Investigation of user involvement and collaboration processes in current and future innovative medical technology environments

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Master of Science Thesis
Stockholm, Sweden 2010
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Abstract

Currently the MedTech industry is worldwide driven by the need for innovations. Basing on a long history which produced radical innovations such as the pacemaker, the Swedish MedTech industry in specific has a special reputation. Over the last decades the innovation process advanced thereby by shifting the focus more and more from the company’s to the user’s needs and also to an integrated approach of involving them. Especially in the MedTech industry this aspect is given great attention. As a continuation of this, a new medical site called Innovationsplatsen is going to be established within the Karolinska Institute in Huddinge near Stockholm. There different stakeholders such as engineers from companies, medical professionals from the Karolinska institute and researchers from the Royal Institute of Technology can work closely together with an intensive knowledge and idea exchange.

Facing this exceptional setting, it is investigated with this thesis how MedTech companies currently perform, measure and document user involvement in the collaboration process. Subsequently an approach and tools are proposed, to support these processes and to overcome the identified drawbacks of the state of the art. By supporting the acquisition of the relevant data, results can be derived then from a subsequent analysis which allows managing the collaboration in the Innovationsplatsen and identifying best practices in a comparison with other similar settings.

To investigate the state of the art and answer the question how user involvement is currently performed and measured, six experts in four MedTech companies are consulted repeatedly by means of guided expert interviews. Following to that a closer look at the process documentation of one of these companies is taken, to reveal what information is documented and can be used to investigate the collaboration processes with a network analysis, as well as what information is missing here for proper results. The ensuing development of the proposed approach follows then the Munich Process Model, to ensure a systematic procedure. Here the investigation of the state of the art is picked up and transformed into specific requirements for
which finally solutions can be identified and adapted. The evaluation of the approach in an expert workshop completes this at last.

The findings from the interviews reveal that, although various implementations of user involvement are common practice even within a company, the influence and impact on the value of different strategies is unknown. This can be attributed to the lack of the process documentation which is mainly used to document information for legal reasons. In addition, the evaluation of ideas and input by different actors as well as retrospective analyses of the processes are very often only examined informally. As conclusion the proposed approach introduces then an innovation value system and assessment tool, to weight every actor’s influence, a continuous data acquisition as well as databases which allow connecting the actors and their properties to another and their ideas in the innovative environment. The proposed approach contributes thereby to collect the relevant data in future development environments and compare them to another. By this means best practices of user involvement can be revealed the communication and collaboration can be improved.
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Introduction

In this chapter the background, problem definition and aims of the thesis are introduced. This includes a glance on the medical technology industry as well as an overview of the appearing problems in collaborative environments.

Background

Worldwide the healthcare and medical device industry is a growing sector because of a growing wealth demand, a continuously aging population, state encouraged health insurance systems as well as new products and procedures. Especially the latter enables a better treatment of diseases, which couldn’t be cured some years ago, and contribute to a wealthy society also through the creation and preservation of many jobs. Around the globe the US, Germany, Switzerland, Japan and Sweden hold the largest share of this industry (ACTION MEDTECH 2008). Within these countries, where education and knowledge build a much stronger future base than natural resources, the complex medical device industry can grow and build up an excellent basis for the future. Furthermore, a strong industry can not only improve the situation of employees and patients, but also enhance the collaboration in scientific work with universities and research institutes. This can have further positive effects on a whole country’s economy and strengthen it considerably.

The Swedish economy for instance profited well from its medical device industry, which can rely on several groundbreaking innovations in the past (GUDMUNDSSON et al. 2007). However these innovations can be “date[d] back 30 to 50 years, which raises the question whether Sweden can sustain and strengthen its position through a continued stream of innovation” (GUDMUNDSSON et al. 2007, p.15). Due to a sophisticated healthcare sector, needs and incentives for innovative developments have to be identified frequently. In order to keep pace with competitors, it is furthermore indispensible to be highly productive and innovative in short terms. In consideration of this background, the competition between medical device producers world- and nationwide can be considered very tough. To compete in this contest successfully, collaborations, processes and methods to increase productivity and innovativeness need to be developed.

In light of this, several projects in cooperation with universities, county councils, hospitals and MedTech companies currently take place in Sweden at the time. One such project is “Innoplant”, a governmental funded long-term program, aiming to improve the innovation capability of the participating organizations. To achieve this goal, successful “forms of collaboration among users, buyers and producers related to innovation questions” (PINEIRO 2009, p.1) are investigated and analyzed. Another example is “Innovationsplatsen” (Swedish for “innovation place”) which is considered in this present work. It provides an excellent setting to apply the findings from these projects and to evaluate their implementation.

Innovationsplatsen

The innovation place is a future clinical site which will be built within the Karolinska University Hospital in Huddinge, Stockholm. Due to statutory provisions, the hospital’s surgery and intervention department has to be rebuilt from scratch. To exploit this
opportunity, new facilities are planned and reserved for the initiator’s idea of an “innovation place” that has been pushed by him for many years now. The ambition is that this will be a highly collaborative setting where healthcare staff can collaborate with academia and people from the industry. That makes Innovationsplatsen a place, “where health care challenges and future developments meet researchers and industry in order to advance medical solutions (including informatics)” (PERMERT 2010, p.2). This in turn provides the chance for the Karolinska University Hospital, to stay on the cutting edge of medical technology, to improve the hospital’s expertise and drive the national specialization in the field of surgical and medical intervention. Researchers on the other hand can benefit from the medical facilities, equipment and physicians’ know-how or investigate the setting itself from the view of organizational management. But also for companies opportunities open up, as they can benefit from the close cooperation during the development of new medical devices and an excellent setting for future clinical trials. In this context especially small companies could benefit from such expertise (PERMERT 2010, p.2). However, besides these three also other stakeholders can take advantage from this setting, as it offers great infrastructural opportunities to the city and region as well as an improved health care for patients, as concluded in Table 0-1 below.

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Benefit</th>
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<tbody>
<tr>
<td>Patients</td>
<td>- patient safety</td>
</tr>
<tr>
<td></td>
<td>- more effective diagnostic</td>
</tr>
<tr>
<td></td>
<td>- better treatment</td>
</tr>
<tr>
<td></td>
<td>- higher patient satisfaction</td>
</tr>
<tr>
<td>Karolinska University</td>
<td>- innovative, safer and more efficient health care</td>
</tr>
<tr>
<td>Hospital</td>
<td>- increase the hospital’s expertise in surgical and medical intervention</td>
</tr>
<tr>
<td></td>
<td>- create conditions for national specialization</td>
</tr>
<tr>
<td></td>
<td>- new cost-effective health care options</td>
</tr>
<tr>
<td></td>
<td>- conduct high-quality and cost-effective care</td>
</tr>
<tr>
<td></td>
<td>- resources can be released without production</td>
</tr>
<tr>
<td>Academics</td>
<td>- interdisciplinary collaboration</td>
</tr>
<tr>
<td></td>
<td>- access to facilities</td>
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<td></td>
<td>- transfer of “tacit knowledge”</td>
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<tr>
<td>MedTech Industry</td>
<td>- Developing medical devices in collaboration with medical experts</td>
</tr>
<tr>
<td></td>
<td>- opportunities for effective clinical trials</td>
</tr>
<tr>
<td></td>
<td>- innovation risky research</td>
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<tr>
<td></td>
<td>- growth opportunities for small and medium-sized MedTech companies</td>
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<tr>
<td></td>
<td>- long-term competitive Swedish medical device industries on a global Market</td>
</tr>
<tr>
<td>Region</td>
<td>- job creation</td>
</tr>
<tr>
<td></td>
<td>- strengthens the reputation for the area</td>
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<td></td>
<td>- generates tax on companies</td>
</tr>
<tr>
<td></td>
<td>- financially sustainable health care in Stockholm, nationally and internationally</td>
</tr>
</tbody>
</table>

Table 0-1 Stakeholder benefits in “Innovationsplatsen” (PERMERT 2010)

In addition to the advantages for the stakeholders depicted in Table 0-1, furthermore the conditions are given, to investigate the collaborative process during the development very closely. Due to the geographical proximity of the participants, an intense communication can be assumed which leads to a depiction of Innovationsplatsen as in Figure 1-1. Only by the means of a systematic application of appropriate methods and utilities continuously in the background, the entire setting can be investigated, to derive how innovations emerge and how
innovation capabilities can be pushed forward. As Kristina Groth, a researcher who is involved in the planning phase of the project, states: “Innovation doesn’t just come, when you put people together. [...] You need methods and you need utilities. But [...] all these together will create a good opportunity.”

Problem specification

Despite all the expected benefits, still huge efforts have to be made to achieve all the goals of Innovationsplatsen. With the attendance of various persons belonging to different institutions the problem arises how the collaboration and user involvement as well as their effect on the innovation outcome in Innovationsplatsen can be investigated. Currently there is no tailored approach that defines what and how to collect, in order to reveal to which extent this collaboration between industry, academia and healthcare has actually resulted in innovation and how every actor contributed to it. Without a prearranged approach that investigates the setting from the very beginning, the improvements within and through Innovationsplatsen won’t be transferable to the industry and thus the outcome of the project would be severely curtailed.
Purpose

The purpose of this thesis is to investigate current MedTech development environments and develop an approach that enables the systematic and purposeful data acquisition within Innovationsplatsen and any other similar environment. By this means the subsequent analysis of the collaboration between different stakeholder and especially the users among them and their impact on innovation should be facilitated. Furthermore visualized models shall be generated, to communicate the procedure to decision makers and stakeholders within Innovationsplatsen. This is why the following key questions have to be answered:

- How do companies perform and measure user involvement today?
- What information about user collaboration is stored in process documentation?
- How can companies manage and evaluate their cooperation in a collaborative environment like Innovationsplatsen?

In addition to these questions a description shall be provided on how to deal with the acquired data and how to interpret the final analysis results. This finally allows the participating companies and research institutions to monitor the collaboration processes and to compare the outcome of Innovationsplatsen with their current practice. This in turn gives them the opportunities to manage and learn from their participation in Innovationsplatsen.

Scope and delimitations

Due to the time limitation of this project, only a restricted number of researchers and MedTech professionals are going to be interviewed, to investigate the state of the art. Hence it is intended to establish this work on a strong base with a goal oriented method development approach and an extensive literature research. Furthermore, the majority of the expert interviews which were conducted with MedTech companies were restricted in time, because of the lack of the interviewees’ available time. A more detailed investigation was therefore only conducted for one company. The approach described in this thesis pursues to investigate the collaboration between healthcare staff, academics and MedTech employees. Therefore it might not seem to be suitable for an investigation of any other stakeholder’s influence. Nevertheless the approach could be expanded and adapted to any other stakeholder, too.

Considering these limitations, in the following chapter the relevant background of the MedTech industry and Innovationsplatsen in this context as well as relevant network and innovation theory will be highlighted, before the methodology of the further proceeding is introduced in chapter 3. According to the presented methods, the state of the art is investigated in chapter 4 by expert interviews and a process documentation analysis. Thus an approach is going to be developed in chapter 5, to overcome the identified drawbacks of the current situation. A final evaluation of this approach by designated experts is then conducted in a workshop, to validate the proposed solution. The temple diagram in Figure 1-2 provides therefore a road map and serves as a comprehensive model for this thesis.
Figure 0-2 Temple diagram of the thesis structure
Theoretical framework

The theoretical framework in this chapter provides relevant information about the medical technology industry, aspects of innovation, network theory as well as data acquisition approaches. To start with and get an understanding of the terms that are used in the course of this thesis, relevant acronyms are introduced.

Acronyms

Regardless of how frequently the following acronyms are used, they all shall be itemized in an alphabetical overview below.

- CiDaD – Competence in Design and Development
- CoP – Community of Practice
- CUI – Clinical Utility Index
- DMS – Document Management System
- FFE – Fuzzy Front End
- FMEA – Failure Mode and Effect Analysis
- GMDN – Global Medical Device Nomenclature
- IMS – Idea Management System
- IPD – Integrated Product Development
- KM – Knowledge Management
- KTH – Kungliga Tekniska Högskolan (Royal Institute of Technology)
- MedTech – Medical Technology
- MINT – Measuring Innovation Capability in Teams
- MMM – Munich Methods Model
- MPM – Munich Process Model
- NPD – New Product Development
- PDP – Product Development Process
- PDCA – Plan Do Check Act
- PIEp – Product Innovation Engineering program
- R&D – Research and Development
- ROI – Return on Investment
- UMDNS – Universal Medical Device Nomenclature System

Medical technology

Worldwide the medical technology industry – also often abbreviated as MedTech industry – achieves enormous yearly turnovers. The countries with the highest spending on medical technology in 2005 for instance were the US (78,5bn €), Japan (18,7bn €) and Germany (7bn €). Yet, Europe considered as a whole is with 63,6bn € second in spending behind the US (WILKINSON 2009). The term “MedTech industry” summarizes thereby a variety of different companies which take part in the development, production and sales of medical devices. Although all these companies are part of “the” MedTech industry, they can differ in many
central aspects such as size, budget or field of specialization. Nevertheless and despite their differences they all have in common to create medical technology which “is characterized by a constant flow of innovations, which are achieved by a high level of research and development within the industry, combined with close co-operation with healthcare” (EUROMED 2007, P. 1). In this context it can be understood that different actors, among which end-users play a special role, contribute differently depending on their characteristics.

After the previous general introduction to the MedTech industry worldwide and in Sweden in particular, subsequently specific aspects of product requirements and classification, company environment as well as the user with its particular importance are highlighted. It shall be pointed out how these aspects relate to each other, how they are determined by legal requirements and how they contribute to a coherent picture considered in this thesis.

**Medical devices**

As indicated, the field of medical technology deals with the development of medical devices. A medical device is defined by the directive 2007/47/ec of the European Parliament and the council of the 5th September 2007 as “any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings” (COUNCIL OF THE EUROPEAN COMMUNITIES 1993, PP. 3–4).

According to the classification in Table 0-1, these devices are separated within Europe in the four classes of I, IIa, IIb and III which are specified in Annex IX of the Council Directive 93/42/EEC. The classification of products in Europe funds on criteria such as the invasive quality, the duration of body contact and the hazardousness to the body. In a simplified conclusion the classes refer to the examples given in Table 0-1. According to the classification, every device also has to meet then specific requirements by law. This means that the device needs to be verified by a “Certificate of Conformity” which is issued by an accredited organization and certifies that the product meets the appropriate standards.

<table>
<thead>
<tr>
<th>Class</th>
<th>specifications and examples</th>
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| I     | Devices, which pose a minimal risk of harm to the human body and are used mostly externally  
**Example: stethoscope** |
| IIa   | Short-term invasive devices and devices which can come into contact with body liquids but are usually not hazardous to the body  
**Example: syringe** |
| IIb   | Devices that could be hazardous to the body as well as long-term implants which don’t influence vital body functions  
**Example: x-ray machines** |
| III   | Devices with influence or direct contact to vital body functions such as the heart, the central circulatory system or the central nervous system even for long time.  
**Example: implantable pacemaker** |
Besides this classification approach which provides a rather rough framework on how to specify medical devices, currently there is also the “Universal Medical Device Nomenclature System” (UMDNS) which will be soon replaced by the “Global Medical Devices Nomenclature” (GMDN). By means of the GMDN a single generic naming system is provided, to enable safe information exchange about the medical devices between healthcare involved persons for the well-being of the patient (GMDN Agency 2010, p. 9). Therefore medical devices are characterized by a device category from Table 0-2 and a generic device group (P = preferred term, T = template term, S = Synonym term, MS = Multiple-linked synonym term), as proposed by the GMDN, as well as a manufacturer specific device type classification.

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<tr>
<td>01</td>
<td>Active implantable devices</td>
<td>11</td>
<td>Assistive products for persons with disability</td>
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<tr>
<td>02</td>
<td>Anesthetic and respiratory devices</td>
<td>12</td>
<td>Diagnostic and therapeutic radiation devices</td>
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<tr>
<td>03</td>
<td>Dental devices</td>
<td>13</td>
<td>Complementary therapy devices</td>
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<td>04</td>
<td>Electro mechanical medical devices</td>
<td>14</td>
<td>Biological-derived devices</td>
</tr>
<tr>
<td>05</td>
<td>Hospital hardware</td>
<td>15</td>
<td>Healthcare facility products and adaptations</td>
</tr>
<tr>
<td>06</td>
<td>In vitro diagnostic devices</td>
<td>16</td>
<td>Laboratory equipment</td>
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<td>07</td>
<td>Non-active implantable devices</td>
<td>17</td>
<td>Vacant</td>
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<tr>
<td>08</td>
<td>Ophthalmic and optical devices</td>
<td>18</td>
<td>Vacant</td>
</tr>
<tr>
<td>09</td>
<td>Reusable devices</td>
<td>19</td>
<td>Vacant</td>
</tr>
<tr>
<td>10</td>
<td>Single use devices</td>
<td>20</td>
<td>Vacant</td>
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</table>

The presented characterization of medical devices can be used later to give an overview of the interviewed companies’ background. As they want to remain anonymous, the GMDN codification is not going to be elaborated further, as specific knowledge about the companies’ products could reveal their identity.

**Company sizes**

Although the companies which are considered in this thesis remain anonymous, they shall be classified, to give an idea of their circumstances. An important aspect is the size of the company as it should represent on the one hand the power and success and on the other hand the opportunities and chances of this company in the field of innovative MedTech. To classify companies by this criterion, different models could be used. Since this thesis deals with a European background, definitions from that economic region are considered subsequently. The “European Commission for Enterprise and Industry” for instance provides a sharp definition of small and medium sized companies. Unfortunately they do not provide a distinction for large companies. However the “German Commercial Code” provides a corporation classification, which is presented in Table 0-3 and distinguishes accurately between small, medium-sized and large corporations. Therefor the criteria of “number of employees”, “revenue” and “total assets” are considered.

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<tr>
<td>04</td>
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<td>14</td>
<td>Biological-derived devices</td>
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<td>Vacant</td>
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<tr>
<td>05</td>
<td>Hospital hardware</td>
<td>15</td>
<td>Healthcare facility products and adaptations</td>
<td>20</td>
<td>Vacant</td>
</tr>
</tbody>
</table>

**Table 0-2 Device category according to ISO 15225 (GMDN AGENCY 2010, P. 11)**

The presented characterization of medical devices can be used later to give an overview of the interviewed companies’ background. As they want to remain anonymous, the GMDN codification is not going to be elaborated further, as specific knowledge about the companies’ products could reveal their identity.
In the case of the here considered multinational MedTech companies a classification that also includes a specification of large companies according to the number of employees appears to be very helpful, as now companies with many internal actors can be identified and considered subsequently. Furthermore, a higher number of employees should also indicate a higher need for organizational methods, which is in turn an interesting aspect to investigate.

**Customers and users**

The involvement of customers in the innovation process is assigned of great importance, as these stakeholders finally decide, if they want to purchase and use a new product or not. That is why they are involved in the innovation process and their needs and ideas are considered from the very beginning. Therefore the relevant customers have to be identified, as they split up in different groups according to their position in the “supply and demand chain” where they can be distinguished in dealer (first tier), installer (second tier) and end-user (third tier) (Setijono & Dahgaard 2007, p. 45). According to this definition, the user can be considered a customer of the third degree.

In addition to this, it also has to be considered that - unlike other industries - the final beneficiary, who in the case of medical technology is the patient, neither can be regarded as user nor as consumer in the original sense. The user in the context of high-technological medical devices has been identified by Shah & Robinson (2008) and can be divided into several groups as depicted in Table 0-4. The group of users can be split up here into primary users who use the medical device directly for therapeutic treatment and secondary users who deal with other uses “such as testing, calibration, learning and research” (Shah & Robinson 2008, p. 6). Both groups are specified and distinguished even further in Table 0-4, to explain the background and spectrum of every group.

<table>
<thead>
<tr>
<th>Medical device users</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary</strong></td>
</tr>
<tr>
<td>Healthcare Professionals</td>
</tr>
<tr>
<td>Dental</td>
</tr>
</tbody>
</table>
In the previously described Innovationsplatsen healthcare professionals, carers, students, researchers and others will be present, whereas only healthcare professionals, carers and technicians can be considered the group of users, which are of interest and hereinafter denoted by the term “user”. In this context they are the ones who work with the medical devices and in that sense use them.

The customer on the other hand who makes the purchase decision is in this case the hospital management, which usually undertakes responsibility for these duties. In general it can be stated that there are cultural differences between the healthcare staff and management, because of different interests as highlighted by COHN et al. (2005). These different interests arise for instance from aspects of focus, customary time horizon and responsibility as shown in Table 0-5. The gap that emerges between users and customers in this setting has to be kept in mind when analyzing the user’s influence, although customers and their buying decisions can be highly influenced by the user (WIND & ROBERTSON 1982).

<table>
<thead>
<tr>
<th>Cultural variable</th>
<th>Physicians</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sources of income</td>
<td>Consultations and procedures</td>
<td>Largely salary, small variable component</td>
</tr>
<tr>
<td>Focus</td>
<td>Patient survival</td>
<td>Organizational survival</td>
</tr>
<tr>
<td>Decision-making</td>
<td>Rapid, based on individual judgment/experience, patient centered</td>
<td>Deliberate, based on consensus, patient and resource centered</td>
</tr>
<tr>
<td>Customary time horizon</td>
<td>Hours-days</td>
<td>Weeks-months</td>
</tr>
<tr>
<td>Responsive to</td>
<td>Patients, families, colleagues</td>
<td>Patients, families, physicians, employees, community, organizations, board of trustees</td>
</tr>
</tbody>
</table>

Table 0-5 Cultural differences between physicians and hospital management (COHN ET AL. 2005, P.135)

Besides its occupation, the user can also be classified by its quality. VON HIPPEL (1986) therefor introduced the term “lead user”. In contrast to common users, they are not determined only “by their own real-world experience” (VON HIPPEL 1986, P. 791), but they have the...
ability to identify future needs that no common user is aware of at the time. Those users usually are the ones which expect a high benefit from a solution that fits their needs. To identify them, it has to be investigated which user has the highest benefit from a solution. As **VON HIPPEL (1986 P. 799)** proposes this can be investigated for example with the equation:

**B = (V) (R) – C – D**

where (B) is the net benefit, (V) is the monetary "volume" of product sales or processing activity to which the solution is planned to be applied, (R) is the increased rate of profit gained by applying this solution, (C) is the user's anticipated costs in developing and/or adopting the solution and (D) is the net benefit which the user would have obtained without the solution. Usually the calculation of this equation is done when the return on investment is assessed. Although this equation presents the benefit more or less by monetary aspects, it has to be pointed out that in general the benefit can be measured by the improvement which is contributed by the user and that it also has to be considered to which aspect of the product or process the benefit is added.

**VON HIPPEL (1986)** investigated the properties of the user furthermore and refers with the term of the “lead user” back to the “innovator” within the model of the “technology adoption lifecycle” developed by **ROGERS et al. (1995)**. This innovator anticipates future needs and represents the vanguard of “early adopters” (visionaries), “early majority” (pragmatists), “late majority” (conservatives) and “laggards” (skeptics). As only a small amount of these innovators exists who can lead best to innovations, the more important it becomes to identify them and involves them properly into the innovation process.

**Innovation**

What is innovation? The field of innovation presents a wide range of research topics nowadays and has been of main interest for companies of every size and background in recent years. Hereinafter the term innovation shall be specified and aspects of its process and measurement are highlighted.

**Definition**

The term innovation descends from the Latin verb “innovare”, which literally means “to renew” (HAU & KULF 1986). Its meaning in which it is used nowadays has been originally introduced by **SCHUMPETER (1939)**. He defines an innovation as a process of different phases where the invention itself only represents only the first phase. What makes an innovation is especially the third phase of diffusion, which deals with the successful commercialization and contributes thereby to an economic growth. In today’s scientific context the term reveals a much more profound relevance:

“An innovation is the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organizational method in business practices, workplace organization or external relations.”

(Oslo Manual 2005, P. 46)
Satisfying this condition, innovation can be further differentiated into:

- product innovation
- process innovation
- organizational innovation
- marketing innovation

As a distinction between the different types of innovation is sometimes difficult and can lead to confusion, in this work mainly aspects of product innovation are addressed. Nevertheless these aspects can very often be adapted by other types of innovation as well.

The term “new” which is used in the Oslo Manual (2005) relates to the quality of an innovation and is even further differentiated by Koen (2005) into “incremental” and “radical”. While “incremental” relates to minor changes, “radical” describes a more or less revolutionary change in product, process, organization or marketing. This more detailed specification has decisive effect for instance on the measurement method, as it can be an important parameter in evaluating the quality of the innovation output.

The innovation process in product development

Generally speaking the innovation process describes the proceedings from the discovery of an idea to the launch of the product and even beyond. According to Schumpeter (1939) also Koen (2005) distinguishes the whole innovation process into three phases:

- “Fuzzy Front End” (FFE)
  FFE represents a chaotic and disorganized phase, where ideas emerge or just pop up. Often this phase also includes parts of the following stage-gate-process that mainly takes place in the second phase. In this case a business plan (as a part of the stage-gate-process) defines the end of Phase I and leads over to Phase II which brings together all product specifications (Koen 2005).

- The New Product Development (NPD)
  NPD follows a stage-gate-process as identified and defined by Cooper (1990). That means “a process is subdivided into a number of stages or work stations [usually represented by rectangles; author’s note]. Between each work station, there is a quality control checkpoint or gate [usually represented by rhombi; author’s note]” (Cooper 1990). To ensure the achievement of partial results, quality criteria are set and checked in a gate. Only if the results meet the requirements, the process moves on to the next work station.

- Commercialization
  In the commercialization phase the product is produced and sold on the market. Including even after-launch-activities such as monitoring, fixing and lifecycle planning this phase is called “commercialization” (Cooper 2005).

The innovation process with its three phases is usually summarized and depicted as shown in Figure 2-2. Here it is also highlighted what different kind of product innovations arise in the
fuzzy front end. This can be either incremental or radical innovations as described earlier, or the intermediate level of platform innovations.

Although KOEN (2005) provides a general valid basis with this valuable framework that bases on SCHUMPETER’s first idea of the innovation process, the innovation process itself has been matter of constant change within the last six decades, where four major evolutionary stages since the 1950’s were identified by ROTHWELL (1994) as depicted in Figure 0-3. The innovation process developed from a “technology-push” to a “market-pull” approach and further to mixed approaches called “coupling model” and the subsequent “integrated model”. While the “technology-push” approach expects innovation emergence from the findings of extensive R&D investment, the “market-pull” approach claims for early market research and customer feedback. Within this second approach market research activities reveal unmet customer needs, which give input and trigger the development process. These two strategies can be considered “the most common strategies to initiate and develop a service for a specific market” (ROTHWELL 1994). With the rise of the new product development (NPD) new approaches emerged with respect to market and technology aspects in the early phases of the innovation process. The “coupling model” combined thereby the first two models and put focus on both of them. However the “integrated model” expanded this model even further with integrated – meaning simultaneous – processes of marketing, R&D, production development, production and manufacturing. This is what is nowadays summarized with the term of Integrated Product Development (IPD) and requires a lot of interdisciplinary cooperation and team communication. Therefore several joint group meetings of engineers and managers have to be conducted during this integrated phase.
As ROTHWELL (1994) expects, a 5th stage of innovation process is emerging currently, where integrated processes consider also external resources such as suppliers, research labs, external distributors and even competitors. This stage shows many characteristics of the so-called open innovation.

**Open innovation**

For most of the 20th century the model of closed innovation was accepted by large companies and practiced worldwide. This model bases on the assumption that companies have to employ the best and “smartest” people and invest as much as possible into R&D. Through this
approach the ability to create radical innovations is brought to such a level that the company is first on market, can protect its intellectual properties against competitors and retracts the most profit compared to its competitors. Spending this profit again on R&D creates new radical innovations and leads in conclusion to an innovation cycle. As several companies in the past 20 years like Genentech, Amgen or Genzyme showed against large companies such as Merck or Pfizer, this cycle can be broke up with an open innovation model. With this approach a company complements its own ideas with the acquisition of external knowledge and commercializes the newly created innovation. In this case the company only has to “find and tap into knowledge and expertise of bright individuals outside the company” (CHESBROUGH 2003, p. 38). To visualize these models and allow a better understanding Figure 2-4 was developed by CHESBROUGH (2003). The boundary of the firm which is presented in by a dashed line is obviously not exceeded in the closed innovation model. Research projects are conducted and developed within the company and brought to the market thereby with no influence from outside. In contrast to this the open innovation model describes a permeable firm boundary where ideas can exceed in both directions at every time. This can represent either the outsourcing of a project into an own company or the acquisition of knowledge to the company.

Thus, the approach of open innovation with spread R&D by pooling different companies could be considered ROTHWELL’s previously addressed 5th stage of the innovation process.

**Innovation measurement**

In general innovation can be considered a “continuous process”, as companies constantly adapt their processes and gather new knowledge. That is why an ongoing procedure is required, to measure the general process of innovation, concerning for instance innovation

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*Figure 0-4 Closed Innovation vs. Open Innovation (CHESBROUGH 2003, PP. 36–37)*
activities, expenditures and linkages (OSLO MANUAL 2005, p. 15). To illustrate this dynamic process and evaluate it in retrospect, it is necessary to reflect the

- inputs,
- throughputs and
- outputs,

as it has been conducted for instance by LEE et al. (1996) in their measuring of R&D effectiveness in Korean companies. This approach is similarly supported by the OSLO MANUAL (2005, PP. 41-42), which describes these three aspects as “inputs to innovation, linkages and the role of diffusion and the impact of innovation”. With this approach two different innovation aspects can be measured: Firstly the innovation activities and secondly the innovativeness of developed products or processes. Both aspects require different approaches which are addressed subsequently.

**Measuring innovation activities**

Numbers of patents and return on investment (ROI) have been a common measure of innovation activities in companies. These investigation of the ROI thereby also enabled to examine the increase of monetary value, which also has been proposed by VON HIPPEL (1986), in order to investigate the value contribution through stakeholders during the whole process. However, measuring the ROI requires a precise breakdown of expenses on R&D (and other processes) as well as the revenue of the examined innovation. As pointed out in the OSLO MANUAL (2005), this implies great effort in precise documentation and can lead to different results depending on the examination time. Furthermore, in the past also the validity of patents as measures has been questioned, as they are registered for different purposes such as tactical reasons for instance (ADAMS et al. 2006). To overcome this disadvantage LANJOUW & SCHANKERMAN (1999) propose a measurement of four patent data aspects. The number of patent claims, forward citations, backward citations and family size are examined concerning their significance and “noise”. While a general counting of patent data is hardly expressive and not even describing the quality of a product, the procedure proposed by LANJOUW & SCHANKERMAN (1999) explores the importance of one innovation and also provides a final point score.

Due to the indicated drawbacks of patent and ROI data, recently other approaches have been promoted which provide a set of different evaluation criteria. However, often enough these approaches did not suggest precisely on how to evaluate the introduced criteria with measurable data (ADAMS et al. 2006). Thus ADAMS et al. (2006) reviewed several approaches and created an overall innovation measurement framework, to provide an overview and reveal room for improvement within the presented approaches. As the authors of this study considered a common literature research insufficient, they relied on recommendations from renowned researchers to identify useful measurement frameworks and parameters. Therefore their approach can be considered having a relevant academic background.

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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Creativity and human resources</td>
<td>Resource availability</td>
<td>Idea generation Technology</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
As shown in Table 0-6 they were able to combine the investigated approaches to an overall coherent framework with seven framework categories and seventeen measurement areas (not depicted here). These seven categories define the fields in which innovation measurement can take place. Depending on every category, specific measurement areas are proposed as shown in Table 0-7 which represent a first step of operationalization of the framework category. The act of “operationalization” specifies hereby with which indicators a theoretical construct shall be measured. In turn, this helps to identify measurable criteria from which innovation activities can be derived and evaluated.

In contrast to this framework which has been derived from an academic background, the MINT-framework by REGNELL et al. (2009) has been created by means of several case studies with large companies. It addresses innovation at the level of the team and is represented by a framework consisting of four categories and twenty-two measurement areas. Furthermore operationalized measurement criteria are proposed for assistance which are not shown in Table 0-7. Since this framework emerged from case studies including engineers and managers at companies it can be considered having a relevant industrial background. Table 0-7 summarizes and opposes both frameworks to each other. The indicated numbering of the framework categories has been introduced here, to clearly distinguish the categories from each other for later purposes.

<table>
<thead>
<tr>
<th>Framework category</th>
<th>Measurement areas</th>
<th>Framework category</th>
<th>Measurement areas</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 Inputs</td>
<td>People</td>
<td>08 Innovation Elicitation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physical and financial resources</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tools</td>
<td>Internal collection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Idea generation</td>
<td>External collection</td>
<td></td>
</tr>
<tr>
<td>02 Knowledge management</td>
<td>Knowledge repository</td>
<td>Internal generation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Informational flows</td>
<td>External generation</td>
<td></td>
</tr>
<tr>
<td>03 Innovation strategy</td>
<td>Strategic orientation</td>
<td>Feedback</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Timing</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Risk</td>
<td></td>
</tr>
</tbody>
</table>
Both frameworks can be considered as helpful input when developing innovation measurement criteria, but do not have to be implemented one by one (Regnell et al. 2009, p. 14). In general, these frameworks with the corresponding categories serve to create comparable results from different investigated settings. In addition Muller et al. (2005, p. 42) state that not “every conceivable parameter”, but a “manageable set of metrics (no more than 8 to 10)” should be selected to investigate innovation capabilities. That is why the subsequent task in an implementation process is to decrease the number of applied measurement parameters and identify only the most important ones that facilitate a coherent analysis. In the study of Lee et al. (1996) for instance only a set of 15 measurement criteria was used, to measure R&D effectiveness. Although the investigation of this aspect is not exactly the same as an investigation of innovation capabilities, it also addresses the measurement of a rather complex development process with the same actors and similar scope as an innovation process. With the data gathered through these measurement criteria a subsequent analysis can give insight to the quality of innovation activities and the innovation process within the company. Nevertheless the results from the analysis do not show the quality of the ideas emerging from the innovation process or set the innovation outcome into a direct or indirect relation to others. Hence approaches to characterize product innovation shall be highlighted subsequently.

Characterizing product innovation
The outcome of the innovation process is by definition supposed to be an innovation. But the quality of innovations can differ. To evaluate the outcome, usually direct or indirect comparison approaches can be applied. An indirect approach would be the classification of every result to a scale according to percentage or point values, whereas a direct comparison requires competing results that have to be set in direct relation to another according to a ranking. While the first comparison approach can be considered quantitative and measureable, the second one follows a more qualitative approach.

To classify an innovation, first of all it has to be investigated, if it is an innovation at all. The Oslo Manual (2005, p. 48) defines therefor the need of “significant improvements in the functional or user characteristics of existing goods and services”. As stated in further examples, a product innovation does not include (Oslo Manual 2005, pp. 151–154):

<table>
<thead>
<tr>
<th>04 Organization and culture</th>
<th>Strategic leadership</th>
<th>Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culture</td>
<td></td>
<td>Internal stakeholders</td>
</tr>
<tr>
<td>Structure</td>
<td></td>
<td>External stakeholders</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>05 Portfolio management</th>
<th>Risk/return balance</th>
<th>Return on Investment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimization tool use</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>06 Project management</th>
<th>Project efficiency</th>
<th>10 Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tools</td>
<td>Interaction</td>
<td></td>
</tr>
<tr>
<td>Communications</td>
<td>Trust</td>
<td></td>
</tr>
<tr>
<td>Collaborations</td>
<td>Intellectual property rights</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Standards and practice</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>07 Commercialization</th>
<th>Market research</th>
<th>11 Ways-of-Working</th>
</tr>
</thead>
<tbody>
<tr>
<td>Market testing</td>
<td>Process</td>
<td></td>
</tr>
<tr>
<td>Marketing and sales</td>
<td>Climate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Incentives</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Competence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Organization</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Process Improvement</td>
<td></td>
</tr>
</tbody>
</table>

Table 0-7 Comparison of measurement frameworks
• minor changes or improvements
• routine upgrades
• regular seasonal changes (such as for clothing lines).
• customization for a single client that does not include significantly different attributes compared to products made for other clients.
• design changes that do not alter the function, intended use or technical characteristics of a good or service.
• the simple resale of new goods and services purchased from other enterprises.

If these requirements are met, it is of interest of what quality the innovation is. Therefore the aspect of “novelty” can be considered. To ensure a further distinction, the novelty of an innovation is differentiated in three degrees by the range of the innovation (OSLO MANUAL 2005, P. 57):

• new to the firm
• new to the market
• new to the world

Such a categorization has to be implemented by an expert group consisting of persons with different backgrounds and knowledge about the firm and the worldwide market. Only such a group of persons with the necessary expertise is able to judge and classify an innovation, in order to achieve comparable and consistent assessments.

Another broader approach to assess an innovation with a qualitative approach is to classify the extent of the “change” which is implemented. Thereby the extent of product and process change is distinguished into four categories from incremental change up to new core product or process. Cross-referencing these aspects to another leads to a classification framework similar to the previously introduced scale of incremental and radical innovation. As WHEELWRIGHT & CLARK (1992) propose with their “typology of new products” in Figure 0-5, a third category of “platform products” results, which is surrounded then by “breakthrough” and “incremental products”.

<table>
<thead>
<tr>
<th>Extent of Process Change</th>
<th>Extent of Product Change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>New Product</td>
</tr>
<tr>
<td>New Core Process</td>
<td>[Breakthrough]</td>
</tr>
<tr>
<td>Next Generation Process</td>
<td>Platform Products</td>
</tr>
</tbody>
</table>
As a result, this 2-dimensional framework facilitates the classification of radical and incremental innovation by its cross-referencing approach and even expands this definition with an intermediate level of "platform products" to a more precise specification.

Networks in organizational management

A network consists of a set of actors (a.k.a. nodes) which are connected pair wise by a set of ties (a.k.a. links). The intention to describe an environment or situation in a network typology is to reveal hidden structures and enable a scientific research approach to analyze them. Therefore, the actors and ties have to be identified, specified, and put into context. This finally results in a linked structure which is denoted as "network". In the following passages, the actors, ties, and graphic presentation of networks shall be outlined, to give a first basic insight.

Actors (nodes):
The actors in a network can represent objects or individuals as well as entire collectivities such as teams, companies, or countries. Depending on the degree of detail, an actor can contain further actors, act as a class of actors, or even represent a network structure on its own. The same kind of actors or elements is then defined as a domain. To give some examples, a domain could be either persons, product elements, documents, or even tasks.

Ties (links):
In general, the network is mainly specified by the ties and how they embed the identified actors in it. A tie connects one actor to another and represents according to Borgatti et al. (2009):

- **similarities** in location, membership, or attribute,
- **social relations** in kinship, affective, and cognitive relations or other roles,
- **interactions** (e.g., talked to, gave advice to, received advice from) and
- **flows** (e.g., of information)

between the considered actors. To demonstrate the quality of this connection, it is furthermore characterized by Borgatti & Foster (2003) by:

- **direction** (directed or undirected)
- **binarity** (also called dichotomous: existing or not existing tie)
- **value** (weighting of the tie strength or importance)
Figure 0-6 summarizes this and shows common depictions depending on their characteristics.

<table>
<thead>
<tr>
<th>Direction</th>
<th>Binarity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>undirected</td>
<td>directed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>not existing</td>
<td>existing</td>
</tr>
<tr>
<td></td>
<td>weak</td>
<td>strong</td>
</tr>
</tbody>
</table>

*Figure 0-6 Graphic presentation of tie characteristics in a network*

With the knowledge about all characteristics of actors and ties a network can be transformed from the information about links to a graphic network presentation.

**Graphic presentation:**

To make networks comprehensible for discussions and a subsequent analysis, the information about ties and connected actors is usually saved in matrices and presented in a graph. The so-called influence or adjacency matrix shows the effects of actors in the first column to the actors in the first line. LINDEMANN & MAURER (2009) denote this matrix with the term design structure matrix (DSM). Depending on the fact, if the matrix consists only of the same kind of actors which influence each other (e.g. persons influencing persons) this is called intra-domain matrix. If the interrelation between different actors (e.g. persons creating product parts) is depicted, this is called inter-domain matrix. According to the characteristics of the ties the influence can be either directed which leads to a full matrix or undirected which leads to a symmetric matrix. Values in the boxes represent the extent of the effect and can be either binary or belong to a defined scale. From this matrix a graph can be easily derived as presented in Figure 0-7 which shows the connections between the actors more comprehensively.

*Figure 0-7 Network presentation of an intra-domain matrix*

**Domain connection**

In addition to this individual consideration of a DSM it is also possible to connect them to one network by means of a so-called domain mapping matrix (DMM). The DMM defines thereby in which way every domain relates to each other. The diagonal contains thereby the intra-domain matrices, whereas the other fields in the DMM contain the inter-domain matrices. From this DMM – respectively its inter-domain matrices – as presented in Table 0-8, it is then possible to derive further networks by simple matrix multiplication. A “person–component” matrix for instance gives insight on who works at or with the same components. If this matrix is multiplied with its own transpose, a “person–person” network can be derived about which actors are connected through a component and could influence each other thereby.
By this means it becomes clear that network theory can be applied in various disciplines with different backgrounds. It provides a very general approach to analyze interaction in social networks as well as mechanical interdependencies in complex product structures and much more. That is why subsequently relevant types of networks which are connected to aspects of innovation and the topic of development processes are presented.

**Social networks**

Innovation can be seen as a social process. It does not only derive from great ideas that pop out of someone’s mind. Innovations emerge in social environments, where people with different knowledge, abilities and needs meet each other and interact. This is why social networks shall be illustrated in the following.

A social network represents a group of persons and lays focus on the direct and indirect social influence among all considered persons. MITCHELL (1969, p. 2) defines it as “*a specific set of linkages among a defined set of persons, with the additional property that the characteristics of these linkages as a whole may be used to interpret the social behavior of the persons involved*”. With further knowledge about the quality of the connections between the actors conclusions on every person’s properties within the social environment can be derived. To reveal a social network, formal and informal information flows, interactions, similarities as well as personal relationships have to be considered.

As a result a social network depicts the information flow between and influence among its actors. It focuses on the role of the actor in the network and facilitates an evaluation of structural patterns. With this approach several social network structures could be analyzed in the past and important patterns and their effects were revealed, such as the benefit of weak ties which imply new knowledge innovativeness (GRANOVETTER 1973) or the positive effect of structural holes in competitive settings (BURT 1987). Nowadays social networks are analyzed in a wide range to investigate topics of social capital, embeddedness, networks organizations and organizational networks, board interlocks, joint ventures and inner-firm alliances, knowledge management, social cognition and group processes as summarized by BORGATTI & FOSTER (2003). What has been less considered in these specific works is how value is created and transported through a network and how this contributes to the final output.

**Value networks**

The term “value” is most commonly used in an economic context and understood as the worth of a product or process calculated by the ratio of benefits to costs. Besides this general understanding ALLEE (2000) stresses the importance of the “*currencies*” in which value is traded as a medium of exchange. These are:

- **Goods, Services and Revenue (GSR)**

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Table 0-8 Exemplary MDM layout with partly existing subsets (LINDEMANN & MAURER 2009, p. 86)
Knowledge

Intangible benefits

The tangible values, which are goods, services and revenue, emerge from formal activities that contribute directly to economic gain. That also includes knowledge products and services that generate revenue. In contrast to this the intangible values emerge from informal activities that help to build relationships and contribute to operational effectiveness. These in turn can be distinguished into intangible knowledge (which flows around and supports the core product and service value chain) and intangible benefits (advantages or favors that can be offered by one person to another) (ALLEE 2000). With this work it is contributed to the investigation of the customer value as relevant criterion, which is “determined from the customer perspective” (SIMPSON et al. 2001, p. 121). Every exchange of these tangible and intangible values “is supported by some mechanism or medium that enables the transaction to take place” (ALLEE 2000, p. 2). By the means of this supporting mechanism it can be assumed that there always exists an interface where the value flow can be tapped and examined.

During the last decades the concept of value networks emerged from PORTER’S “value chain framework” (1985) which considers rather the tangible values. PORTER states that within an organization certain activities have to be grouped and fulfilled by individual units such as marketing or production department for instance. To achieve a reasonable differentiation and integration of these activities in the organizational structure “the value chain provides a systematic way to divide a firm into its discrete activities, and thus can be used to examine how the activities in a firm are and could be grouped” (PORTER 1985, p. 59). With this tool a company can be broke down into its “strategically important activities” (STABELL & FJELDSTAD 1998, p. 413), to identify its core competencies and weaknesses, and the influence of these activities on the value creation can be investigated. Figure 2-8 depicts the ten generic drivers that have been identified by PORTER (1985) which have influence on this process. These drivers split up into the five primary activities of logistics, operations, outbound logistics, marketing & sales and service, as well as into the four support activities of firm infrastructure, human resource management, technology, procurement and the last driver, the margin. By this means it can be derived which unit adds which value or improvements to the product or process and how it performs in comparison to the other units.

Figure 0-8 Value chain framework (PORTER 1985, p. 60)
On the contrary Stabell & Fieldstad (1998, p. 414) claim that it is “not only difficult to assign and analyze activities in terms of the five generic primary value chain categories, but the resulting chain often obscures rather than illuminates the essence of value creation”. That is why they consider the value chain to be suitable only for the activities in “long-linked activities”, and propose alongside it the models of value shops, “where value is created by mobilizing resources and activities to resolve a particular customer problem”, and value networks, where value is created by building up a network relationship to the user and customer.

In contrast to the first linear model of the value chain, the value networks are “sets of roles, interactions, and relationships” similar to social networks, but with the premise of generating “economic or social value” (Allee 2009, p.5). Here also the intangible values are taken into account and a final impact and value creation analysis unbundles the effects of every unit more precisely than the value chain. The examined systems can be of different sizes and consider stakeholders as well as global and regional networks. Depending on the chosen system boundary the networks can either be considered external (customers, intermediaries or stakeholders) or internal (“key activities and processes such as order fulfillment, innovation, lead processing, or customer support” (Value Networks 2010)). The value network finally describes the roles and relations between individuals, groups and organizations similar to a social network, but focuses to reveal the tangible and intangible value that is created during the actors’ interaction. In addition a network analysis can then help to interpret the findings and be useful to investigate the actors’ roles in the value spreading.

**Working groups in organizations**

However, before a network analysis can be implemented, first of all the system of interest has to be specified and the system boundaries have to be set. Even within a system several subsystems can exist which also need to be identified. One approach to further define a group of persons has been proposed by Wenger & Snyder (2000), where they distinguish four different kinds of working groups according to their purpose, the team member composition, the motivation and the relevant timeframe, as presented in Table 0-9.

<table>
<thead>
<tr>
<th>Working group</th>
<th>Purpose</th>
<th>Team composition</th>
<th>Motivation</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community of practice (CoP)</td>
<td>To develop members capabilities</td>
<td>Members who select themselves</td>
<td>Passion, commitment and identification with the groups expertise</td>
<td>As long as there is interest in maintaining the group</td>
</tr>
<tr>
<td>Formal work group</td>
<td>To deliver a product or service</td>
<td>Everyone who reports to the group’s manager</td>
<td>Job requirements and common goals</td>
<td>Until the next reorganization</td>
</tr>
<tr>
<td>Project team</td>
<td>To accomplish a specified task</td>
<td>Employees assigned by senior management</td>
<td>Project’s milestones</td>
<td>Until the project has been completed</td>
</tr>
<tr>
<td>Informal network</td>
<td>To collect and pass on business information</td>
<td>Friends and business acquaintances</td>
<td>Mutual needs</td>
<td>As long as people have a reason to connect</td>
</tr>
</tbody>
</table>

*Table 0-9 A snapshot comparison (Wenger & Snyder 2000, p. 142)*
Although sometimes only two or three characteristics of a group could be know, it still would be possible to derive the remaining ones by scrutinizing this framework. Classifying groups of persons according to this framework can help furthermore to understand the relations and especially the motivation of the groups which represent the subsystems and can support the interpretation of later network analysis results.

**Network analysis**

The analysis of network structures grounds in the graph theory in mathematics. This is why it can claim to provide an analysis method that does not refer to specific types of networks only, as it examines the structure of the graph regardless of the represented topic. However this kind of analysis does not only identify recurring structures, but also certain metrics among the considered actors. These structures and patterns can be revealed with the help of specific algorithms and help the analyst in the subsequent interpretation. However, the final derivation of conclusions can only be done with the knowledge of the network context and not only with the help of algorithms. This is why the analyst is required to interpret the results and conduct a plausibility analysis to verify his findings. Structures in graphs and certain recurring constellations of actors provide here support, as they have been investigated in many studies before, which can be consulted in the final interpretation.

**Structures in graphs**

As mentioned before, various network structures can emerge through the interaction of ties and actors. According to BORGATTI et al. (2009, p. 893) the most common structures that reoccur very often and give the network a recognizable shape, as depicted in Figure 0-9, are defined as the “wheel”, the “circle” or “loop”, the “chain” and the “Y” which also represents a “structural hole”. A structural hole indicates the gap or absence of a tie between two nodes, which are only connected through another node. Below, these structures are presented as “ego-networks”. If a single actor within a network is regarded, one speaks of the “ego” which is indicated in Figure 0-9 by a red diamond, as the network is quasi considered from its personal point of view. Depending on the degree of the ego-network, actors connected through one, two or even more actors are considered.

<table>
<thead>
<tr>
<th>Wheel</th>
<th>Y / Structural hole</th>
<th>Chain</th>
<th>Circle / loop</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Wheel" /></td>
<td><img src="image2" alt="Y / Structural hole" /></td>
<td><img src="image3" alt="Chain" /></td>
<td><img src="image4" alt="Circle / loop" /></td>
</tr>
</tbody>
</table>

*Figure 0-9 Network structures (BORGATTI et al. 2009, p. 893)*

Structures as the wheel, the structural whole or the chain denote very often positions of power in which the ego is situated. The circle on the other hand often represents a structure which is unnecessary complicated as one actor reaches another most likely only through several other actors in a row. Of course this interpretation depends on the regarded topic and can also be very useful, as in the token–ring protocol for computer networks for instance.
Structures in Matrices
Besides these patterns in the graphic presentation, also the DSM in which the information about the links are saved can reveal hidden structures and help to derive conclusions. The two most common methods to analyze and arrange a matrix are the cluster analysis and the triangularization (Lindemann & Maurer 2009). While the cluster analysis intends to identify very strong connected actors and rearranges columns and rows so that clear clusters emerge (Table 0-10, left), the triangularization aims to restructure the actors in order to reveal a sequenced structure (Table 0-10, right). Both approaches are applied in practice, but in different contexts. While a cluster analysis helps to combine actors to create a better overview and defined structure, the triangularization is used to create a time dependent course of action. Elements are placed in order then, to ensure an optimum of the flow without unnecessary loops which may create delay or additional costs.

Both analysis approaches can thereby be excellently executed and depicted within the matrix presentation. However, the bigger the matrices become, the more difficult it becomes to analyze it by hand. Software support as provided by LOOMEO or UCINET is inevitable then.

Roles
Besides these structures also individual roles of actors help to analyze and understand the interaction in a network. The most common ego-networks which have been subject of detailed research in current and past literature are according to Tichy et al. (1979) the roles of the star as investigated for instance by Losito (2009), the gate keeper (Tushman & Katz 1980), the isolate, the bridge and the liaison (Schwartz & Jacobsen 1977). Hence, Figure 0-10 depicts and describes these roles with additional information on their characteristics.
As explained in Figure 0-10, the star is an actor who is well connected to many other actors in the network. He is in a powerful position as he can take control of the information flow from one actor to another that has to pass him. In this context he can also create structural holes, where the two communicating actors are only connected through him. In addition to this, the gate keeper represents an actor who also has connections outside the network. Those actors outside are dependent on the gate keeper, as without him no contact to the network is possible for them. This constellation even increases the star’s power. Isolates on the other hand are not connected to network at all. Usually they play no important role in the network due to their loose position. The bridge and the liaison represent connecting roles, where the bridge is the connecting part of two cliques (completely cross linked groups) and the liaison connects to groups without ebing part of them.

According to their role in the network, actors can fulfill different tasks and wield power. When the network has been revealed and analyzed, a more detailed investigation of everyone’s role is possible which helps to understand how everything works as it does. However, to give even more meaning to the results, the network also has to be analyzed by certain structural metrics.

Structural metrics

Besides the previous evaluation approaches, a network can also be analyzed by various structural characteristics or metrics. These metrics derive from graph theory and allow a rather structural analysis. As an evaluation is less comprehensive and resource-consuming, it needs a lot of computing power and the help of analysis software such as Loomeo or UCINET. Networks can be analyzed by metrics as LINDEMANN & MAURER (2009), TICHY ET AL. (1979) or KREIMEYER ET AL. (2009) defined according to Table 0-11 for instance. Some terms as the feedback loop, triangularization, bridge, gate-keeper, clustering and isolation have been explained already. Furthermore it becomes obvious that several others of the metrics as distance, density, centrality or size reappear frequently in the presented lists.
Depending on the research goal, appropriate metrics have to be chosen from this proposition. A systematic approach to limit the number of examined metrics is thereby useful to avoid unnecessary effort, as every chosen metric leads to the need of more data to acquire. The larger the scope of the collected data, the more arises the need of an approach that can handle this flood of information. Therefore COULONS (2005) conducted a literature research on the use of social network analysis in innovation research. As a result COULONS (2005, p. 7) points out the four most important concepts in network analysis “density, centrality, betweenness and centralization” and argues that the network performance can be evaluated as a combination of

- its robustness to the removal of ties and/or nodes,
- its efficiency in terms of the distance to traverse from one node to another and its non-redundant size,
- its effectiveness in terms of information benefits allocated to central nodes and
- its diversity in terms of the history of each of the nodes.

To highlight his findings, these metrics are explained in Table 0-12 below. Thereby it is remarkable that centrality can be implemented by different measures. Depending on the research focus either one or several of them can be used to investigate the aspects of centrality.

<table>
<thead>
<tr>
<th>metric</th>
<th>explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Density (of a network)</td>
<td>$D = \frac{\text{existing ties in the network}}{\text{possible ties in the network}}$; The density $D$ ranges between 0 and 1 and represents the level of connectedness in the network. The closer $D$ gets to 1, the denser the network is. Otherwise one speaks of a sparse network.</td>
</tr>
</tbody>
</table>
In the case of directed ties, alternatively the greatest possible number of pairs is considered.

<table>
<thead>
<tr>
<th>Centrality</th>
<th>The extent to which connections among actors are guided by a formal hierarchy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>local centrality</strong> (of a node)</td>
<td>Rises with the increase of direct ties with other nodes. If a node is connected to all other nodes, its centrality is defined as 1. If it is an isolate it is 0.</td>
</tr>
<tr>
<td><strong>global centrality</strong> (of a node) (a.k.a. closeness)</td>
<td>Rises with an increase of direct and indirect connections (through other nodes) to other nodes and relies thereby on the distance to the nodes. Such a connection over one ore more nodes is denoted as path then. A node possesses a high global centrality then, if it is in short distance to many other nodes. To put it into a context, all nodes need to be examined accordingly.</td>
</tr>
<tr>
<td><strong>betweenness</strong> (of a node)</td>
<td>Extent to which a particular node is in “between” the other nodes and can play a powerful role as broker or gatekeeper.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Centralization (of a network)</th>
<th>Centralization reflects the differences between centrality measures of the most central node and all other nodes.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[ C = \frac{\text{sum of differences}}{\text{maximum possible sum of differences}} ]</td>
</tr>
<tr>
<td></td>
<td>0 indicates a clique where everyone is connected to everyone, while 1 represents a star network.</td>
</tr>
<tr>
<td></td>
<td>In this way it shows the extent to which a whole network has a centralized structure and how the connectedness of nodes around specific focal nodes is organized.</td>
</tr>
</tbody>
</table>

| Robustness | Ability of a network to stay in more or less the same shape, if one actor is removed. If there is a large number of clusters, the robustness increases, as a removed person from a cluster is most likely balanced by the rest of the cluster and connectivity is not destroyed. |

| Efficiency | Measured “by the number of non-redundant contacts and the average number of ties an ego has to traverse to reach any alter (a.k.a. average path length)” (COULONS 2005, P. 9). The shorter the average path length is in comparison to the network size and the less redundant contacts it has, the more efficient is the network. This aspect is usually investigated to reduce the time and effort spent on redundant contacts. |

| Effectiveness | Effectiveness targets the cluster of nodes that can be reached through non-redundant contacts |

| Diversity | Diversity points out that nodes should be diverse in their nature, i.e. the history of every node in the network is of importance. |

Table 0-12 Relevant metrics of network analysis in innovation research according to TICHY et al. (1979) and COULONS (2005)

With the knowledge about these network properties it should be possible to investigate the most important characteristics of an innovative setting. Nevertheless it is still necessary to achieve the required data for such an analysis. Therefore different approaches can be pursued which have to be documented and finally evaluated.

**Documentation tools and methods**

Knowledge Management (KM) could be considered as parent topic when it is about documentation and the handling of knowledge and information. In general KM refers to the acquisition, capturing, using and sharing of knowledge in an organization. In this context it
takes “an important part of the innovation process” (OSLO MANUAL 2005, p. 24) and can be used to implement “value systems for sharing knowledge and practices” (OSLO MANUAL 2005, p. 87). This suits very well to ALLEE’s (2000, p. 2) claim that the exchange of value needs to be “supported by some mechanism or medium that enables the transaction to take place”. Besides the handling and documentation of informational flows within a company, KM also supports the management of external sources like customers, research institutions or other companies such as competitors or suppliers. Therefore methods and procedures are included to build and strengthen closer relationships with these stakeholders (OSLO MANUAL 2005).

In the broadest sense common documentation tools such as document storage systems (DMS) or databases (DB) can be considered a central aspect of KM and therefor accomplish this task as the “medium” or at least output of that medium, as it has been proposed by ALLEE (2000). In this chapter relevant aspects and tools of documentation and knowledge handling are presented, as far as they can contribute to a useful application in Innovationsplatsen. This regards the handling of knowledge over time as well as the different types of knowledge and the common ways to capture it.

**The knowledge chain**

The knowledge chain, as in Figure 2-11, describes every single phase of knowledge handling within a company. It can be applied in different contexts and be used as a guideline on how to handle knowledge in a process, where information have to be gathered and systematically managed. As DIENG et al. (1995, p. 568) state, the knowledge chain consists of seven links of:

- listing the existing knowledge,
- determining the required knowledge,
- developing new knowledge,
- allocating new and existing knowledge,
- applying knowledge,
- maintaining knowledge and
- disposing of knowledge.

![Figure 0-11 The knowledge chain according to DIENG et al. (1995)](image)

Depending on the process phase certain links of the knowledge chain should have been fulfilled already or will be of interest in a later stage, but not at present. This should be
considered, when adapting the knowledge chain to a specific case, as it reduces the effort that has to be dealt with in the current phase.

**Explicit and tacit knowledge**

When handling knowledge and information, it has to be considered what kind of knowledge is dealt with. In general knowledge can be distinguished into explicit and tacit. Tacit knowledge is in contrast to explicit knowledge “a non-linguistic non-numerical form of knowledge that is highly personal and context specific and deeply rooted in individual experience, ideas, values and emotions” (GOURLAY 2002, p. 2). These properties make it “hard to formalize and communicate” (NONAKA & TAKEUCHI 1995, p. 98). Explicit or codified knowledge, on the other hand, refers to knowledge that is represented by a transmittable, informal and systematic language. Hence tacit knowledge could be described as important knowledge and skills which are connected to specific persons. The more important it is therefore, to share this knowledge and benefit from it in the long-term. The management of tacit knowledge is one very important aspect of KM in general, which also deals with the question of how to transform tacit into explicit knowledge (MOORADIAN 2005). Only if tacit knowledge is revealed and transformed to explicit knowledge, the whole process of knowledge transfer can be investigated in its full extent. By the definition of tacit knowledge it becomes clear that its transfer requires intensive personal contact, for which reason it appears feasible to transform it into explicit knowledge first. Furthermore SWAN et al. (1999, p. 270) argue that “it is tacit rather than explicit knowledge which will typically be of more value to innovation processes”, whereas in the same breath they also adhere that this transformation, which in this context is also called codification, is very limited, as tacit knowledge is too “personal and context specific” and may only produce “useless […], difficult to verify […], trivial […], redundant […], irrelevant […], politically naïve […], or inaccurate” knowledge (SWAN et al. 1999, p. 270). To avoid this, the use of documentation tools, to save and transform tacit knowledge, should be specified well in advance and adapted properly.

**Documentation approaches and tools**

A superficial analysis of common methods in the field of product development indicates that there are different implementation approaches on how to collect information which emerge during the use of these methods with standard forms. The methods presented below in Table 0-13 are an excerpt from the online portal CiDaD (Competence in Design and Development). This list cannot be considered complete, but gives a good overview on applied documentation approaches and their characteristics.

<table>
<thead>
<tr>
<th>Method</th>
<th>Cause</th>
<th>Information content</th>
<th>Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Action planning worksheet</strong></td>
<td>Documentation</td>
<td>Description of aim, motivation, procedure, results (text)</td>
<td>List</td>
</tr>
<tr>
<td><strong>Balanced Scorecard</strong></td>
<td>Measurement</td>
<td>Set and actual values</td>
<td>Matrix</td>
</tr>
</tbody>
</table>
### Table 0.13 Examples of documentation methods (according to CidDaD)

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
<th>Key Figure</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Checklist</td>
<td>Validation</td>
<td>yes – no (binary value)</td>
<td>List</td>
</tr>
<tr>
<td>Decision tables</td>
<td>Supporting the decision process</td>
<td>Yes – no – irrelevant</td>
<td>Spreadsheet</td>
</tr>
<tr>
<td>FMEA</td>
<td>Analysis</td>
<td>Rating (values)</td>
<td>Matrix</td>
</tr>
<tr>
<td>Functional modeling</td>
<td>Visualization</td>
<td>Functions</td>
<td>Diagram</td>
</tr>
<tr>
<td>KM</td>
<td>Documentation</td>
<td>Documents</td>
<td>Electronic database</td>
</tr>
<tr>
<td>Network analysis</td>
<td>Investigation of relations and roles</td>
<td>(un)weighted connection of actors</td>
<td>Matrix / graph</td>
</tr>
<tr>
<td>Portfolio</td>
<td>Documentation / analysis</td>
<td>2-dimensional classification</td>
<td>Matrix/ graph</td>
</tr>
<tr>
<td>Properties list</td>
<td>Documentation</td>
<td>Properties/ explanations (text)</td>
<td>List</td>
</tr>
<tr>
<td>Requirements list</td>
<td>Documentation</td>
<td>Requirements/ explanations (text)</td>
<td>List</td>
</tr>
<tr>
<td>Story telling</td>
<td>Documentation of experience and (tacit) knowledge</td>
<td>Text</td>
<td>Prose text</td>
</tr>
</tbody>
</table>

As these approaches indicate, common activities in product development – no matter if they refer to future or past events – can be documented and saved with often reappearing implementation approaches. These approaches such as lists or matrices can provide apparently enough structure and space to save relevant information for different purposes. Besides these approaches, document management systems (DMS) are frequently used to store documents with any kind of information. This happens either in paper based systems or as nowadays more common in IT-based storage systems. In both cases an assistant method such as an index, tagging system or search engine is helpful, to retrieve these documents and the information saved in them. Concerning IT-based systems, the documents have to be digitalized and sometimes even specially prepared to meet the systems requirements concerning retrieval, file format, layout and numbering. The reasons to maintain a DMS are diverse. In some branches for instance the documentation of development processes is required for legal requirements. However DMS can also be used to administrate document versions and information, in order to keep track of the information flood. In this case the DMS helps to retrieve information that can be used then for the purpose of process analysis, information spreading or quality control.

Finally the presentation of appropriate and commonly used documentation tools completes now the theoretical framework which has been presented in this chapter. At the beginning the background of the MedTech industry has been broke down to the relevant aspects of medical devices and the user’s role as a customer in this environment. With the knowledge about these paramount factors in the context of creating innovative products, it was possible to highlight what innovation means both in general as well as in the current evolutionary context and how it can be investigated. Thereby it could be illustrated that innovation can be investigated with different approaches which respect either the conducted innovation activities or the product innovativeness itself. Furthermore it was highlighted that these approaches require an
appropriate adaption depending on the context in which they are applied. As innovation can be considered a phenomenon with high relevance to social network structures and the value creation within, these aspects were presented as well and supported with the know-how on how to analyze networks. Thus, a wide range of characteristics investigating the role of single actors as well as the holistic view of the network can be considered. The last subchapter dealt then with the handling of knowledge and gave advice on how to acquire the information that is required to capture these processes, in order to allow a final analysis of a setting. In the following chapter the methodological approach will be discussed that forms the basis for the subsequent detailed investigation of the similar MedTech settings and the final development of an adapted approach.
Methodology

In this chapter the applied procedures and methods are presented as well as an approach to method development in general which will be followed in the course of this thesis. This supports the development of the required approach as it has been identified in the problems definition, in order to investigate the user involvement.

To answer the initially defined key questions a systematic approach supported with purposeful method use needs to be followed. The approach helps to investigate the prerequisites in the industry in a structured way. Basing on these findings an approach can be developed systematically.

In general two methodological research approaches are conceivable which have been introduced by ARISTOTLE in his “Analytica Priora et Posteriora” and build there together with the aspects of empiricism and theory the basis of the philosophy of science. These two approaches consider either the extracting of general from specific knowledge or vice versa the derivation from the general to the particular. The first approach can be denoted as inductive reasoning and can consider the extraction of general findings from empirical case studies, while the second one can be called deductive reasoning and specifies the derivation of findings from general theory which have to be put in practice then. For this thesis a combination of both approaches is strived, depending on the situation. Whereas the investigations to illuminate the state of the art in the MedTech industry shall follow an inductive approach, the later development of a solution to the identified problems shall use this input and follow a deductive approach using the results from a literature research. Figure 3-1 provides therefore an overview of the theory of deductive and inductive research approaches and how this shall be put into practice in this work.

![Deductive and inductive approach](image)

**Figure 0-1 Deductive and inductive approach**

**Literature Research**

The results of the literature research have been presented already in the previous theoretical framework. Therefore, depending on the topic, obvious key phrases and words covering this topic in general were investigated within this deductive approach with an internet search engine. Basing on the findings from this search, the list of key words was extended and investigated in online databases for scientific works such as Google scholar or Springer Link. The discovered scientific papers with titles that seemed suitable for a better understanding of
the topic were investigated. If the abstract of a paper implied further relevant information, the paper and references of this paper were studied. Besides this top-down approach from general key phrases to specific scientific papers, also researchers and professionals on the field of interest were contacted for further information and scientific literature on the topic. By this means also a knowledge exchange and discussion with these persons was permitted, who are more experienced in that field. The literature investigated with this approach comprised scientific publications, papers, master thesis’, statistics, industry association publications, industrial process documentation and more. A consideration of such broad band of sources seemed to be sufficient to support the previously depicted proceedings and guarantee a high quality of background knowledge. Nonetheless shall this literature research be supported by additional methods by means of direct interaction with professionals, which is presented in the following.

**Survey methods**

Within the inductive research approach, information acquisition from stakeholders such as users, customers, developers, managers and researchers can be implemented with various methods. The most common ones which are used nowadays, to consult any kind of persons or groups are (GFS BERNE 2010)

- face-to-face interviews,
- telephone interviews,
- written questionnaires and
- online questionnaires.

While questionnaires on the one hand can ensure an inexpensive and fast inquiry of large groups, personal interviews on the other hand deliver more detailed information from few experts in a purposeful conversation. According to the circumstances of the research question, pros and cons of every method have to be considered, in order to pick the most appropriate one. Criteria to choose the right method can contain matters of time, expenses, kind of interviewees and aspired information for instance. Table 0-1 points out furthermore what specific properties the different approaches feature according to their implementation, flexibility, influence and supervision during the inquiry. This even underlines that depending on the intention a different approach has to be chosen.
Especially with interviews it is not only possible to gather quantitative information, but also to “investigate opinions and behaviors regarding certain issues” (Lindemann 2009, p.274). During the preparation, conduction and post-processing of an interview it is important to (Lindemann 2009, p.274)

- define the subject of the questions,
- set the interviewees,
- formulate the questions,
- conduct the interview,
- analyze transcripts and records and
- let the interviewee countercheck the transcripts or results.

To implement this qualitative approach, it is recommended to conduct the interviews in a guided form. This requires the creation of a systematic interview guideline with all questions and important key phrases, which also should facilitate the dealing with different upcoming topics in greater detail. The guideline provides therefore a basic frame for the interview, but still offers the interviewer the freedom to adapt the topic according to the conversational flow. Along this guideline, which can be found in the appendix, the interviewees can be confronted with the previously investigated questions and are furthermore encouraged to answer freely and provide as much information as they consider useful. This kind of questioning technique is also chosen, to get an insight into the industry even before all the details are exposed and can be examined.

Besides the differentiation of personal interviews into face-to-face and phone interviews, it is also important to specify the manner of the interview implementation. Various approaches are conceivable as explained in Table 0-2. They differ in the manner of questioning technique and give the interviewee more or less freedom to answer and express his opinion.
<table>
<thead>
<tr>
<th>Interview type</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Narrative interview</td>
<td>Open question to the interviewee, interviewer listens attentively to the narrations, atmosphere of trust, no guideline</td>
</tr>
<tr>
<td>Explorative interview</td>
<td>Key questions are explored more intensively, interviewer doesn’t need to have expertise necessarily, interviewee’s complete view should be explored</td>
</tr>
<tr>
<td>Depth interview</td>
<td>Permanent questioning with “why”-questions, stimulates the interviewee to think reveal unconscious knowledge</td>
</tr>
<tr>
<td>Expert interview</td>
<td>Interviewee (expert) communicates his knowledge to the interviewer (quasi-expert), flexible guideline</td>
</tr>
</tbody>
</table>

*Table 0-2 Qualitative interview approaches (WPSG 2010)*

Regardless of the chosen method (interview or questionnaire), the results have to be recorded and evaluated in a subsequent analysis. While questionnaires usually provide a representative database for statistical analysis due to the large number of interviewees, personal interviews can also provide qualitative conclusions according to the focus of every interview. Hence a transcription of the interview can help to identify important statements and serve as a documented source. To receive the required information from the interviewees and conduct a proper analysis, a systematic approach is advisable. One way to do this is to follow a PDCA cycle. Thereby the four steps of planning, doing, checking and acting are repeated continuously as depicted in Figure 3-2, until a proper results is achieved.

![PDCA cycle applied for interviews](image)

**Figure 0-2 PDCA cycle applied for interviews**

To compare the information content of one interviewee to another the topics of the questions could be put into a multidimensional sorting matrix as in Table 3-3. Comparing the results within one column reveals lacks of information from an interview or even white fields, where no information has been gathered.
However, both qualitative as well as quantitative results need to be discussed afterwards, to emphasize the findings from the interviews and serve as a basis for further action.

**Method development**

Before the development of methods is discussed, the term “method” needs to be clarified. LINDEMANN (2009, P.57) delimits methods from “procedures” and “basic principles of action” and defines a method as a “description of a rule-based and systematic approach” as requirement for a targeted goal. Furthermore LINDEMANN states that “methods often represent a formalism that defines how working steps have to be performed or results have to be documented”. Yet methods can contain other methods or be supported by them, even if they are of less complexity.

As mentioned above a method stands in contrast to “procedures” and “basic principles of action”, since it explains what tasks have to be performed, while on the other hand a procedure defines how and with which result these tasks have to be implemented. In comparison, basic principles of action only consider general principles that support the developer in his activities, such as the top-down principle for instance. Finally the ultimate goal of a method is to improve cooperation, the handling of information and knowledge, to refine complex problems into clear sub-problems and to minimize the risk of development processes in general (LINDEMANN 2009).

Developing new methods is a task for which the Munich Methods Model (MMM) in Figure 3-3 can be used as a guide through the stages of use clarification, method selection, method adaption and method use.
During the first stage of the MMM, the use of the method is clarified. Therefore the available input, the topic’s range and the aspired output explain the application background for the method. During the second stage – the selection of appropriate methods – the required input and the desired output, including its effects and side effects, is investigated. This is the basis, on which the decisions of method selection can be made. During stage two and three of the MMM also all allocated resources have to be taken into account as far as they can have effect on the method. Basing on this, an adjusted method can be derived and visualized in a schematic figure. Finally in the fourth stage tools are created and suggested which provide assistance during the use of the method. As it is not clear at the beginning of the research if the final result will be a method or procedure as it has been defined, a more general approach needs to be considered as well.

Supplementary to the MMM also the Munich Process Model (MPM) in Figure 3-4 exists, which provides a more general orientation in a research process and contributes to a systematic proceeding. Whereas the MPM is not specifically designed for method development, it serves as a general guide for problem-solving processes and well-considered proceedings. Therefore the seven different tasks of objective planning, objective analysis, problem structuring, solution identification, properties identification, decision pressing and achievement assuring should be pursued. The standard way of proceeding in this model, which is depicted in Figure 3-4, is however not obligatory and can be varied accordingly. Also loops within the procedure or even the application of the whole model within itself are conceivable.
Within the course of this thesis the way of proceeding varies from the standard procedure of the MPM, and has always the MMM in mind, to support the process of the approach development. First of all the planning of the objective is going to be achieved in chapter 4 where the central question respecting the state of the art of user involvement as well as process and idea evaluation in the MedTech industry is investigated. Highlighting these two major aspects with an interview approach will then allow comparing current settings with the aims of Innovationsplatsen and facilitate the derivation of an action recommendation. Subsequently in chapter 5 the problem structure is derived in an examination of current process documentation and by pointing out the possibilities and disadvantages of network modeling with the available data from company A. When this is done, the objective can be analyzed precisely enough in a third step within the MPM, to derive a requirements list. These three steps of the MPM reflect thereby also the first step of the MMM. Subsequently appropriate tools and approaches have to be identified and adapted (step two and three of the MMM), which have already been introduced in the theoretical framework. During the penultimate step of “pressing for a decision” the identified tools have to be selected and adapted according to the requirements, before the developed approach can be evaluated by an expert panel at last. The use of the developed method as it is described in the MMM as step four cannot be considered in this work as it is part of future processes which are beyond the time scope of this thesis.

**Approach evaluation**

To evaluate the proposed approach, a final workshop including participants with different backgrounds is conducted. Therefore the interviewees as well as responsible persons from Innovationsplatsen and network researchers are contacted in advance. Finally a researcher involved in the planning of Innovationsplatsen, the director of innovation at Swedish MedTech and the interviewed innovation manager from company B confirmed. Unfortunately the product manager from company A had to cancel the meeting in the last moment. After
setting date and place for the workshop, the proceeding of the workshop was developed according to the agenda below:

- **Introduction**
  - Self-introduction
  - Participants introduction
  - Reason for the workshop
- **Explanation of the background**
  - Innovationspaltsen and other innovative MedTech settings
  - Problem definition
  - Discussion about problem definition
- **Solution presentation and discussions**
  - Data acquisition
    - presentation
    - questions
    - discussion
  - Evaluation process (presentation and adaption)
    - presentation
    - questions
    - discussion
- **Conclusion and final feedback**

For the workshop a time frame of one to one and a half hours is set, to facilitate a complete presentation and discussion of the presented problems and solutions. By means of different media, such as a PowerPoint presentation to highlight the introduced topics, the workshop is supported and recorded. A voice record of the discussion supports furthermore the noted feedback from the participants and helps thereby to keep track of the results. The feedback received from the workshop has to be examined critically and introduced finally to the developed approach.

*In retrospect, this chapter presented the proceedings and the methodological approach which is followed in this work. Hence, the general approaches of inductive reasoning, to investigate the state of the art, and deductive reasoning, to identify and propose appropriate solutions from literature, have been introduced as background for a scientific proceeding. Subsequently the used methods to investigate persons’ opinions and feedback as part of the inductive approach were presented. At the same time special emphasis was put on the method of guided*
expert interviews, which allow investigating a rather unfamiliar setting, and the actions before, during and after such an interview process were presented by means of a PDCA-cycle. Finally, as guideline for the further systematic proceeding, the Munich Process Model was proposed with regards to the Munich Methods Modell, which have been explained both in detail. By means of their structured guidance in development processes a systematic and reflective approach can be followed, to achieve a transparent and comprehensible progress. To start with this structured procedure, within the next chapter the role of user involvement and process evaluation in the MedTech industry will be investigated as a basis on which then a further adapted approach can be developed.
Investigation of the state of the art in the MedTech industry

The first step in the systematic procedure of the MPM is the planning of the objective, which is conducted by an investigation of the current situation. Here the first key question of how MedTech companies perform and measure user involvement today shall be investigated. Therefore the selection and implementation of the previously presented methods is reasoned and expert opinions are obtained by means of interviews with four large MedTech companies. Derived from this examination the process of user involvement in all of the examined companies is presented and further salient aspects that differ between those companies are highlighted.

Interview procedure

As the future Innovationsplatsen can largely be considered unique in its setting, it is assumed that currently there is no single place that can be examined representatively. That is why a number of companies with similar approaches and background in their innovative development environment is investigated instead. Subsequently a revelation of their practices can reveal drawbacks and help to derive an appropriate approach to overcome them. The first step in the investigation of the background for the approach is the identification of appropriate MedTech companies and the conduction of expert interviews with qualified professionals. Therefore the proceeding for interviews as proposed by LINDEMANN (2009, p.274) is implemented as follows:

- The topic of conversation is defined according to the initially defined key questions. This includes information about the user involvement, the general development processes, documentation and information spreading as well as the procedure of process and output evaluation in the company.

- Companies are selected by following criteria:
  - available for interviews
  - existent user involvement before, during and after the development processes
  - large company size (to ensure a large number of persons in the processes)

- Interviewed professionals are required to work:
  - in that company or branch for a period that enables them, to provide profound knowledge (> 3 years)
  - with development processes, product management or process design

- Questions are formulated and sent to the interviewees in advance, to give them time for preparation. Nevertheless questions are articulated not too specific, in
order to encourage the interviewee to talk free about the interview topics.

- Phone interviews (due to the time limitations) are conducted with three interviewees at company A and one interviewee at each other company. These conversations are recorded with audio recording software and transcribed as well as further notes are taken.
- An interpretation and analysis of the interviews, which can be found transcribed in the appendix, is conducted according to the presented approach with a multidimensional sorting pattern.

According to the PDCA-cycle step three and four were repeated as further questions arose after the first cycle of interviews. The following interviews with every person lasted then for approximately half an hour each in total. But first, all interviews started with a presentation of Innovationsplatsen and an explanation of the thesis background.

**Outline of examined companies**

Following the introduction, interviewees were asked about their position within and the background of their company, such as firm size, geographic origin and type of products. Thus the listed information in Table 0-1 were gathered from the interviewee’s statements and the companies’ public appearance in brochures and online.

<table>
<thead>
<tr>
<th>Company</th>
<th>Firm size</th>
<th>No. of employees</th>
<th>located</th>
<th>Interview partner</th>
<th>products class</th>
<th>GMDN</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>large</td>
<td>&gt; 5.000</td>
<td>Germany / Sweden</td>
<td>Industrial designer&lt;br&gt;Usability designer&lt;br&gt;Product manager</td>
<td>I, II and III</td>
<td>2</td>
</tr>
<tr>
<td>B</td>
<td>large</td>
<td>&gt; 10.000</td>
<td>United States</td>
<td>former technology manager/&lt;br&gt;now innovation manager</td>
<td>I, II and III</td>
<td>1</td>
</tr>
<tr>
<td>C</td>
<td>large</td>
<td>&gt; 8.000</td>
<td>Germany</td>
<td>Product manager</td>
<td>I and II</td>
<td>5</td>
</tr>
<tr>
<td>D</td>
<td>large</td>
<td>&gt; 1.500</td>
<td>Germany</td>
<td>Technical manager&lt;br&gt;project manager</td>
<td>I and II</td>
<td>13</td>
</tr>
</tbody>
</table>

Table 0-1 Basic information about interviewees

The examined companies remain incognito in this work and are hereinafter named (without any judgment) company A, B, C and D. Although the basic information in Table 0-1 have a rather informal character, they are provided in order to highlight the background of the companies and to contribute to a comprehensive understanding. They point out furthermore that the requirements for the interviewees as they have been determined before were met.
Results from investigations

To recall the initial intention of this interview approach, the key question was to investigate how user involvement is performed and measured in MedTech companies. Therefore the feedback from the interviews is summarized according to the revealed topics of

- the scope of user involvement,
- the spreading of information and communication in the company,
- the evaluation of ideas and processes,
- the documentation of processes and
- the feedback on the concept of Innovationsplatsen.

User involvement in MedTech companies

The user, as it has been identified by Shah & Robinson (2008) and listed in Table 0-4, is involved in different ways within the examined companies. In general all four companies involve internal users, who are permanently employed and work at the company’s own facilities, as well as external users, which are called in when needed and employed in short term only, both directly as well as indirectly. The indirect involvement is thereby conducted through persons who are in contact with the users and bring the required knowledge back to the company by “translating this knowledge verbally to the developers” (Project Manager, Company A). While in company A this part is fulfilled by marketing related people, company C and D use also the project manager as transmitter and translator for the user’s feedback. In addition company B sends also clinical system engineers to the user and prompts other developers to get into touch with the users.

Besides these approaches where the indirect involvement of external users is considered, also direct involvement of users can be found. Company A and B conduct therefore meetings, which are in the case of company B called “arenas”, where external users join “market experts, engineers and whoever is part of the team” (Industrial Designer, Company A) for a feedback discussion or systematic method use. These so-called expert panels can then bring competences from different backgrounds together and enable an intensive cooperation. By doing this, the users provide their feedback directly to the responsible developers.

In addition to the indirect and direct involvement of external users, also the direct user involvement of internal users is pointed out by the companies. As internal users shall be denoted here all persons who assume the role of the user, but are employed in the company and do therefore not take the role of a possible customer. Depending on the company, those users have different backgrounds then. While in company A “clinical staff such as physicians, nurses and also biomedicals” (Usability Designer, Company A) are employed and also company B follows this approach with a part-time employed physician “who works for [them] two days a week” (Innovation Manager, Company B), company C only has “product specialists” which have the necessary background knowledge of clinicians, but work now as developers. Company D however has no internal users in the original sense at all. Due to the lower complexity of their products, here also the developers take on the role of the internal user, by trying the developed products. Furthermore also company A pursues an approach where the developers assume the role of the user. In a rather “less structured method” (Project Manager, Company A) they create a “general persona” by means of a
discussion, who is an imaginary reference user so to say. From this reference user needs and properties are derived then which give input to the ideation and development process. Besides this organized user involvement also sometimes external inventors appear, which come up with idea proposals, as it has been stated by company C and D. Unfortunately it is not clear here, how those inventors involved users in their idea generation. Finally, it can be summarized that the interviewed companies derive the users’ needs and ideas for new products from:

- Translators (e.g. marketing & sales, project manager)
- External users, customers and experts (clinicians, physicians, nurses, biomedicals, etc.)
- Internal users and experts in the company (physicians, expert panels)
- Internal research with a methodological approaches
- In rare cases suggestions from external inventors

Figure 4-1 depicts these sources of user involvement and points out how they are implemented within and towards the company.

Figure 0-1 Sources of user involvement

In addition to the revealed different ways also different moments of user involvement can be considered. As depicted in Figure 4-2, the involvement of the user can happen thereby at any stage of the innovation process. Firstly it can take place at the beginning during the FFE, when new ideas and concepts emerge. Company A, B and D involve therefore users in expert panels for the application of ideation methods or draw knowledge into the company through a “needs translator”. Also in the second phase of the innovation process – the NPD – extensive user interaction is required during the evaluation of advanced ideas or prototypes. As company D states, the involved user is supposed to provide feedback then on prototypes for instance, which have to be considered in the further development process. Finally the user can also be involved in the third phase of commercialization. As in the case of company D, the
user serves here as a “promoter”, who valorizes the product with his reputation and could convince new customers thereby.

Communication and information spreading

Following the question in which way users are involved, the question comes up how information among the company staff – and by this means also among the internal users – is communicated. The common ways of spreading information nowadays, such as company journals, emails and phone calls, are used by all interviewed companies. Also digital media like the intranet are used in all companies, as in company A for instance where information about “results and main findings from studies” are communicated rather unidirectional with no participation of the readers. Especially company D highlights the need of communication, when it points out that “communication is the most central topic in a project”. Confronted with the question, if a knowledge map would make sense then, which depicts the company’s social network and draws the ways of where to find which information, company A responds that “it is easier and quicker to ask someone” for which reason “person-to-person conversation” is considered more useful than pre-drawn maps. But also the documentation of processes and activities is regarded as a communication process, as the usability designer from company A states that documentation is “a way of communicating your results to many people”. With the same ulterior motive company A, B and D introduced so-called crowd sourcing systems which enable to submit ideas quickly and efficiently to the responsible persons.

However, also other approaches to spread information can be pursued, as company B demonstrates. In this company also an intranet-based social media application is used. Similar to famous social media as facebook for instance, this application serves as a platform based collaborative communication tool within the company. It can be stated that such kind of tool was not found in the other companies.

Figure 0-2 Moments of user involvement during the innovation process
Processes and idea evaluation

To measure the influence of user involvement it seems inevitable to evaluate what effects the user has on processes and ideas. This is why the companies are also asked about how they implement this kind of evaluation. As stated by all interviewees, the evaluation of the processes is usually conducted in a final qualitative and informal evaluation. Although company A states to have a final project review which is either conducted by “questionnaires” or “a discussion”, they also review project aims constantly, but not “as a formal part of [the] process”. Company C follows the same procedure and evaluates the processes continuously, but also conducts a “retrospective analysis on goal achievement” at the end. In the later course they also evaluate the marketing process “six months after the product introduction to the market” by means of an evaluation matrix. Also company D investigates this phase by criteria like the ROI and also conducts a final “lessons learned” team session.

Besides the evaluation of processes also idea evaluations take place. Company B and D conduct this, in order not “to waste capacities for ideas which are not good” (PROJECT MANAGER, COMPANY D) and to “finalize the idea cycle” (INNOVATION MANAGER, COMPANY B). In this case it has to be added that both are companies where crowd-sourcing systems exist. Furthermore they have evaluation and measure systems which are either classified (COMPANY D) or have “different measures, for different departments and different products or projects” (INNOVATION MANAGER, COMPANY B) and are current topics of investigation in that company. This is why they cannot be presented. However, also company A and B evaluate their ideas, but more informally in discussions. Company A uses therefore a limitation approach which decreases the number of ideas and discusses the left ideas then in “internal audits” (PROJECT MANAGER, COMPANY A) with the participation of external experts.

Documentation of development processes

The final aspect of interest is the process documentation in the companies. With this topic the second key question shall be treated, to investigate what information about user collaboration is stored in process documentation. All examined companies state to run a document management system (DMS) which facilitates the saving and sharing of the data generated continuously throughout the development process. By this it is pointed out again, that companies see documentation as a tool of communication. However, the main purpose of a DMS is to trace the development process due to “legal and regulatory requirements”, as stated by company A and attested by the other interviewees, too. This documentation covers then activities which should take user interaction into account as well as formal process documentation. Within company A this includes for instance:

- prepared studies (e.g. pre-study reports, market requirement specifications)
- documentation reports (e.g. steering group decisions, validation reports)
- planning reports (e.g. usability engineering plan, user acceptance test plan)
- process guidelines (e.g. strategy papers, formal development process)
- templates that support the development process (e.g. brainstorming templates, usability test plans)
completed templates to document the development process (e.g. drawings of ideas, requirements list)

These additional findings could be derived from a closer examination of the process documentation from four projects in company A, which were chosen by their degree of innovation: one radical, one platform-based and two incremental innovation projects. However, within these examined documents no enlightening information could be found about the user involvement, as persons and their collaboration with another was not listed. Besides these examined documents also “any paper, napkin or whatever [they] have ideas sketched on” (INDUSTRIAL DESIGNER, COMPANY A) is digitalized, to be administrable with the used IT system, although sometimes, as in the case of company A, also paper-based systems exist simultaneously. The only company which runs an additional system to this is company B. Here two idea management systems exist depending on the “complexity” of the idea. With this system a traceability of the generated ideas is achieved with respect to the conducted evaluation processes. Finally Table 0-2 summarizes the findings of the four investigated topics in a comprehensive overview.

<table>
<thead>
<tr>
<th></th>
<th>User involvement</th>
<th>Communication in the company</th>
<th>Idea and process evaluation</th>
<th>Process documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>direct</td>
<td>in-direct</td>
<td>personal</td>
<td>informal (discursive)</td>
</tr>
<tr>
<td></td>
<td>internal</td>
<td>external</td>
<td>by media</td>
<td>reduction</td>
</tr>
<tr>
<td>A</td>
<td>C/E</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>B</td>
<td>PS/D</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>C</td>
<td>PS</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>D</td>
<td>E</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

CI = Clinicians, E = Engineers, PS = Product specialists

Table 0-2 Overview of the interview results

Feedback about an innovative setting as the Innovationsplatsen

Finally the interviewees were asked about feedback on Innovationsplatsen. In general, all interviewees showed great interest in the Innovationsplatsen. Company C even mentioned the
existence of a so called “power team” within the company that has the same objective of innovative and “interdisciplinary collaboration [...] detached from the daily business” (PRODUCT MANAGER, COMPANY C). This team apparently proved its success in the last years and is therefore probably going to be expanded in future. The interviewee of company C especially highlighted thereby the verified benefits of the “short communication paths” and the opportunity to “work intensively and concentrated” in a closed setting. Also the project manager of company A acknowledged the benefits which are achieved by “formalizing the network” and “putting the benefits of all the disciplines together”.

Nevertheless the interviewees also raised concerns. It was pointed out for instance that, depending on the size, “a company could not afford to assign several developers” (PRODUCT MANAGER, COMPANY C) for such an effort. Furthermore the project manager of company A highlighted the problem of the Western European oriented background, which might stand in contrast to the need for feedback considering Asian or South American needs for instance. Therefore he suggested an implementation of Innovationsplatsen in these regions as well. Besides this, the innovation manager of company B raised concerns about the legal rights owner of an innovative product created at Innovationsplatsen and suggested a clarification of the problem.

Discussion and action recommendation

As the results from the interviews demonstrate, the ways and moments of user involvement are various. Although the companies consider different types of users at different times in the innovation process, none of the companies could state what precise influence which involvement approach had to the value of a product. As the companies claim to evaluate their processes continuously, also this aspect should be investigated. Additionally, although communication has been recognized as a central aspect, only one company took the step forward and broke new grounds in this field by using social media, while the other companies remained with their common communication approaches. For the future it seems expedient for these companies now, to follow the example of company B by taking new ways of communication as well, which should go beyond the currently applied crowd-sourcing tools. Even though these tools provide a certain opportunity for assessment, the idea and process evaluation is in the most cases not formally a part of the processes. However, evaluation as part of the idea cycle process and as a tool of continuous process improvement can help to establish priorities and contribute to a steady improvement. Moreover, the available documentation in the DMS is currently hardly taken into account for a retrospective analysis processes and serves more to capture the explicit knowledge. Although especially the early stage of the FFE as defined by KOEN (2005) is hardly considered anyway in the documentation, a valuable source of information is left unused thereby. On top of that it would be also necessary to investigate the tacit knowledge of the company. That is why combining the capturing of tacit and explicit knowledge with the same documentation approach would be a great improvement. Finally after the investigation of the MedTech background, needs for future improvements become clear. While nowadays qualitative standards for medical development processes and their documentation are determined by legal requirements and therefore guarantee a rather good process tracking, MedTech companies on the other hand seek to fulfill sometimes only
these requirements and might lack in the feasibility for subsequent detailed process analysis. Furthermore it can be assumed that because of this high quality standard among all companies the competition has roughly relocated to the aspect of innovation. Therefore companies try to take every qualified source for innovative ideas into account and seek salvation in the involvement of future users as early as possible in the development process, to include these valuable sources of information and enhance their own innovation capabilities. Because of all of these reasons an approach should be developed that takes into account all the identified drawbacks and helps Innovationsplatsen to avoid them. To create this approach according to a systematic procedure, an action recommendation is derived, as proposed by LINDEMANN (2009) as part of the “objective planning” within the MPM.

Derivation of an action recommendation
On the one hand the results of the expert interviews provide a good comprehensive overview of the environment of MedTech settings nowadays. On the other hand the Innovationsplatsen project cannot be overviewed absolute precisely yet due to its implementation in the future, but could now try to pick-up the benefits from the current situation and advance even further. Although both environments – current MedTech settings and the future Innovationsplatsen – might differ in their appearance, they still match in important parts and can be outlined by the key aspects of:

- user involvement and orientation
- structured work environment
- high level of cooperation
- documentation requirements (e.g. by law)
- aim for enhancement in products and processes
- economical competition
- high innovation capabilities

The advantage-disadvantage comparison in Table 0-3 shows where the MedTech industry as well as Innovationsplatsen lack and what benefits they might provide concerning these key aspects.

<table>
<thead>
<tr>
<th>key aspects</th>
<th>MedTech Industry</th>
<th>Innovationsplatsen</th>
</tr>
</thead>
<tbody>
<tr>
<td>documentation</td>
<td>available and used documentation system</td>
<td>poor documentation of user interaction</td>
</tr>
<tr>
<td>user involvement</td>
<td>employed users and researchers</td>
<td>low number of internal users and researchers,</td>
</tr>
</tbody>
</table>
extent of benefit is unclear

cooperation
cooperation with universities and some users

involvement
cooperation with users, researchers and possibly several companies

value for the cooperation has to be created and highlighted

investigated so far

enhancement of processes
subsequent project evaluations

project evaluation usually without process analysis

chance to set up new approaches from the beginning

no experiences available

economic basis
money for intense research money is in large companies available

profit driven, less money in small companies

money from the state available

need to justify the project and the spent effort

innovation capabilities
proved in the past to have it

need to increase capabilities

innovation is a central aspect

how can they be created?

work environment
established environment

frozen structures

geographically close to everyone

benefit has to be proven

From this direct comparison various needs and requirements for Innovationsplatsen can be concluded as follows:

- Early commitment for a structured and purposeful documentation approach
- Exploitation of the close user cooperation and involvement in Innovationsplatsen
- Use chance of Innovationsplatsen as “blank paper” to set up new approaches
- Using practices from MedTech industry in IP
- Enhancing practices with requirements to measure and track innovation generation through user involvement

Subsequently the paraphrased action recommendation in Figure 0-3 can be derived from these findings now that takes the outlined advantages and disadvantages into account.

**Develop or adapt procedures and tools which allow to track and measure**

- the information flows,
- the development of ideas,
- the user’s contribution to value creation and
- the change of innovation capabilities

**within the setting, as well as to gather the required information throughout all phases.**
This action recommendation serves now as the basic input for the further approach development, which will be conducted in the next chapter.

Within this chapter the results were presented from the investigations with six interviewees from four companies towards the topics of user involvement, communication in the company, idea and process evaluation, the process documentation and the feedback towards Innovationsplatsen. It became clear that user involvement happens in various ways, but is not matter of constant investigation or evaluation. Furthermore, a complete understanding by the companies about these processes could not be discovered. Although the examined companies revealed an understanding of the central aspects of communication as well as of the idea and process evaluation, these aspects are commonly not a formal part of their defined processes. This is also not supported by their process documentation which is rather determined by legal requirements than by the need for a retrospective analysis. Although an evaluation of ideas and processes usually is conducted, the manner of it varies not only from company to company, but also sometimes from department to department. After a short discussion of these aspects, it was concluded to develop an approach that overcomes the identified drawbacks, which were then systematically implemented in an action recommendation. Therefore also the results from the interviews were opposed to the aspects of Innovationsplatsen in an advantage-disadvantage comparison. In the next chapter, this recommendation shall be picked up and help to further develop the achieved approach according to the MPM. Therefore in the next step first the exact goals need to be defined.
Development of procedures and tools

After the state of the art has been determined and disadvantages of the current and possible future situations have been clarified, now an approach to overcome them is developed according to the MPM. This is why hereinafter goals are defined, the problems of a network model derived from company A’s documentation is investigated, followed by the identification of requirements to improve this situation as well as a proposal and selection of solutions before finally the developed solution can be reviewed.

Goal and requirements identification

The action recommendation derived from the state of the art indicates the need for a new approach including adapted tools, methods and procedures. Consequently the goals which need to be achieved by following this recommendation are specified more precisely and circumstantiated with the requirements that have to be met, to accomplish them.

Goal definition

The aim of this approach is to investigate the user’s role in an innovative network, to depict how it creates or changes the value of an idea, product or process and to detect how different aspects of collaboration affect the innovation output. Creating a general approach to this shall also enable its application in different development environments besides the depicted Innovationsplatsen and towards different actors. As a result, method applicants from these environments can investigate their own implementation of collaboration and compare the results to the ones of Innovationsplatsen, in order to identify benefits and lacks in their own setting. Moreover these results could help to even enhance the implementation of user involvement processes for the future and lead to an improvement of a lean development process as well as a minimization of risks.

The goals that have been specified now need to be achieved by the use of appropriate tools, methods and procedures. In the recent literature research, a specific approach that has been applied accurately in such context could not be found. Nevertheless different approaches exist which can be used to handle some of the required tasks, but don’t consider the given problem in a holistic way. A reason for that could be the very specific background and application setting. Hereinafter the challenges that arise in the analysis of an innovative development network and the requirements concerning input and output for the solution of different sub problems are discussed, in order to identify the required approaches and adapt them subsequently.

Basic investigation of a development network

Now that the goals have been determined, an available project handbook with descriptive process data is examined, to derive and discuss the possible network setting and identify lacks and benefits in process documentation. This is part is considered as “problem structuring”
within the MPM. Although here usually the system is represented and analyzed through the creation of a relations or exchange oriented functional model, a network analysis which is similar in its structure seems to be appropriate as well. Therefore the prescriptive structure of development processes within a project, which are described in company A’s project handbook, is investigated through a visualization of the whole development network. According to this handbook the processes follow a stage-gate-process throughout the whole project. Although the linear stage-gate-approach of the development process, which is depicted here, is most likely not going to be implemented one-on-one in reality and especially not in a loose innovative environment like Innovationsplatsen, it gives insight on how users are connected to everyone else and what problems can appear while measuring their influence. Hence the results of this analysis show the structure of a current development system more superficially and can highlight where problems in a subsequent analysis might arise. Examining the whole network of involved persons from the four phases of

- prestudy phase,
- concept study phase,
- design and production preparation and implementation phase and
- follow-up of production and sales

within company A revealed the network depicted below in Figure 0-1. The network is weighted here by the activity of the actors what is pointed out by color and size of the actors. The data about linkages among actors is derived from the information in the project handbook about who participates in which task in every project phase. There from it can be derived which persons work together on a task and are therefore linked to another. A thin link indicates that the persons are working together in few tasks, whereas a thick link indicates cooperation in several tasks. From this information it could be concluded who can play an important role as information carrier in the network and how that person is involved in the whole process.

![Activity network of company A](image)

*Figure 0-1 Activity network of company A*

In the case of Innovationsplatsen and the aim of the defined goals, it has to be considered what position the user plays in this context and how interaction takes place among them and
all other actors. Referring to the general input from the users and the final innovation output could give then insight on how they contribute to innovations. This is schematically presented in Figure 5-2 where the input is the first basic idea and the output is the final concept or product. This output has then put into relation to the initial input in order to investigate the increase of innovation or value through the network. In addition the results from this analysis can be put into comparison to other networks, wherefrom the characteristics of the more successful setting could be identified.

Unfortunately a consideration of the network as a whole appears to be very complex and less comprehensible. That is why an investigation of smaller sub-networks seems to be more reasonable. As the data on cooperation of different actors have a time reference (according to the development phase in which the task takes place), a separation into different periods could be considered. This is also supported by CARLEY’s (2003, p. 11) claim for dynamic network analysis where “in contrast to traditional SNA […] the role of the agent in terms of processes and not just position” is considered. By this means a network can be created for every of the four phases which have been determined in the project handbook. Although the graph in Figure 5-3 appears now much more comprehensible and reveals interesting structural properties, such as the central star position of the product manager and its close embeddedness in the clique of interaction designer, industrial designer and clinical expert, it still shows some disadvantages:

- The links
  - The links are undirected; hence they don’t give insight into the direction of value or information flow. A “real” activity in the sense of influencing others cannot be derived.
  - The size of the links does not represent the transported value or information; it only indicates the possibilities for this.

- The actors:
  - The denotation of the actors allows misinterpretations, whether one actor is only represented by one person, or whether one person also represents
several actors (e.g.: Can the patent engineer and patent responsible be the same person?). Furthermore an actor sometimes could also represent an entire group. Here it is not clear if the whole group is involved in a task or only one of its members.

- Which actor represents the role of the user (e.g. is the “client” here a user?)
- The network as a whole has no connection to earlier or later networks, why a transformation of the network structure is not visible at the first glance

![Activity network of the concept phase in company A](#)

Figure 0-3 Activity network of the concept phase in company A

A time-dependent presentation through a separate network analysis of the four phases facilitates on the one hand the understanding of the network, but reveals further problems on the other hand. This can be e.g. the recognition of the change of the actor’s roles in several periods as well as the later assembly of the single networks to derive conclusions concerning the network as a whole. As it can be seen in Figure 0-4, the single networks of every phase assume different shapes, become thereby more perspicuous in their distinction and highlight the different intensities of collaboration. In the prestudy phase the users play a central role in the rather decentralized network in which they are inbound very tight. This also moves on to the concept study phase with only a few actors, but the user as one of the important ones. The “design and production preparation and implementation phase” is then characterized by a central structure and a low number of users situated in the core of the network. The fourth phase of follow-up and production is then centrally controlled by the project leader who is also well connected to the clique on the right of actors from all parts of the company (service, users, logistics, product manager, quality assurance, test manager). These results give insight into the development process and highlight that a network analysis can help to identify the role of every actor in the network. Therefore the analyst requires the knowledge about network structures and characteristics, as they have been introduced in the theoretical framework.

Nevertheless it has to be stated that there is one major shortcoming: the data from which this network has been derived is prescriptive and not descriptive. That means it shows how the
situation should be as prescribed by the company in its project handbook, but it does not show how the situation really is and besides that how the actors influence another.

<table>
<thead>
<tr>
<th>1. Prestudy phase</th>
<th>2. Concept study phase</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Network of Prestudy phase" /></td>
<td><img src="image2" alt="Network of Concept study phase" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Design and production preparation and implementation phase</th>
<th>4. Follow-up of production and sales</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image3" alt="Network of Design and production phase" /></td>
<td><img src="image4" alt="Network of Follow-up phase" /></td>
</tr>
</tbody>
</table>

*Figure 0-4 Networks of the four development phases in company A*

Basing on these considerations, the aimed goals and the action recommendation, requirements for new approaches have to be determined now subsequently, in order to overcome the limitations of current methods.

**Action requirements for the procedure**

To identify appropriate procedures and tools, first of all the requirements have to be determined which need to be fulfilled by the final approach. This is derived from the previous investigations as well as from the reflections about networks and is summarized in the action requirements list in Table 0-1 below. On a weighting of the requirements and a change log in the requirements list has been omitted, as this list simply compiles the necessary tasks which have to be fulfilled and serves as a basic overview for the further proceeding. Due to the restricted but very specific set of requirements the development of a problem formulation, which is usually conducted at this stage of the MPM and helps to focus on the important aspects, was omitted. This task is fulfilled here by the requirements list only.

As most relevant condition, the future procedure is supposed to be applied within innovative environments comprising expedient user involvement. It can be assumed that the application of it is not of primary importance there for the firsthand involved persons such as engineers or physicians. Their main goal can be considered developing new medical devices or procedures and not evaluating their own working processes continuously. However the developed approach shall help thereafter to analyze exactly these processes in order to improve the innovation capabilities. Therefore the application of the approach is supposed to require little
time and not to tie up resources. Furthermore the operators involved in the use of the approach should find a personal motivation in applying it, as only with an eager application of the approach finally the results can be significant and comparable to other innovative settings. Besides these requirements concerning the general application, four main purposes have been identified and summarized in Table 0-1, which have to be implemented by the approach.

Following a top-down approach from the general to the more specific topic, first of all an investigation of the general setting has to be strived. Therefore the entire network (engineers, researchers and physicians) – which is hereinafter referred to as “innovation network” – should be analyzed as a whole as well as the specific role of the user in it. Only with the understanding of the entire system’s connections more specific details should be analyzed later on. By this means also information flows and hidden structures should be revealed, what is useful for a later evaluation of the user’s impact.

This all goes hand in hand with a general evaluation of the innovation process in the examined environment. Creating such overview of the main aspects of the innovation network and the innovation process ensures a validated setting for a further detailed analysis. As soon as these important aspects of the setting have been discussed the user’s involvement and role in creating value and pushing innovation in the network can be analyzed. With the knowledge about the innovation network structure the user’s input, throughput and output has to be identified and assessed. Following the track of created value should then enable measuring the impact of every user to the final innovation output.

Already LINDEMANN (2009, p.58) claimed that a method or procedure should help to convert “complex problems into manageable sub-problems, [...] improve and enable cooperation between the multitude of people who are involved in the development process” and also “support the handling of knowledge and information”. That is why finally it has to be investigated how all the required information for the analyses can be retained. As the transfer of the obtained feedback from the MedTech industry additionally indicates, within a MedTech environment commonly there is also a need for extensive information accumulation, which can provide a basic data input to the approach and has therefore to be available at the Innovationsplatsen anyway. According to this, procedures and tools have to be offered which deal with the documented data and possibilities have to be explained on how to evaluate and compare these information.
<table>
<thead>
<tr>
<th>no.</th>
<th>requirement</th>
<th>value</th>
<th>explanation</th>
<th>origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>General application</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>motivate operator to use it</td>
<td>1</td>
<td>show/give him the benefit</td>
<td>interviews</td>
</tr>
<tr>
<td>1.2</td>
<td>little effort in continuous application</td>
<td></td>
<td>only little data and time to document</td>
<td>Interviews</td>
</tr>
<tr>
<td>1.3</td>
<td>divide problem solution into several sub-tasks</td>
<td></td>
<td>make it manageable</td>
<td>LINDEMANN</td>
</tr>
<tr>
<td>1.4</td>
<td>generate comparable results</td>
<td></td>
<td>comparable to other innovative environments</td>
<td>problem spec.</td>
</tr>
<tr>
<td>2</td>
<td>Investigation of the innovation process</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1</td>
<td>define a set of metrics</td>
<td></td>
<td>measurable data</td>
<td>ADAMS et al.</td>
</tr>
<tr>
<td>2.2</td>
<td>limit amount of measures</td>
<td>8</td>
<td>15</td>
<td>number of criteria</td>
</tr>
<tr>
<td>2.3</td>
<td>define how to deal with metrics</td>
<td></td>
<td></td>
<td>REGNELL</td>
</tr>
<tr>
<td>3</td>
<td>Investigation of the innovation network</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1</td>
<td>analyze connections and interactions among persons</td>
<td></td>
<td>analyze the environment as a whole</td>
<td></td>
</tr>
<tr>
<td>3.2</td>
<td>investigate the user’s properties</td>
<td></td>
<td>analyze the individual role of the user</td>
<td></td>
</tr>
<tr>
<td>3.3</td>
<td>analyze the user’s role in this setting</td>
<td></td>
<td>analyze the global role of the user</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Evaluation of the user’s impact on value and innovation creation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1</td>
<td>documenting input</td>
<td></td>
<td>which data is helpful</td>
<td>LEE et al.</td>
</tr>
<tr>
<td>4.2</td>
<td>documenting throughput</td>
<td></td>
<td></td>
<td>LEE et al.</td>
</tr>
<tr>
<td>4.3</td>
<td>documenting output</td>
<td></td>
<td></td>
<td>LEE et al.</td>
</tr>
<tr>
<td>4.4</td>
<td>follow the track of influence</td>
<td></td>
<td></td>
<td>ALLEE</td>
</tr>
<tr>
<td>5</td>
<td>Retaining the data to enable subsequent analyses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1</td>
<td>choose data to investigate</td>
<td></td>
<td>which data is helpful</td>
<td></td>
</tr>
<tr>
<td>5.2</td>
<td>limit data</td>
<td></td>
<td>which data is necessary</td>
<td></td>
</tr>
<tr>
<td>5.3</td>
<td>handling of knowledge and information</td>
<td></td>
<td>create supporting tools and/or procedures</td>
<td>LINDEMANN</td>
</tr>
<tr>
<td>5.4</td>
<td>evaluation documentation</td>
<td></td>
<td>generate final documents for evaluation</td>
<td></td>
</tr>
</tbody>
</table>

Table 0-1 Action requirements list

Breaking these requirements down to the development of an adapted approach, it can be summarized that an approach has to be found on how to investigate interactions among developers and users, the user’s role in specific and its very own characteristics. After that it has to be evaluated how the user takes influence in the value creation and the final innovation output. Building a bridge to the topic of innovation creation enables to include this topic and leads finally to the question what data have to be acquired and how this can be done with little effort respecting requirements number one and five. For each of these tasks a suitable method of implementation has to be investigated in the following.
Identification and proposition of suitable approaches

To fulfill the determined tasks of the future approach within the fourth step of the MPM ("identification of solution ideas"), a discussion of possible solutions for every task is conducted below basing on the previously derived requirements. Therefore arising problems and disadvantages of the proposed solutions are discussed as well, in order to justify the selection and adaption of the corresponding approach. Finally approaches and tools on how to collect these data are discussed and proposed.

Data acquisition

To conduct an analysis on user involvement processes and measure the outcome, different approaches can be pursued. In general three approaches can be considered:

- Either retrospective interviews and surveys among persons who are involved in the development process (a posteriori approach),
- an analysis of process documentation that has been compiled during these processes (a priori approach),
- or a combination of both approaches.

The first two approaches are investigated on their suitability for the present use in Table 0-2 and compared in an advantage-disadvantage comparison. As LINDEMANN & MAURER (2009, p.79) state, “typically, extraction of information that has not yet been documented requires time-consuming interviews”. If following this kind of interview or survey approach on data collection, a lot of effort has to be spent on information gathering and the overall analysis, which is usually conducted after the investigated processes. Although this saves effort and time during the processes, this approach postpones the receipt of beneficial research results unnecessarily. Furthermore the quality of interviews and survey results could be considered not highly precise, depending on the scope of the investigated timeframe. It can be assumed that interviews covering a period of several years lead to lower quality results than interviews covering a short period of some months. Nevertheless this enables the researcher to select and change the investigated criteria according to the current research goals.

The approach of an ongoing documentation of selected criteria and metrics spreads the effort over the entire time period and means therefore less per time, but still an ongoing effort that has to be pursued. However the quality of the data can be considered very high, as it is collected parallel to the investigated processes, so to speak “online” (= at the time of origin), and is therefore not distorted by the effects of time and oblivion. This ongoing collection also enables the researcher to conduct an analysis at any point of time and evaluate the process to reveal the dynamic aspects of the processes. As a matter of course this requires a previous determination of the collected data, what could be changed during time, but then requires a retrospective interview or survey approach to gather these data also for the past. This could then be considered as a combination of both approaches.

<table>
<thead>
<tr>
<th>key aspects</th>
<th>Interview approach (a posteriori)</th>
<th>Ongoing documentation (a priori)</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>

61
As the Innovationsplatsen project is still at the beginning and long-term planned, an implementation of an adapted “online” documentation approach is proposed. In addition this shall be supported by periodic surveys to support the revelation of tacit knowledge. Even if in the course of time a lack of collected data arises, a combination with a belated interview approach can be considered. This requires then less effort, as the majority of relevant data has already been collected. Therefore the evaluation of “online” documented data seems to be more suitable, assumed these data are available and can be documented in general.

Unfortunately it has been revealed during the interviews that process documentation in MedTech companies more likely suits the requirements set by law than the requirements for a subsequent process analysis. With insufficient and impractical data the influence of users on the development process can’t be investigated and best practices can’t be derived. However to collect the required data, reference is made to the seven links of the knowledge chain in Figure 5-5 (VAN ENGERS et al. 1995). With this approach it shall be contributed to the listing of existing and the determining of new knowledge which is usually present in a MedTech environment and determine the data which have to be collected, in order to achieve the previously defined goals. The next four stages of the knowledge chain fulfill the duty of developing new, allocating new and existing, applying and maintaining knowledge. This is where the involved persons need support during their work by the means of appropriate tools, in order to master this task. The final link of disposing knowledge is not of importance for the method application and hence will not be considered in more detail.

<table>
<thead>
<tr>
<th>time effort</th>
<th>no effort during the processes</th>
<th>much effort after the processes</th>
<th>spread over long period → less effort per time period</th>
<th>ongoing effort</th>
</tr>
</thead>
<tbody>
<tr>
<td>data quality</td>
<td>literature claims that interviews are sufficient for data quality</td>
<td>basing on subjective assessment of interviewees</td>
<td>can be collected when data is “generated” → very high quality</td>
<td></td>
</tr>
<tr>
<td>analysis</td>
<td>metrics can be selected afterwards and focus can be changed</td>
<td>analysis only at the end of data collection possible</td>
<td>ongoing analysis possible</td>
<td>once metrics have been set it is hard to changed focus</td>
</tr>
</tbody>
</table>

Table 0-2 Comparison of interview and documentation approach

Figure 0-5 Adapted knowledge chain
Now that an “online” documentation approach has been proposed, an approach on how to collect the required data for all investigated topics is going to be discussed afterwards.

Therefore tools and forms have to be developed and proposed first, before it can be determined what kind of data saving approach has to be chosen. Approaches to save information have already been introduced in the theoretical framework of this thesis and are characterized by:

- qualitative text (story telling)
- tree structure (fault tree analysis)
- matrix structure (consistency matrix/ house of quality)
- table structure (FMEA)
- graph structure (network graphs)

Furthermore the results from the different kinds of evaluation shall be put into a context and final overview at the end of the analysis with the chosen documentation tools. By this means the final results could be clarified again and ensure an easy communication of them to others.

**Investigation of the innovation process**

Now that it has been investigated “*in what manner*” the analysis data should be gathered, the question has to be answered “*what*” has to be measured or investigated, in order to examine the innovation process. To evaluate the influence of single actors (e.g. the user) on changes and a final output within this setting, the innovation process and the change of innovation capabilities needs to be monitored concerning specific criteria. Therefore the innovation process, as it has been presented in all its complexity before, provides many aspects to analyze. Due to the special interest in the user involvement, specific metrics concerning this explicit aspect shall be picked now, so that in later stages it can be investigated “*how*” to gather and track them. From a broad range of metrics revealed in the theoretical framework only a limited number can be picked according to the requirements list in Table 0-1, where a little effort in continuous application is claimed. In order to decrease the number of metrics, several steps of reduction are applied:

- Preselection of appropriate framework categories
- Comparison and a possible combination of measurement areas derived by **REGNELL et al.** (labeled with R) and **ADAMS et al.** (labeled with A)
- Evaluation and selection of measurement areas
- Plausibility analysis and discussion

In order to call it again to mind, the action recommendation is repeated which claims:

*Develop or adapt procedures and tools which allow to track and measure the information flows, the development of ideas, the user’s contribution to value creation and the change of*
innovation capabilities within the setting, as well as to gather the required information throughout all phases.

In the case of a mixed setting with academic and industrial aspects, it might be reasonable to consult approaches from both backgrounds, as they could cover the investigated mixed setting better together. To quantify the identified measurement areas from the frameworks, they need to be operationalized, as LEE et al. (1996) conducted in their measurement of R&D effectiveness in Korean companies. This process of operationalization has already been implemented for the MINT-framework and suggests quantitatively measurable criteria that can be documented during the development process and put into comparison to another. During a preselection approach the framework categories from Table 0-7 are compared with this recommendation that defines the aim of the future approach. Only if the framework categories facilitate the achievement of this goal or are touched significantly by it, they shall be considered further. That is why the categories wherefrom measurement areas are chosen should enable to

- draw conclusions to the influence of the user in the process,
- consider also very early stages such as the FFE,
- contribute to the investigation of input, throughput or output in a foreseeable time frame and
- investigate the information flow.

If the framework category doesn’t meet these requirements and is finally rated with a “minus”, it is discarded and its measurement areas are not considered further. To follow this procedure a preselection template is used according to Table 0-3 (PAHL ET AL. 2005). However in this case there is no KO-evaluation applied, but framework categories are chosen by the majority of ratings. The ratings provide a basis of decision-making, but are not obligatory to pursue.

<table>
<thead>
<tr>
<th>category</th>
<th>analysis and evaluation</th>
<th>decision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+ Yes</td>
<td>+ pursued</td>
</tr>
<tr>
<td></td>
<td>- No</td>
<td>- eliminated</td>
</tr>
<tr>
<td></td>
<td>? lack of information</td>
<td>? gather more information</td>
</tr>
<tr>
<td></td>
<td>! check requirements list</td>
<td>! check requirements list</td>
</tr>
<tr>
<td></td>
<td>A alternative proposal</td>
<td></td>
</tr>
</tbody>
</table>

- considers the influence of the user
- considers input, throughput or output examination in the setting
- considers also early stages
- considers information flow within the setting

<table>
<thead>
<tr>
<th>category</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>data available (staff list), idea flow through people</th>
<th>+</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 Inputs</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>data available (staff list), idea flow through people</td>
<td>+</td>
</tr>
<tr>
<td>02 Knowledge management</td>
<td>?</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>too much of information, knowledge is put in database very late</td>
<td>+</td>
</tr>
<tr>
<td>03 Innovation strategy</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>considers rather future settings</td>
<td>-</td>
</tr>
</tbody>
</table>
Table 0-3 Preselection

Subsequently the framework categories of “innovation strategy”, “portfolio management” and “commercialization” which appear to be rather future oriented are eliminated. The measurement areas of the remaining categories are now compared to each other and combined if reasonable. This happens when both frameworks propose a similar or in fact the same area of measurement. Hence the following areas are combined:

- “climate” (R) and “culture” (A) → “work climate”
- “interaction” (R) and “collaboration” (A) → “interaction”
- “informational flows” (A) “communications” (A) → “information flow”

After this combination, in the third step of the reduction procedure the measurement areas of the remaining framework categories are assessed and selected by their rank. Therefore three evaluation categories are introduced below, in which the measurement areas are evaluated to which extent they

- change over time (as especially for those it is hard to capture them later on)
- allow to draw conclusions concerning the influence of the user in the process,
- can be documented in files or on paper according to the presented approaches

These criteria were chosen to indicate what has to and can be documented “online”, as it is difficult to implement after a long period, but still covers the central aspect of user involvement. Therefore every criteria was ranked by 1-3-9 point ranking is chosen, to clearly identify favorites, whereas the evaluation criteria themselves were not weighted to another. For the better overview the final values and a ranking were added in Table 0-4 below.
In the ranking list several measurement areas reach the same value. Following the requirement of eight to fifteen metrics (MULLER et al. 2005), the fifteen best rated measurement areas are chosen, because considering the groups of same values would only allow to pick four (with the value 21), seven (from value 19), fourteen (from value 15) or fifteen metrics (from value 13). To operationalize these measurement areas, now the “measurement inspirations” which are indicated in the MINT-framework (REGNELL et al. 2009, pp. 9–11) and marked with (R) in Table 0-5, are consulted and further operationalized criteria are proposed.

<table>
<thead>
<tr>
<th>Measurement area</th>
<th>Operationalization</th>
<th>Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>People</td>
<td>(R): name; role; role specification; group membership; work experience</td>
<td>person details (database)</td>
</tr>
<tr>
<td>External collection</td>
<td>(R): number of visited external events; number of and time between collection activities with external stakeholder influence</td>
<td>task – person task – task</td>
</tr>
<tr>
<td>Feedback</td>
<td>number and quality of advice; number of revived ideas</td>
<td>idea – person idea – idea</td>
</tr>
<tr>
<td>Area</td>
<td>Description</td>
<td>Survey</td>
</tr>
<tr>
<td>-----------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Interaction</td>
<td>(R): number of persons in the team’s contact network; number of collaboration activities with internal and external stakeholders; number of internal promotion meetings with relevant stakeholders</td>
<td></td>
</tr>
<tr>
<td></td>
<td>person–person</td>
<td></td>
</tr>
<tr>
<td></td>
<td>person–task</td>
<td></td>
</tr>
<tr>
<td></td>
<td>survey</td>
<td></td>
</tr>
<tr>
<td>Idea generation</td>
<td>Number of ideas; quality of ideas</td>
<td></td>
</tr>
<tr>
<td></td>
<td>evaluation of ideas</td>
<td></td>
</tr>
<tr>
<td></td>
<td>idea database</td>
<td></td>
</tr>
<tr>
<td>Information flow</td>
<td>Number and quality of advice; number of revived ideas</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(evaluated) idea–person survey</td>
<td></td>
</tr>
<tr>
<td>External generation</td>
<td>(R): number of projects based on ideas from external stakeholders; number of workshops with customers on future needs</td>
<td></td>
</tr>
<tr>
<td>External stakeholders</td>
<td>(R): number of projects based on radical future scenarios; number of projects with end-user relevance; number of projects with future customer or new market relevance</td>
<td></td>
</tr>
<tr>
<td>Knowledge repository</td>
<td>Number of saved documents in the DMS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>document details (DMS)</td>
<td></td>
</tr>
<tr>
<td>Structure</td>
<td>Network structure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>person–person</td>
<td></td>
</tr>
<tr>
<td>Internal collection</td>
<td>(R): number of incoming proposals from different sources; number of and time between activities of collaboration with patent team.</td>
<td></td>
</tr>
<tr>
<td>Process</td>
<td>Sequence of activities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>task–task</td>
<td></td>
</tr>
<tr>
<td>Organization</td>
<td>(R): number of projects per year; number of involved persons per project; lead time per project</td>
<td></td>
</tr>
<tr>
<td></td>
<td>person–person</td>
<td></td>
</tr>
<tr>
<td>Product features</td>
<td>Number of and quality of new product features</td>
<td></td>
</tr>
<tr>
<td></td>
<td>idea database</td>
<td></td>
</tr>
<tr>
<td>Internal generation</td>
<td>(R): number of and time between activities of presenting the work of the innovative team; Number of and time between activities of systematic idea generation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>task–person</td>
<td></td>
</tr>
</tbody>
</table>

**Table 0-5 Operationalization of measurement areas**

It will be the task of the tools which are presented later, to capture these proposed data. Therefore in Table 0-5 an implementation approach considering different inter- and intra-domain matrices (domain1 – domain2) as well as databases is already indicated, what will be discussed in the following.

**Investigation of the innovation network**

Now the network has to be investigated, including its actors and interrelations among them, with the approaches that are commonly applied in such context. Within an innovation network, where actors create new ideas and influence each other either in a structured or loose setting, the domains of ideas, persons and the communication among them is of major interest. To form this relevant basis and describe the background for later user involvement investigations, it has to be considered to reveal:

- the communications and advice network and
- the idea network.

Therefore the track of the information flow among persons and the referencing between ideas
has to be captured. In order to document the time aspects and the dynamics of network changes as well, the referencing of tasks and their chronological occurrence should be considered. The networks in Figure 5-2 which were derived from a person-task inter-domain matrix previously indicated that this aspect can be portrayed very well by referring to time connected “tasks”. This documentation of the tasks contributes thereby to an investigation of the measurement areas of “process” and “internal generation” as seen in Table 0-5.

Nevertheless the network presentation lacked due to the absence of a directed information flow, to indicate who influenced whom. To investigate this aspect as well, an approach is needed that facilitates the revelation of actor influence concerning advice input and output. As the domain of “ideas” obviously is of major interest in this innovative setting, it also seems adequate to investigate the connection of these ideas to persons and the further reconsidering of the ideas by other persons. Picking up someone else’s idea can hence be considered a denotation of influence from the origin person. Hence a complete “person – idea – task” DMM as shown in Figure 0-6 is strived to investigate the influence of ideas and persons among and to each other including all relevant dynamic aspects.

<table>
<thead>
<tr>
<th>person</th>
<th>task</th>
<th>idea</th>
</tr>
</thead>
<tbody>
<tr>
<td>connections between persons: revealing the social network</td>
<td>person involved in task: documenting collaboration</td>
<td>person coming up with idea: documenting idea capabilities</td>
</tr>
<tr>
<td>task following task: capturing the process</td>
<td>idea influencing person: investigating “advice input”</td>
<td>idea came up in task: time aspects of idea generation</td>
</tr>
<tr>
<td>idea referring to idea: documenting idea evolvement</td>
<td>idea came up in task: time aspects of idea generation</td>
<td>idea referring to idea: documenting idea evolvement</td>
</tr>
</tbody>
</table>

*Figure 0-6 Aim of every domain in the MDM*

This DMM now facilitates the previously claimed and introduced measurement areas. Nevertheless, still further aspects of persons or and ideas for instance have to be captured. To keep track of all these domains and facilitate the subsequent analysis, it is furthermore proposed to label every domain element with a tag and record them in the available process documentation and an idea database as indicated in Table 0-6. The documents which thereupon contain the reference to these domains form then furthermore a skeleton which facilitates the assembly of all these domains and support the generation of the network by the means of a DMM.

To evaluate the user involvement process later on and draw conclusions, it seems also suitable to capture further information about every actor’s properties which are not only related to the user’s position in the network, but also to his specific properties. The information connected to these domain elements are of special interest, as they do not only reveal the connections among the elements, but also contribute to an extensive analysis of the network later on regarding various characteristics. As it is also important for the analysis to access this information easily, it is proposed to save the tags and their connected attributes in special databases, which have to be kept updated. This shall enable an easier management of all the
information on every element and decrease the amount of redundant data.

That is why for persons it is proposed to document besides the name and their role as user, physician or engineer also further specifications like the company, institute they’re working for and their years of experience. In order to investigate the role of the actor (or in specific the user) within the team, it is proposed to also conduct a behavioral test such as a Belbin test (Belbin Team Inventory) and record the result in the person database as well. This test might help to assign every actor a specific role within a team and identifies thereby how an actor behaves in a team environment. Concerning this approach should help to investigate the actor’s role in a small network of the team in comparison to the large network of Innovationsplatsen. With these data, the previously designated measurement area of “people” is completely covered then.

For the recording and tracking of ideas it is proposed to set up an idea database similar to the concept of crowd sourcing, which is according to the interviews also nowadays in some MedTech environments in use. Crowd sourcing bases on the principle of “swarm intelligence” and supports the idea input from all available sources in a system. Ideas are collected and after an expert evaluation pursued or discarded. Associated to this is also often a monetary benefit to the originator of an idea. The most useful aspect of it in this case is the collecting of all ideas in a central database, which enables an ongoing documentation and evaluation of the ideas. By this means ideas can be connected easily to persons and tasks. In addition to the specific domain database, most of these information can also be captured in all the created and saved documents such as protocols, meeting notes and common MedTech process documentation by means of a preceding blank datasheet (template). This allows generating and recording much of the data connections later on by a systematic document analysis and avoids thereby the time consuming effort to put all data directly in the database. Moreover this approach adapts also to the common processes of documentation in MedTech environments and could be implemented and communicated easier.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Tag variable</th>
<th>Information connected to the variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons</td>
<td>P(xxxx)</td>
<td>Name</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Role: user, researcher or engineer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Role specification: company/institute, kind of user ) as shown in Table 0-4), researcher or engineer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Work experience</td>
</tr>
<tr>
<td></td>
<td></td>
<td>belonging to group G(xxxx)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result of behavioral test</td>
</tr>
<tr>
<td>Ideas</td>
<td>I(xxxx)</td>
<td>Tag of origin person P(xxxx)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Date of idea coming up in task T(xxxx)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Number of ideas</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Quality of ideas</td>
</tr>
</tbody>
</table>
However, also the personal advice networks, which arise outside of scheduled tasks and are therefore not documented, have to be captured. Although certainly a part of the communication between persons could be captured by an evaluation of phone and email conversation among them, this might entail an enormous evaluation effort which stands in contrast to the pursued approach requirements, possibly give no insight in the quality of the information interchange and touch the person’s privacy in an unacceptable way. As possible approach it might be considered to implement a social network platform within the setting that supports the communication and its evaluation.

To achieve this goal anyway, it seems inevitable to consult the involved persons periodically. In order to keep the effort low, it is proposed that a standardized computer based survey or spreadsheet-template should be filled once every month by all involved persons, about whom they have been in contact to and exchanged advice with. In order to ensure a high data quality which is not distorted by personal point of views, this survey should cover the receiving and providing of advice to countercheck the indications by the involved persons. A critical factor doing this is the response rate. Only with a high rate of participation a reliable database can be built. Due to the nature of the investigations, which includes a connection to a name, the anonymity cannot be guaranteed completely. This might lead to a lower response rate, if it is not guaranteed that the data is only available to a limited group of researchers.

As Deutskens et al. (2004, P. 22) point out, the highest response rate at mail surveys for instance is achieved with “follow-up mailings and incentives”. Transferring this to electronic spreadsheets or templates, which have to be filled independently and is also taken into account by Deutskens et al. (2004), the possibility of follow-up mailings is not acceptable. Only an automatic reminder in the form of an email could be considered here. To motivate the participants nevertheless, incentives should have to be given. This can be either monetary incentives comparable to the incentives within a crowd sourcing approach or other personal benefits. In this case personal benefits seem to be more suitable as a high monetary effort maybe cannot be raised. That is why participants should be able to use their generated data directly for their own personal benefit. As the interviews showed, in the interviewed MedTech companies a knowledge map which indicates “who asks who and what hasn’t been applied, as this knowledge of “who knows what” usually develops over time by personal networking. In the case of new and changing participants though, this approach can be of great interest, as it helps to improve everyone’s cognition about the persons around and
facilitates a purposeful information search. Finally of course the value for the whole project has to be communicated by the responsible managers and motivate the participants thereby to contribute to this approach.

With this data the entire advice (respectively communication) network can be established and completed. Subsequently it can be analyzed by the metrics summarized by COULONS (2005) in Table 0-12. The most specific investigations should therefor deal especially with the

- density,
- efficiency,
- robustness,
- openness and
- cluster or clique formation

of the network and specific metrics concerning single actors (e.g. the users) such as

- centrality (local, global and betweenness) and
- activity and passivity (participation in the process),

in order to investigate the roles of the actors in the network and to reveal for instance how much influence the brokerage in indirect user involvement and the closeness in the direct user involvement constituted. These aspects should give then insight into the quality of the innovative setting and provides then the possibility to investigate the user’s role and involvement in the network.

**Evaluation of the product or idea innovation output**

To put generated ideas or products into a comparable context to another, an evaluation of them is inevitable. Similarly to von Hippel’s (1986 P. 799) proposal of an equation to calculate the net benefit, an evaluation can reveal then the increase of benefit for the user which is achieved through a proposed solution. Only with the knowledge about the value change over time and final output it can be investigated, if and how a specific actor’s involvement added value. As the literature research and a document examination of company A indicated, evaluation processes in MedTech environments nowadays are commonly conducted by an analysis of clinical data, which have been collected in long-winded studies. Therefore product specific criteria are determined, traced and recorded. These criteria can be summarized in a so called clinical utility index (CUI), which has been proposed for instance by KORSAN et al. (2005) for drug development and “openly evaluates a product’s attributes – and chance of success”. Unfortunately current evaluation criteria which are applied in the interviewed MedTech companies could not be revealed due to confidentiality agreements (e.g. company D) or a lack of transparency (e.g. company B). Hence they have to be derived and proposed subsequently. To achieve this, a glance was thrown on relevant sources including literature on the previously referred CUI (KORSAN et al. 2005), the handbook for clinical engineering (DYRO F.J. 2004) and a guideline for clinical evaluation published by the European Commission (2009). Therefrom the criteria in Table 0-7 could be concluded.
An evaluation of ideas according to these criteria has to be conducted then by an expert panel consisting of different persons, who have the expertise and the required background knowledge, to estimate the worth of an idea and create comparable and comprehensible results over time. Of course an evaluation considering all the criteria from Table 0-7 appears to be very time consuming. That is why the number of the criteria has to be decreased, in order to limit the evaluation effort for the expert panel. Through this decrease process the amount of criteria should also be limited to only those which are meaningful towards the topic of innovation and can fill the gap between common evaluation criteria towards this aspect later on. The selection and explanation of the final evaluation criteria in Table 0-8 was then also reviewed and discussed by an expert panel during the workshop conducted in this work. The term of “costs” has been extended here to “life-cycle costs”, to specify it further more and pay tribute to this important topic of sustainable product development which is getting increasingly more attention.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>safety</td>
<td>The state of being safe from harm or danger</td>
</tr>
<tr>
<td>performance</td>
<td>Manner or quality of operating</td>
</tr>
<tr>
<td>life-cycle costs</td>
<td>The entire acquisition and ownership costs of a system considering its full life-cycle from planning, developing, acquiring, operating and support to disposal</td>
</tr>
<tr>
<td>clinical usability</td>
<td>“Effectiveness, efficiency and satisfaction with which a specified set of users can achieve a specified set of tasks” in a clinical environment (according to ISO9241-11)</td>
</tr>
</tbody>
</table>

Subsequently, future ideas and products should be evaluated by these four criteria or categories towards the fulfilling of innovative aspects. Therefore a set of innovation values is induced, in order to facilitate a subsequent classification. As the categories themselves reveal no explicit connection towards innovation or innovativeness, a measure shall be provided that fills that gap and includes this aspect. Previously it has been highlighted in the theoretical framework that innovation is mainly determined basing on the degree of novelty separated into incremental and radical improvement. To make the term “novelty” more tangible and divisible for evaluators, it can be separated into “new to the firm”, “new to the market” and “new to the world” (OSLO MANUAL 2005, P. 57). Putting this in cross-reference to the
definition of the **European Commission** (2009) about “incremental change of an existing technology”, “new clinical application of an existing technology” and “new technology” generates a matrix in which an idea can be classified by a value according to its novelty (horizontal) and the range of its impact (vertical). With this matrix the aspects of novelty in matters of effective range and extent of product change are brought together, as it has been conducted similarly with the extent of product and process change by **Wheelwright & Clark** (1992). Although here the extent of novelty is split up into the four categories:

- incremental change
- upgrade
- next generation...
- new core...

the fields of upgrade and next generation have been summarized in Figure 0-7 according to the **European Commission** (2009) to “new clinical application of an existing technology”. Thus a value system is established by means of a 3x3 matrix, to support the assessment process. According to Figure 0-7 the 3x3 matrix facilitates the introduction of a value distribution approach, where at the same time horizontal and vertical increase of innovation is respected as well as a diagonal value increase. Thereby finally a value range from one to five is induced. Besides that also the value of zero has to be existent, if none of the criteria is met. The letters indicated after the value shall help to make the selection of a value even in retrospect transparent, as this information might be of interest for the subsequent analysis.

<table>
<thead>
<tr>
<th>Range of Change</th>
<th>Extent of Change</th>
<th>Value Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>new to the world</td>
<td>incremental change of an existing technology</td>
<td>3a</td>
</tr>
<tr>
<td>new to the market</td>
<td>new clinical application of an existing technology</td>
<td>4a</td>
</tr>
<tr>
<td>new to the company</td>
<td>new technology (radical innovation)</td>
<td>5</td>
</tr>
<tr>
<td>new to the market</td>
<td>2a</td>
<td>3b</td>
</tr>
<tr>
<td>new to the company</td>
<td>1</td>
<td>2b</td>
</tr>
</tbody>
</table>

*Figure 0-7 Innovation value matrix*

An evaluation of an idea should be conducted then in every of the four categories following the consideration: “Idea I(xxxx) is an improvement in category X to such extent that it makes the product an innovation rated Y (zero to five).”

Despite this preliminary evaluation of ideas, it has to be concerned to validate the expert panel’s evaluation on prototypes and final products as well if possible. This could be done at a
later stage when ideas can be reevaluated basing on other verified data. As indicated before in the case of products that have been introduced successfully at the market, the degree of innovation could be also investigated then by criteria of:

- Patent data (citation...)
- Return-on-investment

as it has been proposed by LANJOUW & SCHANKERMAN (1999). During the development of an idea or product it should be therefore considered to keep track of the invested expenditures and put them into comparison to the gained monetary benefit, in order to derive the return-on-investment. If patents are applied it has also kept track of the further development of patent citation.

**Evaluation of the user's impact on value and innovation creation**

Basing on the revealed network structures of the idea and advice network the role of the user in creating value and contributing to the creation of innovation can be investigated. Therefore analysis criteria like activity, passivity and distance/closeness to other actors have to be investigated closer. By the aspect of activity especially it becomes clear who contributed the most within the network. Furthermore the activity of a user can be put into relation to the value he added by improving an available or creating a new idea. An actor with a high score of the ratio value/activity obviously contributed with little participation comparably high value and should be included more intensively in the future. An actor with a low score on the other hand obviously did not add an appropriate amount of value to the product despite a close involvement. Moreover it can be investigated how the value increased over a chain of actors and which actors were the starting node and promoters for an idea that finally created high innovative value. Especially the emerging of value over an actor path could reveal successful structures of stakeholder cooperation.

However to derive such a network, to every advice or connection from one actor to another, which has influenced an increase of value to the product, a specific value in numbers has to be added. That is why ideas and products in process have to be evaluated in constant periods. These periods should match also the periods of surveys to ensure significant results. To follow the track of these values easily an evaluation sheet as in Table 0-9 is proposed. There the value change of an idea can be reviewed over time concerning every of the four evaluation criteria and also connected to the originator. By the means of common spreadsheet tools the value change over time can then easily visualized in a graph. As it is exemplary given here, one can see that the life-cycle costs for instance have not been improved at anytime, while Idea I(0003) that came from Person P(0033) in Task T(1554) increased at the same time the safety to a value of three and the performance to five. Investigating now where that idea came from and from whom that person received a lot advice can even give insight on how this great value was added.

<table>
<thead>
<tr>
<th>start value</th>
<th>value change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>safety</td>
</tr>
<tr>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>
The evaluation sheet helps to investigate and highlight the actors’ roles in the process of value creation, but needs nonetheless support from other tools which help the applicants to collect the required data. The need for these tools has been highlighted now in the previous chapters, where also was identified what these tools need to collect and prepare.

**Tool and template development**

The tools should support the gathering and final interpretation of the collected data. As the most data cannot be collected automatically by a special software at the time, it has to be ensured that some basic criteria are fulfilled that facilitate their use. As it also has been pointed out in the workshop, the tool user must be motivated to apply the tool. Everything that decreases the motivation either a confusing layout or a time-consuming effort needs to be avoided as much as possible. Therefore the tools should have a comprehensible layout and an explanation of how to use the tool. In the best case, the tool is self explaining. That also includes the specification of technical terms which might not be familiar to all participants. In order to facilitate the later use of the entered data, it is recommended to use electronic forms such as spreadsheets or online based forms. Thereby a time consuming transfer of scripted to digital data can be avoided.

Another important aspect is the time to spend on documentation. Again, the motivation and response rate might decrease the more time consuming it is. That indicates even more the need for a simple and quick tool. The advice table in Figure 0-8 for instance shall be used to implement the monthly survey to investigate the advice network. Every participant receives his own form, where he notes in the monthly columns if he has been in contact with person A, B, C and so on. In the last column the values are added and represent the quantity of contact.

### Table 0-9 Evaluation sheet

<table>
<thead>
<tr>
<th>Idea</th>
<th>Date/ Task</th>
<th>Person</th>
<th>0</th>
<th>1</th>
<th>4</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>I (0001)</td>
<td>T (1234)</td>
<td>P (0020)</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>I (0002)</td>
<td>T (2345)</td>
<td>P (0013)</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>I (0003)</td>
<td>T (1554)</td>
<td>P (0033)</td>
<td>3</td>
<td>1</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>I (0004)</td>
<td>T (1524)</td>
<td>P (0011)</td>
<td>3</td>
<td>1</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>I (0005)</td>
<td>T (2564)</td>
<td>P (0002)</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>
received advice* from  

<table>
<thead>
<tr>
<th>Month</th>
<th>January</th>
<th>February</th>
<th>March</th>
<th>April</th>
<th>May</th>
<th>June</th>
<th>July</th>
<th>August</th>
<th>September</th>
<th>October</th>
<th>November</th>
<th>December</th>
<th>SUM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Person A</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Person B</td>
<td></td>
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<tr>
<td>Person C</td>
<td></td>
<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Person D</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Person E</td>
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<td>...</td>
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</tr>
</tbody>
</table>

*advice = supply of useful input or feedback

*Figure 0-8 Advice table*

This is the only tool which should be applied by everyone without any exception. This is why here even more the use of it needs to be pointed out to the participant. As mentioned before, the data from the advice network could be used to generate a knowledge map. If the additional use of such a knowledge map can be made clear to the participant, a better response rate might be achieved. Other tools such as the template for the process documentation in Figure 0-9 only need to be completed by one responsible person similar to the role of a minute taker. This template needs to precede every document that is saved in the document storage system. Important information concerning this document such as time and date, the previously introduced tags for person, tasks and documents shall be saved here.

<table>
<thead>
<tr>
<th>Project/product:</th>
<th>“project/product name”</th>
<th>“document tag”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task</td>
<td>T(xxxx)</td>
<td>“document type”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“date”</td>
</tr>
<tr>
<td>Participating/ involved persons:</td>
<td>P(xxx1)</td>
<td>P(xxx2)</td>
</tr>
<tr>
<td></td>
<td>P(xxx3)</td>
<td>P(xxx4)</td>
</tr>
<tr>
<td>responsible person for this document</td>
<td>P(xxxx)</td>
<td></td>
</tr>
<tr>
<td>responsible person for this task</td>
<td>P(xxxx)</td>
<td></td>
</tr>
</tbody>
</table>

*Figure 0-9 Document template*

This template represents besides the idea and person database the skeleton of the dataset which puts the information together in a common context. The idea and person databases have been introduced in their function already. The required data which should be saved there have been identified in Table 0-6 and don’t need further comments. Important is only to keep the data up to date.

Now that it has been identified what has to be collected and how it can be dealt with the required data, finally a comprehensive overview is presented in Figure 0-10 which points out in which environment these tools will be employed and what context they should reveal.
As depicted in Figure 0-10, the tools shall finally ensure to capture not only the time aspects considering the sequence and time of phases and tasks, but also the collaborative aspects and influence processes of actors and ideas, to reveal the intangible knowledge. It shall be revealed how persons influence each other either directly within a task or indirectly through their ideas and contribute according to the identified value of the idea more or less to an overall product concept.

At the beginning of this fifth chapter, the action recommendation to develop a new approach has been picked-up from the previous chapter and was further supported by an investigation of the opportunities from network analysis considering prescriptive process documentation. From this analysis the drawbacks could be derived which need to be overcome, to satisfy the proposed action recommendation. These drawbacks resulted mainly from lacks of information respecting the undirected and unweighted links, the imprecise denotation of actors, the lack of traceability of the network change over time and the descriptive character of the process documentation. Together with the findings from chapter four, these results were incorporated to the definition of a requirements list as part of the “objective analysis” within the MPM. As main requirements were then denoted the general application of the approach as well as the investigation of the innovation process, the innovation network and the user’s impact on value and innovation creation within this network. Finally also the requirements for a proper data acquisition to achieve these goals were defined. Basing on these requirements, appropriate solutions for the single aspects were derived and subsequently adapted by means of a preselection approach, a weighted comparison as well as an advantage-disadvantage comparison. As a result tools were proposed which support the purposeful data acquisition and help thereby to evaluate the user and stakeholder impact. These tools are a MDM which defines what data have to be gathered including associated domain tagging specifications, an innovation value matrix that helps to assess the identified criteria for product and idea evaluation, templates for the ongoing data acquisition in documents and surveys as well as databases to collect and save the data which are generated through these tools. In the next chapter finally a concluding review of this work shall be conducted where the findings from
the investigation of current settings as well as the proposal for the future Innovationsplatsen can be discussed and an outlook to future can be given.
Final reflections

With this work the current state of the art in user involvement and collaboration processes in the MedTech industry has been investigated and an approach has been proposed on how to deal with the appearing issues in future settings. Hence, the three key questions which have been investigated thereby shall be recalled:

- How do companies perform and measure user involvement today?
- What information about user collaboration is stored in process documentation?
- How can companies manage and evaluate their collaboration in the Innovationsplatsen?

In order to investigate these questions, the relevant theoretical background has been highlighted and a systematic procedure was introduced. In the following the results of this thesis shall be presented and discussed, before a final conclusion provides a glimpse into future tasks.

Result summary

During the interviews with four large MedTech companies the aspects of user involvement, communication, idea and process evaluation as well as process documentation have been investigated. Furthermore the process documentation of one company considering four projects has been examined. As a result it can be stated that user involvement takes place in all phases of the innovation process and includes direct as well as indirect involvement of a variety of external and internal users, as they have been identified by Shah & Robinson (2008). Indirect user involvement is thereby conducted by means of a broker who translates the users’ needs and feedback to the developers, whereas direct involvement focuses on putting the users in direct contact to the developers. In this context the aspect of communication and information spreading takes place in formal and informal structures and is regarded as central aspect by all companies. Moreover, the process and idea evaluation was stated to take place in a rather informal than formal way within two of the examined companies. The other two companies revealed to have value systems for a systematic evaluation, but were not able to give further insight. Finally also the scope of process documentation was investigated. All companies stated to have document management systems mainly because of legal requirements. These systems are used to store empty or filled templates and save the documents which are finally required by the authorities, in order to certify the product.

In consequence of these findings an approach was developed according to the Munich Process Model, to ensure a systematic and purposeful proceeding. First, the investigation results were picked up and further evolved during the “problem specifications”. Here the “problem” was regarded as the current setting which has been investigated then by a network analysis instead of the commonly applied functional modeling. Therefrom a requirements list could be derived then. Subsequently solutions were proposed and adapted, to overcome the identified drawbacks of the state of the art. To overcome the identified drawbacks and to facilitate a
participation in the Innovationsplatsen, the proposed approach bases on the three partial solutions approaches of innovation measurement frameworks, social und value network analysis as well as a continuous data acquisition. To support these approaches, additional tools have been developed. These tools are a multiple domain matrix that defines what domains have to be captured including further domain tagging specifications, an innovation value matrix for the assessment of life-cycle costs, performance, usability and safety aspects and templates for documents and surveys as well as specifications for idea management and person databases. In a final step the developed approach and tools could be verified then in an expert workshop.

Discussion

The investigated state of the art in the interviewed MedTech companies reveals that the companies seem not to know what kind of user involvement that adds value to a product in a certain stage of the innovation process. Still, user involvement together with an intensive communication in projects is regarded as central topics. The fact that companies have no implemented approach to investigate this either continuously or in retrospect might derive from the sticking to habitual patterns. Procedures which resulted in a success earlier are not re-examined formally, but only in informal discussions what appears to be not sufficient for a process examination and improvement from scratch. Moreover, the companies involve users which have been involved before. Other user identification processes than relying on familiar users or at least an examination of them was hereby not conducted by the companies. In addition current idea evaluation and tracking approaches also hamper a proper analysis of these processes. As evaluation processes are sometimes only conducted informally and can therefore not contribute to a consequent assessment of the idea quality, they also cannot reveal the value of an actor’s contribution to it. Moreover, the process documentation misses the crucial aspect of purposeful data acquisition, which would be required for a subsequent analysis of the collaboration process. As the results of the interviews showed, documentation is an elaborate part in the development process and is therefore conducted mainly, to satisfy legal requirements and save explicit knowledge. In order to avoid further documentation effort, the companies seem to stick only to these requirements then. Unfortunately thereby the presence and flow of tacit knowledge cannot be revealed. These findings are also supported by the analysis of the process documentation of company A. Here it could be seen that even the descriptive data which is captured in process documents can be incomplete and is insufficient to investigate the collaborative setting, as no information about the involved persons and the created value is given. Only the prescriptive process specifications from company A’s project handbook were able to deliver these information, but displayed only the target state and did not describe the actual state. Hence, a transfer of this structure from the target to the actual state could create the necessary data input for a social and value network analysis, as pointed out by ALLEE (2000), and help to investigate the metrics which were introduced in the innovation measurement frameworks developed by REGNELL et al. (2009) and MULLER et al. (2005). However, among all investigated companies one exceeded the standard ways of personal and media based communication by the use of a social media and established idea management systems, which enable a detailed documentation of idea generation and evolvement processes. However, this company struggled then in the creation of a homogeneous approach, for which reason the idea management system and the evaluation approaches are revised currently. With these findings the initial two key questions
could be discussed well and subsequently the third key question could be faced about how companies could manage and evaluate their participation in the Innovationsplatsen. The final approach and the associated tools which were developed then provide a general procedure to facilitate the investigation of user involvement and collaboration in an innovative MedTech setting like Innovationsplatsen. Therefore the tools enable the recording and tracking of data which give feedback on the innovation increase of an idea or concept by evaluating the four fundamental criteria of safety, performance, usability and life-cycle costs with an innovation value matrix. Moreover, these tools define what data have to be collected, to investigate the innovation activities and provide therefor the necessary assistance. In order to receive a relevant response rate, the tools were kept simple and based on the currently common procedures of the MedTech industry. However it is necessary to motivate the participants to use of them and teach the value that can be achieved with it. With this approach it can only be contributed to proper analysis results, if the required data are completely and continuously collected. By its application finally a network can be derived that gives insight in the aspects of influence and collaboration among all involved persons and the value as well as the knowledge flow can be revealed. At last it can be highlighted who contributed what to the setting at which time. Although it sometimes might not be possible to connect an idea or value input to one person only, also the connection of an idea to several persons can provide valuable insights for an analysis. By this means soon the collaboration processes and the user’s role in it will be understood in the case of Innovationsplatsen. This can serve then as a reference setting to which later investigated environments can be compared then, in order to derive best practices. The differences between these settings can then point out which collaboration strategies were more or less successful. Furthermore, as the companies pointed the importance of communication in the projects out, these results could be used then as well to improve and develop future communication approaches. What remains unanswered with this work is, if the proposed approach and tools can and will be used in the intended way, so that the strived goals can be achieved. Furthermore it might happen that during the course of the approach application additional metrics and aspects of interest come up which are not supported by the proposed approach currently, but are worth to be investigated as well.

Conclusions and outlook

After the summary of the achieved results with this work and a short discussion of them, it can be concluded that the processes of user involvement are unclear and need to be investigated. Applying the proposed approach and tools in the Innovationsplatsen can serve therefore as a starting point in a long lasting course of investigations. That is why the need for such an approach and the approach itself has to be promoted in the industry and improved continuously in future works. Only if it is applied in different settings then, the best practices can be derived basing on a comparable basis of high qualitative data. Therefore it has to be ensured that the users of this method are proper motivated, as otherwise the required data could not be gathered and the quality of the database would not be significant. A possible approach to that might be to let them benefit either directly from the created value map or with other conceivable bonuses. Furthermore the proposed tools need to be implemented in a proper software tool, even better in a complete intranet-based platform, to facilitate their application. Moreover, later during the application of the proposed approach also the defined
criteria and the value system have to be validated and possibly adapted, as the process of verification and validation in the field could not be implemented due to the time limitation of this work. If these future tasks can be implemented and the remaining drawbacks can be eliminated, the findings, approaches and tools from this thesis will be able to contribute to an even deeper understanding of collaboration and user involvement processes.
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Appendix

Interviews

Interview guideline

Company: ____________________________
Contact person: ____________________________
Date: ____________________________

Warm-up:
Greeting and small talk

Introducing the background of the interview and the project:
Innovationsplatsen
This is going to be a clinical site in Huddinge, where physicians, researchers and engineers work together in one place. There they are trying to develop new medical devices and products. The aim is now to create an approach to investigate the benefits of Innovationsplatsen and apply it.

The interviewee’s role in the interview
The aim with this interview is to get an overview of how things work at your company and to find a way, how this new approach could be implemented and what methods and tools are applied at the time.

Information about the interviewee:

- What is your position and task in the company?
- For how long have you worked in the company?
- What class of medical products does your company produce?
- In what way do you take part in/influence the development processes?

Documentation and processes of the “front end phase”

- Are there documented criteria for evaluating, selecting and prioritizing ideas?
- How are they put in practice?

Use of methods and tools
Do you use tools to:

- tag/trace ideas?
- document customer involvement?
- visualize/ analyze the groups interaction
- visualize/ analyze the status of the project?
- measure innovation output?
- review the ongoing development process?
- document knowledge (and trace the flow/influence)?

**User involvement**

- How is the user identified, who is involved in the development or ideation process? What are the selection criteria?
- At what time in the development process does the user provide feedback and input?

**Project and Process evaluation**

- How do you evaluate a project afterwards?
- Do you investigate the innovative potential of an idea or of a product subsequently? If so, how is this implemented?

**Feedback to Innovationsplatsen**

- What benefits do you see in Innovationsplatsen benefits?
- Is that interesting for you?
- What problems could appear?

**Cool down**

Contact to further contact persons
Leave-taking

---

**Interview analysis**

<table>
<thead>
<tr>
<th>Company</th>
<th>Infos about interviewee</th>
<th>User involvement</th>
<th>Idea input for development</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (1)</td>
<td>Industrial Designer (product design &amp; interaction design) 6 years at the company</td>
<td>Method use with user</td>
<td>Product refinement/ enhancement from - Market department - Clinics - intern research “through the projects” Method use (crowd</td>
</tr>
<tr>
<td>Role</td>
<td>Responsibilities</td>
<td>Methodologies</td>
<td>Notes</td>
</tr>
<tr>
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</tr>
<tr>
<td>A (2) Usability Designer</td>
<td>In interaction design group, 7 years in MedTech, working with SW-interfaces, cognitive scientist</td>
<td>Interviews with clinical staff such as nurses, physicians and also biomedicals</td>
<td>Sourcing, generative sessions, brainstorming) together with users, market experts, engineers.</td>
</tr>
<tr>
<td>A (3) Main Project manager</td>
<td>Manages all phases of development process</td>
<td>User identification: 1. Users and marketing related people in the company who know and translate the users’ needs (well structured) 2. General persona as reference user (less structured)</td>
<td>No formal evaluation and “innovation” rating of ideas. But number of ideas is minimized by informal discussion. Final evaluation with expert panel.</td>
</tr>
<tr>
<td>B</td>
<td>Previous worked as technology manager (&gt;10 years) now 1 year as industrial PhD on innovation management</td>
<td>Clinical system engineers talking to physicians and collecting/sharing information with them all the time. A physician working part time (2 days a week) at the company. Physicians are invited to arenas, come up with ideas and are consulted for feedback/advice.</td>
<td>People come up with ideas in teamwork with customers and experts depending on the situation (hours – months).</td>
</tr>
<tr>
<td>C</td>
<td>Product manager</td>
<td>Personal contact with users in hospital. No physicians in the company but “product specialists” (clinical staff: caretaker, surgical manager)</td>
<td>Discussion with users in the hospital (product manager is link to the user) Discussion with marketing and sales department “product specialists” -&gt; technical specification</td>
</tr>
<tr>
<td>D</td>
<td>Technical Project Manager</td>
<td>Feedback to developed products from physicians, normal users, company employees as user. User Network</td>
<td>Marketing (product management) &amp; Sales, physician, private inventors. Expert panel (technical, biomedical, … staff) Method use: Morphological Box Crowd sourcing with evaluation and reward.</td>
</tr>
<tr>
<td></td>
<td>3,5 years in the company</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Company</th>
<th>Documentation</th>
<th>Information spreading</th>
<th>Process evaluation</th>
<th>Feedback on IP</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (1)</td>
<td>On everything available “paper, napkin, computer sketches…” No KM-system but “project files” and requirements list</td>
<td>“Do you know what others in your company know?” Personal relationship, informal way of knowing Sometimes it is easier to ask someone</td>
<td>Final project review (project leader is responsible) Sometimes questionnaires, sometimes discussion</td>
<td></td>
</tr>
<tr>
<td>A (2)</td>
<td>Usability engineering plan Requirements from the authorities (safety focus) Process of what to documentation is steadily improved Documentation with presentations, prototypes, written reports (data and paper based) -&gt; paper based system</td>
<td>Documentation is “a way of communicating your results to many people” Intranet (test results, finding from studies) Everyone in the project has access</td>
<td>Documentation is also used</td>
<td></td>
</tr>
<tr>
<td>A (3)</td>
<td>No tagging system where the ideation process is traced There is a document storage system which is kept for legal reasons, but it is not involved in the development processes as “database” which gives insight in the user perspective</td>
<td>Projects and aims are reviewed continuously, but more in an informal way than a final formal evaluation</td>
<td>Very good thing, to formalize a network by drawing all the disciplines together. Several Innovationsplatse n around Europe should be considered due to the different user needs in ways of working and problems around the world</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>Everybody is educated in organization tools Paper templates that are scanned for ideas Different idea management systems for small and substantial ideas with tagging and idea status Documentation time is short and not a problem</td>
<td>Intranet, Homepage for Innovation related activities, newsletter, Social media (to create groups)</td>
<td>Difference: incremental – radical ideas Incremental ideas easier to measure radical ideas: takes a long time general it is hard to measure how much of value creation a specific idea contributed to the final product different</td>
<td>Generally interesting approach but problems of patent utilization: “who owns ideas?”</td>
</tr>
</tbody>
</table>
| C | technical specification central document storage (documents, templates, tools and description of processes) = document manager Product main file (legal requirement) Tracing of ideas is possible | Product manager is interface between development, user, marketing & sales and production | Product creation process (R&D)
Product launch process: Retrospective analysis on goal achievement continuous improvement process (evaluation of processes)
Improvement of development process with 2 master thesis (confidential)
evaluation matrix for the marketing process: 6 months after market introduction.
evaluation of the product’s establishment on the market and required changes for the next series | Similar: “Power team” interdisciplinary team works intensively on one task
Problem: exempt personnel for this team only
Collaboration of the power team with external development agencies. Due to the time advantage of the short information ways the concept is maintained
Sees IP as a chance, where in an intensive working environment short information ways are used to evaluate product ideas and contribute to a better quality (Better communication) |
| D | Technical specification with milestones Documentation required by law Document management system | Communication is the most central issue in development processes Intranet | Lessons learned in team session Project leader with subproject leader, evaluation of results Evaluation of technical specification
Evaluation of the innovation grade of every idea is conducted with a value table (before the development) |
Interview with an industrial designer (company A)

(Warm-up)
Hello Karin. How are you?
I am fine, how are you?
I am fine, thanks. Do you have some time right now for this interview or are you busy?
No, I have time.
I am recording this call, just to let you know. That makes it easier for me afterwards, if I forgot to note something.

(Introducing the background of the interview and the project)
First of all I’d like to give you a short introduction from my side about my project: Currently I am writing my master thesis in Stockholm at the KTH. Initially it was intended to have a look at innovation processes and customer integration at company A. Unfortunately it was not possible to find the data we were looking for in the project documentation. The purpose now is, to create a method, which enables to collect the requested data “online” in the front end of the development process. Furthermore it is intended to apply this method within the upcoming “Innovationsplatsen” project. Do you know about this?
Yes, I know about that.
The aim with this interview is to get an overview of how things work at company A* and to find a way, how this new method could be applied and what methods are applied at the time.

(Information about the interviewee)
First of all, I would like to know: What exactly is your task and position in the company?
I’m an Industrial Designer. I work with product design and interaction design on mainly ventilation products, but also with anesthesia products.
For how long have you been working in the company?
I think it is 6 years now.

(Documentation and processes of the “front end phase”)
Can you tell me, what kind of tools you use, to document the development processes especially in early phases, when new ideas come up and how in particular you come up with these ideas?
Mainly we just keep any paper, napkin or whatever we have ideas sketched on. So we don’t really keep any formal sort of documentation of everything, when we start up. Usually we have sketches on the computer, on paper or on whatever we can find. How do you come up with new ideas? Do you have any kind of creativity sessions or surveys?
Well, it depends. Since we work an industry and have an “R&D project phase”, usually the products or projects come up, because we need to either refine or enhance some product or function, or we get the information from the market department or clinical that we need to develop a new function or product. That is pretty much how requirements for new features and products come in - they come through the projects. That is how we discover a need for something.
So this means that the input comes from the customers like the hospitals?
Yes.
...and also through the marketing department sometimes?
Yes, not only through marketing, but also through research, that we do ourselves, depending on the phase of the project that we’re in.
(use of methods and tools)

Do you use any specific methods then, maybe not only in the early phases but also later on?

We have many methods that you can think of. We do crowd sourcing, generative sessions and we sketch in brainstorms with interdisciplinary teams.

Can you specify this a bit more?

These are specific methods with users, together with market experts, engineers and whoever is part of the team.

Do you then also work with some kind of knowledge management systems, where you put in the information you got from these group sessions?

Not on a digital database basis. But we put some of the information in the project files. Some things go to the requirements, but some things never go anywhere.

So in this case you mostly stick to the company A* “project handbook”, which is a guideline to the development process?

No. Methods, that we use, are commonly used methods for the user, designer and usability. We do a lot of formative design research. There are so many specified methods, that you can use to find out future needs and requirements. Depending on the situation, your aim and the information you want, you choose the method that you need to work with.

Do you also review the project when they are finished?

Yes, we do reviews of projects and of course we do summative usability testings, so that we know, if the ideas are OK. So “yes”, we do review of projects.

How do you do that? Is it just an informal talk to the involved persons?

That depends on the project leader, because we’re always a part of the bigger project. Project teams have people from all departments of the company. So project leaders are the ones that decide how to evaluate the project. Sometimes this happens with questionnaires, sometimes they have a talk. Actually I don’t know, if there is a standard company A* way of doing it. So you have to ask somebody else about that.

Do you think it would be interesting for you as an industrial designer to know about how the project worked in specific afterwards and to see if there would be room for improvement?

Well, these are things that we do. So “yes”, we can use them.

An interesting question is also, how information and ideas spread in the company. Do you know what others in your company know?

You pretty much know, but nothing of this information is documented. You work here for a very long time and you build up personal relationships to people, who know other people. This is how you get to know, who knows what, if you have any specific questions. It’s an informal way of knowing about information. But we don’t keep it in databases and we don’t keep it written somewhere.

Do you think you would have the time to put everything in databases? Because putting down all the data on paper would probably take a lot of time. There definitely should be a motivation for someone who uses these databases. Do you think you have the time, to write down information or do you just think “I have the information in my mind and that is enough”?

When you’re looking for information on who knows what, it is easier and quicker to ask someone. And I kind of like having person-to-person conversation, too.

(further contact persons)

Carl Wadell told me that there is another person I should have a talk to. Her name is Anette. Are you also in contact with her?
Anette and me, we both work on the usability process. She’s the one that is actually a lot better on the usability process than I am. We’re doing a review – we’re trying to finish it off before summer – of some operation procedure, if we do have the usability that we’re mapping to the standards. She’s much better than I am in working with usability… she’s a cognitive scientist.

Do you work a lot with researchers, who are looking at your processes, as you said Anette is a scientist, did I get that right? Her focus is more to do research?

Her authority is the usability, usability testing and creating workshops and collecting and testing new requirements. But she’s also big part in generative sessions and creating ideas. We all work together, we have a very nice small interdisciplinary team, sort of specific design usability team. When we work in the projects we have some technicians, engineers and so on.

Do you think you could forward my email and let her know that I would be happy to have a call with her. I could send you another email if you like, that you can forward.

Yes, please do that.

(cool down)
So that is all the questions I had so far to get a first overview on how it works at company A*. Thank you very much for your time.
Sure, call again if you have any further questions.
Thank you very much and have a nice day.

Thank you, you too!

*amended by the editor

Interview with an usability designer (company A)

(warm-up)
Hello Anette. How are you?
Fine, thanks. How are you?
I am fine, too. Thank you! I am recording this call, which makes it easier, as I don’t have to write down every word.
Yes, I know.
Have you talked to Karin about my project and questions already?
Yes, a little. She told me a bit about your interview.

(Introducing the background of the interview and the project)
Then I’d say I start to explain some things about my master thesis at KTH and my project, to give you a good overview about the background. Initially it was intended to have a look at innovation processes and customer integration at company A*. Therefore we requested project documentation on several projects. Unfortunately it was not possible to find the data we were looking for in the project documentation. The purpose now is, to find out how you could collect the required data, what information is it that we’re looking for and how can a method be derived to perform an analysis on user integration and innovation output. Have you heard about the upcoming “Innovationsplatsen” project?
Yes, Karin mentioned it.
This is going to be a clinical site in Huddinge, where physicians, researchers and engineers work together in one place. There they are trying to develop new medical
devices and products. The aim is now to create this method and apply it within the “Innovationsplatsen” project.

OK, that sounds interesting.

(Information about the interviewee)

So now I would be interested in the development processes at company A* and would like to ask you some questions about that. First of all, what exactly is your task and position in the company?

I'm a usability designer within a group called “interaction design group”. We just choose that term to make it easier, in order not to use too many terms. We all mainly work with the software interface.

For how long have you been working in the company?

I’ve been here for 3 ½ years. Before that I’ve been working in other companies in the medical and biotech field. So I’ve been working for almost 7 years. I am a cognitive scientist, that’s my background.

(usability)

Karin told me you’re working a lot with usability engineering plan. Can you describe and explain this a bit more in detail?

Do you mean the plan or the process?

Probably the plan bases on the process, but could you explain both and describe the difference?

The plan is a document, where we sum up all our activities within a project, to ensure that we have a good usability.

What kind of information do you document in this plan? Does it concern the development phase only, or even before that when you are carrying out interviews and surveys?

It's even before that. We do design research before we start the development project and then we conduct interviews with clinical staff such as nurses, physicians and also biomedicals, who are users that are more survey focused.

So there should be a lot of documentation somewhere in the usability plan?

Yes, there should be. We keep extending the documentation, as we have a lot of requirements from the authorities to do the review. They look more into these processes today, than they did for a couple of years ago. So historically we have not been doing so much documentation on these design research activities, but now we do it currently. The process we have is used to be very safety focused, because the standard that we ensure you’re aware about the usability standard that we follow with the IEC-Standard 62366 and there is some other AAMI-Standards, that we have to follow. They are process oriented standards. They focus a lot on safety. Historically we have had this usability process here that is really safety focused, but now we’re working on extending it, so that it includes much more of these early activities.

So the whole process improvement is still in progress?

Yes, we’re improving it. We know that there is a lot more focus on these issues from the authorities and therefore we’re working on this.

Can you explain in your own words how you improve the process?

We improve it by rewriting it, because we have our own internal process. But the internal process that we have is supposed to reflect the standard, because that is something that we have to interpret. The standard is actually kind of high level. So it is not so clear exactly what activities you have to do and exactly how much you have to document. That is an ongoing work for us, to review that interpretation and find out, if it is good enough for the authorities. We do a lot of activities, that we have
been doing before like the design research also, but we haven’t documented everything.

How do you document your information and data then? Do you use a software tool?

It’s mainly reports, so it’s written on paper. And we also have raw materials such as videos and prototypes, which also can be a kind of digital format. We always have to have it on paper, as we have a paper based system today.

Does it take a lot of time for engineers and developers, to keep written record of all these information?

We try to keep the time as low as we can. That is what I mean, when I say “we have to interpret, how formal everything has to be”, because of course the important thing is that we follow the process and do the required activities. But it’s not totally clear, when you read the standard, how much you have to document formally. We try to keep it down, but we also know that it’s the paper what the authorities review, when they come here to review us.

So this review is required by current law?

Yes, but sometimes it doesn’t feel so modern the way they review us. There could be other ways to do it, but now it is absolutely paper based.

Is the documentation just for the purpose of the review or is it also used afterwards by developers?

It’s not just for the review, but also a documentation tool.

And it is also used to get information from past activities?

Yes, from people, who have been involved. It is a way of communicating your results to many people. It definitely has a value. It is just that we do that in other ways also, as we do presentations for example. It’s not something that counts as a formal documentation, but you always have to do the paper work also.

Do you have another tool then, which spreads information in the company besides this one?

We’ve got the Intranet. There’s a project I am working on, where a lot of information is communicated through the Intranet. We do show a lot of results there also.

What kind of information and results is that?

It could be test results and main findings from studies. Do you have feedback on how this tool is used? Does everybody have access to these information?

Everyone in the project has access. I think it is a really good and fast communication tool.

Are the teams composed of internationals in different geographical places?

No, we don’t have any outsourcing resources.

So this is more like a knowledgebase for the team?

Yes. Especially in some projects the teams are really big. Even if we’re all in the same place not everybody is speaking to each other on a daily basis.

What do you define as a “big team”?

Could be up to a hundred people.

*amended by the editor
Interview with a project manager (company A)

(warm-up)

Hello Magnus. How are you?

Fine, thanks. How are you?

I am fine, too. I hope it is OK, if I am recording this call, as I don’t have a second person to write down every word.

Yes, that’s OK.

(Introducing the background of the interview and the project)

I guess I should start to introduce first of all myself first, to let you know who I am and what I am doing. Currently I am writing my diploma thesis here at the KTH, but usually I am studying at the Technical University in Munich and I am writing now about user integration and user involvement processes. We started with this almost four months ago and initially we wanted to analyse the processes at company A*. But then we recognized that some documents and important information was not available and now we switched the topic to what can we do to document the required data from the beginning on. Soon there will be a project called Innovationsplatsen, which is a clinical site in Huddinge, where physicians, researchers and engineers can work together in an innovative setting. We plan to apply this method approach on what data to collect there, so that afterwards we can evaluate this process and setting, and compare it maybe to other innovative setting such as medical companies like company A* for instance. That is why I am doing now some research on the current processes at medical companies, to derive the state of the art. I want to know how is it working at the companies, what are you doing, what are you not doing, what could be better.

(Information about the interviewee)

To start with, I would like to know first a bit more about you, who you are and what tasks you and which position you have have at company A*.

OK. Well, I am the main project manager.

And for how long have you been working at company A*?

For ten years now and for the last five years as a project manager.

Do you supervise only a special kind of project class within the company?

I manage ventilation projects.

What kind of medical product class from I to III is this then?

Actually I don’t know.

In what way do take part in the development process then? Are you only supervising or also involved in the ideation process for instance?

Actually it depends on what project we run. For example, the projects I have been managing now have started in the concept study phase and basically I can say that I can manage all parts of the development process also before the concept study phase including the ideation phase. We follow thereby the V-Model.

(user involvement)

So my first question about the user involvement would be: How is the user - the physician - which is integrated in your processes identified in the beginning? How is the user identified, the one that you want to include in the process, the one that works at the hospital for instance. How can you specify that you want exactly this user to give input and take part in a pre-study phase?

I should say that I have seen two different approaches to this. The first and the most common approach in our house is that we have clinicians and marketing related people who have the knowledge about what the customer needs. And then they
translate this knowledge verbally so to say to the developers. The second which we have used in my focus now has been to make a “general persona”. We use these to create a general and defined picture of different users to be like a reference user, when we define the user in a debate concerning the product. So we have a less structured method which is very common and a structured method with the persona.

(traceability)
Do you then also use some kind of tools to track the idea flow that comes from the user and how this idea develops during the whole process?

Maybe someone else uses this, but I haven’t seen that. Do you mean a tool like a database where you log the behavior?

Well, a tool with which you can log for instance: User A came up with an idea and we used that idea as input to that brainstorming session, or we came up with an improvement to this idea. And finally this idea went into the development process at this stage, because there we needed that solution or however this could work. This is just an imagination, I don’t know if something like this exists at all or is even used. As I know you have some kind of document storage system where you can save the reports, prestudy reports and more, my next question would be, if this is used frequently also during the development phases to recover information again from the prestudy phase for instance.

Not this far as I know. Of course we have a documentation storage place, but that is not like a special database, where we go back and read it again for user perspective. As far as I know this should probably be the same in Sweden as in Germany that you have legal restrictions to document the development process to certify your product.

Definitely! That is more like a legal and regulatory requirement level so to say. And of course part of it links to the market specifications where we have to validate the market requirements towards that specification form. From that point of view of course we have 100% tracking. But that is more like a top level.

(ideation)
And when you come up with new ideas, how do you select the ideas which should be followed and go into the development process? Do you have any documented criteria for evaluating and selecting ideas, in order to give them some kind of an innovation rating?

Not formally defined in our processes. In that project I am managing now we use something like it, but it was more like a new innovative way of working despite the process we have. I follow what you mean, but actually we don’t have it in our system.

(evaluation)
So how did you know that your new idea was innovative? Just because it was new to the world? Is that some kind of criteria you use?

What we have internally done so far, is that we have presented from the beginning something like ten examples and then we worked it down to three. Then we had internal audits where we asked some of the different disciplines in our house just to come up with their opinion. As a next step now we will invite also external references like doctors from all around the world and have their opinion as well. Also I think that according to Karin we have the same criteria both for internal references and external references, so that some of us know what way to go. But as I say, my feeling is that we don’t have it as a formal part of our processes, to investigate if there is something innovative, as Karin might see it from her point of
view. And I think one reason for this could be that it’s not very often that you do a very innovative project. So this could be also one reason.

How do you evaluate a project in retrospect then, when the product is developed? Do you only use the common criteria of return on investment to identify a success or do you also have other criteria to state that a product was a success although it did not return a lot of money, but it was maybe a good input to our ongoing projects? Do you have any criteria to add any kind of success factor to the product?

I should say that this is also something we take hand of currently, but I can’t find it in the processes. In my project we have been very clear with the goals on what we should reach with this project after four years. This could be several things. So I should say yes, we do that, but I can’t see it as a formal part of the process.

So there is a discussion with responsible persons who were involved in the process about this? Is this some kind of an informal discussion?

To be honest, since we got our new development manager – the boss of all the developers – he introduced a lot of those things you have been asking questions about now. The last thing you said was: How do we reach in our projects and how should we track it up then. But the thing is he is quite new and he has been able to implement those elements we have been talking about only informally. So it is not part of a process, but on the other hand it has been very clear that it is part of the project. Can you follow the difference?

Sure, it is not officially manifested in some kind of a process description, but you do it because you have it in your project as an aim to reach.

Exactly, like that.

(Innovationsplatsen)

I see company A* as an innovative MedTech company, which is similar to the project which I am focusing on right now. The Innovationsplatsen is also supposed to be an innovative place especially because there is supposed to be many researchers, physicians and engineers coming and working together but not in a fixed setting. What I would like to know from you know is, if you see any benefits from that setting or would you say that you already have these benefits from Innovationsplatsen now at your company?

Actually, up until you contacted me I didn’t even know that Innovationsplatsen existed.

It does not exist yet. Due to legal reasons they have to rebuild the hospital every twenty or thirty years which is now. The rooms for the physicians and their equipment are planned and also the KTH is planning to send some departments with a MedTech and surgery background in these facilities. The intention now is of course as well to have some engineers and companies included as well as innovation drivers. Do you think this is a good approach or do you see any relevant disadvantages towards the current setting at your company for instance?

Just let me repeat this, to make things clear. Is then Innovationsplatsen, a place with those people from KTH, company A* and the…?

...the physicians from the hospital.

...and is it also people from KTH there?

Yes.

...and maybe people from company A* as well?

Yes.

What would be the purpose with it?
The purpose would be that you have a close cooperation between those people and a close user integration. For the KTH it would be also a great opportunity to do research in this MedTech setting, where product ideas come up and are developed, but also the feedback from the users which are the physicians also that the physicians can use the products and also the KTH has access to the medical equipment of the physicians. Involving the companies should give then a more professional touch so that products can be produced later on to use them and profit in an economic sense. And not only for research purpose.

Actually, I think this could be a very good thing, because if I got you right, you’re trying to formalize like a network to put the benefits of all the disciplines together. What I would see then is maybe then you should have several of them.

Do you mean several buildings?
Several sites of Innovationsplatsen. It should be placed in different places in Europe and for example one place in Asia or India for example, because the users may have – and I know it is like that – different ways of working and different problems. So this should not only be a western thing, it should be more global.

Yes, I can see it as well that it might be a disadvantage to see things from a western point of view.

You also have to see it from the economical side. The present market is India, where we sell a lot of machines, South America, for example also China. Maybe you can Innovationsplatsen for your purpose as it is now, but I think you should have this in mind.

(cool down)
Yes, that’s sure right. My own purpose is now, to develop an approach on how to evaluate Innovationsplatsen or at least to reveal the networks with a value network analysis, to identify which part of the users can contribute to great innovations and how they contribute to innovations in which way. I am currently trying to figure out some tool, method, approach – whatever you want to call it – to achieve this goal and I am having a presentation in two weeks on the 18th. If you have time I would be happy if you could join. It will be also a discussion with someone from Innovationsplatsen and Carl Wadell, the director of innovation at Swedish MedTech, and hopefully an innovation manager from another company. So if you would have the time for a discussion of the results I would be more than happy.

I have an important meeting on that day, so please send me an invitation quite fast and then I can maybe place my important meeting in between.

That’s great! I will send you an invitation then. Thank you very much for your feedback.

I think that was very interesting as well, because the questions you were asking me quite get the picture. From my point of view it is that you have a formal process for handling how to integrate users in a product and I should say that maybe we have them in one level but it could be a lot better. I should say also that from my point of view it should be like Karin’s usability design. They have those processes and want to work with them but somehow – at least up to now – they are kind of too new. It is like new school and old school meeting here. So if you’re asking Karin, you’ll probably get the answer that probably not all of the methods are implemented in the processes.

All right, it’s good to hear that my questions pointed in the right way. Thank you very much for your feedback.

Yes, they definitely did. Thank you, too.
Interview with an innovation manager (company B)

(warm-up)

Hello Susanne.

Hi.

(introduction and information about the interviewee)

I think I should start to introduce myself and what I am currently doing first. At the time I am interviewing development professionals and researchers from companies on innovation processes and how development processes work at their company. Because the upcoming Innovationsplatsen which is going to be a hospital site where engineers, researchers and medical staff like physicians and nurses come and work together and also develop and be creative together. So I am trying to find out what is the situation right now in MedTech companies and this is why I wanted to interview you, because you are an innovation manager.

Previously, I've been working as that for quite a long time, but now since the last year I have a position as industrial PhD student and I am also working in parallel as an innovation manager. There I prove the innovation work at the company. So you're working in this position for one year? Did you work as innovation manager before?

No, before I was the director of technology being responsible for development.

How long was that?

Over ten years in different kind of technologies.

But in the field of MedTech

Yes, in this company.

In what manner did you take part and influence the development process at this time? Did you come up with your own ideas, where you involved in creativity sessions or did you organize the processes at the company?

In my present position or earlier?

It would be great if you could describe both. But I think you can tell me more about the work you did ten years before.

But also general you mean, how did we come up with ideas? We have different kinds of working. I do of course the more anarchistic way, where people do come up with ideas all the time, but we also have organized types of works. Either temporary work for a couple of hours in a certain team or we have teams working temporarily for three to six months, in order to generate ideas and achieve new knowledge. And those kind of temporary settings are all from a few people to a large number of people and involve either only people internally, but also externally with customers or experts. It depends on the area.

(documentation)

Do you use any tools to document these processes and sessions?

Yes, we have been educated – basically everybody in the whole company has been educated – in certain types of creativity tools. [interruption] We have different types
of problem solving tools. Everybody has been exposed to that type of organized tools, but also some people are more knowledgeable, because they have been taking more caution in that type of tools. And then of course we also have setups of taking care of the ideas.

How do you put these ideas on paper? Do you write down your process or do you have tools like crowd sourcing where everyone can take part?

Are you talking about the evaluation part of ideas?

Well, more about the documentation, not the evaluation. Because when you come up with ideas you have to put them down somewhere.

Yes, we have created some place for documenting ideas. Basically first people speak and then we have posted notes, but then we have also developed templates; templates that help to visualize or give questions.

Can you specify what a template is?

A template is some kind of a written thing with questions or things like that. You can actually conceptualize your ideas with it.

So everyone can draw ideas on some kind of a form or something similar.

Yes, you can say form. Template is the same as a form.

This is on paper then? Not in any digital form?

Yes, this part that I am describing now is on paper and then we scan those papers into the system. Then also depending on what ideas will be selected, those ideas are documented and further conceptualized.

Do you have any process of tagging the ideas, to follow how the idea developed over time?

It depends on what ideas. Ideas come and go all the time. We have different idea management systems. We have some for small ideas, where everything is tagged all the way. It is a very easy, very good system. There you can put in your ideas and describe them. Then it’s tagged, who is taking the decision and if it is in an implementation place or not. You can follow it completely.

And you can follow, who started with it?

Yes, perfectly but just for small ideas. And then we come to ideas which are more related to the product, which are more substantial changes. There we have other idea management systems where you put in ideas which also get tagged along the way. They go to the board, where decisions are taken and so on. So we have two different idea management systems.

Do you also involve customers in common sessions then and invite them to the company?

That could be. As I mentioned: If we are talking about the organized idea generation – I think that is what you are talking about – ideas are generated all the time. We have a certain group of people who are called clinical and system engineers which are talking in their position to physicians all the time and collecting information and sharing with them. And all developers are encouraged all the time to go out to customers and discuss things with them. Then we have one person, who works for us two days a week.

And he is a physician?

Yes.

So it is also that doctors come to you with their ideas and not only you going to the doctors?
Yes, it's both. We also invite them to different arenas. Both for advices and coming up with ideas.

What would you say, how much time does it take to document all these things? Is it a time-consuming process?

Yes. Right now we are looking into that, because we are going into a phase where we try to switch idea management systems. We are evaluating at the present. We kind of try to understand, where do we have time stops and bottlenecks. I couldn’t answer that. The one system that I mentioned that is really smooth, there things can go really quickly in a day or two, because we have even distributed the responsibility for the idea provider to accept their own ideas, because they are so small ideas, that you can improve it by yourself. But if they have bigger ideas, they need to get approved. And that of course could differ. It could take a couple of weeks at the most for those, the small ones. And the bigger ideas could take at the most a couple of months maybe. But it depends on what you mean. Do you mean the time it takes to document or the time of the process steps? Do you see what I mean? It is a difference. In manufacturing we talk about the lead time and the hands-on time.

Well, both. Also the hands-on time to document things. Are you more busy with documenting.

It's hard. If you look at small ideas, it is very easy and fast. In hands-on if I have an idea, it takes me a couple of minutes. If you include the whole process from when you put in your idea until it's implemented and the documentation has on-time during the whole process, is that what you’re asking for.
Not in specific but as well. I don’t know how you are documenting, if you just put it somewhere and it is OK then or if it takes much time.

I don’t think the documentation is a problem. Not really.
And the lead time you just mentioned is the time from the idea input until the...
...until the implementation or approval for a project depending on the degree of novelty or complexity of the idea.
How is it afterwards, when you do an evaluation of the idea to figure out if it should be implemented or not? If someone comes up with a new idea, do they do an evaluation?
Yes, that’s right.
And then you think about if you implement it in a product?
Yes, if it is product relevant.

Then afterwards, do you also measure, if that idea really turned out to be successful or even innovative?
Yes, exactly if it really created value. If we come back to the division of big and the small ideas – I think that is really important to discuss – if we look at the small ideas, it’s including in the process that to make an assessment is about the value, so it is kind of included. You can’t finalize your idea cycle if you haven’t done an assessment of the value that is betrated. So that is part of the process. If you look at the big ideas it’s harder, because some of these big ideas are small ideas in terms of complexity I am talking about mostly. So I would say that the incremental ideas are more easily to measure the effect of. And you can talk about that and describe that. But if you look at the more novel ideas, I think it takes such a long time. To some extent people measure that. But it’s a general thing that we have a problem in measuring of how much of value creation this specific idea contributed to the final...
product out on the market. Especially in our branch with high tech products, when you have such a long cycle, you don’t have the small quick improvements all the time, because it’s such a long process going to have the changes approved. You make many things while doing a version 1.2 or something like that. And then it’s hard to figure out how much of the success created value, if you look at the output and compare to the others and the synergies etc. So it’s hard.

But by what criteria do you measure it then? By monetary criteria?

If we are talking about the final output, then we have other measures earlier to how does this and that improve.

And how do you do that? Do you have certain specific criteria where you have a look at?

It depends on. Different measures for different departments and different projects and products. It differs quite a lot.

And those criteria a created every time newly again when you have a new project?

I am just investigating this right now, so I will have a better answer soon. It is quite interesting. What you can see in a big company is that there are some general measurements and indicators on the whole organizational level, but then each department, team or individual has different measures. And I am developing if it should be like this and be adjusted to the needs. We’ll see…

When do you think you will have results?

We will have it in a couple of months or so concerning the specific measurements.

Another question I would have is, how spreads the information in your company? You have these session with certain persons, do you have some kind of tool then with which you communicate the results?

Yes, we have the intranet and we have homepage for innovation related activities.

Is it something like yellow pages then?

Yellow pages? What do you mean with that?

A list in which you can look for persons with special qualifications.

…like an expert list. No, we have different things. We have social media where people can create and share content and we have the intranet with different pages where we inform what happens concerning innovation related activities. The communication is spread in different ways.

And if the decision makers want to spread something they use a newsletter?

Yes, there is a newsletter.

OK, thanks. I think that’s it. Thank you very much.

Alright, you’re really good at short distinct questions.

It might be that I come up with new questions and then I would come back to you.

Yes, alright.

Interview with a product manager (company C)

(warm-up)

Hallo Herr….Hier ist Matthias Butz. Wir hatten ja für drei Uhr einen Interviewtermin. Haben sie gerade Zeit?

Hallo, ja ich habe Zeit.
Ich hatte ihnen ja schon geschrieben, dass ich das Gespräch gerne aufzeichnen würde, damit ich mir nicht so viele Notizen machen muss. Ist das OK?

Ja, das hatten sie ja schon geschrieben. Das ist OK.

(information about the interviewee)


OK.

Da wurde ich im Unternehmen jetzt an sie verwiesen, da sie Produktmanager sind. Wie lange arbeiten sie nun schon bei company C*?


Inwiefern nehmen sie dann am Entwicklungsprozess teil? Sind sie beteiligt im Sinne von Kreativität oder Ideengenerierung oder geht es mehr um die Verwaltung von Produkten und Bestimmung von Produktklassen, die neu erschaffen werden müssen?

Prinzipiell ist es meine Aufgabe den Produktlebenszyklus des Produktes zu betreuen. Das bedeutet einmal eine Preisliste dazu zu machen, das Produkt zu beobachten, wie es sich am Markt verhält, Wettbewerbsanalysen zu machen und auch vor Ort in Krankenhäuser zu gehen, um dann eben im Gespräch mit dem Vertrieb und Nutzern Ideen aufzugreifen für neue Produkte. Das ganz wird dann in ein Lastenheft gebracht, welches dann Grundlage für die Entwicklung ist. Während der Entwicklungsphase bin ich dann sozusagen das Sprachrohr des Kunden, was die Entwicklung konstruiert hat zu prüfen, über verschiedene Stufen zu bringen bis es schließlich als Serienprodukt verfügbar ist und das dann auch am Markt zu positionieren. Produktmanager bei company C* bedeutet im Prinzip genau die Schnittstelle zu sein zwischen dem Vertrieb und der Entwicklung und der Produktion. Es ist eine sehr starke Schnittstellenposition.

(user involvement)

Haben sie den auch Ärzte im Unternehmen selber?

Sind diese Personen dann auch beteiligt ganz am Anfang des Ideenschaffungsprozesses, in dem es darum geht überhaupt auf neue Ideen zu kommen?

Ja, die sind mit dabei, vor allem auch um noch einmal bestimmte Anregungen vom Kunden zu validieren. Dann haben wir nicht nur die Kundenmeinung, sondern auch ein zweite Meinung. Denn es gibt ja oft auch Kunden die etwas unbedingt wollen und bestimmte Sachen für eine ganz tolle Idee halten. Mit den Produktspezialisten haben wir noch einmal eine zweite Meinung, die das aus unserer Sicht sieht, um sagen zu können: Ja, das ist grundsätzlich ein Problem oder das ist nur „eine“ Idee von „einem“ Kunden, damit wir da auch schon mal das Marktpotential ein bisschen hinterleuchten.

(documentation)

Haben sie dann auch ein Knowledge Management System I dem sie die ganze Dokumentation wie Lastenheft und Pflichtenheft zum Beispiel ablegen?

Es gibt bei uns eine zentrale Dokumentenablage, wo die Vorlagen dafür sind, wo die Prozesse verwaltet werden. Das nennt sich TDM Dokumenten Manager, dort sind die Prozesse beschrieben, wie sie funktionieren und auch die ganzen Checklisten und Formulare finde ich in diesem System. Wenn ich neu bei company C* anfange, kann ich mich an dem im Prinzip durchdrehen, was dann meine Aufgaben sind. Die Dokumente selber, die dabei entstehen, kommen in eine organisatorisch zentrale Ablage, wo alle betroffenen Abteilungen darauf zugreifen können, damit wir nicht doppelt oder dreifache Ablagen haben, sondern nur eine Ablage die entsprechend immer die aktuellsten Dokumente enthält. Und dann gibt es zum Schluss für die Produkte – weil wir ja Medizinprodukte herstellen – eine Produktthauptakte, die entsprechend immer die Basis für dieses Produkt ist. Dort ist dann alles dokumentiert, alle Test, alle Zulassungen und auch diese Dokumente.

Das ist dann das, was aus rechtlicher Sicht notwendig ist für die Zulassung des Produkts?

Ja, genau.

Werden diese Dokumente dann auch im Nachhinein genutzt, um eine Evaluation des ganzen Projektes durchzuführen?


Haben sie dann auch noch ein crowd sourcing? Das ist ein Informationssystem womit jeder seine Ideen, die im Unternehmen auftauchen und umgesetzt werden könnten, einbringen kann, sowohl vom Marketing als auch von der Entwicklung als auch vom Vertrieb.

oder zwei Nutzern und fragen nach ihrer Meinung ob das Sinn macht in diese Richtung zu gehen oder nicht.
Sie wissen also immer von wem die Idee gekommen ist, um am Schluss noch eine zweite Meinung einzuholen.
Ja genau, das können wir nachvollziehen.
Hat das auch einen Einfluss, wenn sie von bestimmten Personen wissen, dass sie nicht so viele gute Ideen beigetragen hat? Würden sie daraus Schlüsse ziehen diese Person dann weniger am Prozess zu beteiligen?
Wenn dann ein Produkt entwickelt wurde, wird nachträglich noch einmal eine Evaluation stattfinden, das sagten sie ja bereits. Überprüfen sie dann aber auch ob sich ihre eigenen Prozesse im Unternehmen verbessert haben oder wird nur untersucht ob das Produkt gut war?
Wir haben einen kontinuierlichen Verbesserungsprozess, wo wir alle unsere Prozesse hinterleuchten. Wir haben den Produktentstehungsprozess auch eben neu aufgesetzt. Wir haben ihn seit einem Jahr nochmal überarbeitet, weil wir festgestellt haben, dass wir Reibungsverluste gehabt haben.
Das passiert innerhalb ihres Unternehmens, dass neu strukturiert wird?
Ja, genau.
Könnten sie darauf eingehen, wie sie die Prozesse beleuchtet haben. Haben sie da eine spezielle Methodik?
Das heißt die Methodenentwicklung hat dann im Unternehmen stattgefunden?
Ja, genau. Es war dann Thema einer Diplomarbeit, um auch ein bisschen die externe Brille aufzuhaben, da man ja doch recht eingefahren ist. Man ist an die Situation gewöhnt und wundert sich doch warum es manchmal nicht geht.

(feeback Innovationsplatsen)
Dann hätte ich noch eine allgemeine Frage an sie. Ich hatte Ihnen am Anfang das Innovationsplatsen Projekt kurz vorgestellt. Sehen sie das als gute Idee an, denken sie dass die Unternehmen die daran teilnehmen einen großen Nutzen ziehen können? Wie würden sie das mit Ihrer Erfahrung aus der Produktentwicklung bewerten?
Wir haben os etwas Ähnliches. Wir nennen das ganze „Powerteam“. Wenn wir neue Projekte treiben wollen können wir uns wirklich separat zurückziehen und die Leute aus dem Tagesgeschäft herausnehmen, um entsprechend dort strukturiert an einem Problem oder einer Fragestellung arbeiten zu können. Ich denke es macht auf alle Fälle Sinn ein interdisziplinäres Team zu bilden. Für Unternehmen an sich ist es etwas schwierig, weil man die Entwickler dann nur in diesem Team hat. Das sehe ich bei uns auch. Die Entwickler, die viel beisteuern sind dann in zu vielen Projekten eingebunden. Die in ein Team zu setzen, in dem sie nur an Innovationen arbeiten ist in der Theorie denke ich sehr schön, aber in der Praxis dann schwierig
von der Unternehmensgröße sehr stark abhängig, ob das Unternehmen sich leisten kann Entwickler abzustellen.

OK, Dankeschön. Aber eine Frage noch: Sind diese beiden Diplomarbeiten öffentlich oder unter Verschluss?

Die sind fünf Jahre gesperrt und zurzeit nicht öffentlich verfügbar.

(second call, process model)

Was ich noch vergessen hatte zu Fragen: Welche Klasse von Produkten wird den bei company C* hergestellt?

Klasse I und IIb. IIb deswegen weil wir bei den ...einheiten* medizinische Gase durchleiten. Daher rutscht man automatisch in IIb.

Ich hatte ja auch schon gefragt, wie sie Nutzer in ihre Prozesse integrieren. Nach welchem Modell laufen denn die Entwicklungsprozesse bei Ihnen ab? Ist das ein Stage-Gate-Modell oder haben sie da ein eigenes Prozessvorgehen?


(external user involvement)

Um nochmal auf den Nutzer zurückzukommen. Sie haben ja gesagt, dass sie persönlich in die Krankenhäuser gehen und die Nutzer nach Meinungen fragen beziehungsweise Feedback einholen. Wie identifizieren sie denn diese Nutzer? Haben sie bestimmte Ansprechpartner, die sie immer ansprechen oder wird das von Fall zu Fall unterschiedlich eingeordnet?

In der Vergangenheit gab es die typischen Ansprechpartner. Ansonsten werden auch durch den Vertrieb entsprechend geeignete Ansprechpartner gesucht. Teilweise wenn wir einen Nutzer haben wollen, aber es gibt auch Fälle wo durch den Vertrieb Nutzer gemeldet werden, die eine Neuentwicklung haben wollen. Sind das dann Nutzer die schon Produkte von company C* benutzen, oder sind das Nutzer die durch Marktforschungsaktivitäten identifiziert wurden?

Sowohl als auch. Schwerpunkt sind aber zu 70% Nutzer eines company C* Produktes.

...die dann auch entsprechendes Feedback geben können bezüglich Verbesserungen und Änderungswünschen.


Es gibt auch ab und zu den Fall, dass externe Erfinder auf Firmen zukommen. War das bei Ihnen auch schon einmal der Fall, dass sich Erfinder oder kleinere Firmen bei Ihnen gemeldet haben, weil sie Ideen haben die sie selber nicht umsetzen können?

Selber hatte ich den Fall jetzt zweimal, aber es ist nie von company C* aufgegriffen worden. Man hat sich das angeschaut, hatte eben die Information bekommen, aber man hat kein Potential gesehen um das als company C* zu übernehmen.

(idea evaluation)
Und wie bewerten sie so eine Idee? Gibt es da ein Schema mit Kriterien oder besteht das aus einem informellen Treffen von Spezialisten?

Genau, ein informelles Treffen. Es gibt keine Bewertungsmatrix. Auch nicht am Ende, wenn ein Produkt fertig entwickelt wurde?


Sie hatten auch vom “Powerteam” gesprochen. Das ist eine Expertengruppe, die sich abgetrennt vom Tagesgeschäft mit speziellen Aufgaben befasst. In dieser Gruppe sind dann einzelne Produkt-, Marktspezialisten und Ärzte zum Beispiel.

Genau. Es gibt das “Powerteam” gerade deswegen, um konzentriert an einem Projekt zu arbeiten und nicht durch das Tagesgeschäft unterbrochen zu werden. Haben sie mit dem Powerteam auch Kooperationen mit Universitäten oder Forschungsanstalten oder betreibt dieses Team in gewisser Art selber theoretische Forschung?

Es wird mit externen Entwicklungsbüros zusammengeführt. Wir haben ein externes Labor mit dem wir zusammenarbeiten zum Beispiel oder ein externes Designbüro.

Dieses Innovationsplatsen Projekt, das hier in Stockholm gebaut werden soll, ist ja in gewisser Weise auch ein Ansatz, bei dem man versucht Spezialisten an einem Ort zusammenzubringen. Sehen sie denn da einen Nachteil oder gewisse Vorteile, die es haben könnte, wenn gerade besonders viele Spezialisten an einem Ort zusammenkommen?

Neutrale Spezialisten oder von bestimmten Firmen?

Eher thematische Spezialisten wie Ärzte und Forscher.

Ich kann mir schon vorstellen, dass die Vorteile bringt, weil man einfach nochmal konzentrierter in der Materie ist oder eben auch konzentrierter Informationen sammelt und auch mit kurzen Wegen abwägen kann ob diese Idee wirklich gut oder schlecht ist. Da gibt es teilweise im normalen Entwicklungsprozess Kommunikationsprobleme oder eben Zeitverzögerungen. Haben sie dann auch die Erfahrung gemacht, dass das Powerteam in genau diesen Aspekten, die sie genannt haben besser arbeitet?

Ja, deswegen nutzen wir dieses Team auch, vor allem um den Faktor Zeit besser nutzen zu können. Es ist also schon lange etabliert und sie haben es beibehalten, weil es gut funktioniert?

Ja, genau. Das ist also nicht gerade noch in der Probephase?

Nein, das hat sich jetzt bewährt und wird weiter genutzt auch bei den nächsten Entwicklungsthemen.


Vielen Dank!
Interview with a technical project manager (company D)

(warm-up)
Hallo Herr….Hier ist Matthias Butz. Wir hatten ja einen Interviewtermin jetzt ausgemacht. Haben sie gerade Zeit oder sind sie schon im Aufbruch?
Ja, wir versuchen es.
Eine Frage: Kann ich das Interview aufzeichnen, weil ich sonst niemanden habe, der mitschreiben könnte?
Ja, klar. Können sie mir erst mal genau erklären was sie denn machen?

(background)

Der Nutzer ist dann der Kunde oder der Patient?
Bei den bisherigen interviewten Firmen sind die Ärzte als Nutzer anzusehen. Die Leute, die die medizintechnischen Produkte letztendlich bedienen. Gerade bei Krankenhausequipment ist der Patient selten der Nutzer.
Bei uns ist es ja auch so. Wir haben den Patienten und dazwischengeschaltet ist der …techniker*, aber auch oft der Arzt.
Das passt sehr gut, da ich eben zurzeit auf der Suche nach Unternehmen im medizintechnischen Bereich bin, bei denen die Ärzte als Nutzer gesehen werden, da das auch dem Projekthintergrund entspricht. Haben sie die Fragen schon angesehen, die ich ihnen vorab geschickt hatte?
Nur überflogen. Am Besten sie stellen sie mir nochmal.
Ok, dann gehen wir die ganz normal durch.

(information about the interviewee)
Welche Position haben sie in ihrem Unternehmen.
Ich bin technischer Projektleiter.
Wie lange sind sie schon bei company D*?
Dreieinhalb Jahre.
Beeinflussen sie in ihrer Position auch die Entwicklungsprozesse an sich indem sie teilnehmen oder sind sie eher organisatorisch tätig?
Ich bin vom ersten Startschuss, wenn die Idee irgendwo aus dem Vertrieb, oder aus dem Produktmanagement oder vom Arzt hochkommt. Dann bin ich von Anfang an dabei das Team aufzustellen, wer dort mitarbeitet.

(idea generation)
Die Ideen kommen aus verschiedenen Bereichen, wie sie eben gesagt haben. Haben sie auch bestimmte Methoden die sie nutzen um selber Ideen zu generieren oder bekommen sie ihre Ideen mehr von aussen heran?

In der Regel ist es so, dass unser Vertrieb an das Marketing kommuniziert und dann das Produktmanagement was im Marketing sitzt diese Ideen an die Entwicklung weitergibt. Natürlich haben wir auch unzählige Anfragen von Externen. Mein Chef bekommt sicherlich täglich Anfragen bezüglich neuer Ideen. Wenn irgendein Entwickler etwas entwickelt und will das company D® zeigen, um das company D® zu verkaufen. Das hat dann meistens eine Qualität, dass wir uns das ansehen, aber da muss das dann erst mal weiterentwickelt werden. Ab dem Moment haben wir dann im Prinzip gewisse Vorgehensweisen.

Also selber von Anfang an eine Idee zu entwickeln, wenn sie etwas neues brauchen, machen sie nicht?


Ja, das kenne ich.


(documentation)

Dokumentieren sie diesen ganzen Prozess auch?
Das geht los bei einem Protokoll. Im kleinen Rahmen bei einer Studie ist natürlich wichtig, dass dokumentiert wird, wer die Studie leitet. Da gibt es hier auch ausgebildete Leute, die so etwas machen.

Haben sie dann auch medizintechnische Standards, die sie dokumentieren müssen? Bei der Entwicklung von medizintechnischen Produkten müssen ja schließlich gewisse Standards eingehalten werden, damit das Produkt dann nachträglich überhaupt genehmigt wird.

Genau. Wir haben hier Medizintechnikprodukte der Klasse eins bis zwei. Das Medizinproduktegesetz gibt da den Rahmen vor. Wir dürfen Produkte erst – also auch hier hausintern – am Menschen testen, wenn die ein CE-Kennzeichen haben. Das heißt im Vorfeld darf keiner mit einem Produkt herumlaufen, was gegebenenfalls irgendwelche toxischen oder sonstige schädliche Wirkungen hat.

(find) Findet bei ihnen nach dem Abschluss des Projektes dann auch noch ein Bewertung des Projektes statt?

Ja, genau. Lessons learned machen wir ganz normal am Schluss.

(find) Findet das in einer Teamsitzung statt?


Wie kommunizieren sie dann die Ergebnisse?

Wir haben sozusagen einen Auftrag, der beschreibt auf zwei Seiten ganz genau was ist die Aufgabe, was ist das Ziel des Projektes und was sind die Meilensteine. Das ist alles genau aufgeschlüsselt. Im Prinzip beschreibt der Auftrag genau, was in dem Projekt stattfinden soll. Sozusagen wie ein Lastenheft. Das liegt im Endeffekt am Schluss noch einmal als leeres Dokument auf dem Tisch und wird nur mit einer etwas anders gearteten Fragestellung durchgearbeitet. Dort wird dann Unkt für Punkt durchgearbeitet wie die Ziele verfolgt wurden bezüglich Qualität, Kosten und Zeit.

(documentation) Haben sie dann auch ein Dokumenten Management System?

Ja, genau.

(documentation) Darauf hat dann jeder im Projekt auch Zugriff?

Genau. DMS heißt das bei uns.
Habt ihr dann auch Intranet oder ähnliches über die jeder Ideen oder sonstiges kommunizieren kann? Sagt ihnen in diesem Zusammenhang crowd sourcing etwas?

Ja, das haben wir auch.

Also neben der Dokumentation gibt es noch andere Möglichkeiten von Mitarbeitern zu kommunizieren?

Das ist ein ganz großes Thema für die Produktion z.B. wenn dort festgestellt wird das etwas zu kompliziert hergestellt wird und ein Vorschlag gebracht wird wie das besser oder schneller von der Reihenfolge oder Maschine gemacht wird, kann das derjenige z.B. als schnelle Idee einreichen. Dafür gibt es dann 8€ und das ganze kann dann bewertet werden. Dazu haben wir hier Mitarbeiter, die das ganze auswerten und gewichten, denn teilweise gibt es gute Ideen, die als schnelle Ideen angedacht sind, aber es zeigt sich dann ab und zu, dass dort doch mehr Potential drin steckt. Dann muss noch einmal ein extra Formular ausgefüllt werden und dabei kann dann doch schon mal eine ganz ordentliche Summe entstehen für den einzelnen.

(second call)

Bisher ging es ja eher um die Ideenentwicklung und wie Prozesse bei ihnen ablaufen. Sie haben ja bereits erwähnt, dass sie neu entwickelte Produkte auch selbst im Unternehmen ausprobiert bzw. Ärzte im Unternehmen haben oder externe Ärzte befragen.

Ja.

Gibt es da gewisse Auswahlkriterien, nach denen ein Arzt ausgewählt wird? Nach Position, Berufserfahrung oder bisheriger Zusammenarbeit mit company D*?


Geben diese Ärzte dann auch nach der Entwicklung noch einmal Feedback zu dem Produkt, das ihr entwickelt habt oder passiert das nur während dem Prozess wenn sie die Prototypen testen?

Die betreiben sowohl die Studie, als dass wir sie später auch als sogenannte Promotoren einsetzen, um das Produkt dann im Markt durch Vorträge und Erwähnungen bekannt zu machen und die Promotoren dann in den Broschüren und Produktbeschreibungen auftreten.

(evaluation)

Sie hatten ja auch schon bereits erwähnt, dass am Ende des Projekts eine Evaluation stattfindet, bei der das ganze Team zusammenkommt und der Projektleiter und die Teilprojektleiter den gesamten Verlauf noch einmal bewerten. Findet in diesem Rahmen dann auch eine spezifische Innovationsbewertung statt?

Ja, das machen wir auch.

Gibt es da bestimmte Kriterien? Können sie dazu etwas sagen?

Es gibt so eine Art Punktetabelle. Danach wird jede Idee, bevor es überhaupt richtig losgeht, eingestuft.

Und nach welchen Kriterien findet das statt? Dürfen sie das sagen?

Hm. Es geht in Endeffekt darum erst mal grundsätzlich abzuwägen, weil man ja auch nur eine gewisse Kapazität und logischerweise auch eine Interesse daran hat
etwas weiterzuverfolgen. Es macht schließlich keinen Sinn ein Produkt weiterzuverfolgen, das nicht gut ist.
Das passiert dann bevor die Entwicklung losgeht?
Ja, auf jeden Fall. Das ist ganz elementar, wenn das nicht stattfindet blockiert man sich selbst. Dann würden Kapazitäten für irgendeine Sache gebunden und die Leute mit zu vielen Themen belastet.
Findet dann auch nach dem Projekt eine Bewertung der Innovativität anhand des Gewinns statt, der durch das Produkt umgesetzt wurde?
Das wird dann nicht mehr in meinem Bereich gemacht, sondern von Seite des Managements.
Aber das findet statt?
Ja.
Vielen Dank, das waren dann die letzten Fragen, die noch offen waren.
Kein Problem. Für weitere Fragen, wissen sie ja wo sie mich erreichen können.

*amended by the editor

**Timetable**

|                  | CW 22 | CW 23 | CW 24 | CW 25 | CW 26 | CW 27 | CW 28 | CW 29 | CW 30 | CW 31 | CW 32 | CW 33 | CW 34 | CW 35 | CW 36 | CW 37 | CW 38 | CW 39 | CW 40 | CW 41 | CW 42 | CW 43 | CW 44 | CW 45 | CW 46 |
|------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| Literature Research |      |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
| Interviews       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
|                  | conduction |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
|                  | transcription and analysis |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
| Method Building  |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
| Evaluation Workshop |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
| Method improvement |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
| Writing          |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
|                  | introduction |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
|                  | theoretical framework |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
|                  | final examination |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |       |
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_________________________________________  _______________________________________
Name                                                                                     Place / Date