping* that describes a transition from an uncertain decision-making context, which is *exploring*, to a risk decision-making context, which is *normalising*. Therefore, development teams constantly adapted individual concept components and hence de-radicalised the product concept after initial generation. That way teams modified product concepts to enable project continuation and finally completion/implementation in a corporate setting.

Normalising as a second concept helps to unfold critical steps in which the (perceived) level of radicalness might be maintained or decreased. On the one hand, the perceived radicality declines, based on the internal knowledge and capabilities that are built up and formerly unknown or new aspects are considered as known and established. On the other hand, the stepwise transition from product definition to product development revealed a gradual process of de-radicalisation of product concept features. Indicators that have an impact on radicality include process elements such as tightened internal formal procedures that limit the ability for creative interpretation of the context. In addition, innovative elements of the

product concept are diminished or eliminated. These may include a review of customer segments that are addressed as well as a cancellation of radical product features for the sake of risk-mitigation. Furthermore, as part of business model design, new-to-market revenue model options may for example be eliminated and well-known revenue models preferred. This way, various types of uncertainties such as market adoption seem to be mitigated.

The second dimension relates to the **capability view** on newly emerging product concepts and it builds on two key concepts: *dynamic capabilities* and *substantive capabilities*. Both have a significant impact on the dynamics of new product concept *Scoping* and are outlined in Figure 43 below.

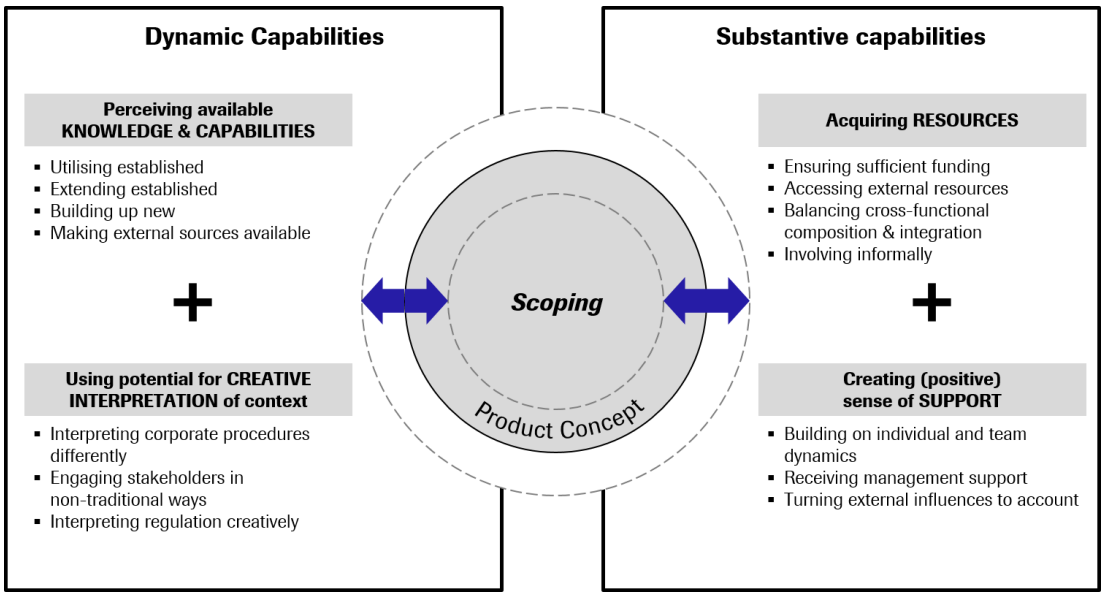

Figure 43. Capability view on *Scoping*

In this context, *dynamic capabilities* are about the perceived availability of knowledge and capabilities and the team's ability to use its potential for a creative interpretation of the NPD context. It means a team can build up dynamic capabilities and make use of them if it believes that it has the right internal and sometimes even appropriate external knowledge and capabilities available, believing that plenty of and necessary resources are out there to grasp and that it can at the same time acquire necessary knowledge and capabilities. Indicators that have an impact on the perceived availability of knowledge and capabilities are for example the perceived ability to build up totally new knowledge and capabilities in

a certain field. Apart from the perceived availability, knowledge and capabilities can only be used effectively if the team manages to also make use of the available potential for creative interpretation of the context. For example, in the area of regulation, which marks an important element of the context, a creative interpretation of formal regulation is a key dynamic capability that allows for further exploitation of the radical potential of the product concept.

The *substantive capability* concept on the other hand is about the ability to actually acquire necessary resources as well as to create a (positive) sense of support for the product concept; otherwise, the expanding power of the set of dynamic capabilities will not come into force. The acquisition of resources comprises for example monetary aspects such as ensuring sufficient funding but also non-monetary, informal aspects allowing the team to access resources on a temporary basis. A sense of support may be expressed in manifold ways which range from explicit endorsement of a decision body to implicit support or the pure absence of hurdles or roadblocks. Findings also suggest that both capabilities (dynamic & substantive) are heavily intertwined, meaning that the exploratory power of dynamic capabilities only comes into force if their implementation is supported by a set of substantive capabilities. For example, in the area of regulation, which marks an important element of the context, a creative interpretation of formal regulation allows for further exploitation of the radical potential of the product concept but it is only adequately followed-up if the team also believes in and senses the support of management as well as regulatory authorities.

Taking the above into account, it can be summarised that *Scoping* contributes to our understanding of concept shifting by suggesting two temporal states of *Scoping* (shifting): *Exploring* (*wide scoping*), which allows for enlarging the product space to explore the full radical potential that might come along with a new diagnostics technology and *normalising* (*narrow scoping*), a more restricted, bound space of the product concept. The former takes place within uncertain decision-making contexts, whereas the latter within risk decision making contexts. During these phases, multiple capability as well as contextual influencing factors help to better understand and potentially explain the dynamics of *Scoping* new product concepts.

The graph below (Figure 44) depicts and interconnects *Scoping* dimensions:

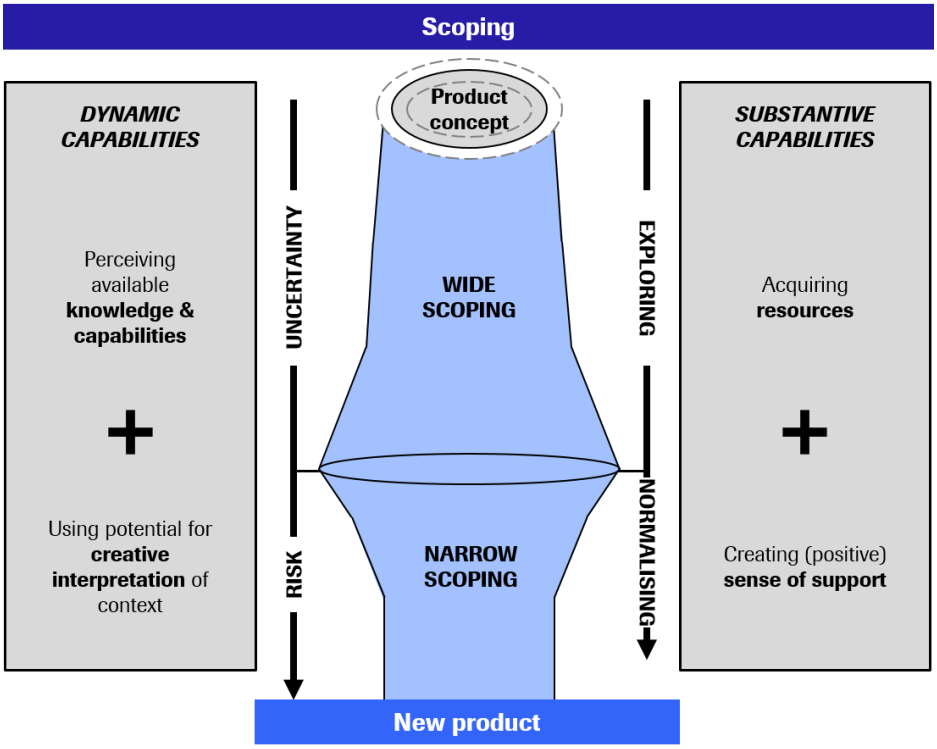

Figure 44. Holistic model of *Scoping* incl. dimensions and underlying concepts

Scoping and its two temporal and capability dimensions are grounded in data and conceptualised over various levels of abstraction. These levels of abstraction shall subsequently be outlined to depict the individual layers in theory building (Figure 45) – from core-variable <> to dimensions <> to concepts / types <> and indicators.

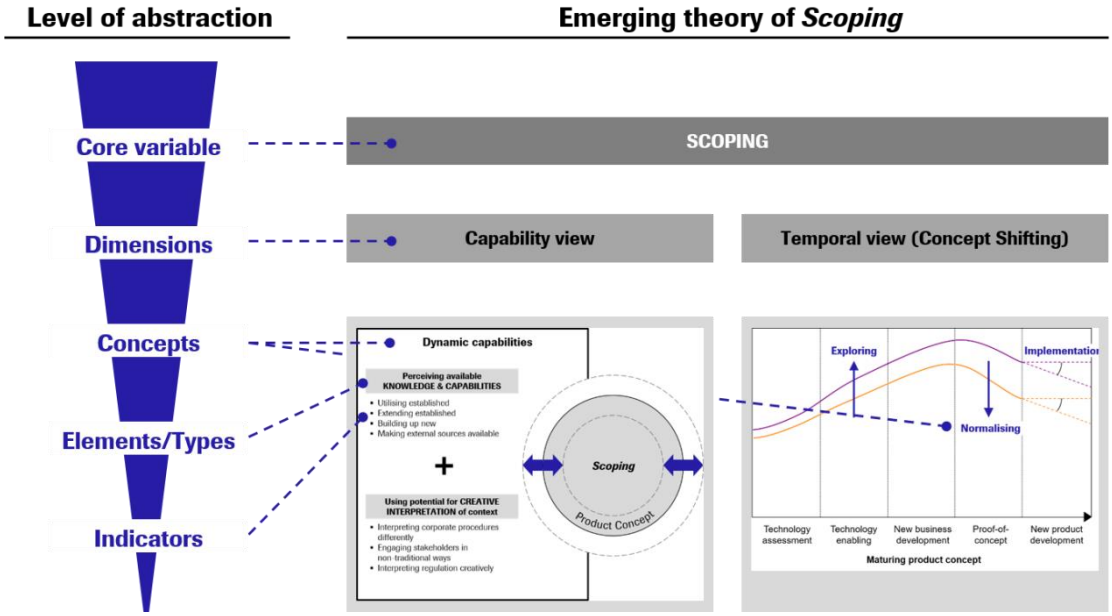

Figure 45. Core-variable - levels of abstraction

The **core-variable** *Scoping* represents the highest obtained level of abstraction. It tries to conceptualise the main concerns and explains most of the variations of behaviours (Glaser, 2005) that could be observed in the context of newly emerging product concepts under uncertainty.

On a lower level, a **dimension** is from a conceptual perspective located below the core-variable but directly relates back to it (Glaser, 1978, 2005). In general, multiple dimensions may exist in parallel. In this research study, the two *temporal* and the *capability* dimensions are used to characterise *Scoping* from two positions.

In this regard, various **concepts** are used to characterise the two dimensions in more detail. A concept refers to an inclusive cluster of aspects that explains how certain concerns are resolved (Glaser & Strauss, 2010). In line with Grounded Theory study, the results of empirical research shall not be the reporting of facts but the generation of probability statements about the relationships between these concepts (Glaser, 2005). In the context of *Scoping* and the temporal dimension, an exemplary concept is *normalising* that tries to explain the dynamics in adapting a product concept after its initial exploration.

An **element or a type** can be characterised as an integral part of a concept. On a lesser level of abstraction, it refers to the descriptive level of findings which are further defined (Glaser, 1978). More precisely, the concept of *dynamic capabilities* is further explained by the two elements “Perceived availability of knowledge and capabilities” as well as “Potential for creative interpretation of context”. Finally, **indicators**, or “data indicators” as they are called by classical Grounded Theory researchers, are at the lowest level of conceptualisation (Glaser, 1978). In a very descriptive and **data-related** fashion, they symbolise the concepts or types they are referring to. The property “Ability to acquire resources” for example is further outlined by descriptive indicators such as “Accessing external resources” that are deeply grounded in data.

Appendix D provides an illustration of these layers of abstraction including the individual steps of analysis based on the example of dynamic capabilities.

Reporting of the case study results takes place, similar to the analysis, on an individual-case level and a cross-case level. To ensure a rigorous development of Grounded Theory, the case study report presents an integrated chain of evidence (Yin, 2013), meaning that it systematically builds up on the research questions and the rationale for the research protocol informed by grounded theory methods (Figure 46). Furthermore, findings were consistently developed from evidentiary sources/data that were gathered in a research database.

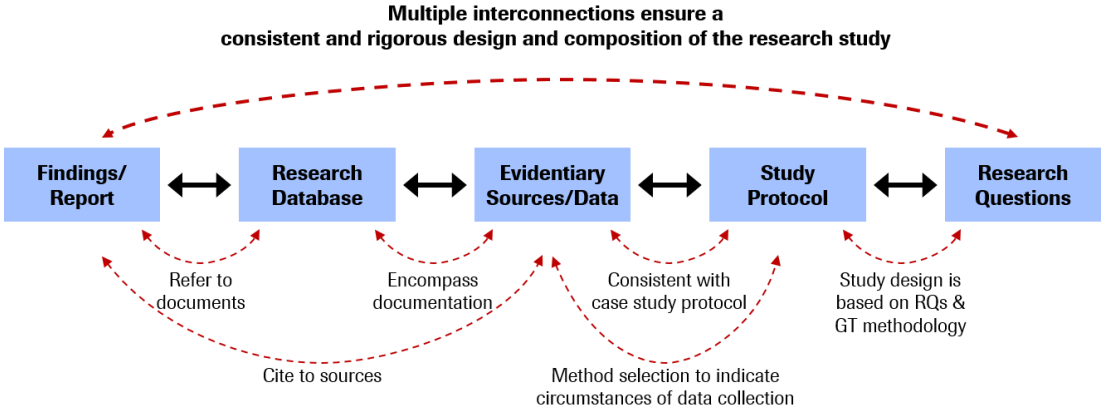

Figure 46. Chain of evidence (Adapted from Yin (2013), p.128)

The following chapter will focus on the first temporal dimension and its underlying concepts, *exploring* and *normalising*.

5.2 Temporal dimension of *Scoping*

Data indicated that *Scoping* also comprises a dynamic temporal change of the envisioned product concept. In the course of the early development phase the dynamics of *Scoping* changed massively while moving through the individual sub-steps from technology assessment to proof-of-concept. A detailed description of the individual process steps (a) technology assessment, (b) technology enabling, (c) new business development, (d) proof-of-concept and e) product development including their specific goals and deliverables is part of section 4.1.3.

The product concept at the beginning of the development process looked quite different from the various intermediate versions as well as the one that actually

entered into formal product development. A marketing manager from Case A described this extensive change in the scope when passing through these steps:

> *"…, the project as it started is not the project we are working on today, very clearly. […] Probably the project when it started was ok, oh no really right at the start it was purely a handheld, when it really started. […] And then it became a platform and then instead of doing a platform now it's going back and it's sort of a hybrid. (S6)*

Following an exploratory phase in which the scope of the initial handheld idea was enhanced to a whole new point-of-care platform, the team was afterwards reducing the scope so that the platform idea was eroding. When using expressions like "going back" or "it's sort of a hybrid" this implies that team members were perceiving a certain loss of product concept components.

In that context, data analysis also suggests that the change to the product scope followed a certain pattern as illustrated in Figure 47.

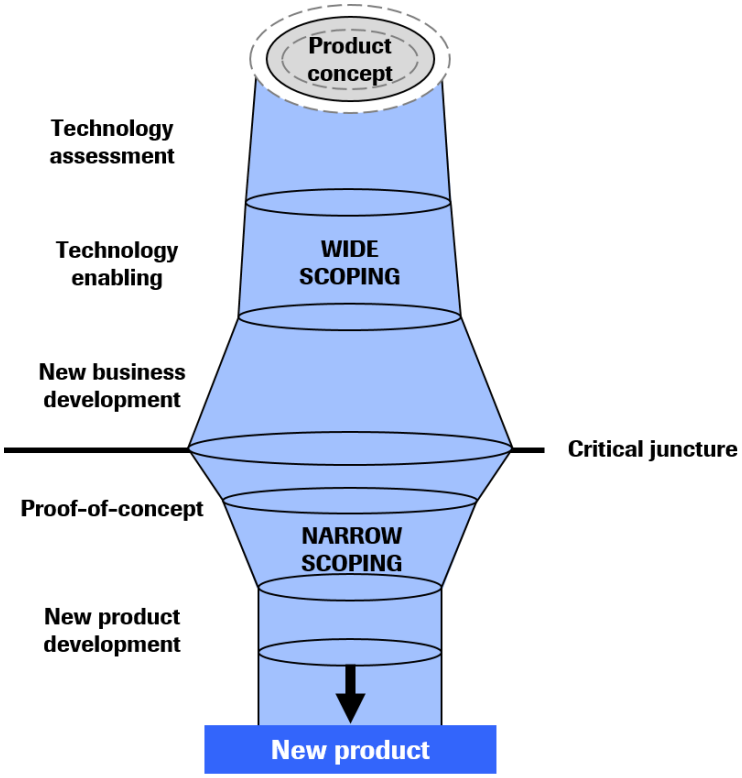

Figure 47. Changes to scope of product concept

The initial process steps from technology assessment through to new business development can be characterised by a *wide scoping*, meaning that the scope is constantly expanding. While following the logic of divergent thinking, the teams

were gradually *exploring* new aspects of the technology as well as the associated business model. As a result, new product concept options were developed that expanded the scope at the same time. These newly, sometimes even creatively, developed options found increasing acceptance in technological as well as business-related components of the product concept; comprising of:

- New technological features/performance
- New product configuration
- New customer segments
- New revenue models
- New product-/solution-delivery models

However, following a phase of *wide scoping*, dynamics change towards a narrower *scoping* during the process steps of proof-of-concept and the start of new product development.

In this context, *narrow scoping* means that the scope is constantly contracting, following a convergent thinking. Instead of maintaining the wider scoping, *narrow scoping* was leading to an elimination or modification of product concept options. This change of dynamics must not be seen as a sharp turning point; it is rather a gradual change that is triggered by examining, assessing and evaluating aspects such as:

- Increasing technological insights
- Constant internal discussions (technological & business aspects)
- Targeted external consultation of partners, experts and potential customers

This pattern of initial *wide* and subsequent *narrow scoping* and its impact on NPD is per se neither negative nor positive but it needs to be clearly pointed out as these changes also seem to have a significant impact on the radical nature of the product concept. Data suggests that not just the product scope but also the nature of radicality of the new product concept changes in a similar way; the impact being either an increased or reduced radicality.

Before entering the implementation phase, the gradual changes of product concepts in both cases followed a certain pattern, which includes two distinct phases, *exploring* and *normalising* (Figure 48):

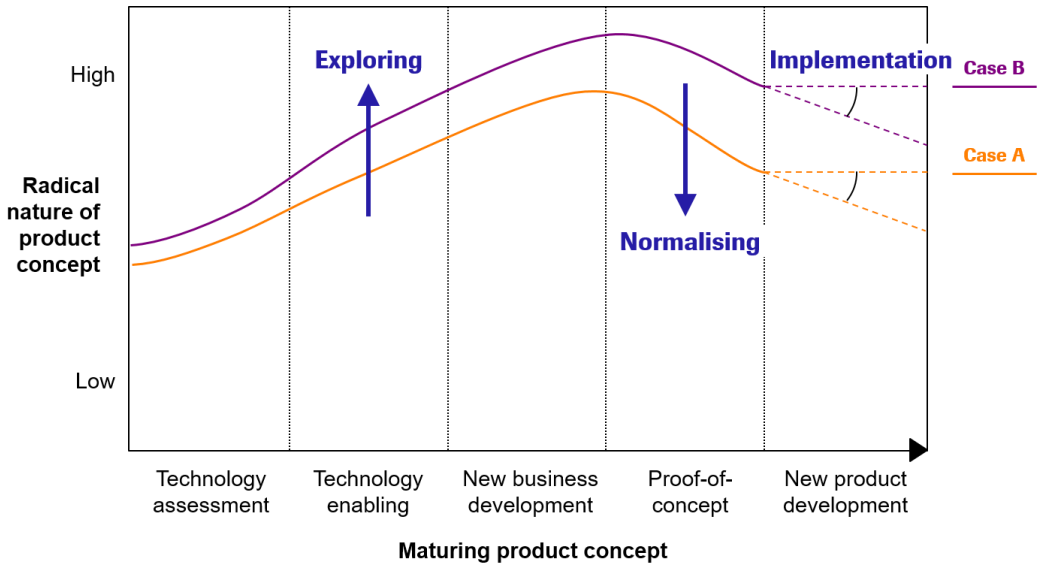

Figure 48. Pattern of temporal changes of radical nature

As a consequence of *wide scoping*, it could be observed that following project initiation the degree of radicality was rising during a phase of "Exploration". The teams were exploring the radical potential up to a shift from new business development to proof-of-concept when the radical nature of the product concept reached its peak. Subsequent to this critical juncture, a phase of n*ormalising* set in, meaning that due to decisions to reduce product scope, more radical product concept elements were either modified, cancelled or replaced by less radical alternatives.

As a result, during the *normalising* phase, the radical nature of the product concept was reduced. However, the difference between the initiation of the project and the transition to product development was positive, meaning that in both cases the product concept that entered into formal product development was actually more radical than envisioned in the beginning. Nonetheless, the organisation did not fully exploit the radical potential that was theoretically provided by the technology.

The above-described pattern and phases, more specifically e*xploring* & *normalising* as well as the critical juncture, shall subsequently be explained in more detail.

5.2.1 *Exploring* phase – Expanding product scope (*wide scoping*)

During the "*exploring*" phase the scope of the future product is following a pattern of constant expansion. This means that development teams are gradually including new concept components (divergent thinking) that increase its overall radical nature.

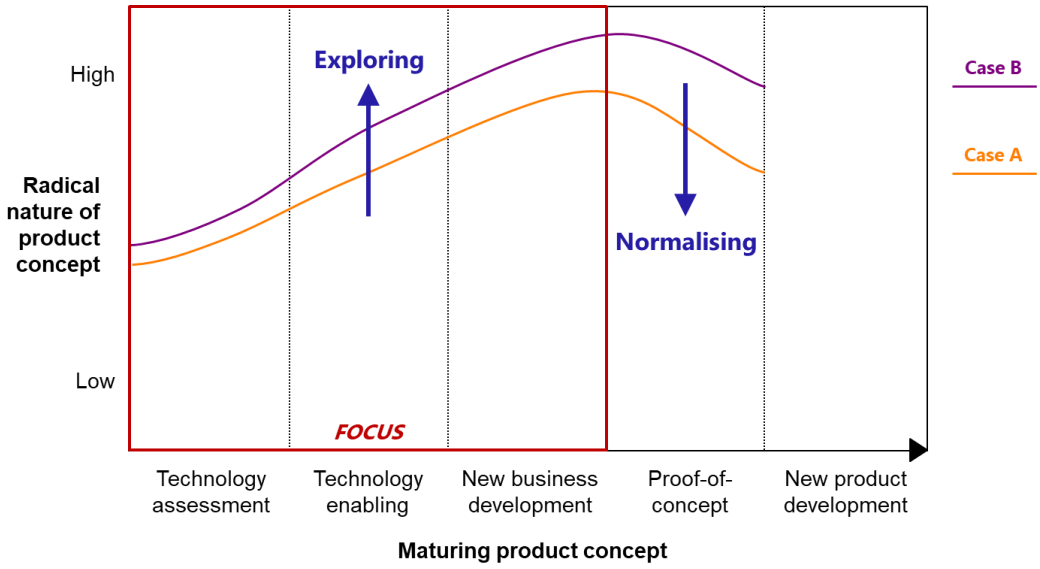

Figure 49. Increasing radicality during *exploring* phase

This expansion of the product scope becomes evident on a technological as well as business level. The **technological layer** comprises, for example, the exploration of new radical product features that become an integral part of the overall product concept.

> *…we're really breaking new ground, and that's a combination of new, new technologies developed here at XXX (annotation: company name disguised for confidentiality reasons), here in-house, combined with new technological developments out there, such as XXX (annotation: technology name disguised for confidentiality reasons), that's what you'll get access to for two years only. (S2 - translated)*

This statement illustrates that *exploring* is not purely about new technological features not yet adopted in another product. Here, the technological exploration is to a large extent about the combination of existing and new technological elements as well as merging these potentially into established product platforms. This was highlighted by a respondent when referring to a riskier, technologically integrated solution:

"Well, from the technology side one would approach that totally different, well putting a stand-alone of XXX (annotation: product name disguised for confidentiality purposes) there […] then everybody who runs lab-developed tests today would applaud and would say fantastic. So much easier. But this is far away from what we envision for XXX (annotation: product name disguised for confidentiality purposes), for the platform when it comes to throughput and efficiency. Such a solution would have been an easy access to the market, low risk and fast. […] Something like that was never discussed by marketing, never seriously talked about this. What we have today is technology-wise by far more challenging, more difficult more expensive and riskier. Also interesting that we as XXX (annotation: company name disguised for confidentiality purposes) want to go the more dangerous paths then." (M2 - translated)

This example also illustrates that the technological layer is directly interlinked with the marketing/business layer of the product concept.

With regards to the **business layer** to a product concept, data suggest that the exploratory nature of this phase is mainly expressed through exploring new business model options. These business model options might for example include addressing new customer segments, implementing new revenue models or envisioning new solution-delivery models. In the context of addressed customer segments, a marketing manager clearly highlighted the complexity when expanding the scope of addressed customers to new segments:

"…one needs to know the respective countries, how are the reimbursement systems set-up and how I'd say do they push or how do they foster innovation in a way that they say, ok for a more sophisticated technology I'm willing to pay more. In which customer segments do we go then?" (M8 - translated)

Another example for exploratory business model options is associated with a new revenue model that might even require challenging the pre-dominant revenue model that successfully generates revenue streams for existing products. A marketeer who was in charge of defining and reviewing different commercial business model aspects put it like:

"…well, essentially it's all about what we have done in the past 15 years, this "reagent leasing" business model that will by default not work automatically for XXX (annotation: product name disguised for confidentiality purposes)." (M7 - translated)

This indicates that the pre-dominant revenue model of an industry might "by default" not work for all new, radical products. This perception was also in line with other team members such as a research participant from Business Development who was explicitly asking for new business model options to be considered,

no matter what organisational units or other corporate bounding conditions might ask for:

> *"Well, at least two business team were affected […] because we looked at it from a different perspective, purely what could be possible with XXX (annotation: technology disguised for confidentiality purposes) independent from any organisational units." (M5 - translated)*

In essence, during the *exploring* phase it can be found in many statements that the general perception of the team was to constantly push the boundaries of the available solution space to allow for a *wide scoping* of the new radical product concept.

5.2.2 Critical juncture and going beyond pre-development

In the process of defining, bounding and leapfrogging the new radical product concept, the transition from the new business development phase to the proof-of-concept phase marked a key turning point (Figure 50). During the technology enabling and new business development phases a *wide scoping* was observed, meaning that the teams were future-oriented and proactively dealing with different kinds of technological as well as market uncertainties related to the exploration of radical elements of the product concept.

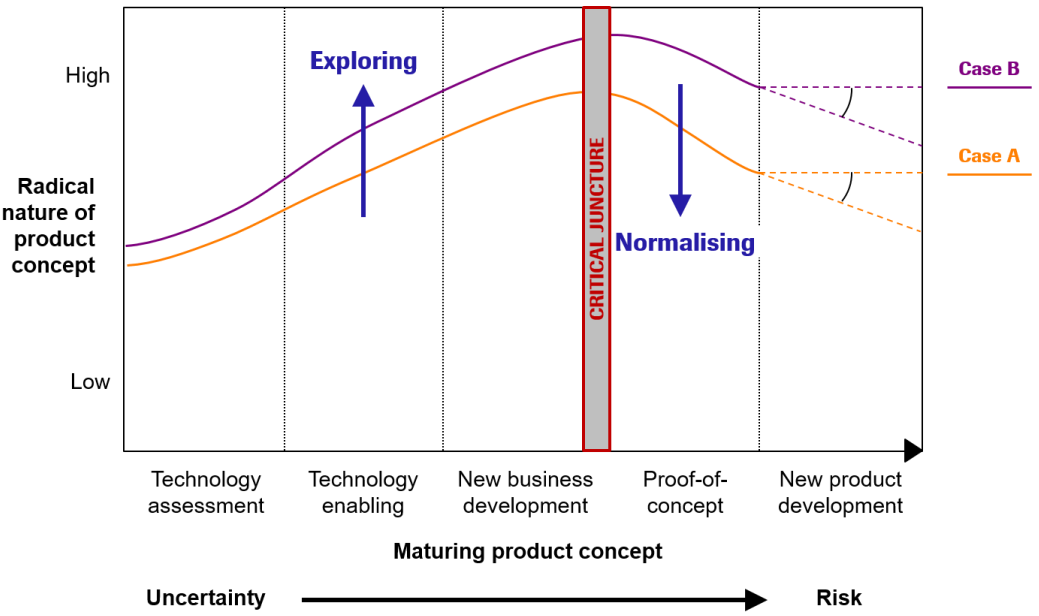

Figure 50. Critical juncture when Scoping a product concept

However, with an increasing maturity of the radical product, starting with the initiation of the proof-of-concept, **a shift in mindset occurred**. From this juncture onwards, the exploratory focus started to **gradually shift** to a more formalised, implementation-focused and backwards-looking phase of *narrow scoping*. This means that in the increasingly risk-based setting of *narrow scoping,* the product concept gets adapted in a way so that radical product components are either gradually modified, removed or replaced by less radical variants. This critical juncture is seen as a turning point in the process of *Scoping* but must not be regarded as a sharp pivot point; it is rather a gradual change and transition from an uncertain decision-making context to a risk decision-making context.

A marketing manager in Case A described this extensive change in the scope when passing through these phases (*exploring*, turning point, *normalising*) in the following way:

> *"Yea, the project as it started is not the project we are working on today, very clearly. […] Probably the project when it started was ok, oh no really right at the start it was purely a handheld, when it really started. […] And then it became a platform and then instead of doing a platform now it's going back and it's sort of a hybrid. (S6)*

Following an exploratory phase in which the scope of the initial handheld idea was extended to a whole new point-of-care platform, the team was afterwards reducing the scope so that the platform idea was eroding. When using expressions like "going back" or "it's sort of a hybrid" it implies that certain radical elements survived this process of **de-radicalisation** but many product concept components seem to get lost.

It appears that from that point onwards development teams in a corporate setting tend to adapt certain product concept components through de-radicalising, to ensure project continuation. At this early point in time, the main goal of project continuation seems to be the start of a formal product development project.

But this observation triggers the question: what causes such change?

Two potential factors were identified that might influence the *Scoping* of a new product concept in this particular process phase.

Firstly, a shift of mindset could be observed that also goes back to a change in the team composition during proof-of-concept. With the team getting bigger during that phase, new people get involved who tend to look at the product concept from a more implementation-focused and risk perspective. This means that following the more future-oriented *exploring* phase, new guiding principles come into effect that are influenced by risk-oriented factors such as product robustness, manufacturability, regulatory compliance or capabilities of established suppliers/partner. A newly joined team member from Case B who is holding the position of a business liaison manager and has a functional background in engineering has taken and defended this view quite clearly:

> *"I'm just asking because that is always an issue when I do research for the system and the same person shall now also move it to development and this is mentally an absolute change. That's why product definition is super difficult with these guys because they are always so academic in their heads, we play a bit here and tinker a bit here to come up with the best solution. […] you need to manage to do the shift, allowing this from a mindset perspective. […] You need to go away from the technology, what else could we try out and improve. You really need to think about what do we want in the end? Development also means, I have a product in the end that I can reliably build with the same characteristic features once again. (M10 - translated)*

This change of mindset was also clearly expressed as part of Case A, when another liaison manager was, for example, pushing for more formal documentation of the product concept on a global scale:

> *"Well, one could make an additional step towards formalising and especially systematic documentation in the compliance-relevant documentation." (S9 - translated)*

This example does not just highlight the shift in mindset, it also introduces a second potential influencing factor of more formalised procedures that needed to be applied in new product development. At the turning point, a change in corporate procedures could be observed. When approaching the proof-of-concept phase, corporate governance was asking for more formalised procedures. Due to the rising investment level, product development procedures were now requiring more detailed project planning, rising risk management and stricter cost controlling, just to mention a few elements. In addition, these standard procedures are applied for

all kinds of products that are developed, not reflecting the radical, new technology element of these projects.

While these changes were taking place, the team was still thinking ahead towards product implementation and market launch but now much more influenced by an environment informed by backwards-looking experiences from past development projects.

5.2.3 Normalising Phase – Contracting product scope (*narrow scoping*)

Following the critical juncture, the product concept is modified in a subsequent phase of *normalising* (Figure 51), which means that its scope is constantly contracting. This happens as part of *narrow scoping* which is following a convergent thinking approach.

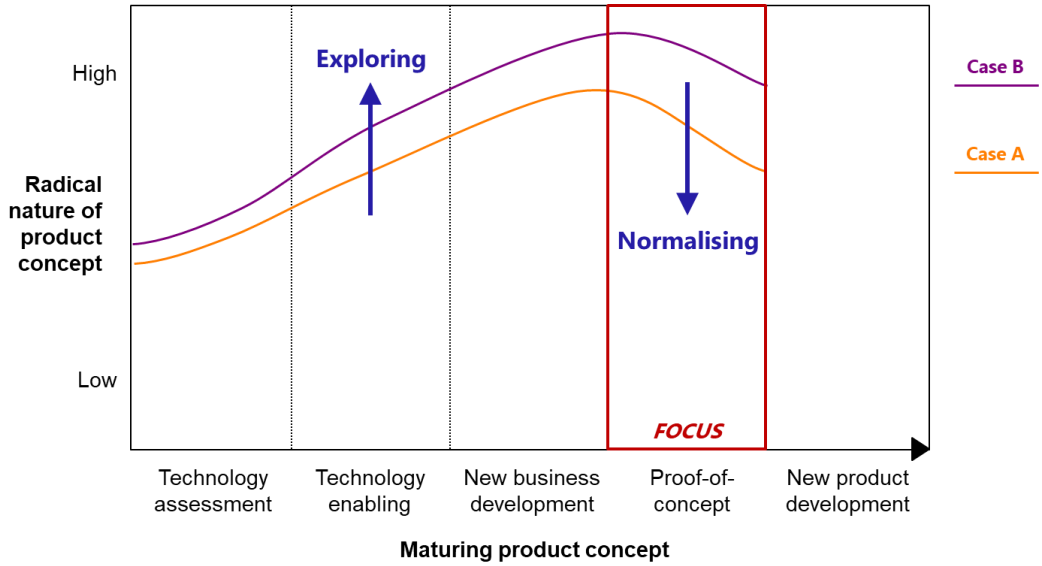

Figure 51. Decreasing radicality during n*ormalising* phase

Instead of maintaining the wider scoping, *narrow scoping* was leading to an **elimination or modification of radical product concept options**. Therefore, the radical product concept is gradually adopted to the existing corporate and industry context to ensure project progression. This means that as part of *narrow scoping*, the product concept is brought in line with internal as well as external trends by either discarding, replacing or adopting key radical product components.

As a result of the combination of internal/external alignment on the one hand and decreasing product radicality on the other, this phase can be characterised as *normalising*.

In line with the previously described *exploring* phase, *normalising* is perceived by team members throughout the course of the project on technological as well as business levels of the product concept. This change of dynamics must not be seen as a sharp pivot point; it is rather a gradual change that is triggered by examining, assessing and evaluating aspects such as:

- Increasing technological insights
- Constant internal discussions (on technological & business aspects)
- Targeted external consultation of partners, experts and potential customers

From a **technological perspective**, *normalising* expresses itself in a reduction of radical product concept features such as measuring sensitivity of the product, the overall sample throughput or novel analytes that are measured. During this technological adaptation or alignment process, development teams try to maintain and ensure the internal as well as external support for the new product by prioritising aspects like:

- Ensuring manufacturability (large scale)
- Building on existing knowledge and development partners/supplier
- Leveraging existing platforms/products

In the context of manufacturability, the teams increasingly focus on a later, large scale production of instruments and reagents. In doing so, novel product concept components that for example require new production technologies are replaced by ones that leverage existing technologies, allowing for instance for a higher degree of automation or improved predictability of costs of goods sold. As a result, existing technologies are favoured as they typically come along with a lower risk of manufacturability. A business liaison manager stressed this point, though with a caveat, telling the story of another product development project that failed in this regard:

> *"…we see this currently in many projects. XXX (annotation: name of further system project disguised for confidentiality purposes) is also an example for that, this little box it is from a biological perspective very innovative. […] 50-60% of steps in manufacturing are manual there. You then realise uuups, we can't manage that in a large scale production. […] and that's the way it is, it is always about understanding what does that mean and what kind of consequences might that have on further product development. Manufacturability is one of these topics that researchers are only interested in to a small extent in their early phase. Another topic that is directly associated, is that I simply must not look at all system components separately." (M10 - translated)*

In line with this, amongst others, a liaison manager, as well as a requirements engineer, pointed to the pressure that is put on teams to build on existing knowledge and suppliers. This can be seen as an additional driver for *normalising* the product concept during proof-of-concept.

> *"That's for me not a secondary aspect, because if we limit our solution space to the toolkit of off-the-shelf solutions of our service provider, then this is in the long-term quite dangerous. XXX (annotation: name disguised for confidentiality purposes) what is your opinion on that? (translated)*

> *"I'm totally with you on that, I have experienced that frequently, that this in part also means that we are not able to deliver that; because we have our suppliers and they don't provide that." (translated)*

This aspect marks another important influencing factor for *normalising* the novel, radical product concept rather than sticking to new radical elements that, for example, require new capabilities internally or externally on the supplier-side.

An additional aspect that is influencing the degree of *normalising* was observed in the interplay between the newly developed product concept and the portfolio of already existing products. Figure 52 illustrates that the prioritisation of new product features was based on existing products as well as a competitive assessment. The dimensions of this so-called "spider-diagram" elucidate on envisioned product features (green area) in relation to current (red area) as well as future competitive offerings (orange area):

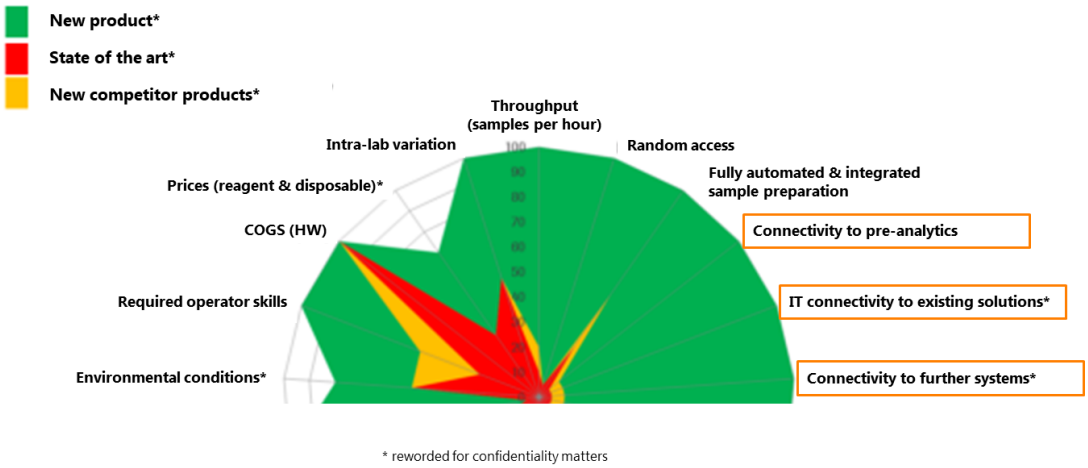

Figure 52. Portfolio and industry perspective of prioritisation

By taking trade-off decisions during the process of *normalising* based on criteria such as connectivity to pre-analytics systems or connectivity to existing systems, the decision making-process clearly favours an adaptation of the overall product concept to the existing, "normal" state of the art. This way the graph as well as the subsequent statement of a marketing manager exemplarily lead over to the business layer of new product development that is highly interrelated to the technological layer of a product concept.

> *"Because the critical thing is, at a certain point we will approach customers that so far had used Immuno-Assays, we have here something better, implication so what you had until now isn't good enough anymore. Well that needs to be positioned very, very carefully and then really also to have a look at it." (M8 - translated)*

The business side to *normalising* comprises various elements of the overall business model ranging from:

- reducing the magnitude of product cannibalisation (product portfolio view),
- focusing on existing, well-known customer segments
- to adopting the predominant revenue model.

As a consequence of potential overlaps with further already existing products, the scope of the product concept was significantly reduced to minimise the risk of cannibalising own products that are already sold to the market. A project lead as well as an R&D expert were describing this sensitive and highly political, internal discussion as follows:

"…, either as supplement, competing tests and expansion. Particularly those, who (pause). A lot is not perceived as supplement but rather is part of discussions to what extent a cannibalisation of X or Y (annotation: product names disguised for confidentiality purposes) exists." (M6 - translated)

"We have an immune assay for vitamin D, why should I transfer this to XXX (annotation: technology name disguised for confidentiality purposes), why? And that way one can argue for another 50 parameters the same way." (M2 - translated)

These examples in the context of the test offering illustrate that a significant aspect of the new test menu was subject to significant debate, questioning the need for product components that compete with existing internal products. Additionally, these statements demonstrate the shift in mindset, from a future-oriented exploratory thinking that envisions new business opportunities to a backwards-oriented view on the product concept that rather perceives new product components/offerings as a threat and risk to the established business.

As a result, the teams tried to **adapt or even reduce the scope** of the product concept to ensure internal alignment to ultimately carry the development further. In the case of adapting a product concept to legitimise it, the team tried to at least maintain certain envisioned product features even if they just "survive" in a less radical form. These dynamics of adaptation are highlighted by an R&D leader through a shift in the intended uses of diagnostic tests:

"Portfolio implications were and are key elements of the business assessment and the development of business cases. Potential future applications were for example mapped with the existing portfolio. As a result, dependencies were identified and classified as either (a) overlapping, (b) complementary or (c) expanding. A detailed assessment and design of the product is required as for example initially overlapping tests might easily complement each other through different intended uses e.g. screening & confirmation tests of the same analyte. (M3)

If a de-radicalisation was not possible by adapting the scope of the product concept, the scope was simply reduced. This means that controversial product concept components such as new, radical diagnostic tests that were not capable of winning support were excluded from the initial launch test menu. The headline "Expansion and complementary" as well as the content of a slide from a steering committee meeting (Figure 53) illustrates that the team was trying to **circumvent any potential opposition** by e.g. postponing sensitive elements to potential later product updates.

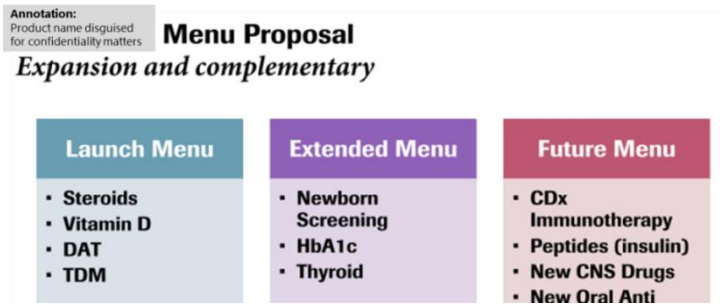

Figure 53. Portfolio implications - Reducing/postponing product concept components

A second dimension of business-driven *normalising* can be spotted in the exclusion of certain customer segments that would be approached for the first time. Instead, the organisation is focusing on existing, well-known customer segments where a business opportunity can easily be assessed (with minimal risk). An R&D lead from Case B was getting to the heart of this aspect by explaining:

> *"Assessment of business opportunities is demanding as the product is addressing a just partially existing market in a different customer segment." (M3)*

Similarly, as part of Case A, the team was excluding highly attractive customer segments during a second business assessment due to a lack of available (internal) knowledge on the respective customers or indication areas (Figure 54).

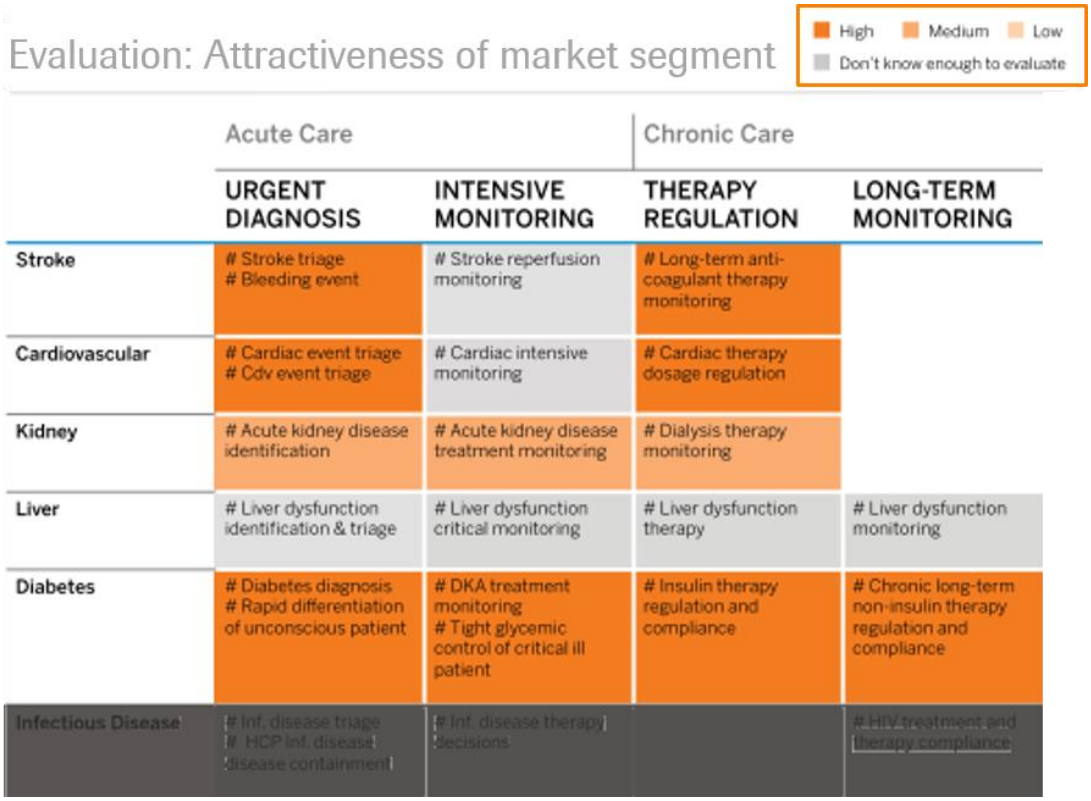

Figure 54. Opportunity assessment - Reduction of addressed customer segments

A third important business aspect to the product concept that was influenced by *normalising* dynamics is the revenue model. Instead of adopting value-based revenue models that would have suited the new product, the team was discarding such novel ideas due to a lack of management support. Particularly in Case B, the team was neglecting the most radical elements of the revenue model to drive forward further radical technology and business aspects of the product concept. A business development manager described the need to take trade-off decisions when aligning the revenue models:

> *"Maybe another aspect where I think that the corporation rather struggles is with totally new things. It was then the case that we introduced a totally new technology but please somehow make it fit to our business model because otherwise we cannot cope with all that. As a consequence, this was the kind of a frame condition that we of course tried to fulfil. […] so much was new for many people. I mean one has to somehow communicate and promote this within the organisation. […] you also need support from different functions, we simply love to strive for consensus. That's simply the way our corporation works." (M5 - translated)*

Even progressive business development managers whose job would be to introduce novel approaches to the case company abandoned such plans in the end even though this was contradicting their mandate and basic beliefs. The same business development person phrased these contradicting *exploratory* or *normalising* dynamics as part of the adoption:

> *"…more related to the business model. Really to tell people, you know that and this is nothing new for you. […] This is for us from Business Development rather not our goal because my goal is to go beyond the scope of things and to look at what actually is possible. Also simply proposing new business models. […] the next step would have been that I think about something new for the overall business but at an early point in time where you try to sell a new technology, putting that on top, that's gonna be difficult. (M5 - translated)*

Taking the above stated into consideration, it can be summarised that *normalising* is a phase of *narrow scoping* in which the scope of a product concept is reduced by eliminating/replacing or modifying radical product concept components. That way, a product concept is gradually adapted to the existing corporate and industry context to ensure project progression; bringing the overall scope of the product concept in line with internal as well as external stakeholders.

5.2.4 Discussing temporal findings and deriving propositions

This study offers an in-depth look into the emergence of new product concepts under uncertainty in the context of medical diagnostics that build on new technologies. While previous empirical as well as theoretical studies have mostly focused on either the process nature (Arrighi et al., 2015; Cooper, 1990, 2006), the radical product typology (Frishammar et al., 2016; Garcia & Calantone, 2002) or success factors for NPD in general (Florén et al., 2018; Verworn et al., 2008), this research study aims to shed light on the emergence process of new product concepts before R&D projects enter formal product development. This led to the development of *Scoping* as a core-variable that tries to explain most of the key dynamics in this process.

One characteristic of *Scoping* refers to its temporal dimension. When looking at the two within-cases, findings indicate that the product scope is constantly adapted during *exploring* but also *normalising* phases, leading to the following first proposition in the context of pre-development:

> ***Proposition 1****: The scope of a radical product concept is constantly adapted across multiple steps of pre-development to reflect new insights.*

In that sense, product concept *Scoping* can be seen as a social process that builds on several processual sub-steps. In addition, the changes that occur over time involve certain turning points (Glaser, 2005). Results further support the idea of Florén and Frishammar (2012), who developed a theoretical model of refining a new product concept in a process of repeated adaptation due to a set of internal/external alignment as well as legitimisation steps. These steps shall allow an organisation to reflect upon new insights and to align with internal as well as external stakeholders to ensure project continuation. Further prior research such as the new concept development model (Koen et al., 2001) or opportunity recognition (O'Connor & Rice, 2001) support this proposition of a constant adaptation of a product concept already in an early phase and support the claim that during the emergence process of a new product concept, new insights may trigger new opportunity identification or recognition events, which is what O'Connor and Rice

(2001) call such adaptations. These events may lead to initial but also recurring adaptation in the lifecycle of a radical product concept.

Another important finding was that the above described adaptive nature of *Scoping* seems to follow a certain sequence and pattern of *wide* and subsequent *narrow scoping*. This leads to the second proposition on the pattern of concept shifts:

> ***Proposition 2****: The adaptation process of a product concept scope follows a specific pattern of exploring (wide scoping) and subsequent normalising (narrow scoping) to ensure project continuation.*

During the initial phase of opportunity recognition, the development team is exploring the scope of a new product concept. This phase of *wide scoping* is characterised by divergent thinking, pushing the boundaries of scope by exploring new customer segments, business model options, product features but also regulatory interpretations (Reid & De Brentani, 2004; Veryzer Jr, 1998).

These results further support the ideas of Reid et al. (2014) who see a sequence of divergent and convergent thinking during the early development phase. That way the teams are exploring new radical product concept components that allow for not just expanding the scope but also stepping outside existing innovation paradigms (Dosi, 1982; Johannessen et al., 2001). A possible explanation for this might be that organisations are able to capitalise on certain dynamic capabilities that seem to be required for a wider scoping. This capability view is analysed in more detail as part of the next chapter 5.3. Prior studies that were mostly of a theoretical nature have already noted this importance (Easterby-Smith et al., 2009; Easterby-Smith & Prieto, 2008; Eisenhardt & Martin, 2000).

Interestingly, the exploration phase was found to be followed by a phase that was defined as *normalising.* A period of *narrow scoping that* is characterised by rather convergent thinking which leads to a significant reduction of the product scope and that has already been brought up by researchers like Reid et al. (2014).

Findings of this case study indicate that this process of *normalising* is mostly driven by new insights as well as internal/external alignment. These findings match those observed in earlier studies such as O'Connor (1998) or provide empirical evidence for so far theoretical models such as the corroborated product definition of Florén

and Frishammar (2012). This contraction of scope seems to be a desirable path for organisations to ensure project continuation. Having said this, findings herein grounded in data match and even extend those observed in an earlier study by Seidel (2007) that was leading to the idea of *concept shifting*. The investigations of Seidel (2007) focused on changes to product concepts during implementation and he found that concepts are shifted through elimination or adaptation of key product components so that development teams manage to ensure project continuation as well as ultimately market introduction. Building on these findings, this research even suggests that concept shifting, so far limited to product development, can be extended to pre-development steps.

To further characterise concept shifts in the context of radical innovation, one also needs to consider the velocity of *Scoping* to reach a certain innovation goal. Data showed that patterns of shifts can be further specified based on two key elements of **velocity: speed** and its **direction of movement** respectively a change of speed and/or its direction. During the two identified phases of Scoping, exploring and normalising, several changes to the velocity of product concept emergence could be observed. Whereas several studies on NPD, such as Brown et al. (2008) or Cooper and Kleinschmidt (1995), highlight the importance of time to market particularly in the context of incremental innovation, the overall speed apparently does not seem to play a major role in the early phase of radical product concept emergence. One potential reason may be that the speed of concept development depends on several internal and external factors that may not directly be influenced by an organisation. Technological advancements in healthcare are one example of potentially highly complex topics that can only be driven by multiple stakeholders with different levels of development speed (e.g. academia, medtech, healthcare providers and insurers). A possible further explanation might be that in contrast to incremental development, success for radical innovation rather depends on *Scoping* the product in the right way instead of being fast to market (efficiency vs. effectiveness). In that sense, radical or even disruptive products by definition enter a market with a different competitive situation, typically with no similar products in that market or even creating a completely new market itself. As a result of these

uncertain and unpredictable developments, the speed of product concept emergence may be characterised by a constant change with episodes of acceleration and deceleration.

Furthermore, when looking at *Scoping* not from a mere speed perspective but rather from a more holistic velocity perspective, the second element of direction of movement plays a significant role. Data from the case study suggests that throughout the early phase of new concept development several changes in direction occur. These changes were frequently also linked to a change in speed (acceleration/deceleration). During exploring for example, new insights or newly created knowledge lead to an extension of the product scope (*wide scoping*). Then when entering the *normalising* phase the concept shifts, the direction of concept development is inverted to reflect divergent thinking and narrower *scoping*. As a result, the scope of the product concept as well as the level of radicalness decreased.

These observed changes to the speed and direction of *Scoping* (for details see Figure 47 and Figure 48) led to the development of a proposition on the velocity of a concept shifting in early NPD:

Proposition 3: The velocity of Scoping varies in terms of change in speed and direction (expanding vs. contracting).

The findings above in this study on *exploring* and *normalising* phases and the change in velocity suggest a considerable change in *Scoping* dynamics that can overall be seen as a turning point in the emergence process of a new product concept under conditions of uncertainty. The transition between these two phases was rather observed as a gradual change than a sharp point in time, as it occurs over a certain timeframe with the initiation of the proof-of-concept. Thereby it is in line with existing literature on turning points (Abbott, 2001; Turcan, 2013) that particularly highlight the successive changes in direction. In the context of this research study, this could for example be observed through the change in directions from a *wide* to a *narrow scoping* along with a change from divergent to convergent thinking. There are several possible explanations for this; a change of mindset but

also a change from uncertainty to risk management settings. These changes as part of concept shifting called forth the fourth proposition:

> ***Proposition 4****: The transition from exploring to normalising marks a turning point from uncertainty to risk decision-making settings.*

A potential explanation is the change of research context and mindset of people involved leading to such turning points. During project progression in the front-end, this refers to stricter regulatory requirements or a noticeably increasing orientation on the implementation of the project possibly triggering a change of mindset. These findings are consistent with results from research on ambidextrous organisations (Awojide et al., 2018; He & Wong, 2004; March, 1991).

Furthermore, these changes come along with a change from uncertainty to risk management settings that could also cause such a turning point. In this context, change refers to a gradual transition from uncertainty settings, in which one is not able to assign a likelihood to a certain outcome, to risk settings that are characterised by an ability to assign probabilities to specific incidents and outcomes (Gifford et al., 1979). As a result, proposition 4 on the turning point of concept shifting can be seen as a critical juncture between *exploring* and *normalising* that have different uncertainty and risk decision making settings.

These findings are in line with prior studies such as O'Connor and Rice (2013) which highlight the impact of uncertainty types such as technology-, market-, organisation- or resource-driven uncertainties, particularly in the context of radical innovation projects. This aspect also received attention in related research streams such as entrepreneurship, that address the role of uncertainty settings on the emergence process of new ventures (McMullen & Shepherd, 2006; Turcan, 2018).

Extant findings further indicate that *narrow scoping* during *normalising* not only refers to a reduction of the scope of a product concept but also to its de-radicalisation, meaning that as a result of *normalising*, not only is the scope reduced but also radical product concept components are eliminated. Very little was found in the literature on this de-radicalisation in early development (Christensen, 2013) leading to the fifth proposition:

***Proposition 5**: Normalising leads to a reduced and de-radicalised scope of a product concept to ensure its implementation.*

De-radicalisation means that the radical nature of the product concept is reduced by removing or replacing radical technological features or business model options through less radical options. Even though the radical potential might in the end be more exploited than during its initiation (see also Figure 55 below), a considerable de-radicalisation compared to the peak of the *exploring* phase could still be observed.

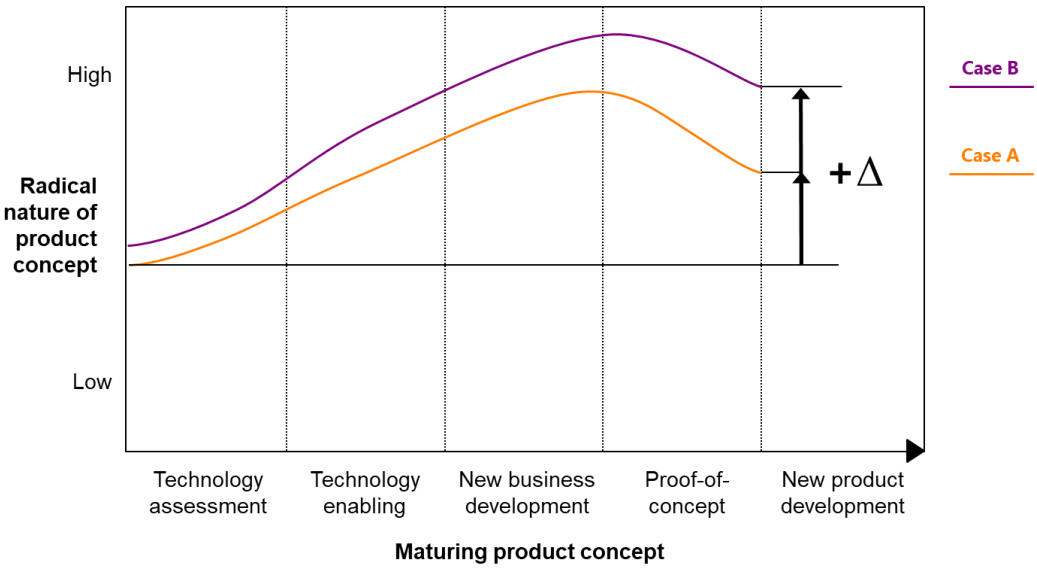

Figure 55. Radicality pattern - exploring radical potential

These results suggest concept shifting introduced by Seidel (2007) might not just be extended along the temporal dimension to pre-development. In fact, results point to shifting for radical product concepts occurring alongside a radicalness dimension. Potential explanations might again refer to the shift from uncertainty to risk decision-making settings that ask for a reduction of associated risks through reduction of the scope i.e. reduction of radical product concept components. Furthermore, it is seen as a process to implement and integrate a specific practice in its social and organisational settings. It appears that by reflecting on normative and structural constraints of an organisation, *normalising* provides an adequate pathway to secure internal/external alignment as well as legitimisation to ensure continuation and ultimately implementation of an NPD project towards the end of pre-development. As a result, findings support the so far purely theoretical concept

of Florén and Frishammar (2012) about idea and concept refinement, alignment and legitimisation to attain a corroborated product definition.

Moreover, these findings suggest a further key contribution to the broad research field on NPD, leading to two additional propositions that refer to a different view on NPD processes and a broader meaning of *normalising* when it comes to *Scoping* and implementing a new radical product concept on a corporate setting:

> ***Proposition 6****:Normalising is a bridging step between exploration and exploitation (implementation) of a new, radical product concept.*
>
> ***Proposition 7****: A new product concept is defined and implemented in three distinct NPD phases: exploring, normalising and exploitation (implementation).*

As outlined in the findings chapter on *Normalising* (5.2.3), this step can be characterised as a set of adaptation measures to align and legitimise the concept within the existing corporate and industry context by bringing the envisioned product concept scope in line with internal as well as external stakeholders. In that regard, it may be seen as an intermediate step to carry over the product concept from an early development phase to formal product development and implementation, depicting an adaptation process at the interface between an exploration (early phase) and exploitation (product development) (He & Wong, 2004).

In contrast to earlier research that just recognises these two distinct organisational phases/set-ups (Birkinshaw & Gibson, 2004; Duncan, 1976; March, 1991), these findings suggest three steps to conceptualise new radical product development in a corporate setting; *exploring*, *normalising* and *exploiting* (implementing) (Figure 56).

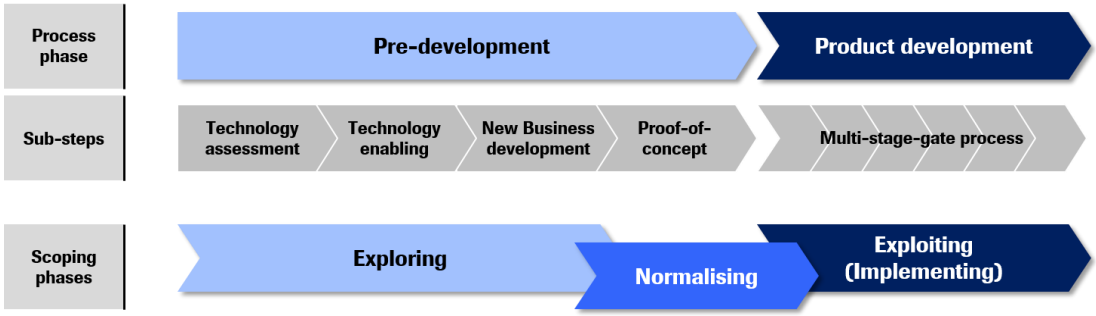

Figure 56. NPD process steps incl. *normalising*

Taking the above into account, one can summarise that the temporal dimension of *Scoping* provided several contributions to research, comprising aspects such as a constant adaptation of a novel, radical product concept over the course of pre-development. This adaptation process includes a phase of *exploring* (*wide scoping*) as well as a subsequent transition to *normalising* (*narrow scoping*) following a turning point that can be observed with the initiation of the proof-of-concept sub-step. *Concept Shifting* (Seidel, 2007) is extended with regards to the point at which the shifts start. In addition, for radical innovation projects, a proposition is made on the nature of shifting and its velocity in specific phases such as *exploring* or *normalising*. Furthermore, *Scoping* provides a new view on interrelating pre-development with the sub-sequent development or implementation phase of NPD, positioning *normalising* as an intermediate step between the exploration and development phase to ensure continuation and ultimately implementation of innovation projects in corporate settings.

Besides the temporal dimension to characterise the core-variable *Scoping*, a further capability dimension was identified. This capability view shall be outlined in more detail in the next chapter.

5.3 Capability dimension of *Scoping*

Besides the temporal dimension of *Scoping*, the capability perspective was found to be a further key dimension to elucidate associated dynamics. In this context, capabilities refer to a broad set of knowledge, skills and routines that come into play in the course of a newly emerging product concept under uncertainty. The capabilities that were identified during the within- and cross-case analysis of the two embedded cases can be assigned to two specific types of capabilities, *substantive capabilities* and *dynamic capabilities* (Figure 57).

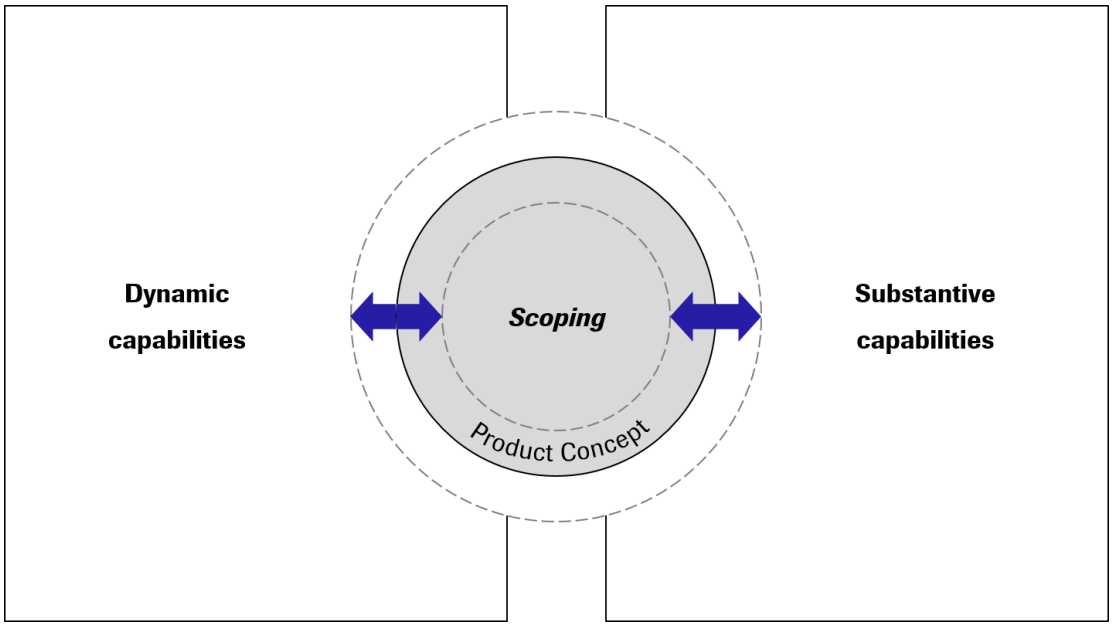

Figure 57. Dynamic and substantive capability view on *Scoping*

Substantive capabilities can from an ability perspective be seen as a set of established abilities that are utilised to reach a specific, desired outcome (Turcan & Juho, 2016; Winter, 2003). In the context of this research study two key *substantive capabilities* were identified, (a) acquiring resources and (b) creating a (positive) sense of support. Building on these, the second type can be considered as organisational abilities to go beyond the substantive capabilities, referring to an organisational ability to build up new capabilities in a creative way and to also integrate these in the context of new product development. In that sense, the ability to have (a) knowledge and capabilities available as well as being able to (b) creatively interpret the research context are two key examples of *dynamic capabilities*.

Data from both case studies showed that these two types of capabilities cannot be explored independently. Indeed, both types have an impact on the capability dimension of *Scoping* and need to be considered in an integrated way. Next, each of the two capabilities (substantive as well as dynamic) shall be outlined in more detail before depicting the findings in the context of existing capability research in NPD.

5.3.1 Dynamic capabilities

Dynamic capabilities form a key element of *Scoping*. This dynamic aspect of capabilities refers to a team's or management's ability to build up and integrate a diverse, novel set of knowledge and skills. An organisation can capitalise on diverse functional backgrounds, such as technology research, marketing or medical and scientific affairs, that are available internally or externally.

In the context of this research study, this particularly applies to *dynamic capabilities* that, on the one hand, cover the team's ability to subjectively have the right knowledge and skills available to explore the radical potential of a new technology. On the other hand, the ability for a creative interpretation of the development context forms a further key element (see also Figure 58).

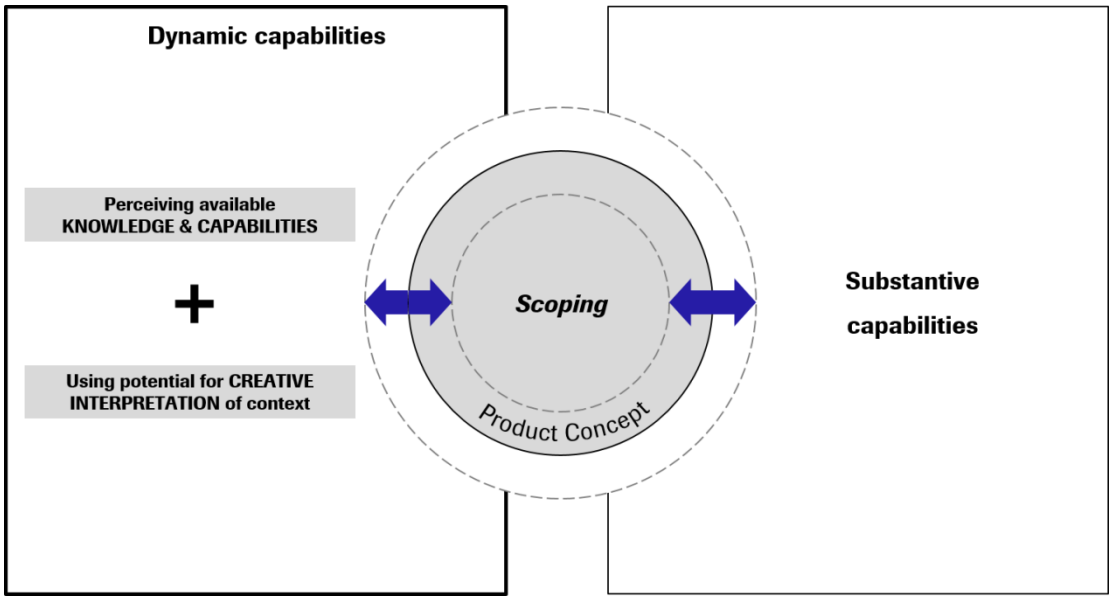

Figure 58. *Dynamic capabilities* affecting product concept *Scoping*

These two elements help to understand how *dynamic capabilities* influences the NPD process through the extension of existing or the creation of new knowledge,

skills and capabilities that in some cases replace existing organisational capabilities. Findings suggest that these capabilities are required to allow an organisation to tap into new technological, medical or business areas when exploring the radical potential of new product concepts and components.

Furthermore, there is also a creative side to *dynamic capabilities*, meaning that aspects like curiosity, ability to improvise but also openness to external inputs are key when interpreting the context of NPD. Findings suggest that these aspects are particularly important in the initial *exploring* phase to deal with unknown and unpredictable uncertainty decision making settings.

Next, both dynamic elements including their indicators are outlined in more detail.

5.3.1.1 Perceiving available knowledge and capabilities

A first element of the capability dimension of *Scoping* is related to "perceiving available knowledge and capabilities" to build *dynamic capabilities*. This availability refers to knowledge and capabilities required for new product development and in reach of the development team. In this context, availability means a subjective perception of a development team or a single individual that appropriate knowledge as well as capabilities are available. Thereby availability does not terminate at the borders of a team, a functional/business unit or even a corporation. Relevant knowledge may include practical as well as theoretical knowledge about a technology or a market, whereas capabilities refer to an individual's or entity's ability to integrate and make use of skills and competencies to develop innovative solutions.

In this context, several indicators were extracted from the data that characterise and have an impact on "perceiving available knowledge and capabilities":

- Utilising established knowledge & capabilities
- Extending established knowledge & capabilities
- Building up new knowledge & capabilities
- Making external knowledge & capabilities available

These indicators describe a first set of necessary conditions to make use of *dynamic capabilities*. In addition, this contextual element forms the basis to explore the full radical potential of the technology and eventually expand the product scope.

INDICATOR 1 – Utilising established knowledge and capabilities

This indicator refers to the perceived availability of knowledge and capabilities that already exist within an organisation, for example in the areas of customer and medical/clinical knowledge. A research participant from product management highlighted this by **referring to the market and clinical knowledge** he was bringing to the team in the context of specific indications such as drug-of-abuse-testing:

> *"…well, already very early on, in fact in the role as product manager that I was in for Drug-of-Abuse-Testing and for Therapeutic-Drug-Monitoring at that time,[…] there I got dragged in along the lines, in the sense of, hey listen to that, what do you think?" (M8 - translated)*

This applies not only to medical and market-specific knowledge but also established knowledge and capabilities in various domain-specific fields ranging from knowledge on regulation and technology to pure methodological capabilities. This established knowledge appears to be very important as it forms the basis for additional knowledge and capabilities that later on accrue during product definition. In addition, it informs decision making in an early phase of product definition.

INDICATOR 2 – Extending established knowledge and capabilities

A further identified indicator in the field of a perceived availability of knowledge and capabilities concerns the ability of the team to actually build on and extend already established knowledge and capabilities. Such resources may be used effectively if the teams believe in the potential of their existing expertise and utilise it to develop it further. A research participant commented on this key aspect in the context of technological expertise:

> *"…marker assessment, development of reference methods for clinical chemistry, hence reference methods for clinical chemistry applications is one of the core-businesses of the department for ages. In that regard we are indeed familiar with*

the use of methods in diagnostics but have once more intensified this." (M2 - translated)

The statement above suggests that this applies to fields like reference method development that are already well-known but it can also apply to adjacent areas that are closely linked to established fields of knowledge and capabilities. A research participant who had led several new technology projects illustrated this process of knowledge building:

"…but it is specific for XXX (technology name removed for confidentiality reasons) because we make a new technology accessible for us, for an established market segment that we already cover. It is simply the fact that we need to build the organisation for it, that we establish the processes and the knowledge for it and we have already initiated this now." (M6 - translated)

In essence, the teams are able to explore the scope of a new product concept if amongst other aspects they believe that by **extending the already established knowledge and capabilities there is plenty of new things out there to tap into**; either by simply extending the already established knowledge and capabilities or by enlarging them to adjacent areas so that they can exploit this potential.

INDICATOR 3 – Building up new knowledge and capabilities

Particularly in the context of new technology projects, the perceived availability of knowledge and capabilities in new domains seems to be an important indicator for *Scoping* a product concept. This means that novel knowledge and capabilities may be built up within the organisation/team during the emergence process of a novel product concept. This knowledge creation happens to take place in a "learning space" as one research participant called it.

"This goes into the direction that we indeed, from my perspective, well it is, I call it a bit overstated "learning space" for the organisation. […] Because different global organisations have to date, prior to this have not dealt with this subject before. (M6 - translated)

This "learning space" seems to build the foundation to explore new things, be it in a business, technological or further area. In the context of technology research for example, a senior R&D expert expressed this "learning space" and the ability to build up specific cutting-edge knowledge as an experimentation field:

> *"We then actually had concepts ready within R&D that we had already developed in multiple, diverse technology projects. […] we provide technology for highly diverse R&D issues and we rely on the fact that we are technology-wise always one step ahead, we are at the forefront of state-of-the-art." (M2 - translated)*

A further characteristic that was brought up in this context is the **process nature of building up novel knowledge and capabilities**. An R&D expert highlighted this gradual, longitudinal process by stating:

> *"…this proof-of-concept phase is actually just possible because one has already dealt with the technology before and let's say related adjacent issues for years. Worked in the pre-investigations in the end." (M2 - translated)*

And this process might take longer particularly if the technology or market has not been fully explored.

In general, it emerges from the data that the ability of an organisation or a team to build up specific new knowledge and capabilities is an important indicator to what extent they are able to exploit the radical potential of a new technology and successfully integrate it into the product concepts.

INDICATOR 4 – Making external sources of knowledge and capabilities available

The fourth and final indicator to evaluate the perceived availability of knowledge and capabilities opens up the horizon of so far purely internal expertise to the broad external world. This indicator refers to the availability of not just internal but also external sources when defining a product concept. Amongst others a research participant who is a technological expert opened up the space of indicators to external kinds of knowledge and capabilities when reporting on a workshop that included external guests:

> *"At that time the colleagues from Business Development were invited as well from XXX (location deleted for confidentiality purposes) and these were well represented for that topic. And that was the opportunity to in just three days completely condense the world of XXX (technology name deleted for confidentiality purposes) in diagnostics. And the good thing about it was that we had external experts there." (M2 - translated)*

In addition, he highlighted the added **value of bringing in external experts** to have access to external knowledge and capabilities specifically to gain insights into technological potentials:

> *"Some of the external attendees were actually really people who earn their living with XXX (annotation: technology name disguised for confidentiality purposes), […] That's when one got a feeling for the potential of it." (M2 - translated)*

As a result, the enrichment of in-house knowledge and capabilities with external expertise seems in both cases to have a beneficial effect when exploring the scope of a new, radical product concept. This not only applies to technological areas as indicated above but also to further areas like medical or regulatory affairs as well as market insights. Accordingly, a project lead commented on a more formalised way of engaging with external stakeholders via the sales organisation:

> *"There are many aspects that one can fob off, where we would instead have run into danger to stew in one's own juice. And the best thing about it is that we have done all that without any budget, we have the access (annotation: to customers) through the Sales department and you would be surprised how interested some customers are to contribute to new topics." (S5 - translated)*

Likewise, a business representative commented on it, stressing also the sometimes informal character of external liaisons to have external expertise available quickly.

> *"…what I do anyway is that I have still a few customers in the Netherlands that I know really well and that I can always involve. For instance, we once had a question regarding the XXX (product name deleted for confidentiality purposes) with the ICU and the use of blood types. […] so I quickly texted a message to a friend. I asked what is the reason why you prefer arterial blood over venous blood? About 15 minutes later I received his answer, that's the kind of interaction and also the kind of pace we need." (S7)*

Taking the aspects mentioned above into account, it can be concluded that opening up the available body of knowledge to external sources forms an integral part of the dynamic capability set an organisation has available or is able to build in the course of early new product development.

The following graph provides a summary of all four indicators of the dynamic capability element of perceiving available knowledge and capabilities (Figure 59):

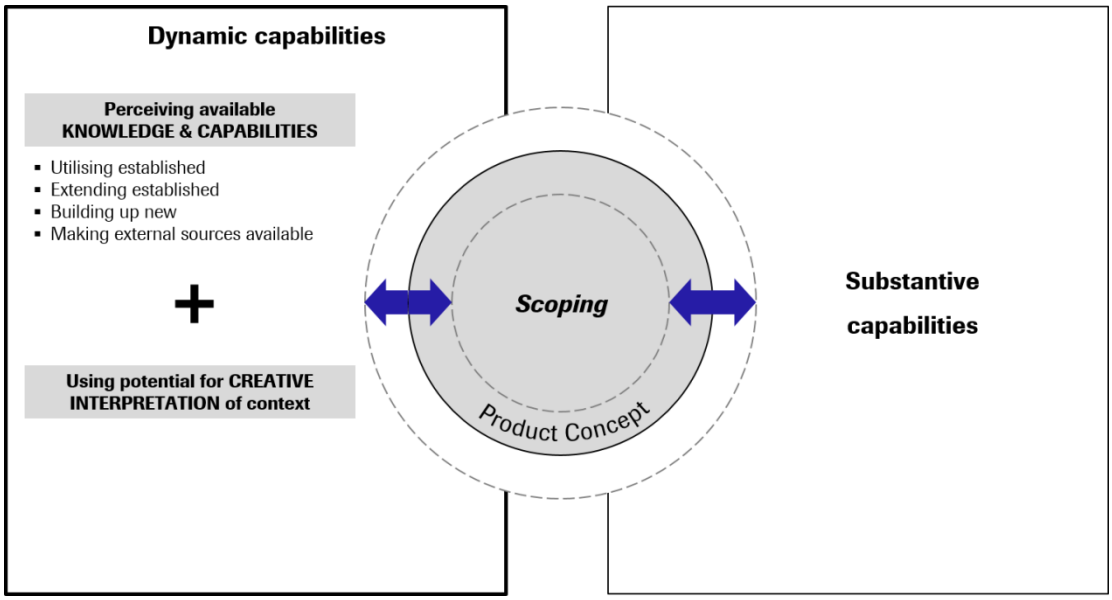

Figure 59. Indicators characterising "Perceiving available knowledge & capabilities"

Overall, in an early phase resources might be used effectively to build *dynamic capabilities* if internal as well as external knowledge and capabilities are available. In this context "available" refers to existing, extended or totally new knowledge and capabilities that are built up and utilised throughout this process. As research participants from both cases reported, this dynamic capability aspect also shows that a "learning space" builds the framework for the ability to have an internal as well as external body of knowledge at hand that is needed to scope a product concept. In addition, these findings suggest that a theoretically perceived availability of knowledge and capabilities forms the basis for tapping into new, innovative areas.

5.3.1.2 Using potential for creative interpretation of context

In the context of *dynamic capabilities*, the potential for a creative interpretation of the development context is identified as a key influencing factor. Whereas the previous element regarded the general, subjective availability of knowledge and capabilities, whether internally or externally available, this second capability element of *Scoping* refers to a team's ability to use the potential for a creative, flexible interpretation of the development context. This includes internal aspects

such as corporate procedures as well as external aspects like regulatory requirements.

As the phrase “creative interpretation” implies, this element of product *Scoping* involves certain creative powers on new product development. Such creativity allows the team on the one hand to use the freedom within existing boundaries and on the other hand to deviate from “established routes”, pushing the boundaries of the development context through constantly challenging the status quo. This in turn provides the development team with an increasing freedom to open up new approaches to radical product development as well as to explore new product concept components.

Overall, this dynamic capability element of *Scoping* can be further characterised by the following three indicators that emerged from data of the two embedded cases:

- Interpreting corporate procedures differently
- Engaging stakeholders in non-traditional ways
- Interpreting regulation creatively

These indicators form the basis for getting to the bottom of dynamics involved in *Scoping* a new radical product concept. Subsequently, they will individually be explained in more detail.

INDICATOR 1 – Interpreting corporate procedures differently

The first indicator makes the creative interpretation of corporate procedures such as internal processes or policies its main subject. This means that on the one hand the available flexibility offered by procedures is fully exploited. On the other hand, creative approaches may be employed to **push the boundaries of these procedures** to extend the scope of a new product concept. This specific situation of interpreting corporate procedures differently to not follow established paths, was described by a research participant in the following way:

> *“Well, I believe the main challenge is that such a new development of a system can’t follow a standard procedure in our company.” (M1 - translated)*

It appears to be necessary to follow new ways for new, radical product development by adapting, for example, internal procedures; a research participant from Business Development stresses that:

> *"This is not exactly the same way as we have done it before. We consciously want to be different here. For that reason, it is for example an opportunity to be faster. We, so to speak, don't have to operate outside of the DCC (annotation: DCC stands for the internal development process "Design Control and Commercialisation") we don't have an Immuno-Assay-DCC but we have and need a XXX-specific DCC (annotation: product name disguised for confidentiality purposes). For this we need to somehow think differently. Yes, this is a kind of opportunity and this is the way we tried to address it." (M5 - translated)*

The teams are trying to think differently, utilising the potential radicality of the product concept to also **challenge the status quo of established corporate procedures**. In this sense the product radicality triggers an often not fully documented flexible interpretation and sometimes even a change of such procedures e.g. to increase customer proximity or to increase the speed of early radical product development. A marketeer commented in this respect:

> *"Yea and then just, we challenged the current state of the art. Say, can we do it better? Is there another way of doing it? What does the customer really want to do? […] And you know, you may not find it absolutely documented to the n-th degree." (S6)*

Another example in that context refers to a flexible interpretation of the development processes by changing the original sequence of process steps or establishing new sounding boards as part of the project organisation. A research participant reported for example the shift of a key milestone or activity to have a first prototype available much earlier:

> *"…because it is a system project the milestone breadboards are brought forward. This is done more just for us because we see a need for that for a long time. […] Officially, we would not need that at the current point in time but for that we take the freedom". (S4 - translated)*

Changes like that indicate that the teams were critically reflecting on the impact of established corporate procedure on a team's ability to explore the radical potential of a product concept and that they were able to creatively interpret procedures in manifold ways to make them fit better to this specific project type.

INDICATOR 2 – Engaging stakeholders in a non-traditional way

Unlike the first, more formal, indicator on *dynamic capabilities* concerning corporate procedures, this indicator refers to the more interpersonal, social aspects of engaging with key stakeholders in the context of the new product concept *Scoping*. In this regard, the indicator comprises aspects such as creative ways of how to approach and involve stakeholders in the first place, utilising unconventional ways of arousing interest but without raising at the same time concerns.

In terms of different ways of engagement, the teams seem to build connections through multiple channels; either formally, for example through the establishment of novel boards, but also informally. As part of Case A, a novel technology sounding board was formally established to involve various other R&D functions early on that might either contribute or just be affected by the new product concept.

> *"…the formal R&D core team was extended by an expert review team that was (a) providing input on technological questions and (b) allowing to informally involve key stakeholders within the R&D community. Otherwise the opponents of such a new thing are successful in hindering or better say thwarting; you simply don't get the support you need."*

The **informal engagement** mostly took place through personal one-to-one sessions or in small group meetings that can be characterised as private, safe and protected environments. A marketing manager referred for example to a key lunch meeting at senior management level:

> *"We need to have a clear set of key topics in mind especially when it comes to applying the business rules and approaching the management team. For example, the COGS will limit ourselves in implementing every feature the customer might ask for. The project lead will have a lunch meeting with some of the DLT members (Annotation: DLT stands for Divisional Leadership Team) in the next days, which will bring a lot of clarity, this is the most important filter step. We need to wait until then. At least this is what I believe." (S8)*

A further example that illustrates the informal but also **creative engagement with key stakeholders** is the promotion of the development project as part of an idea contest. That way a broad audience was directly involved in shaping the product concept which, on the one hand, helped to promote the new product concept but at the same time new ideas were collected from a broad group of people.

"…conducting interviews with different people, well partially with Life Cycle Leaders, with representatives from the regions and in that year we also had a little idea contest where different new ideas came up." (M5 - translated)

The second element of this indicator was primarily driven by the key messages the teams were communicating but also through the **careful wording** of these. Its aim is **to create interest in the new product concept**. Through conscious messaging the teams tried to carefully balance raising attention to the topic on the one hand but at the same time avoid excessive concerns. A research participant from Business Development illustrates this with an example of fostering a certain anxiety through a business assessment on which portion of the existing sales might be at risk through competitors entering the market with the new technology. At the same time, this negative message is combined with the positive perspective of also showing the future market opportunities that are associated.

"Also causing a bit of anxiety, is what one needs to work with. Yes, one sometimes needs to pull up big numbers to push some things forward. […] this was also to show if we do nothing, decide not to assess it at all. This particularly applied to the early phase, there I said basically if one looks at what labs are doing with XXX (annotation: technology name disguised for confidentiality purposes) then this portion of the business may be affected. […] such threatening scenarios but also which future markets we are missing; for example vitamin D in the US. (M5 - translated)

This tactic was not just applied to the business side of the product concept; from a technical perspective this **interplay of fear<>safety, loss<>opportunity or uncertainty<>certainty** is used in messaging stakeholders to raise their attention as well as to ensure their support. A project leader illustrated this by outlining the example of a freedom-to-operate-assessment (FTO) in the context of Intellectual Property (IP). This way certainty and confidence increased in the early phase, which is characterised by a high degree of technological, regulatory and market uncertainty.

"When talking about IP: We did first assessments then, now it is all about, I call it creating a bubble where we are not vulnerable, so that we can run our future business and are not vulnerable at all or the least possible." (M6 - translated)

However, this aspect of engaging with stakeholders is not just limited to the specific content of a message, it also comprises the way stories are phrased. In the context of business model scenarios for example, novel product concept features were

often introduced with the supplement that one is already familiar with it and that this aspect is not new to the corporation.

> *"…and then there was this other topic I already touched upon earlier, more related to the business model. Really to tell people, you know this and this is nothing new for you." (M5 - translated)*

Furthermore, even the perceived meaning of a single word, be it positively or negatively connoted, might play an important role in this context. A research participant illustrated such different meanings with the example of the expression "disruptive" which was used initially to emphasise the huge potential of the new technology. Since this expression was internally perceived with a negative connotation, the team replaced it with the term "transformation" which seemed to have a more **positive, proactive and forward-looking association**.

> *"That's why we later on stopped calling it disruptive but rather a transformation instead (smiling)." (M5 - translated)*

This example as well as the ones stated above, illustrate that creative ways to involve stakeholders as well as the messaging and wording appear to have an enormous impact on how stakeholders can be engaged on different hierarchical levels. In addition, particularly in the context of radical innovation, it seems to play a superior role on how a new product concept is perceived within an organisation.

INDICATOR 3 – Interpreting regulation creatively

The third and last indicator, characterising the potential for a creative interpretation of the development context, refers to the regulatory framework in which a radical product concept is developed. When teams manage to **use the free space that formal regulation offers**, they will be able to exploit the radical potential of the product concept further. Be it the full utilisation of the solution space that is available based on already effective rules and regulations or the additional free space that needs to be created, for example through a **new interpretation or even modification of rules and regulations**.

In the context of making use of the free spaces of currently effective rules and regulations, two research participants from requirements engineering described this creative flexibility in the following way:

> *"M9: Well, I once met someone from a railway company who told me that they already get more than 4.000 requirements defined externally. We in the end get from FDA for IVD only a few concrete requirements. I believe the reagent folks may have a few more because they have to deliver some statistics […]*
>
> *M10: Bottom line, you need to specify and define a process for development beforehand and afterwards you show that you have followed it, that you have evaluated and documented deviations." (M9 & M10 - translated)*

But even when going beyond this already available freedom, this indicator also comprises aspects in which the current interpretation of rules and regulations is challenged, where an adaptation or even new interpretation is evolved allowing further exploitation of the scope of a new product concept. In this context, a novel approach for calibration and control measures was highlighted by several research participants as part of Case B. This novel approach seems to be a truly radical aspect of the novel product concept, resulting in a fundamental shift in operating principles and accordingly a change of relevant regulation. A marketing expert described this in the following way:

> *"When we looked deeper into some of the regulatory requirements we for example identified the whole area of calibration and control measurements as really critical. Well, the current regulation is favouring a let's say batch-wise measurement but we rather envision random access for XXX (annotation: product name disguised for confidentiality purposes) to increase flexibility but also optimise throughput. […] After lots of internal discussions we did a workshop to brainstorm potential solutions or let's better say workarounds. […] (pause) In the end we then said, let's build two scenarios, scenario (a) the classical approach, let's stick to the rules as we apply them now and (b) let's interpret regulation in a slightly different way to make the random access possible. We currently don't know if it will be accepted in the end but we try to do it this way for now. After all, with scenario one we have a solid fall-back-solution already in place. […] Let's see how things move on. At least we managed to get in touch with FDA to discuss our proposal and new ideas. That's already a good sign because they have been quite open so far. It is definitely worth pursuing this initiative and let's see how far we can get. (M7 - translated)*

Taking the above into account, it can be concluded that regulation marks an important part of the development context that should not be seen as a limitation to new product concepts. In fact, scrutinising and creatively interpreting existing regulations may be a promising lever to come up with new interpretations of rules

and regulations that allow for an exploration of the radical potential of a new product concept.

The following graph provides a summary of all three indicators of the dynamic capability element of using the potential for a creative interpretation of the development context (Figure 60):

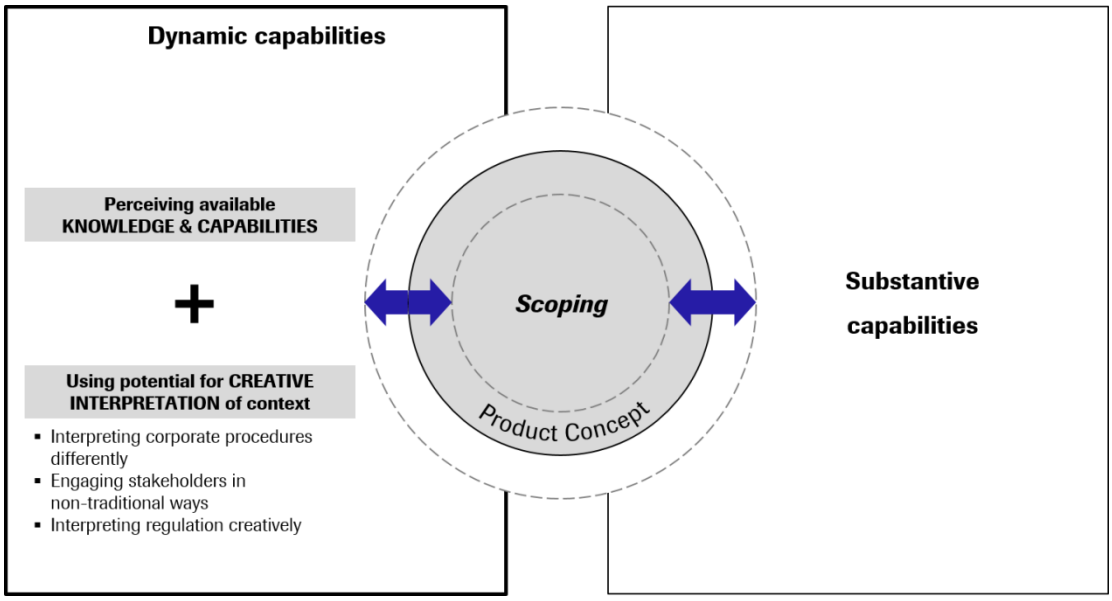

Figure 60. Indicators characterising "Using potential for creative interpretation of context"

Overall in an early phase, the new technology as well as R&D context appear to play an important role when *Scoping* a new product concept. To use the available scope for development and to fully exploit the radical potential associated for example with a new technology, a team's mindset and creativity play a significant role. Such creative interpretation of the development context may be relevant in different fields, including corporate procedures, the engagement of internal as well as external stakeholders and, last but not least, relevant domain-specific regulation.

Besides the dynamic aspect of capabilities, the established set of substantive capabilities forms the foundation of a portfolio of organisational capabilities in the context of new product development. Therefore, the next section builds on the concept of substantive capability and investigates to what extent substantive capabilities are required to make the expanding power of dynamic capabilities come into force.

5.3.2 Substantive capabilities

To cover the capability dimension of *Scoping* in a holistic way, data points to the role of *substantive capabilities* in early development. This element of *Scoping* is important as it addresses the role of established capabilities to reach a given goal.

This study addresses the substantive nature of capabilities in **resource acquisition as well as an organisation's ability to create a positive sense of support** for a new, radical product concept. Several indicators in both areas were identified to further characterise the substantive nature of capabilities. For the acquisition of resources, indicators comprise for example the ability to access external resources or to involve resources informally. Besides this, the ability to create a (positive) sense of support includes aspects such as individual and team dynamics as well as taking external influences/stimuli into account.

Figure 61 illustrates the interplay of the two *substantive capabilities* as well as the substantive side to the product concept *Scoping*. Findings also suggest that *dynamic* and *substantive capabilities* must not be treated as two isolated aspects of the capability dimension. They are interconnected in the sense that firstly *substantive capabilities* are needed to implement and make use of *dynamic capabilities*. Secondly, newly built *dynamic capabilities* can in a process of adoption gradually become part of the substantive capability set of an organisation.

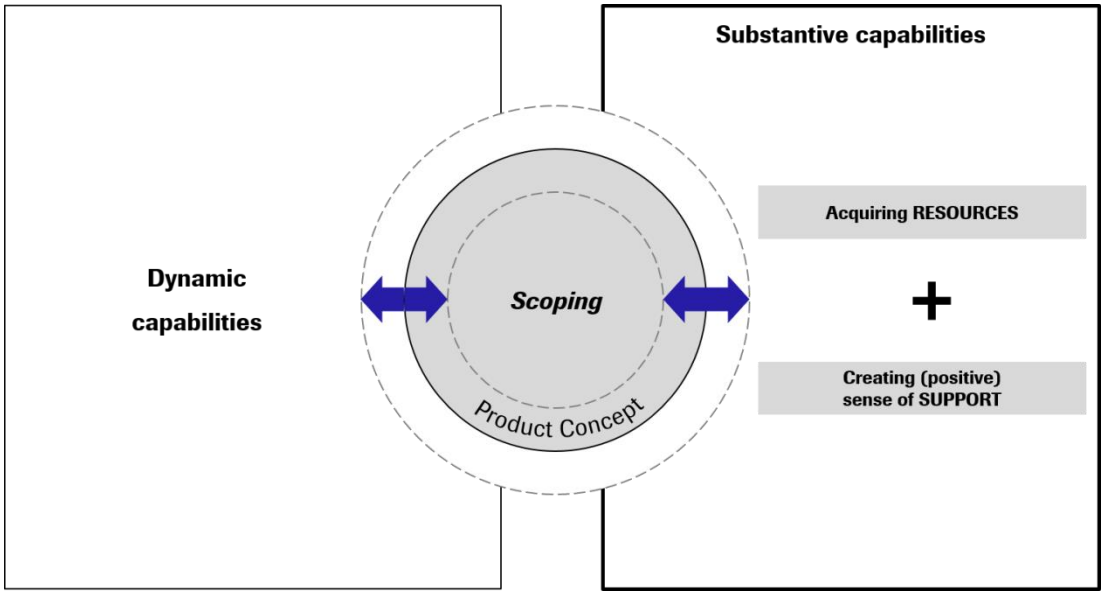

Figure 61. Effective use of scope for development as dimension of product concept *Scoping*

5.3.2.1 Acquiring resources

In the context of *substantive capabilities*, *acquiring resources* was identified as one of two key elements. In that sense, the term refers to a team's *ability to acquire resources*, meaning the actual acquisition of available resources to make use of the *dynamic capabilities*. This acquisition of resources comprises monetary aspects such as ensuring sufficient funding but also non-monetary, informal aspects allowing the team to access resources e.g. ad-hoc or on a temporary basis. Overall, this property is characterised by the following four indicators that were identified in the course of the research study:

- Ensuring sufficient funding
- Accessing external resources
- Balancing cross-functional composition and integration
- Involving people informally

These indicators and the attempt to define the aspect of *ability to acquire resources*, highlight the immanent interrelation of the two resource based properties "Acquiring Resources" as well as the dynamic capability element of "Perceiving available knowledge and capabilities".

<u>INDICATOR 1 – Ensuring sufficient funding</u>

This indicator refers to the financial side of new product development, meaning that certain monetary funds are required to conduct the work related to *Scoping* a new product. On the one hand this primarily includes formal ways of funding e.g. via an official budget for project work. In that regard, associated hours of work or other investments need to be charged to a specific project budget. If those funds are insufficient or even lacking, then certain expertise would not be drawn on, even if theoretically available. A product manager described this need for resources to ensure sufficient functional input as follows:

> *"…in the initial phase MSA (annotation: MSA stands for Medical and Scientific Affairs) was very, very much involved in the initial phase. At the moment however due to the given resource scarcity, they simply cannot deliver the input as it would be required." (M8 - translated)*

On the other hand, one additional aspect of funding emerged from the comment of a senior technology expert:

> *"…what is for example running as a technology enabling project. We have initiated separate TMB projects (annotation: TMB stand for a technology board) to look at and assess different technologies. In that case some IP (annotation: IP stands for Intellectual Property) came about. […] and one has to say, without this preparatory work that started long before the actual XXX (annotation: project name disguised for confidentiality purposes), we would not have been able to close that gap." (M2 - translated)*

Statements like this suggest that besides the official, formalised way of funding, individuals and teams also **explore alternative ways of funding**. As stated above, alternative resources may for example be acquired under the pretext of IP generation in a specific field. In addition, separate, ring-fenced budgets e.g. for technology enabling are tapped into, to ensure sufficient funding for new knowledge and competencies that are required to develop new products.

<u>INDICATOR 2 – Accessing external resources</u>

The second indicator opens up the scope of resources beyond what is available within a single corporation. These additional resources may span a broad range of opportunities including, but not limited to, external partnerships with research institutions or co-operations with suppliers to access further knowledge and capabilities (co-development). A project lead highlighted this external collaboration by stating:

> *"And we have then relatively early used this setup, to establish a so called Joint-Project-Team, a common expression that we use when we work together with XXX (annotation: name of partner disguised for confidentiality purposes).[…] Yes, this team still exists and it will hopefully be in place onwards." (M6 - translated)*

This need, to access external resources, goes back to the initial, general point and first aspect of *dynamic capabilities* that new knowledge and capabilities might be required when dealing with a novel product concept that builds on new technology. To fully explore the radical potential that might be associated with novel

technology, it is important to access the best resources available, whether they originate from inside or outside a corporation. A research participant explained that with the words:

> *"Well, I have a quite neutral view on that. Of course one is emotional, one prefers to work with internal people but one needs to use one's brain and we need facts to analyse. We need the best as partners." (M6 - translated)*

During the research encounter in the context of partnerships he also highlighted always striving for the best resources available and to look for partnerships where ideally the expertise of partners complements each other.

> *"…in our case that are for example different partnerships, if one has taken a wise decision then competencies complement each other in an optimal way and that then means that one plus one equals more than two. One needs to manage each one in a specific way, that is then the art of project management I would say or the essence of partner management." (M4 - translated)*

As outlined above in Case B the team partnered with a company that has specialised in the automation and instrumentation of diagnostic devices and instruments. In that case the engineering and manufacturing capabilities for hardware and software are combined with the biochemical and medical expertise of the organisation under investigation. If properly managed, such access to external resources appears to have a positive impact on the overall effective use of resources.

INDICATOR 3 – Balancing cross-functional composition and integration

The third indicator reflects that the acquisition of resources goes beyond pure monetary aspects. In fact, it is also about a well-balanced composition of functional disciplines and a proper integration of these in a team. As one research participant put it, particularly for new, radical product concepts that build on new technology a holistic view on the topic is key:

> *"The novelty of the future product to the customer as well as to the XXX organisation (anonymised for confidentiality purposes) required a holistic assessment of the product concept incl. marketing, R&D, regulatory, operations, service, etc." (M3)*

This holistic view on the topic seems to match with a diverse, cross-functional composition of domain expertise in the teams. The comment below illustrates this explicit need from the perspective of a requirements engineer as well as implicitly from the perspective of an international liaison manager who experienced a severe lack and imbalance of cross-functional integration within Case A. The requirements engineer on the one hand illustrated the need for a diverse interplay of knowledge and capabilities with the example of making the later implementation of the product concept work. To ensure this, different sets of expertise and functional perspectives seem to be required:

> *"Team members look at a new product from different functional perspectives and with different background knowledge. Be it a different level of knowledge or a different focus regarding the implementation." (S10)*

The liaison manager on the other hand highlighted this need by illustrating the consequences of lacking cross-functional insights, which seem to result in missing out on certain essential considerations:

> *"Well, when we addressed the IT integration, there was no representative available, these topics were then simply excluded. One can by implication say that one needs to pull together an adequate team to describe a product concept conclusively". (S9 - translated)*

Moreover, for new, radical products that build on new technology R&D experts even highlighted on a more detailed level the need for a diverse, cross-R&D integration, suggesting:

> *"…not just cross-functional in the sense of Marketing to sit there and Regulatory or what ever, but rather cross-R&D" (M1 - translated)*

A further important characteristic of this indicator seems to represent the proper integration of these cross-functional resources. A research participant emphasised that it is necessary to go beyond the mere acquisition of certain cross-functional resources; it is in fact also about the proper integration of the individual "knowledge packages":

> *"This is a process of identification, honestly speaking such a group needs to converge initially; one also aligns mutual interests a bit this way." (S3 - translated)*

These comments suggest that the cross-functional element goes beyond the pure cross-functional composition of teams to bring together diverse sets of knowledge

and capabilities. In fact, this capability element covers the comprehensive integration of diverse functional backgrounds; a social process, a "process of identification" and convergence how one research participant phrased it, in which team members seem to combine resources and align interests by integrating different sets of knowledge and perspectives.

Taking the above into account, this indicator seems to comprise **several more social, informal elements of resource acquisition besides the pure formal aspects** of a cross-functional team composition.

INDICATOR 4 – Involving people informally

The fourth and last indicator, to involve people informally, addresses an important additional channel to acquire resources. It refers to *informal* structures, processes and approaches to ensure resources that have immediate access to people or just support on a temporary basis. Such informal measures seem to be an answer or a workaround for organisational issues that development teams seem to be frequently confronted with such as lacking functional support or long time-spans in recruiting new people.

In this context, a project leader clearly raised the issue that in an early phase small teams are lacking specific functional support:

> *"I think that applies to every team, that one cannot have experts for all kinds of topics at the table. Yeah and then the question is, how do I reach the point that I attain knowledge there?" (S5 - translated)*

A further project leader added to this challenge that even when an additional **resource is officially approved it still doesn't mean that the resource is available in a timely manner**; on the contrary, it may even take a long time to actually recruit this person for the team:

> *"Really fast access to people; this getting people in an organisation like ours can take easily half a year, up to one year." (M6 - translated)*

To meet this challenge, both teams tried to informally approach people to ensure sufficient resources. A research participant expressed this need for fast access and flexibility like this:

"No, don't get me wrong, particularly in the early phase where you want to be flexible and be able to put together a prototype quickly, just to get feedback, then it's fantastic when colleagues can give a hand promptly." (M5 - translated)

In addition, these informal structures help to ensure support for very specific, dedicated topics that also require access for a time-boxed period and not a permanent involvement in the development project.

"We have compiled the key topics so to say in a round that you have just described (annotation: means R&D plus International Product Managers). In addition, we have then involved further functions particularly Operations and GCS (annotation: GCS stands for Global Customer Support). […] But not to a high extent, not formalistic but rather short and clearly marked out; it was up to the instrument Development Lead and the GCS people and one of the IPM's who felt responsible for the instrument. But not in any kind of big, dedicated group." (S2 - translated)

This aspect is of particular relevance when it comes to making effective use of the *dynamic capabilities* an organisation might be able to build upon. Furthermore, by assigning, involving, terminating participation and re-assigning relevant people as needed, the team tries to balance on the one hand the need to have the required resources available and on the other hand to manage to keep the list of core-team members relatively small. This way, the team can move fast and maintain a high degree of agility at the front end of new product development. A marketeer stressed this need for agility and informal, ad-hoc involvement of certain experts by commenting:

"Yes, and what I do anyway is that I have still a few customers in the Netherlands that I know really well and that I can always involve. For instance, we once had a question regarding the XXX (annotation: product name disguised for confidentiality purposes) with the ICU and the use of blood types. Why do ICUs prefer arterial blood over venous blood? This was a topic I had an idea about because of the contamination risk but didn't know it for sure so I quickly texted a message to a friend. I asked what is the reason why you prefer arterial blood over venous blood? About 15 minutes later I received his answer, that's the kind of interaction and also the kind of pace we need." (S7)

As summarised by the four previously characterised indicators, acquiring resources takes place in manifold ways. Firstly, there is an individual as well as team perspective to resource acquisition, but also internal as well as external aspects play an important role in this regard. Furthermore, there is a financial as well as non-monetary side to an organisation's ability to acquire sufficient resources. In

addition, findings suggest that formal as well as informal aspects need to be considered during the early phase of new product concept development.

The following graph provides an overview of all four indicators of the substantive capability element, acquiring resources (Figure 62):

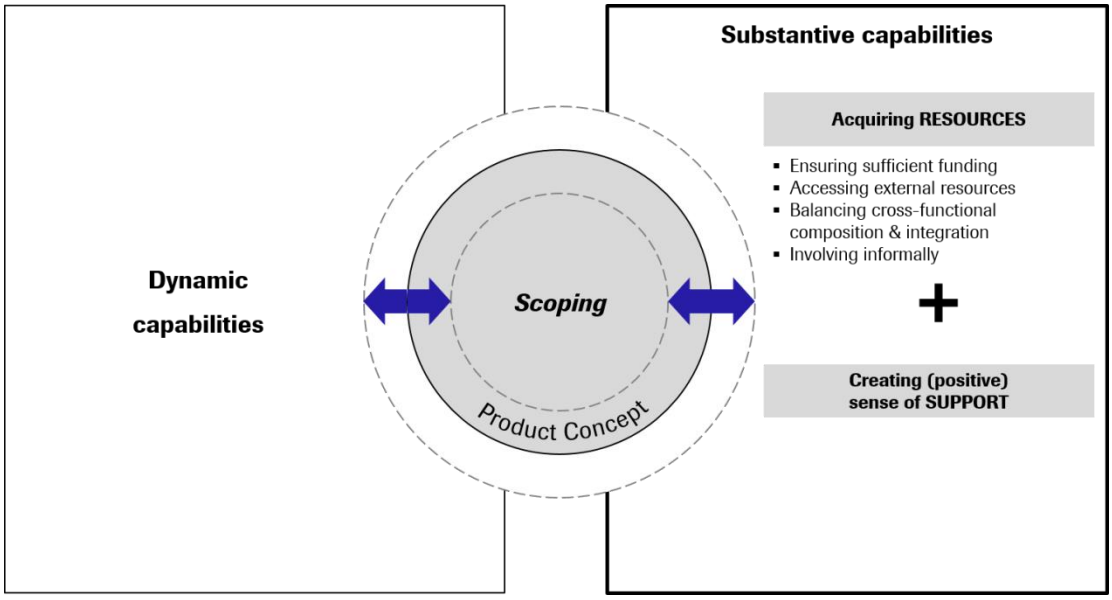

Figure 62. Indicators characterising "Acquiring resources"

Taking the above into account, one can summarise that the acquisition of resources is a fundamental substantive capability that allows resources to be used effectively. This suggests that only if a team manages to also acquire the available resources, can they be used effectively for *Scoping* a product concept. This way a team may be able to expand the scope of the product concept by exploiting the radical potential that may for example be associated with the novel technology.

Next, the second property of *substantive capabilities*, *creating (positive) sense of support* including its key indicators is outlined.

5.3.2.2 Creating (positive) sense of support

Based on the data analysis a *(positive) sense of support* is generally understood as a broad range of different kinds of stimuli that promote and encourage further action of team members. This support is perceived by the team as an internal

legitimisation and acceptance in the recurring steps of refining, aligning and legitimising a radical, new product concept.

Such stimuli may be expressed by different groups of people, be it single individuals that are part of the project team or key stakeholders within the organisation. Furthermore, external individuals or organisations like decision bodies (e.g. regulatory authorities) are also in a position to trigger further actions. Data showed that these groups can express their stimuli in manifold ways. Firstly, through the mere **absence of roadblocks** further actions can encourage in a non-obvious way. Secondly, accruing stimuli which can be characterised as **implicit support**. In this context, a simple agreement to let things slide may for example be seen as significant support for single individuals within the team. Thirdly, **explicit support** can be added to the list of ways of support.

Grounded in data, the concept of *creating (positive) sense of support,* is further characterised by the following three indicators that are subsequently explained in more detail:

- Building on individual and team dynamics
- Receiving management support
- Turning external influences to account

As a result, these stimuli may either trigger further pursuance of a chosen track or be seen as an encouragement to tap into new paths. In this context, management support can be explicitly mentioned as it is inter alia seen as a source to internally legitimise new ways of working. In that sense, this substantive capability facilitates the effective use of *dynamic capabilities*.

INDICATOR 1 – Building on individual and team dynamics

The first indicator of the property *creating (positive) sense of support* refers to support and encouragement that originates and evolves within an individual or a team. It embraces aspects such as individuals that are fully committed to the project and truly convinced of the opportunity that lies in the product idea. This

aspect became apparent when a researcher remembered the roots of the project and the strong individual commitment of single individuals that created momentum and reception of the initial product idea.

> *"In former times, technological and business assessments revealed a still insufficient technological performance and a missing strategic fit (annotation: particularly no fit with SWA). However personal commitment and visionary ideas of just a few people ensured a continuous development of the technology within XXX (annotation: company name disguised for confidentiality purposes) for example via technology projects" (M3)*

This commitment was also expressed in a way that in the initial phase of the project, *Scoping* a new product concept was for many people not part of any business or personal objectives. For almost all contributors the project came so to speak "on top" of their daily business.

> *"We from Business Development, we actually don't really have any budget to finance whole projects. We for example paid for parts of the market research but I also had to acquire some parts of the funding from the LCTs (annotation: LCT stands for Life Cycle Teams). This was actually what I meant earlier. That this was not planned for all of us and somehow was on top. We had no cost centre in that sense. […] a lot of that was simply done unaccounted, on top." (M5 - translated)*

In this context, it was not possible to charge any working hours to a cost centre; instead the initiative was primarily driven by self-propulsion of single individuals. As a result, this **self-motivation gave rise to a strong momentum** amongst the members of the team. But this belief of mutual support does not just originate from a great commitment from individuals, it also goes back to the **strong empowerment of these individuals and teams** in the first place. A research participant who was leading several early stage development projects highlighted the aspect of empowerment to foster a broader engagement of the team in the following way:

> *"We in our LCT (annotation: LCT stands for Life Cycle Team) we live these projects that applies to me as project leader and the same applies to my co-project leader and that's the way it's gonna work. […] there, it's not written team member but really co- (annotation: Project Lead) this expresses responsibility, this understanding of one's role, that meaning is conveyed thereby." (M4 - translated)*

Such granting of responsibilities is seen as empowerment and is perceived as a backing to explore the radical potential of a new product concept. Moreover, the teams also critically reflected on that responsibility aspect and clearly highlighted

that such empowerment is a core intangible resource which cannot be delegated to any other party such as ancillary functions or even externals.

> *"…realising, what do I need, what do I want to have. This is something the project team has to do, in fact the project team not in some ancillary function that assists, but rather in the core function that actually later on take the responsibility for the outcome. This is for me only delegable to a limited extent." (S2 - translated)*

Besides the strong empowerment and commitment of individuals as well as the overall team, it could be observed that this way positive dynamics within the team are enforced. A research participant from R&D referred to this "momentum" within the team:

> *"…we saw a high personal engagement of a diverse, highly skilled and young team that was highly motivated to open up a new technology for XXX (annotation: project/company name disguised for confidentiality purposes) The team managed to maintain this momentum over a period of >18 months and even spread these "good vibrations" to further parts of the organisation." (M3)*

As a result, this momentum, or the *"good vibrations"*, as a research participant put it, leads to a mutual understanding and belief of support within the team that seems to have stimulated further actions.

<u>INDICATOR 2 – Receiving management support</u>

The second indicator addresses the role of senior leadership in the context of supporting radical innovation projects. Data clearly showed that a strong endorsement from this end is essential from two perspectives. Either research participants expressed that strong explicit support is required to explore radical product concepts or interviewees referred to the fact that a subjectively perceived lack of support would choke such initiatives. In this context a research participant from Business Development commented:

> *"The only thing that comes to my mind. What I find is a real pity, that we don't have the courage for example to earlier on start a feasibility study. That we really need two years to get management to buy in to at least invest at least a little bit of money. […] This is I think an enormous challenge, where it would be nice if one actually had some commitment at an earlier point in time for example to just simply start some kind of research (annotation: customer research)". (M5 - translated)*

But it is not just about the extent of support; it also seems to be essential in which way the support is expressed; be it through an **empowerment of team members** or through **fast decision making by senior leaders**. A senior project manager raised this point and also mentioned that this aspect forms a key responsibility of senior leaders. Showing a negative attitude towards exaggerated delegation of management core-tasks, for example to externals such as consultancy firms, appears not to be a suitable approach:

> *"The responsibility lies amongst this management team, yeah and here I attach great importance on it. […] others delegate this externally. The company Accenture has made millions with us. […] This is outsourcing of responsibility, well with regards to that one organises oneself in a way to fail and here I'm distinct in what I'm saying." (M4 - translated)*

Besides who and to what extent management support is needed, the kind of support seems to play a significant role as well. Clearly the two aspects of empowerment as well as financial support have to be mentioned within this context. As they were already outlined in previous sections, they will not be explained in detail again. However, a further facet in this context is a clear business guidance by senior leadership, a vision for the future business as well as management expectations regarding business performance:

> *"We need to have a clear set of key topics in mind especially when it comes to applying the business rules and approaching the management team. For example, the COGS will limit ourselves in implementing every feature the customer might ask for. The project lead will have a lunch meeting with some of the DLT members (Annotation: DLT stands for Divisional Leadership Team) in the next days, which will bring a lot of clarity, this is the most important filter step. We need to wait until then. At least this is what I believe." (S8)*

The teams apparently seem to appreciate such guidance and see it as strong support if management tries to provide such clear guidance in an early phase usually characterised by a high degree of uncertainty and hence fuzziness.

INDICATOR 3 - Taking external influences into account

In the context of *Scoping* a product concept, the third indicator summarises an area that is about taking external influences into account. Besides the two former indicators on internal sources of support, this one covers a field of stimuli that

originates from the external world, outside the corporation. Thereby the indicator takes into account that external sources of support and encouragement seem to play an important role when exploiting the radical potential of a product concept. This recognises that the scope of a product concept is shaped by internal as well as external factors and that its implementation is heavily dependent on legitimisation from both ends (internal as well as external stakeholders).

This aspect is particularly about the influence of external stakeholders on internal development activities, who first work with the development team on a partnership basis. Secondly, it seems to involve the role of external individuals and institutions such as external decision bodies (e.g. regulatory authorities).

External partnerships like the one that can be found in Case B, where the corporation under investigation has teamed up with an instrument developer and manufacturer, appear to provide a broad range of impulses/inputs. Such a partnership seems not to be just a source of stimuli to explore the context of product development differently, it is also about reinforcing the team's ability to implement such new ideas. In the subsequent quote an experienced project lead mentions the crucial role of a trusted relationship to a partner and the impact of explicit support from that end.

> *"I like to also mention our three success factors here (smiling). […] This is professional competence, personal commitment also for the whole and the collaboration, the good, efficient and in particular trustful cooperation in which a partner is fully involved. […] Well, thereby a team spirit is created, in particular the idea of trustful cooperation and support is extremely important in that context; also together with the partner, the partner XXX (annotation: company name disguised for confidentiality purposes). if they commit to something, if the hierarchy says we take part in it, then as already mentioned the whole organisation is fully committed." (M4 - translated)*

Besides the influence of external partnerships, **external decision bodies** seem to assume considerable importance as well when it comes to executing a new, creative interpretation of the development context. Regulatory authorities for example with their decision-making power may trigger an important stimulus in this context. As a marketeer highlights, this influence may already be expressed through very small gestures such as the willingness to talk about and discuss new, creative

interpretations of regulation. This example illustrates that already small stimuli may be sufficient to create a significant sense of support within the development team.

> *"When we looked deeper into some of the regulatory requirements we for example identified the whole area of calibration and control measurements as really critical. […] In the end we then said, let's build two scenarios, […] We currently don't know if it will be accepted in the end but we try to do it this way for now. […] At least we managed to get in touch with FDA to discuss our proposal and new ideas. That's already a good sign because they have been quite open so far. It is definitely worth pursuing this initiative and let's see how far we can get. (M7 - translated)*

Consequently, external stakeholders are not just seen as an important piece of the puzzle when it comes to the creative interpretation of the context, as outlined in the previous section. In fact, the implicit as well as explicit support from external stakeholders such as partners or regulatory authorities, significantly influences the motivation and encouragement development teams are experiencing when it comes to the exploration and implementation of new radical product concepts. Such a positive sense of support from external sources seems to legitimise a proposed new route particularly during its implementation.

Taking the above into account, one can summarise that an exploration and maintenance of radical product concept components as well as a project continuation are highly dependent on a team's ability to *create a (positive) sense of support* for the new radical product concept; hereby recognising that the scope of a product concept is shaped by internal as well as external factors and that its implementation is heavily dependent on the support and legitimisation on manifold corporate hierarchical levels which range from individual, team to management levels.

The following graph summarises all three indicators of the substantive capability element, *creating a (positive) sense of support* (Figure 63):

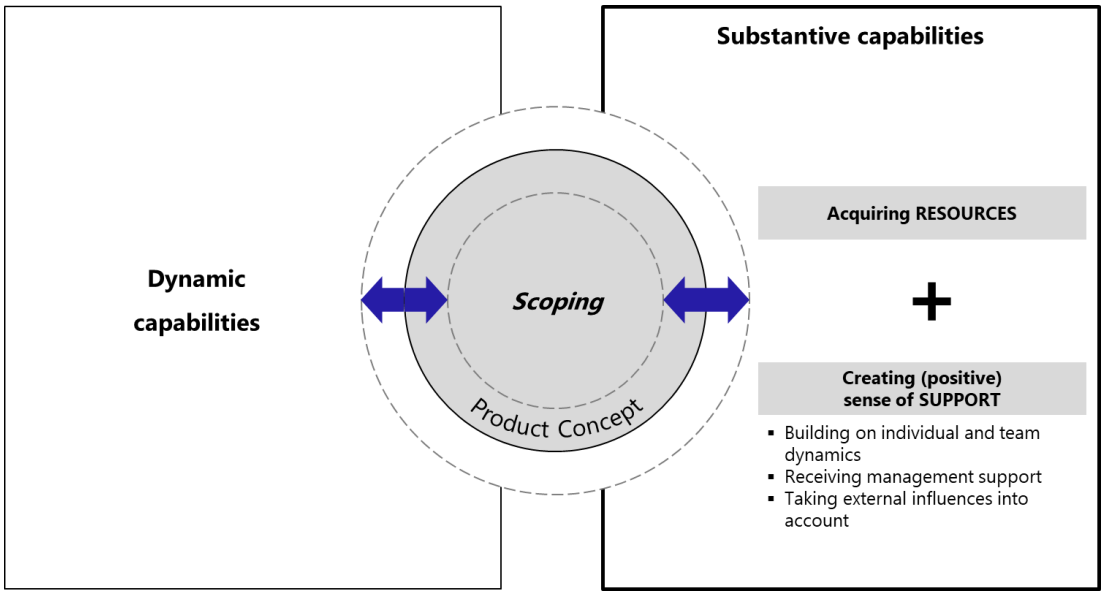

Figure 63. Indicators characterising "Creating (positive) sense of support"

As the two, substantive as well as dynamic, capability concepts appear to be highly intertwined, the next chapter will discuss their interrelation in more detail and will also reflect upon the findings of this study in the context of prior research.

5.3.3 Discussing capability findings and deriving propositions

This empirical study offers deep insights into the emergence process of new product concepts under uncertainty that build on new technologies in the context of medical diagnostics. Findings led to the development of *Scoping* that explains key dynamics in this process. It is addressing the initial part of the NPD (pre-development – exploring and normalising) that is followed by exploitation. In other words, it is suggested that NPD contains two major phases: *Scoping* and exploitation, where *Scoping* consists of two sub-phases: *exploring* and *normalising*.

Besides the temporal dimension to characterise *Scoping*, a further *capability dimension* was identified and previously introduced. When looking at the two within-cases, data indicated that the exploratory nature of *Scoping* is mostly driven by the development and exploitation of dynamic capability; leading to the following first capability-based proposition:

> ***Proposition 8****: Dynamic capabilities affect wide scoping (the expansion of the product scope) and the exploration of the radical potential by tapping into new, innovative areas.*

The current research study found that dynamic capabilities are defined as an ability to adapt internal as well as external competencies to new, changing environments (Teece et al., 1997). Particularly, the perceived availability of knowledge and capabilities as well as creative interpretation of development contexts have an influence on building these dynamic capabilities to deal with high uncertainty settings. Through these elements, organisations seem to be put in a position to build, revise and integrate new capabilities. In line with earlier research, findings support the idea of **divergent thinking and creativity** that may be applied in early development, allowing multiple unique solutions to be develop to find answers to specific problems (Griffiths-Hemans & Grover, 2006; Reid et al., 2014). Creative capacity, to find new ways (Arrighi et al., 2015), and divergent thinking, to open up the solution space to multiple options (Reid et al., 2014), go hand in hand as part of this exploratory process of new technology (March, 1991).

The findings match those of earlier studies on dynamic capabilities (Winter, 2003; Zahra et al., 2006) in the area of resources and skills (Bowman & Ambrosini, 2003). With the present study and the empirical evidence generated, a contribution to the so far mostly theoretical research domain on dynamic capabilities is made (Eisenhardt & Martin, 2000; Helfat & Peteraf, 2003). Furthermore, results support transferring the so far mostly general capability findings or domain-specific contexts, such as the investigation of Turcan and Juho (2016) in the field of entrepreneurship, to the field of NPD.

Besides the mere focus on the role of dynamic capabilities on *exploring* dynamics, another important contribution was made by shedding light on the interplay of dynamic and substantive capabilities when it comes to implementation of the product concept. This led to the second capability-driven proposition:

> ***Proposition 9****: Dynamic capabilities come into force if supported by a complementary set of substantive capabilities.*

This proposition refers to the role of substantive capabilities that are characterised as organisational procedure or routine which allow a specific outcome (Easterby-Smith & Prieto, 2008; Winter, 2003). Very little was found in the literature on the role of substantive capabilities (Turcan & Juho, 2016; Winter, 2003) and their link to

dynamic capabilities. One potential link may be that they turn into a part of substantive capabilities if they become routine within an organisation. Still, findings match those of Koen et al. (2014) who highlight for example the role of management and substantive capabilities in providing commitment and resources for innovation (Poskela & Martinsuo, 2009). Furthermore, findings are in line with Poskela and Martinsuo (2009) who emphasise resource acquisition in the context of NPD and empowerment of teams to deal with front-end uncertainties and creative problem solving. In addition, results are consistent with those of key scholars in the research field of organisational ambidexterity (He & Wong, 2004; March, 1991) who point out the need for exploring capabilities (dynamic capabilities) as well as exploitative capabilities (substantive capabilities) to make use of the radical potential that might come with new technology.

As per the findings, the capability types are for the most part intertwined on a resource or contextual level (Figure 64).

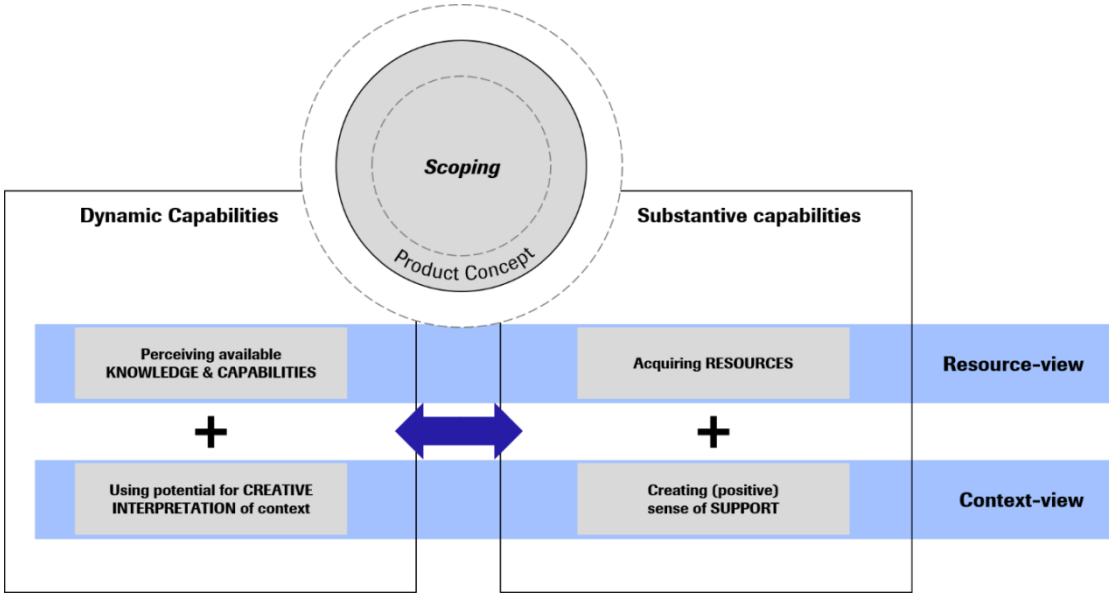

Figure 64. Resource- and context-view on organisational capabilities

It appears that the substantive capability is a necessary condition to unlock the potential of the corresponding dynamic capability. Findings are consistent with He and Wong (2004) who also suggest that ambidextrous organisational capabilities are required to exploit the radical potential and ensure a proper implementation.

From a contextual perspective, it is suggested that the dynamic piece is about providing free space (Blauth et al., 2014) as a basis for creativity, improvisation as well as trial and error to build dynamic capabilities (Turcan & Juho, 2016). This potential for creative interpretation comes into force if it is contextually promoted.

From a resource perspective, the required new knowledge and expertise do not just need to be perceived by the development team, in fact one can summarise that the acquisition of resources is a fundamental substantive capability that allows effective use of resources. This suggests that only if organisations manage to also acquire the available resources, can they be used effectively for *Scoping* a product concept. This way a team may be able to expand the scope of the product concept by exploiting the radical potential that may for example be associated with a novel technology.

As a result, it can be concluded that the two aspects are highly intertwined; if just one of these is met or fulfilled, it will not be possible to explore the full radical potential of the technology to eventually expand the product scope. These findings led to the following proposed **capability-based typology** (Figure 65).

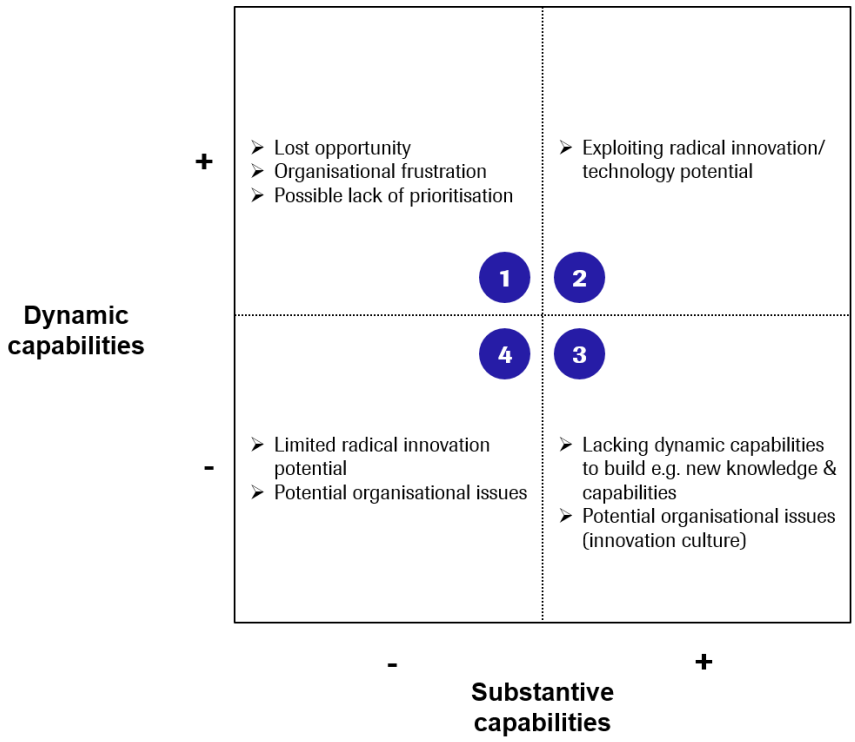

Figure 65. Typology of dynamic and substantive capabilities

Type 1 is characterised by extensive dynamic capabilities such as the availability of knowledge and capabilities or the creative interpretation of the development context. However due to a lack of substantive capabilities, it is not possible to fully exploit the given radical potential. Data suggests that this might lead to organisational frustration. Further possible explanations are either a lack of management support, prioritisation issues or a risk-averse business strategy.

Type 2 depicts the set-up of a fully explorative as well as exploitative organisation by balancing dynamic as well as substantive capabilities with organisational processes, resources, values, etc. Findings suggest that in this scenario new capabilities also gradually replace established substantive capabilities. Hereby the organisational capabilities are constantly renewed to effectively make use of resources as well as a dynamic development context.

Type 3 characterises a case that is in principle equipped with a strong set of substantive capabilities e.g. in acquiring resources but lacks dynamic capabilities to explore the radical potential. This type covers organisations that are not able to develop radical product concepts although it is generally provided with sufficient substantial capabilities such as funding.

Type 4 refers to a limited radical innovation potential due to a lack of dynamic and substantive capabilities at the same time. There are several possible explanations for that, for example a lack of innovation culture, an organisational inability to build up knowledge and capabilities or a lack of strategic fit for innovation leadership (vs. cost leadership).

Both within-cases that were part of this research study can be categorised in between type 1 and 2 as the radical potential of the technology was largely explored in the initial phase of *Scoping* the product concepts. Later on, they moved more to the centre of the 2x2 matrix due to resource limitations as well as certain normalising dynamics that took place to ensure project progression.

Capability findings and the developed typology not only apply to organisations and their development projects. In fact, results suggest that they can also be broken

down to the level of individuals. They support the idea of *Serial Innovators* introduced by Vojak et al. (2012), being able to command a balanced set of visionary and exploratory capabilities as well as substantive capabilities, to ensure support and resources for project continuation at the same time.

Overall, one can summarise that the capability dimension of *Scoping* made some noteworthy contributions to capability theory. Firstly, it provides empirical evidence for the significant role of dynamic capabilities when shaping a radical product concept, a research field that has been dominated by theoretical research. A proposition is made that dynamic capabilities form the basis to expand the scope of newly emerging radical product concepts. Secondly, findings interrelate such dynamic capabilities with substantive ones to make an effective use of resources as well as the development context. In this regard, a 2x2 typology is proposed to categorise organisational capabilities.

Next, a summary of all propositions that were developed as part of this study will be outlined.

5.4 Summary of propositions developed

Data analysis within but also across the two embedded-cases led to a set of findings along the temporal as well as the capability dimensions of *Scoping*. Hereby they contribute to the current debate and inform further research to better understand the phenomena of the emergence of new product concepts under uncertainty. The development of this set of theoretical propositions can be employed to explain implementation and integration in organisational contexts.

Scoping that emerged grounded in data contributes to our understanding of concept shifting by suggesting two temporal states of *Scoping*: *exploring* (wide scoping) that allows enlarging the product space to explore the full radical potential that might come along with a new diagnostics technology, and *normalising* (narrow scoping) with a more restricted, bound space of the product concept.

The former takes place within uncertain decision making contexts, whereas the latter within risk decision-making contexts. Table 7 summarises the proposition developed which forms the basis of an explanatory model that may have practical as well as policy relevance:

Table 7. Overview of propositions developed

Scoping a product concept		
Phenomenon/Theme	**#**	**Proposition**
Adaptation of scope	**1**	The scope of a radical product concept is constantly adapted across multiple steps of pre-development to reflect new insights.
Concept shifts	**2**	The adaptation process of a product concept scope follows a specific pattern of *exploring* (*wide scoping*) and subsequent *normalising* (*narrow scoping*) to ensure project continuation.
Change in velocity of *Scoping*	**3**	The velocity of *Scoping* varies in terms of change in speed and direction (expanding vs. contracting).
Turning point	**4**	The transition from *exploring* to *normalising* marks a turning point from uncertainty to risk decision-making settings.
Normalising	**5**	Normalising leads to a reduced and de-radicalised scope of a product concept to ensure its implementation.
	6	Normalising is a bridging step between exploration and exploitation (implementation) of a new, radical product concept.

NPD process	**7**	A new product concept is defined and implemented in three distinct NPD phases: exploring, normalising and exploitation (implementation).
Organisational capabilities	**8**	Dynamic capabilities affect *wide scoping* (the expansion of the product scope) and the exploration of the radical potential by tapping into new, innovative areas.
	9	Dynamic capabilities come into force if supported by a complementary set of substantive capabilities

6 Conclusion: research findings and limitations

Building on the discussion of findings in the context of existing research in the field of NPD, the final chapter of this doctoral research study concludes by providing a summary of key findings and contributions to knowledge as well as implications for practitioners and policy making. Furthermore, it critically reflects upon the limitations of the study and opens several avenues for further research.

My main contributions to theory are related to the substantive area of new product development. Before my research, the NPD field lacked a clear understanding of product concept definition in an early phase of radical product innovation. Furthermore, concepts such as *concept shifting* (Seidel, 2007) were limited to a risk decision making setting at a later stage of NPD.

With *Scoping*, this research study introduces a concept that tries to explain the dynamics and behaviours within an organisation when defining a novel, radical product concept in an early phase. As per the findings, *Scoping* recognises that anything like "the ultimate" product concept – with fixed definition and clear parameters – does not exist. Rather, the scope of a product concept is subject to constant adaptations and revisions to reflect new insights across several stages of development. These adaptations appear to follow a certain pattern of expansions (*wide scoping*) and contractions (*narrow scoping*) of the solution space. Thus, *Scoping* extends the so far limited concept of *concept shifting* to uncertainty decision making settings at an early development stage. In addition, this case study research further characterised *concept shifting* in terms of its impact on product radicalness, revealing that shifts are frequently used to de-radicalise a product concept to ensure its implementation in a corporate context. Moreover, my research extends the so far two-phased NPD approach (exploration / exploitation) to a three-phased one by introducing the intermediate phase of *normalising*. Furthermore, *Scoping* accounts for the significant role of dynamic capabilities when exploring the radical potential of a new product concept and thereby further refines the idea of organisational ambidexterity (He & Wong, 2004).

Despite the limitations of this research study (section 6.5), its findings may be transferred across diverse substantive areas such as new ventures or mergers and acquisitions.

The contribution claims are discussed in more detail in the following section.

6.1 Research findings and their implications for theory building

This study makes a number of contributions on how new product concepts are emerging under uncertainty and how they are adapted and modified over time to ensure future implementation. This study has identified *Scoping* as the main concern of the organisation involved in the process of defining product concepts based on fundamentally new technologies.

This concept recognises that the scope of a radical product concept is constantly adapted across multiple steps of pre-development to reflect new insights. In that sense, ***Scoping*** helps to exemplify and visualise a product concept as a **multidimensional space of solutions** for a new product that is heavily vested in the individuals who define it. Over time, these groups of people create a shared, aligned understanding of a future product by attaching specific meaning to it.

Moreover, *Scoping* describes the **process of defining and bounding this solution space** which offers the opportunity to extend and broaden the current conceptual and theoretical understanding of the emergence of product concepts under uncertainty (Cooper, 2006; Reid & De Brentani, 2004).

Findings suggest that the outcome of *Scoping* mainly depends on two capability variables: *substantive* and *dynamic capabilities* as well as two temporal variables: *exploring* and *normalising*.

The ***capability view* on *Scoping*** refers to a set of substantive, as well as dynamic, capabilities to make effective use of resources as well as the development context. Findings also point to the fact that, with the right set of dynamic and substantive capabilities, organisations are able to explore the scope of a product concept and exploit at the same time the radical potential that might for example be associated with a new technology component (Ernst, 2002; Holahan et al., 2014; Krishnan &

Ulrich, 2001). Empirical evidence has shown that dynamic capabilities are needed to explore the radical potential of a new product concept. In this context, findings also suggest that the expansion of the product scope only comes into force if dynamic capabilities are kind of "enabled" by a complementary set of substantive capabilities.

Such expansion of a radical product concept is common in the front-end of innovation (Reid & De Brentani, 2004) and depends for example on resource availability and knowledge (Akbar & Tzokas, 2013; Edmondson & Nembhard, 2009; Goffin & Koners, 2011). The same applies for the creativity piece of early development that has been researched in specific phases at the front-end of innovation (Frishammar et al., 2016; Gordon, 1961). Prior research as well as findings of this research study foster a positive connotation of creativity in an early phase. That way it is in line with findings on the key role of creativity in the emergence process of newness (Blauth et al., 2014; Griffiths-Hemans & Grover, 2006) in general and the invention process in particular (Cooper, 2009; Johannessen et al., 2001; Schumpeter, 1934).

From a temporal perspective, the progression during the *exploring* and *normalising* phases is viewed as an elaboration and later **de-radicalised adaptation of concepts** rather than as an iteration backwards to prior stages. This resembles concept shifting as suggested by Seidel (2007). According to Seidel (2007), concept shifts take place in later phases of new product development when the product concept has initially been defined; in other words, it manifests in risk decision-making settings such as *normalising*. In uncertain decision-making settings, as per the findings, extensive exploratory changes to the scope of a product concept are observed in earlier phases and the impact of these changes are considered for the radical nature of the product concept. That is, the findings extend *concept shifting*, suggesting that the concept components are being shifted earlier on in the process of *exploring* within uncertain decision-making settings.

In addition, present findings suggest that larger organisations use shifts in concepts and de-radicalisation of concept components to facilitate a completion of a radical development project (*normalising*). As per the findings in the face of uncertainty,

which is inherent in radical innovation projects (Herstatt et al., 2004; Zhang & Doll, 2001), the ability to shift and adapt a product concept allows the development team to maintain the required momentum right from the start of a project.

In doing so, findings **extend the so far two-phased development process (exploration and exploitation) into a three-phased approach** with a particular pattern of radicality. The establishment of a third, intermediate phase, called normalising, further supports and even refines the idea of organisational ambidexterity (He & Wong, 2004), with a clear differentiation between exploration as well as exploitation capabilities. In contrast to earlier research that just recognises these two distinct organisational phases/set-ups (Birkinshaw & Gibson, 2004; Duncan, 1976; March, 1991), *normalising* can be seen as a third step in the overall NPD process. In this context, *normalising* refers to a turning point in NPD, bridging between an exploration on the one hand and alignment as well as legitimisation of the product concept within the existing corporate and industry contexts on the other. As a result, this adaptation, in the form of a de-radicalisation, allows a development project to pass through these distinct sections of NPD.

The graph below provides an overview of key findings that were observed in the context of this empirical research study (Figure 66):

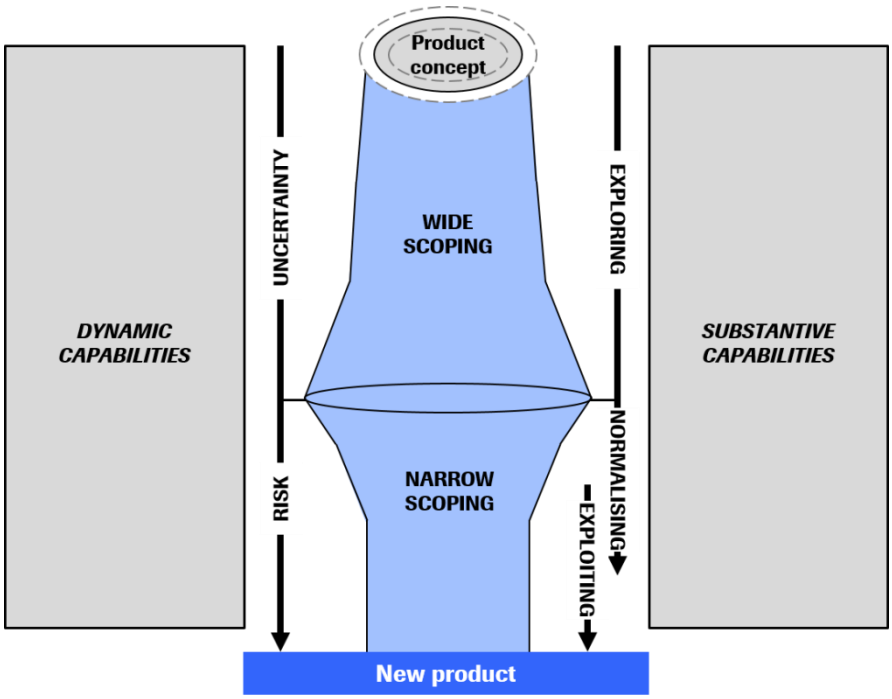

Figure 66. Holistic model of *Scoping* incl. dimensions and underlying concepts

Going beyond the substantive area of emerging product concepts in the context of NPD, findings can also be **abstracted to the general phenomenon of the "emergence of newness"**. Table 8 summarises the developed propositions on this higher level of abstraction. In addition, it introduces three distinct contexts the emergent theory of *Scoping* may be transferred to; i.e. emergence of newness regarding new ventures and Mergers and Acquisitions (M&A).

With regards to **new ventures**, *Scoping* may refer to a constant adaptation process of a venture's business strategy. New business insights or a potential lack of funds and capabilities at hand may trigger such strategic shifts to ensure a survival of the new venture. This dynamic adaptation may result from an alignment with multiple internal/external stakeholders such as investors or customers. In that sense, normalising can be seen as a potential intermediate step in between different levels of maturity of the venture, e.g. in between creation of a new venture and growth/scaling phase. This example also illustrates the turning point between the uncertainty setting before market entry and risk decision-making settings such as market access and acceleration.

Another substantive area, that *Scoping* might play a significant role in, is the **field of M&A** as well as the integration process of the business / organisation that comes with it. During the M&A process a new organisational unit is emerging. As part of this new corporate context, the integration process might for example trigger a constant adaptation process of key elements such as business strategy, organisational set-up and organisational culture. Given this, *normalising* may refer to a change in organisational scope based on internal alignment and legitimisation of the new organisation. In that sense, *normalising* marks a turning point in the development of an organisation to ensure exploitation of the acquired business in the new corporate setting. This may lead to a de-radicalisation of the legacy through dynamics such as (a) integration of acquired solutions into existing product platforms, (b) adaptation of business/revenue models to pre-dominant ones but also (c) assimilation of risk awareness/tolerance within the newly emerging organisation. Furthermore, integration measures in particular may reassemble the set of substantive and dynamic organisational capabilities available.

Table 8. Transferring Scoping into further contexts (new ventures, mergers & acquisitions)

Findings on a higher level of abstraction: *Emergence of newness*	
Phenomenon	**Abstraction of Proposition**
Adaptation of scope	The scope of a radical product concept is constantly adapted across multiple steps of pre-development to reflect new insights.
Concept shifts	The adaptation process of a product concept scope follows a specific pattern of *exploring* (*wide scoping*) and subsequent *normalising* (*narrow scoping*) to ensure project continuation.
Velocity of Scoping	The velocity of *Scoping* varies in terms of change in speed and direction (expanding vs. contracting).
Turning point	The transition from *exploring* to *normalising* marks a turning point from uncertainty to risk decision-making settings.
Normalising	Normalising leads to a reduced and de-radicalised scope of a product concept to ensure its implementation.
	Normalising is a bridging step between exploration and exploitation (implementation) of a new, radical product concept.
NPD process	A new product concept is defined and implemented in three distinct NPD phases: exploring, normalising and exploitation (implementation).
Organisational capabilities	Dynamic capabilities affect *wide scoping* (the expansion of the product scope) and the exploration of the radical potential by tapping into new, innovative areas.
	Dynamic capabilities come into force if supported by a complementary set of substantive capabilities

Transferability to further contexts	
New ventures	**Mergers & Acquisitions**
▪ Constant adaptation of business strategy based on new insights. ▪ Adapting business strategy and business models based on impact of multiple internal/ external stakeholders such as investors, customers or competitors. ▪ Normalising as intermediate step in-between creation of new venture and growth/ scaling phase. ▪ Normalising as turning point between uncertainty settings (before market entry) and risk settings (during and after market entry). ▪ New venture scoping builds on limited set of substantive capabilities. ▪ Lack of funds or capabilities may trigger strategy shifts to ensure continuation of venture.	▪ Mergers and acquisitions form basis for the emergence of a new organisation. ▪ Integration process triggers adaptation and alignment process in new corporate contexts (new normalising). ▪ Normalising may lead to reduction of scope due to internal alignment and legitimisation steps: → integration into existing product platforms → adaptation to predominant business/ revenue model → adaption of risk awareness to new organisation ▪ Normalising as turning point to ensure exploitation of business in new corporate setting. ▪ Reassembling set of substantive and dynamic capabilities.

These two examples demonstrate that the emergent theory of *Scoping* has a certain relevance in further substantive areas beyond NPD, trying to explain general dynamics and behaviours during the emergence process of newness under uncertainty. The next chapter provides suggestions for further research, by reinforcing the explanatory power of *Scoping* and addressing potentially open, not fully answered questions.

6.2 Suggestions for further research

Future research is called for to strengthen the explanatory power of *Scoping* and its two, potentially time- and context-transcendent behaviours, *exploring* and *normalising*. This research study put forward a set of propositions to guide research in the area of NPD. Theory building through comparative study approaches may be employed to enhance our understanding of newly emerging product concepts under uncertainty by making, for example, comparisons of an array of diverse contexts or milieus and structures.

A deeper conceptual understanding of the phenomenon and related theory could firstly be attained through a more detailed exploration of *normalising* and associated dynamics. This involves a more precise understanding of the temporal dimension of *normalising* in the overall innovation process (ideation to product implementation) but also the degree of de-radicalisation. In this area, the adaptation process from a technological but also business perspective may be analysed on a more detailed level of product concept components.

Secondly, more profound insights could be gained by investigating *concept shifting* in a broader, longitudinal timeframe, covering the whole emergence process of product concepts from opportunity recognition to definition product concept towards the end of the pre-development phase as well as the subsequent development, implementation phase (Seidel, 2007). That way the adaptation process could be observed in a much more comprehensive way, which would close the research gap as most empirical research studies either focus on the emergence process during pre-development (Eling & Herstatt, 2017; Florén et al., 2018; Gassmann & Schweitzer, 2014) or the efficient implementation during the development (Cooper et al., 2002; Medina et al., 2013; Seidel, 2007).

A third and last suggestion for further research refers to the uncertainty aspect of radical new product development and its impact on the course of early development adaptations. In the context of *dynamic capabilities* for example, the generation and absorption of new insights and new knowledge are key levers to cope with uncertainty in an early phase. The concept of *absorptive capacity* (Griffith, Redding, & Van Reenen, 2003; Zahra & George, 2002), which is defined as

an organisation's ability to recognise, absorb and make commercial use of new information, could be investigated in this regard. That way it could be compared to what extent a team or organisation's ability to cope with newness such as new technological information might impact on the product concept *Scoping*.

Since this research was limited to new product concept emergence in the context of the IVD industry and a single, multi-national corporation, further research might explore the concept of *Scoping* in a broader array of diverse contexts and milieus. This could on the one hand be achieved by increasing the number of cases (case companies) within the same industry or a larger variety of industry contexts. On the other hand, new venture contexts might be explored by subsequent research projects as in contrast to multi-national enterprises, such emergent entities may not be able to build on a limited set of established *substantive capabilities*.

Besides a focus on additional theory building, one could also undertake further quantitative research testing the propositions developed. When taking this research avenue, it is suggested that theory testing and confirmation can be achieved through quantitative research in this field that is looking at a broad variety of development projects. That way, the propositions developed as part of this empirical research (*exploring*, *normalising*, de-radicalising, capability view) can either be confirmed or disproven. This would not only shed further light on this research field but also provide practical insights into the management of new, radical product development projects in the context of large, multi-national enterprises.

6.3 Implications for practitioners

New, radical product development can be challenging for corporations. Therefore, aside from the theoretical contribution, the findings of this empirical research study may also have implications for practice in areas such as the role of senior management, or R&D governance, knowledge management and innovation culture. In this context, the study identified some challenges and successful practices on a team as well as management level that particularly reflect the diverse set of market and corporate contexts that need to be taken into account when new, radical product concepts are emerging (Figure 67).

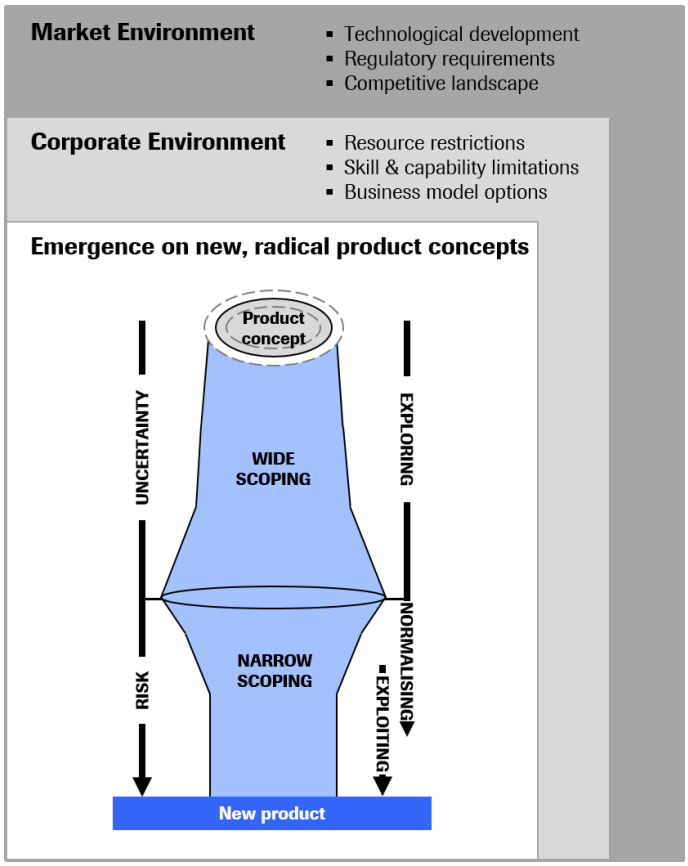

Figure 67. Market and corporate environments

As a result of these contextual aspects, organisations and particularly managers are facing several challenges in application. *Scoping* provides a theoretical concept that is trying to explain dynamics in such uncertainty-decision making settings. Going beyond theory, it additionally suggests a broad set of implications for practice.

Challenges related to the **market environment** are mainly composed from external aspects such as technological developments, regulatory requirements/changes or

the competitive landscape. Several of these aspects were already mentioned in the context of discussing uncertainty-drivers related to new product development (for details see sections 2.6 and 5.2.4). This is because these market-related aspects are largely both known and controllable to a limited extent. A second contextual field managers need to consider when taking NPD decisions refers to **corporate, organisational factors**. Challenges that arise in this field are for example resource restrictions, skill and capability limitations as well as business model options. In contrast to the market environment, the corporate context is typically well known and refers rather to the organisation's ability to flexibly adjust and adapt for radical NPD.

As a result of these complex contexts, managers need to shape the future directions of a corporation in a field of tension with multiple influencing factors. **Corporate leaders need to balance a potential competitive advantage that might come along with a new, radical product ("opportunity") with organisational abilities ("feasibility")** to deliver on that. *Scoping* as a theoretical concept is characterised as a process of constant adaptations and trade-offs to ensure project progression and *normalising* as a concept for internal alignment and legitimisation. These concepts provide practical guidance in this field of tension, facilitating to de-radicalise the product concept regarding specific concept components to balance "opportunity" and "feasibility" factors.

Proposition #1 (adoption of scope) and #3 (pattern of concept shifts) refer to findings that R&D processes should be designed in a way to allow for product concepts to be constantly adapted. This means that R&D governance (e.g. R&D process, decision bodies, etc.) provides sufficient flexibility to reflect new insights such as from market environment but at the same time corporate limitations are also taken into account to ensure project continuation. In addition, *Scoping* suggests from a managerial perspective that concept shifts should firstly follow a certain pattern of an internal/external exploration that is secondly, after a specific turning point during proof-of-concept, followed by a *normalising* phase. Each phase needs to be managed individually considering aspects such as risk tolerance, openness/need to collaborate with external partners, funding and knowledge

creation. Apparently as per findings, the velocity of Scoping (proposition #2) only seems to play a minor role in the context of early development and high uncertainty. This suggests that for example in terms of project planning, management should rather allow for some free space to explore the radical potential of a new technology than to put immoderate time pressure on development teams. In contrast to the efficiency-driven exploitation/ implementation phase during formal product development, pre- and early development requires freedom and creativity to produce the right product concept options.

Furthermore, proposition #4 (turning point) and #5 (radical nature) address the specific need for/act of *normalising* as part of the overall adaptation process to reduce radicalness of the product concept to make it fit to the corporate context for implementation. This step needs to be proactively managed in a deliberate manner to maintain radicalness but to also ensure a transition of the emerging product concept from exploration to its exploitation (ambidextrous organisation). A key strength of the present study is grounded in its empirical, case-study approach that provided deep insights into the *normalising* phase, enhancing our understanding of business processes and organisational dynamics leading to an adaptation and de-radicalisation of initially more radical product concepts. As per findings, normalising summarised key product concept components such as the revenue model and radical product features provided by external suppliers/partner as well as dynamics like portfolio implications that have a significant impact on the radical nature of a new product.

As a result, R&D governance needs to not only reflect the two well-known phases of exploring and exploiting; in fact, propositions #6 (three-phased NPD process) and #7 (bridging-role of *normalising*) propose that R&D processes and governance need to reflect a three-phased approach that includes *normalising* as a bridging phase. In this regard, the role of management is particularly highlighted as senior leaders with their decision-making power have a significant impact on the availability of resources and a positive sense of support to explore new, radical product concepts. A further key management priority during normalising should be to consider

portfolio implications of NPD as an overlap of product scopes or contradicting business/revenue models might result in potential cannibalisation that in turn triggers internal conflicts. These identified challenges as well as the proposed countermeasures/successful practices allow managers to reflect upon their crucial role in not just *exploring* radical product concepts but also making them "survive" the pre-development phase to be implemented as part of formal product development.

Lastly proposition #8 (dynamic capabilities) as well as #9 (interplay of capabilities) highlight the significant role of the capability dimension of an organisation when S*coping* a product concept. Similar to balancing market and corporate aspects, managers need to be aware of the interplay of dynamic and substantive capabilities. On the one hand dynamic capabilities are required to tap into new product concept elements as part of an exploration, calling for funds to build up new knowledge, an open mindset fostering creativity, and a supportive management that empowers people to explore newness and creates freedom and space to give rise to informal structures.

Alternatively, dynamic and substantive capabilities must be levelled, as both are equally needed to bring a new radical potential into force. Based on two real-life development projects, this study shed light on the interplay of *dynamic* as well as *substantive capabilities* when *Scoping* a new product concept; suggesting that the proper management of knowledge and skill creation as well as creativity have a major impact on teams' abilities to explore and capitalise on the radical potential of a new technology. Without a balanced set of organisational capabilities, an organisation will not be able to capitalise on the solution space of a new product concept.

As a result, *Scoping* can from a practical perspective be seen as a concept for management to **navigate NPD in a field of tension** in between externally-driven, mostly uncontrollable environments, and internally-driven, mostly controllable corporate environments. That way it tries to provide guidance for the key managerial challenge to balance these market and corporate influencing factors of new, radical product development.

However, these findings are not only relevant for NPD, as outlined in section 6.1; they might actually go beyond the substantive research context and make several noteworthy practical contributions in fields like entrepreneurship and post-merger-integration of radical innovation solutions or ventures. Firstly, *substantive* as well as *dynamic capabilities* might also play a similar role in these contexts when it comes to *exploring* the radical potential of a new solution as well as maintaining this level over the course of a post-merger-integration or a maturing new venture. Secondly, the concept of *normalising* might also apply to a certain extent to new radical solutions/ventures that are integrated into a larger corporate context. Such solutions/ventures also require resources and to create a positive sense of support to ensure progression in a dynamic organisational context.

Overall, *Scoping* and its temporal and capability characteristics has made several noteworthy contributions to practitioners in the field of radical new product development and beyond.

6.4 Implications for policy making

A further substantive area where the phenomenon of the emergence of newness and *Scoping* might be of relevance is **policy making**. This means that the concept of *Scoping* is transferred from a mere corporate, organisational setting into a social/political one. This transfer seems possible as the emergence process of new policy making is characterised by constant adaptation to reflect new insights and to ensure social acceptance/legitimisation.

The relevance of *Scoping* might apply for policy making in the specific field of new medical/healthcare regulation but also more broadly how new developments are enshrined in legislation in general.

For general policy making, *Scoping* may refer to an adaptation of a novel political idea or a new legislation initiative through shifts to its scope to reflect new insights and ensure their broad legitimisation and eventually institutionalisation. The described adaptation process in this context often seems to follow a similar pattern of exploration, normalising and exploitation/implementation. This means that

initially more radical scenarios are considered during exploration. However, the scope of these new legislative opportunities often requires a refinement and ultimately de-radicalisation (*normalising*) to make its way through the legitimisation process. As a result, similar to NPD, radical concept components need to be modified or substituted by less radical alternatives to gain broad consensus for implementation. In this context, normalising can, thus, be seen as a turning point in the adaptation process to ensure social and political support by different institutions and society.

For the healthcare context, *Scoping* may also be of relevance to reflect new developments (e.g. technological) in industry-specific regulations. New medical or technological insights may trigger new policy making to potentially advance the state-of-the-art of healthcare. However, even though new radical aspects might be explored, these opportunities need to be aligned with multiple industry-specific requirements such as patient safety or financial feasibility of healthcare systems. When balancing these opportunities (wide scoping) with requirements (narrow scoping) in healthcare policy making new regulation may be scoped in a similar pattern of exploring, normalising and implementation.

These examples demonstrate that the emergent theory of *Scoping* can be applied in various substantive areas beyond NPD, trying to explain diverse dynamics of behaviours. Following this section, the concluding section addresses the limitations of this research study by reflecting on the chosen research design as well as limitations in terms of generalisability.

6.5 Limitations of research

Given the research methodology this study employed to explore the emergence of new, radical product concepts that build on new technology, the results are limited with regards to scope and generalisability. Furthermore, when critically reflecting on the chosen research design which was outlined in chapter 3, three potential methodological limitations can be spotted in the areas of:

- Methodological choice - Single case study design
- Access and availability of data
- Sample size of research encounters

Firstly, the research study may be critiqued for its single case study design which is just building on two embedded cases. Due to this limited scope and insights into just one corporation, the ability to generalise findings to further application areas might be confined. However, this seems acceptable due to the fact that the research focuses on a deep-dive into real-life product concepts in a specific industry. Including a broader range of companies appears unfeasible, as this would involve disclosure of early development activities of direct competitors. Gaining access to such sensitive information would for an employee of an IVD company be very difficult, if not impossible.

Indeed, one could argue that the two embedded cases do not allow for a proper cross-case analysis due to their differences. It is correct that they are contrasting for example with regards to the applied technology or the employees that were involved in the respective cases. However, both cases share characteristics such as an allocation within the same Business Area and hence the same project governance structure (e.g. identical decision bodies). Further elements that showed similarities were the timeframe of project initiation and hence the same strategic framework as well as certain consistency on a management level.

As a result, the narrow scope might cut back on the ability to generalise potential findings to a broader field of application to which the propositions might eventually be applicable (Dul & Hak, 2007). Nevertheless, a single investigation may be of value for knowledge creation as this limitation also represents a major benefit, allowing

the researcher to gain deep insights into real-life development projects of a market leader in the IVD field. In addition, it can be argued that exploratory research that is building upon single-case study findings does not claim for generalisability and universal validity. In fact, it is appreciated that the data and knowledge created is socially contextualised (Brinkmann & Kvale, 2015).

Secondly, the access to and availability of data of this research study is limited. This directly relates back to the phenomenon under investigation, the emergence of new product concepts that build on new technology. In this context, it is important to highlight that new technology development might bring competitive advantage in the market and is therefore typically treated as highly confidential. Consequently, it is necessary to withhold certain pieces of information and it is not possible to publicly disclose all parts of data as part of this doctoral thesis. This should not be seen as a downside of this research study; the granted access to real-life development teams and highly confidential information of early research projects should rather be seen as a unique feature, which would have been difficult or impossible to achieve for external researchers.

Ultimately, it is a trade-off decision one needs to take, to either favour broad access to multiple corporations and new development projects or to strive for deep involvement in a smaller number of new product development cases to generate rich data (even if it needs to be treated confidentially).

Thirdly, the research design may be critiqued for its relatively small sample size of just 20 research participants. Due to the small number of encounters and the single application, the research design and its findings may be questioned for its potentially erroneous conclusions. The number is small, particularly compared to quantitative research studies, but it has to be noted that the sample size was driven by theoretical sampling and theoretical saturation of the emerging core-variable *Scoping* rather than by any constraints like resources or time. When a saturation was reached, single additional research encounters were conducted, changing even the sequence in-between the two embedded cases to be sure about the level of saturation.

When checking the number of research encounters with key publications in the field, Creswell's (2013) meta-study on sample size showed for example that 20 research participants are well in line with common practice in the field of exploratory, qualitative case study research and Grounded Theory methodology.

Considering the above stated arguments, one could assert that the single case study research design that employs interviewing as a key method of enquiry involves a set of weaknesses when trying to delve into the research phenomenon. Having said, one could also argue that a reasonable research design as the chosen research methodology, including the applied methods, helps to unfold the potential of a focused, deep investigation of the research phenomenon. Thereby a set of controversially discussed and open research questions are put forward. In that context, this research study rather strives for rich data and deep insights to depict the meaning of findings than aiming for broad generalisability of findings.

The generalisability of this research is limited to a specific industry and company context as the case study originates from a multi-national enterprise in the IVD industry; an industry that is special due to its stakeholder structure and regulatory framework, compared to industries that are characterised by direct consumer-centricity (B2C) or are less regulated. However, it also has to be noted that further industries such as pharmaceuticals or aviation have similar characteristics. Furthermore, results are bound to an analysis of newly emerging product concepts in a pre- and early development stage, thereby focusing rather on the conceptual part of NPD, cutting back on the execution part of NPD addressed in multiple research in the past.

Given the research phenomenon, emergence of newness under uncertainty, and the research methodology employed, R&D teams and managers need to carefully reflect upon the above summarised characteristics and limitations of this research when trying to transfer the results to further contexts (corporations, industries, product types).

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Summary of appendices

Appendix A - Exemplar invitation and introduction letter

Invitation to participate in an academic research study
"Exploring the emergence of new product concepts in the context of IVD industry"

Dear colleagues,

I am happy to invite you to contribute to an academic research study I am pursuing as doctoral candidate at the University of Gloucestershire. The objective of the research study is to explore the emergence of new product concepts in the context of the IVD Industry.

Therefore I'm interviewing a broad variety of functional representatives of diagnostics system-development-projects and I would very much appreciate if you could also take the time for a one hour research interview.

Your management has already given the general consent to this study being performed in the context of your development project. Nevertheless it is solely up to you to decide whether you would like to participate in this research study or not. It also has to be noted that you retain the option to withdraw from the study at any point in time.

Research proceeding:

- A one hour individual face-to-face interview will cover the topic of how the new product concept of XXX (anonymised for confidentiality purposes) project has emerged.
- For documentation purposes it would be desirable to record the conversation.
- The conversation will be documented in a brief summary and a transcript.
- After an initial analysis I will get back to all participants to review the findings.
- Further interviews with colleagues of yours will be conducted in the next couple of weeks and it is planned to come back to you with the preliminary findings of the analysis probably in October/November 2016.
- The entire analysis results will be provided to all participants in the end.

Ethical notes:

- All information provided is considered as confidential.
- All information will be incorporated in an anonymised way.
- All recordings will also be treated confidentially and will be deleted immediately after the completion of this study.
- You retain the option to withdraw from the study at any point in time.

I would very much appreciate if you could take the time to share your valuable insights into new product development with me.

In case of any questions, feel free to contact me.

Kind regards, Matthias Zach

Appendix B - Interview protocol

UNIVERSITY OF GLOUCESTERSHIRE

Exploring the emergence of new product concepts under uncertainty: A case of cross-functional teams in the In-vitro Diagnostics industry

Interviews with key team members of development projects

INTERVIEW PROTOCOL

Interviewee:		**Interviewer:**	Matthias Zach
Functional role:		**Date & Time:**	dd.mm.yy – hh:mm
Location:	City, Country	**Language:**	English or German
Duration:	mm:ss	**Audio file:**	Interview_AA_20160404

Introduction:

I very much appreciate that you take the time to share your valuable insights into new product development with me. As you may know I'm currently working on my PhD at the University of Gloucestershire. The goal of the research project is to explore how new product concepts emerge. Therefore I'm interviewing a broad variety of functional representatives of this project. This means that, besides our discussion today, further team members will be involved in a similar way.

Before we start I would like to emphasise that your participation is absolutely voluntary and that all information you are providing throughout our interview is considered as confidential and will only be incorporated in an anonymised way. If you don't mind, I would like to record this conversation to document our interview. Of course all recordings will also be treated confidentially and will be deleted immediately after the completion of this study.

Are there any questions you would like to ask at the moment? [Pause] Otherwise I would like to provide you some more details on the proceeding.

Research procedure:

Today's interview will basically cover the topic how the new product concept of the XXX (anonymised for confidentiality reasons) project emerged.

After the interview I will send you a brief summary of the conversation. If I do miss or misinterpret something you will directly have the chance to comment on that point. After your review of the data I will conduct the analysis. You will become an

important part of that as well; this means that after an analysis of mine, I will get back to the whole team again to review the findings.

Do you have any questions before we now actually begin?

Main interview part:

Section	Questions (Q = Leading question, S = Supplementary question, C = Concluding question)
Personal background	**Q1:** To get started, can you please briefly explain your functional role within XXX (company name disguised for confidentiality reasons) as well as within the project. ▪ **S1:** What are your main tasks in that respect?
Emergence of new product concepts	In my thesis I'm exploring the specific characteristics of the emergence of new product concepts. **Q2: From your perspective, what are the major concerns in that respect?** *(Introductory question)* ▪ **S2:** Could you please describe that in more detail. *(Specifying question)* ▪ **S2:** I understood that ..., could you please elaborate a bit more on…? *(Probing + Interpreting question)* ▪ **S2:** Can you think of anything else that has an impact? *(Follow-up question)* ▪ **S2:** To what extent is that from your perspective a unique proposition? *(Critical follow-up question)* **Q3: How are these elements connected to the development of a new product concept?** *(Specifying question)* ▪ **S3:** Can you please give an example for that. *(Specifying question)* ▪ **S3:** Can you think of anything else? *(Follow-up question)* ▪ **C3:** Is there anything else you would like to add? *(Concluding question)* **Q4: Were there also (further) aspects you were experiencing challenges with?** *(Structuring question)* ▪ **S4:** I understood that…, could you please elaborate a bit more on…. *(Probing + Interpreting question)* ▪ **S4:** Could you please describe a real life situation you were experiencing that time? *(Specifying question)* ▪ **S4: What other ideas do you have in mind that might help to meet one of these challenges better?** *(Structuring question)* ▪ **S4:** Can you please give an example for that. *(Specifying question)* ▪ **S4:** What else can you think of? *(Follow-up question)* ▪ **C4:** Is there anything else you would like to add? *(Concluding question)*
Way of working	Thanks a lot; you mentioned a lot of really interesting aspects. Now I would like to shift the focus to the way you were working. **Q5: Could you please elaborate on how you were working to overcome some of these challenges?** *(Introductory question)* ▪ **S5:** Could you please describe … in more detail. *(Specifying question)* ▪ **S5:** Why did you do that? *(Critical, interpreting question)* ▪ **S5:** Who was actually involved into that? *(Specifying question)* **Q6: Were you making any changes in the course of the project?** *(Structuring)* ▪ **S6:** What do you exactly mean by that? *(Specifying question)* ▪ **S6:** Why did you do that? *(Critical, interpreting question)* ▪ **S6:** Is it correct that you were doing… to…. *(Probing + Interpreting question)* ▪ **S6:** Who was actually proposing/taking care of that? *(Specifying question)*

	Q7: Was there anything you were not satisfied with? *(Direct question)* ▪ **S7:** Can you please give an example for that…. *(Specifying question)* ▪ **S7:** Can you think of anything else? *(Follow-up question)* ▪ **S7:** Is there anything else you would like to add? *(Concluding question)*

Summary:

Great, at this point in time we have from my side covered all main topics. But before we proceed, is there anything we have missed so far? [Pause]

Otherwise, I would briefly summarize today's discussion.
[Presenting an abstract of essential statements for summary and confirmation purposes.]
Do you agree with that or is there anything you want to add or correct?

Closure:

Great, let me thank you again for your time and for answering so openly today. When I look back at our discussion, we have covered quite a broad range of topics. That is fantastic.

As a next step, I will send you a summary of our discussion. In case you would like to make any amendments or if something else comes to your mind, please let me know. I'm happy to add this to your data set.

With regards to the timeline I will, as mentioned before, conduct further interviews with colleagues of yours in the next couple of weeks and I plan to come back to you with the outcomes of the analysis probably in October. I'm already looking forward to jointly reviewing the findings with all of you then. I hope you are okay with that.

Again thank you very much!

Statistics:

Education / qualifications:	e.g. Biology & Business studies, PhD, specific trainings or experiences
Nationality	e.g. German, Dutch, Swiss
IVD-Industry experience:	Experience Categories: (a) <2 years (b) 2-5 years (c) 5-10 years (d) >10 years
Employment with corporation:	Experience Categories: (a) <2 years (b) 2-5 years (c) 5-10 years (d) >10 years

Appendix C - Structure of research database

Table 9. Structure of research database

Context of research study	**External**	**IVD industry**	▪ Key facts on industry ▪ Key characteristics such as regulatory requirements
		Point-of-Care Diagnostics market	▪ Key facts on market segment (e.g. sales, competitive landscape, etc.) ▪ Application field incl. examples of devices ▪ Role in healthcare system ▪ Customer diversity
	Internal	**Corporation**	▪ Key facts (e.g. sales, key products, etc.) ▪ Organisational structure ▪ R&D development processes
Research design	**Research design**	**Research topic**	▪ Research questions ▪ Research propositions
		Research method	▪ Draft interview guideline ▪ Pilot interviews… ▪ Interview guidelines
		Individual role	▪ Role in company / function ▪ Role in Project
	Execution	**Application of approaches**	▪ List of interviewees ▪ Meetings calendar incl. follow-ups
		Data analysis	▪ Coding hierarchy
	Reporting	**Analysis and interpretation of findings**	▪ Case-specific analysis summary ▪ Cross-case approach ▪ Cross-case analysis summary
Data collection	**Case A & B**	**Interviews**	▪ Recordings of interviews ▪ Interview memos ▪ Reviewed interview transcripts ▪ Coded interview transcripts (In NVivo software)
		Artefacts	▪ Product vision - Objectives ▪ Project team structure ▪ Project timing (milestone planning) ▪ Further documentation e.g. meeting / workshop minutes

Appendix D – Interconnected analysis steps (example dynamic capabilities)

The following figure shows an integrated picture of the analysis process that was described in chapter 3.3 Data analysis and interpretation of case study findings.

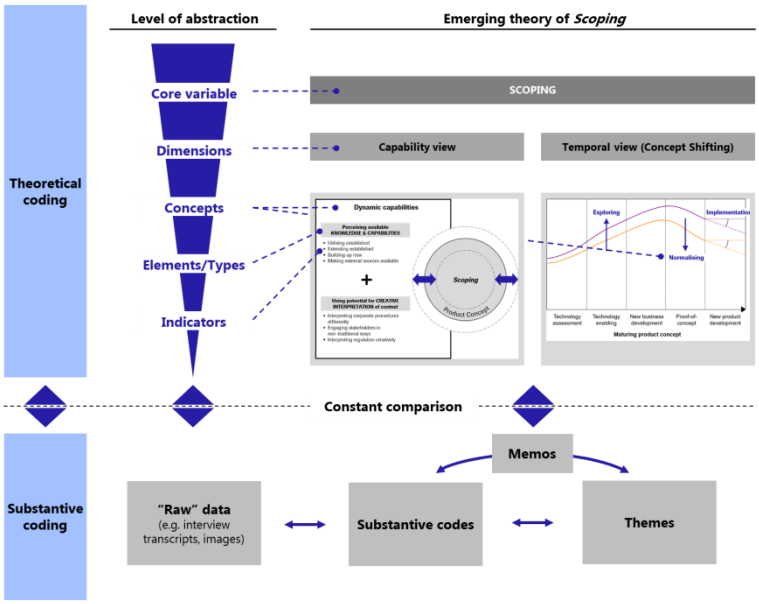
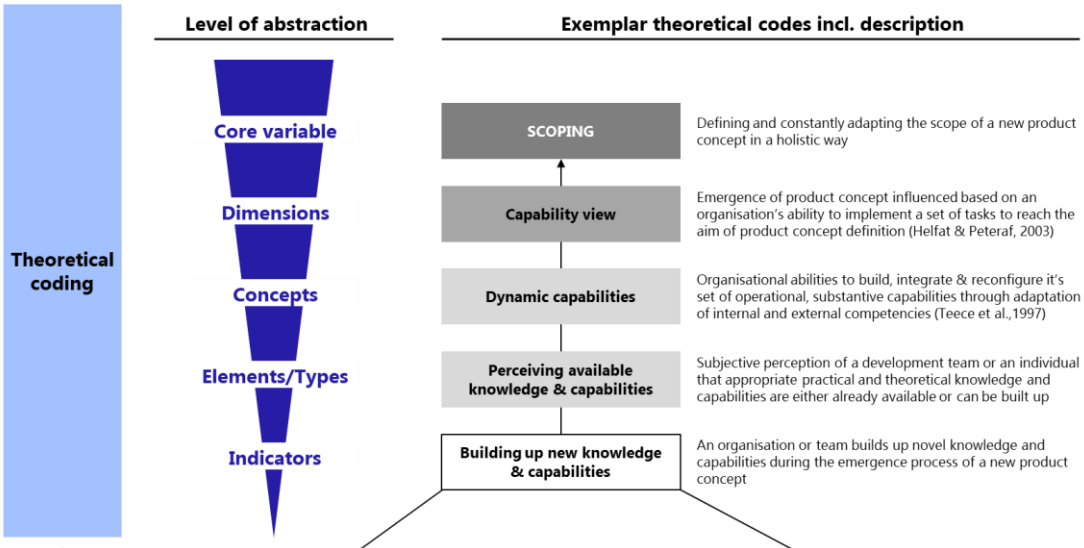


Figure 68. Integrated view on data analysis

Based on the example of "dynamic capabilities" the overall process including its individual steps of analysis from raw data to the core-variable *Scoping* are shown to illustrate the transition from a substantive to a more abstract theoretical level of analysis (Figure 69).



"Raw" data - Exemplar quotes	Substantive Codes	Description	Themes
"This goes into the direction that we indeed, from my perspective, well it is, I call it a bit overstated "learning space" for the organisation. [...] Because different global organisations have to date, prior to this have not dealt with this subject before. (M6 - translated)	**Learning space**	Experimentation space to explore new things, building up new knowledge and capabilities incl. trial and error	- **Experimentation** - **Building up new knowledge & capabilities**
"We then actually had concepts ready within the R&D unit that we had already developed in multiple, diverse technology projects. [...] we provide technology for highly diverse R&D issues and we rely on the fact that we are technology-wise always one step ahead, we are at the forefront of state-of-the-art." (M2 - translated)	**Process nature of building up knowledge and capabilities**	Longitudinal, stepwise process	- **Process nature** - **Building up new knowledge & capabilities**
"...this proof-of-concept phase is actually just possible because one has already dealt with the technology before and let's say related adjacent issues for years. Worked in the pre-investigations in the end." (M2 - translated)			
"...but it is specific for XXX (technology name removed for confidentiality reasons) because we make a new technology accessible for us, for an established market segment that we already cover. It is simply the fact that we need to build the organisation for it, that we establish the processes and the knowledge for it and we have already initiated this now." (M6 - translated)	**Building on already established knowledge and capabilities**	Tapping into adjacent areas by building on established fields of knowledge and capabilities	- **Extending established knowledge and capabilities**
"At that time the colleagues from Business Development were invited as well from XXX (location deleted for confidentiality purposes) and these were well represented for that topic. And that was the opportunity to in just three days completely condense the world of XXX (technology name deleted for confidentiality purposes) in diagnostics. And the good thing about it was that we had external experts there." (M2 - translated)	**Involving external experts**	Enriching in-house expertise through external sources	- **External sources of knowledge and capabilities**

Figure 69. Exemplar chain of evidence "dynamic capabilities"