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A SPIRAL MARKET STUDY GUIDELINE FOR THE EARLY PHASES OF RADICAL INNOVATIONS IN THE MEDICAL DEVICE SECTOR

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ABSTRACT

In the medical device sector, at least the first steps of many radical product innovations are developed by medical lead-users in cooperation with technical university research groups. Together, they have sound technical and application competencies, but weak marketing competencies in terms of quantitative market studies. To improve the practice of quantitative market studies, an easy-to-use guideline was developed and tested in one medical device product innovation use case. The guideline contains the 39 most important marketing tasks for radical innovations and follows a three loop spiral: the preliminary first loop, the quick and dirty second loop, and the quantification third loop.

OBJECTIVES AND RESEARCH METHODOLOGY

The purpose of this paper is to provide an easy-to-use market forecast guideline for radical medical device innovations. Presentation of the guideline is preceded by a literature- and experience-based analysis of medical device innovations in general. The guideline was developed, tested, and refined by applying it in one medical tool research project and comparing it to actual market research activities of eleven other medical device development projects.

RADICAL MEDICAL DEVICE INNOVATIONS

In today's environment of rapid technological changes, radical innovations have become crucial for firms' long-term competitiveness. In order to enhance their capability for radical innovation, they must involve capable actors within and outside the firm (Chesbrough, 2003).

Lead users as sources of radical innovation

The integration of lead users already is a widespread good practice in the medical device sector. Corporate lead users can be found in university hospitals and technical universities. The dominant—and successful—role of lead users in medical device innovations has been shown by von Hippel (1976), Shaw (1986), Roberts (1988), Biemans (1991) and Lettl et al., (2006). Medical device lead users, like doctors or surgeons, contribute especially to radical innovations because they:

- have the medical knowledge and experience to understand the customers' needs (Roberts, 1988; Lettl et al., 2006); customers for medical devices are manifold: patients, doctors, clinic administration, etc.,
- have access to first clinical trials (Roberts, 1988),
- are extrinsically motivated to conduct and even more publish clinical trial tests,
- are intrinsically motivated by severe difficulties in their day-to-day work (Collins, 1999, and Boden, 1994), and
- have access to technological knowledge and seed funding when their hospital is part of an university.

Role of lead users in the entire innovation process

Other important characteristics of the lead users in medical device development are not only important in idea generation but decisive in the concept generation phase: the openness to new technologies and the access to interdisciplinary know-how (Lettl et al., 2006). The surgeons abstracted from their current use context by searching for appropriate technologies outside the medical domain, and they work at university hospitals affiliated with a technical university or that had access to departments of technical universities (Cohen/Levinthal, 1990). The in-depth knowledge about user needs is difficult to transfer to manufacturing firms. Consequently, users have almost exclusive access to this type of knowledge. This reasoning might explain why users, rather than manufacturing firms, developed these radically new concepts.

Lettl et al. observed during their study an important entrepreneurial role of users (Lettl et al., 2006); in fact, the users are initiators and builders of innovation networks for radical innovation projects. They established and managed the networks required to transform their radically new concepts into, first, prototypes, and later, into marketable products. Nevertheless there are severe reasons why, especially for medical devices, lead users need not only technological support but a corporate partner to succeed. The time to generate a radical new product can, for sure, be shorter in a small company or research group but, as described, regulations can be barriers for the new product's transfer in the market. Only large companies possess the resources, money, manufacturing capability, well-organized channels of distribution and field service, understanding of how to deal with regulatory issues posed by the FDA, the opportunity to bridge across and potentially integrate multiple areas of technology, and overall knowledge to accelerate the complex approval process.

Entrepreneurial lead users and their research partners should not wait until bigger companies understand the potential of their product innovation. They should evaluate what type of partner and what type of cooperation is appropriate, using, for example, the tool presented by Imelli et al. (2006a). If they need a bigger partner, they have to present market studies to convince it.

Lack of business skills in the early stage of a radical innovation project

As described by Lettl et al. the users (for example, the surgeons) in the early stage of the radical innovation project perform an entrepreneurial role as innovation network builders. They establish and manage the networks required to transform their radically new concepts into first prototypes. They provide funds and recruit the talents of experts from research institutes to supply the necessary technological know-how and expertise. The problem is that the networks almost always have a low degree of density or interconnectedness: user-inventors were highly central within the networks (Lettl et al., 2006) and seldom present any kind of experts with business skills and experiences in the transfer of marketable products in the market. In the early stage of the project, they provide minimal market research to assure the existence of a potential market. The potential of the project outcome is declared only by surgeons and based on the experience and vision of the users, in most cases only a little circle of users.

In this early phase of the RI projects, potential manufacturers were not willing to adopt the users' radically new concepts, perhaps because, in all cases, the projects did not fit with the core competencies and technology strategies of the manufacturing firms. Manufacturers normally are deterred by the high technological and market uncertainties associated with these innovations. They were confronted with a situation in which the medical application of the respective technologies was just emerging,

and the volume, market share, and growth rate of prospective markets were as yet unknown. The users lacked marketing competencies and knowledge that are required to implement the radical innovation into the market successfully. For this reason, the innovative users were dependent upon external support from technological experts: development partners in the early stage, and medical equipment manufacturers in a later stage, with strong competencies in very important areas as marketing, engineering, packaging, and international regulations.

It is not easy to find a manufacturer in the second stage of the project if the team isn't able to demonstrate the business benefit and the existence of a real market of the new radical innovation. The team also can increase the possibility of finding a manufacturer by performing basic market analysis.

Requirements for market study guideline

The analysis of our project use case (Robotics in Cardiovascular Surgery) with the objective of developing a complete semiautomatic tool for bypass anastomosis, and the analysis of eleven other radical innovation projects in the medical equipment field, gives us a clear image of significant and particular elements, problems, and needs in this kind of project—and especially the needs and requirements of the marketing domain during the early stage. The choice of projects is dictated by the research interest: all projects are in the medical device sector; all projects are based on radical innovations; and, in all projects, there is at least one partner from the academic area. The content of the projects differs radically among the projects: cardiovascular sector (two projects), orthopedics sector (four projects), diabetics sectors (two projects), ophthalmology sector (one project), dermatology/oncology (one project), and computer-aided surgery sector (two projects). The composition of the project networks is exactly balanced: in six projects, there is a manufacturer, and in six projects, all partners are universities (technical and university hospitals). All projects were analysed on the basis of 36 questions about the role of lead users, IP's management, norms and regulations, organization of the project, cooperation and project management, and marketing activities. The study was designed for a complete research about the early stage of medical device innovation and, for this paper only the important observations about the marketing activities during the early stages are reported.

Observation and considerations were based on the answers to 36 questions to the project leaders and some important (experienced) project members:

1. In almost all cases, the user was the originator of the idea. In two cases, the idea came from companies but they are based on user considerations.
2. In the early stage of a radical innovation project, there are very few ways to convince a manufacturer to work with universities. In almost all the analysed cases, in which the idea was born in an academic environment, the potential interested manufacturer waits for clinical results or tests before concretizing cooperation with universities.
3. The role of the user after the idea generation is different in function of the project's content. Normally, in all cases, the user supports the team during the concept development with:
    - Describing the problem
    - consulting and participation: he gives suggestions, describes possible solutions, addresses the team about other existing principles or products

- organizing using analysis: organize visits during the utilization of similar tools or during the addressed procedures (for example, during surgical interventions)
- helping the team to evaluate and choose possible solutions
- testing some partial solution prototypes.

4. During the concept development phase, all teams identified a product requirement list. At the end of the concept development phase, a complete requirement list exists in only six projects. On the requirement list, almost all product requirements are dictated by lead users, with fewer coming from market and competitors analysis.
5. Regarding all projects, it is found to be very important to provide some basic market research in the early stages. For half of these projects, this cannot be done without external support. The reason is the lack of business skill in technical and medical university teams. The project leader normally finds this support among private marketing consultants, business university institutes, or patents experts. In six projects, the problem was identified as lack of business skills in the team, and in five cases there is a problem of resources (time). In three cases without manufacturers, the teams alone provide the market research, but in all three cases, the project leaders admit a chaotic approach.
6. In all cases in which the medical team is not an integral part of the project, or has only a secondary role, the team contacts more users from different hospitals to have feedback on the product concept and to have a first market feedback. If the medical team is an integral and active part of the project team, it is very difficult for the rest of the team to build a connection with other medical research teams. The integrated medical teams tend to maintain their leadership in the medical domain and in publication of the results.
7. The objective of all projects is to develop the radical innovation in as little time as possible. In such a dynamic market, it also is important to arrive in the market at the right moment, and if the project is long, the risks are higher. If the project is as long as four years, all project leaders find it very important to provide some forecasting study, but in only two cases the team is able to provide a long-term market forecast.
8. The analysis of competitors' products is a frequent activity in all projects, especially with the support of users.
9. In a few cases (three cases), the user supports the team to provide a complete market analysis. The market analysis, in almost all cases, is based on information collected by reports of international health associations (generalist or specialist).
10. In all projects without an industrial partner, the project leader declares that it always is desirable to order a market analysis from an expert consulting office, but the high costs discourage this praxis. Normally, the marketing analysis was done internally, and seldom did the project integrate a marketing or business partner coming from the academic environment.
11. In all projects, there is a need of easy and fast methodology to implement the market analysis.
12. From the existing methodology or activities description, all projects identify the following problems:
    - The teams don't know exactly which tasks to provide and in which moment of the early stage → model requirement: clear sequence of the tasks

- The existing models identify some tasks only once, but these have to be repeated several times during the early stage, provided with different depth → model requirement: clear description of repetition and placement of some tasks (example: competitor analysis)
- Every phase of the early stage needs the right resources for the market analysis → model requirement: collection of tasks at different times in function of their characteristics and number.
- It must be extremely easy to use → model requirement: easy identification and understanding of the model.

13. From the 36 questions to the project leaders and our analysis come 42 considerations and observations in the areas of cooperation management, intellectual property, project management, information management, and communication (with all the cultural implications).

In the medical device sector, at least the first steps of many radical product innovations are developed by medical lead users, in cooperation with technical researchers—which together have sound technical and application competencies but only weak marketing competencies. Nevertheless, market studies about actual and future markets are absolutely necessary, at least in the early phases. These market studies are needed to apply for research funds, to deduce product requirements, to motivate the project's members, and later to identify and convince potential manufacturer.

MARKET STUDY GUIDELINE

Position in the innovation process

Since no process model (especially for the medical device industry) is available in literature, we use the product innovation process model of the Center for Product Design, ETH Zurich (see figure 1) to position the market study phases. The model can be used in any kind of industry and sector as a reference model, but for real application in a company, the process needs to be customized. Figure 2 shows the model adapted to radical medical device innovations. The adapted model lists all sub-processes, from the initiation phase to the production and test of the first production 0-series for clinical trials (Figure 2).

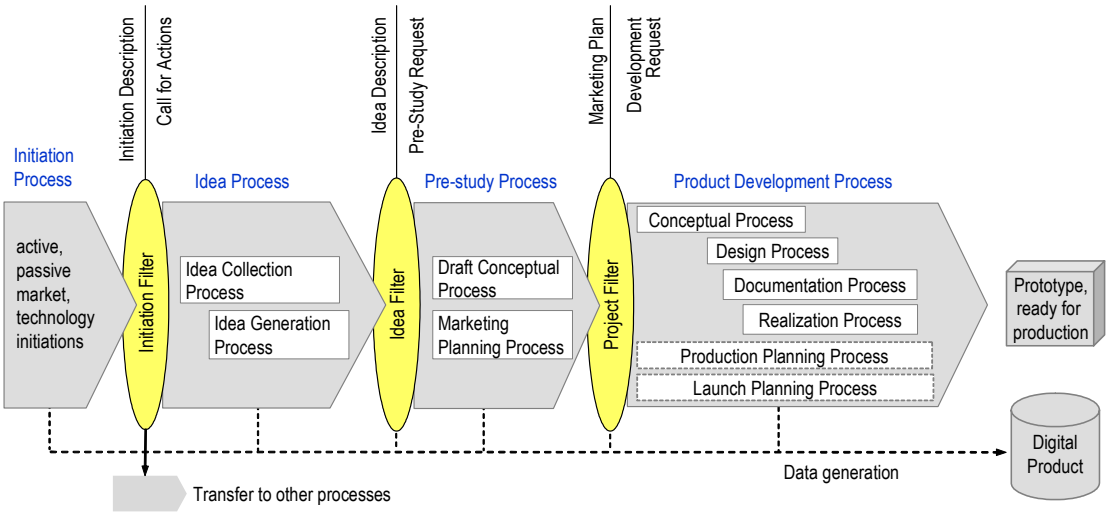

Figure 1: Product Innovation Process – Reference Model. Source: Center for Product Design, ETH Zurich

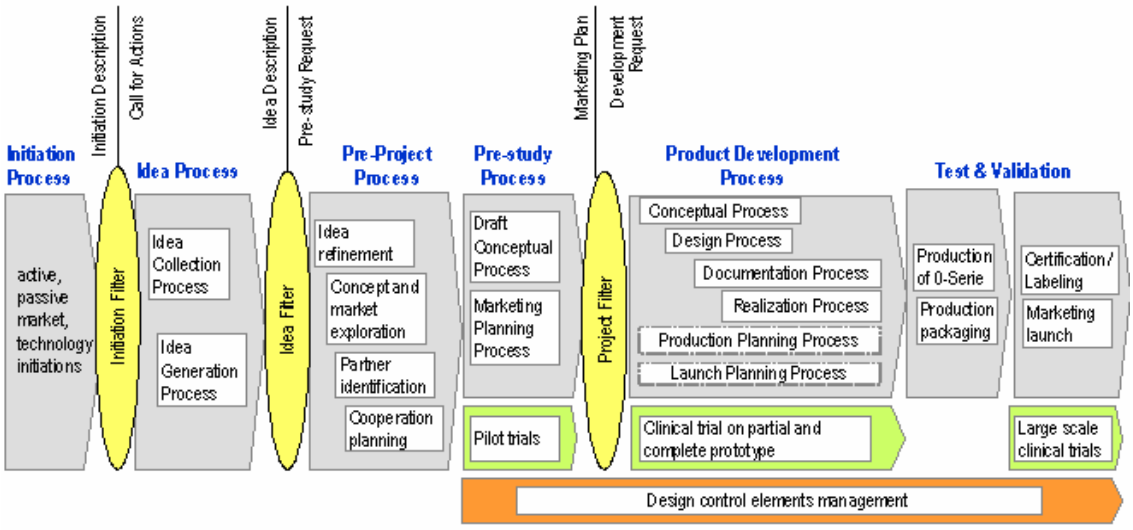

Figure 2: Innovation reference process for medical device. Source: an adaptation of the model of Center for Product Design, ETH Zurich.

The presence of the Pre-Project Process depends only on the profile of the project. If the project needs the participation of more project partners and includes target research, the project needs the pre-project process after the idea generation and the pre-study phase. If the project is conducted by a single entity (manufacturer or university), the pre-project is a part of the pre-study process. The design control is a typical activity for the certification provided from the manufacturer. But even when the manufacturer does not enter the project before the product development phase (for the critical engineering activities), it is suggested to begin the design control in the pre-study process. The first steps of the design control are a design control plan, a complete design input list, and a Design History File.

The three filters symbolize choice decisions—between competing ideas and projects, but also between solutions or paradigms during the project. Normally, the target research (basic technology development targeted to application idea) takes place in the idea process, pre-project process, and pre-study process. At the moment that the project advances in the product development process, and the engineering of the product is central, even in the case of radical innovation, target research activities should be finished.

Three-loop process

For market study in the early phases, we propose a spiral-like approach with three loops to conduct while three different phases of an innovation project. The first and the second loops take place in the pre-project process and the third in the pre-study process.

The first loop is the preliminary loop, preliminary because in this stage of the project, the team only has to demonstrate the existence of a potential market and eventually convince the government of their universities' or other research funds to be invested in this project (with target research characteristic). The second loop is quick and dirty, because the team has to collect all available information in the shortest time possible. The collected information is used for two purposes: 1. to deduce product requirements that are used to check the concept feasibility, and 2. to provide a market forecast to demonstrate the existence of the market at the end of the project. The third and last loop is the quantification loop. In this loop, the team has to analyse the

market in depth, to have a complete view of it and to convince a potential investor or manufacturer at the end of the early stage to invest in a potential start-up, or to begin a cooperation project focused on the product development.

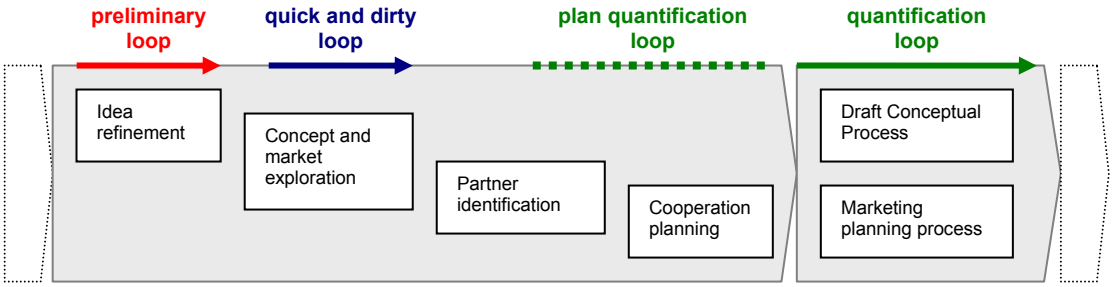

Figure 3: Placement of the single loops of the spiral model in the early stage

The three loop spiral proceeds through four main fields: customers, market, competitors, and epydemiological/need trend (Figure 4). In the customers' field, the team has to analyse all elements and the dynamic of customer decisions concerning the new medical device. The market field includes all information about the market itself (size, geographical diversities, etc.), and in the competitor field is all information about the products, market share, strategies, etc. of competing companies' products and therapies. The last field, epidemiological trends, deals with the expected number of patients. All identified influencing factors are projected to estimate the future epidemiological trend. To compile the three-loop guideline, we used tasks described, for example, in Pegler (2006) and Gerhards (2002), who identifies more than forty activities of marketing collected in four different categories: market, competitors, customers, and company.

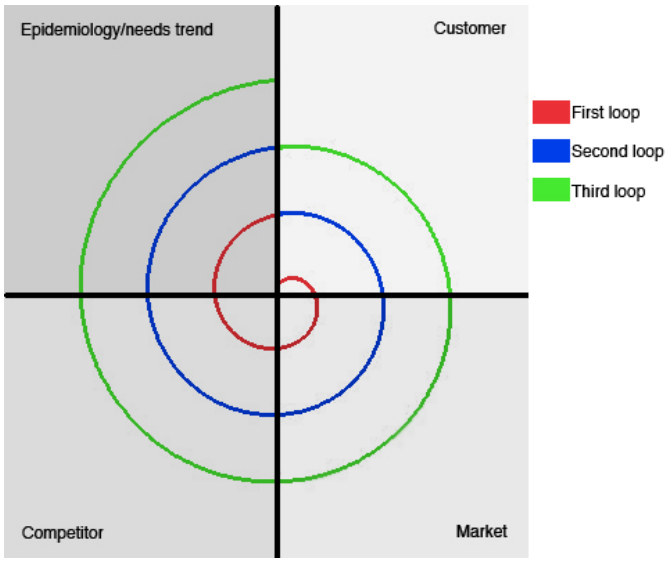

Figure 4: the three loops in the four model fields

First loop: Preliminary

The preliminary loop coincides with the "idea refinement process." The objective of the idea refinement process is the draft product concept. It provides the basis for the decision to proceed in a deep market and concept exploration (next process step of the project initialization phase).

In this preliminary loop, the team has to answer the following market questions:

- What are the customers' needs? (Need)
- What product or solutions do we want to offer? (Approach)
- How big is the estimated global expenditure for the product/solution? (Market Size)
- What is our Unique Sell Proposition (USP)? Why will the customer buy our product instead of the competitors' products/solutions (Benefit)? Does the product or solution satisfy the customers' needs?
- Will this market increase or decrease? (Macro trend)

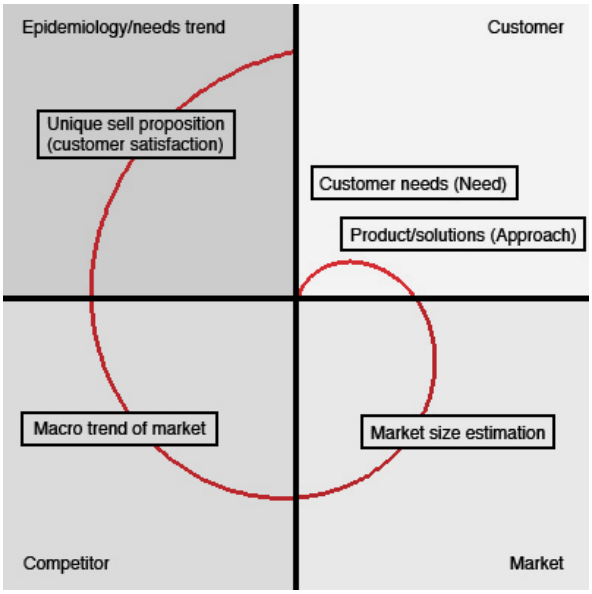

Figure 5: The first loop – preliminary, with five tasks

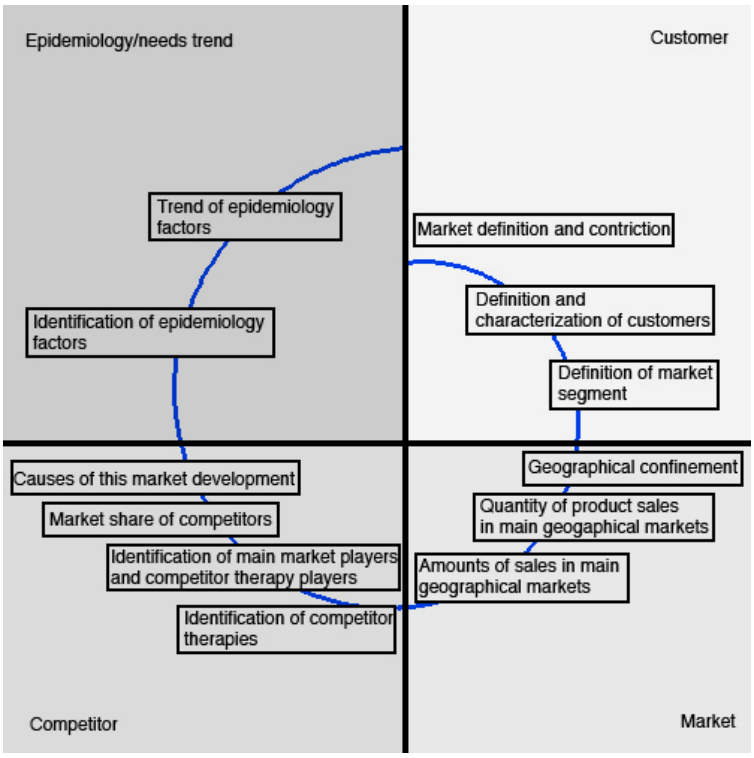

Figure 6: The second loop- quick and dirty, with twelve tasks

Second loop: Quick and dirty

The second market analysis loop already contains many of the important aspects but—due to time and available resources—the team has to absolve all tasks quite fast and not very deep; therefore, we name the loop "quick and dirty." The objective of the process "market and concept exploration" is to estimate the duration of the project through a technical feasibility study, and at the same identify whether, at the end of the project, the market exists and its size. To have this information about the market, the question to answer in this "quick and dirty loop" are:

- Market definition: What is the business? Can the business system be easily described (product or service)?
- Definition and characterization of customers: Who is the customer? Is it the doctor/surgeons, the patient, or the government? What are its needs? How does the customer decide? What are the customers' requirements concerning core-product, formal product, and extended product? How much is the customer willing to pay?
- Definition of market segments: Does market segmentation exist? What kind?
- Geographical limitation: Is the market global or in single geographical areas? Which areas? Are there differences among single geographical areas?
- Quantity of product sales in main geographical markets: How many products could be sold in the main geographical markets?
- Amounts of sales in main geographical markets: How big is the market size in the main geographical market?
- Identification of competitor therapies: Are there competitors or alternative therapies?
- Identification of main market players and competitive therapy players: Who are the direct competitors? With which products? Who are the indirect competitors (competitive therapies)? With which products/therapies?
- Market share of competitors: Are there many important competitors? How big is the market share of the main competitors? Who are the market share winners and losers?
- Causes of the market development: What are the causes for success or failure of competitors?
- Identification of epidemiology factors: Which kind of epidemiological factors define the development of the number of patients?
- Trend of epidemiology factors: Does the trend of every single factor decrease or increase? All factors together? What is the trend for the number of patients?
- Identification of competitor therapies: Do competitive therapies exist? What kind of therapies? What are the trends of these therapies in relation to the epidemiology trends?

At the end of the quick and dirty loop, the team owns all the information needed to provide a long-term forecast of the system, with integration of market and epidemiological elements (see also Imelli, 2006).

Third loop: Quantification

The third loop market study loop is conducted during the pre-study phase (concept development). After conducting the first two loops, the team disposes of a very good basis of information about customers, market, competitors, and trend. The conception of the medical device has advanced and, at this point of the project, the team knows more about the product design and performance, and eventually it already has some

results from clinical tests. The team has to repeat almost all tasks from the first two loops, with the objectives to analyse in depth the market and quantify the potential of the tool. The quantification of the market can help the team convince potential investors or companies to cooperate in a product development project. The third loop is surely more demanding, and the team has to invest more resources than during the quick and dirty loop. In total, 22 tasks have to be completed in this "quantification loop" (figure 6).

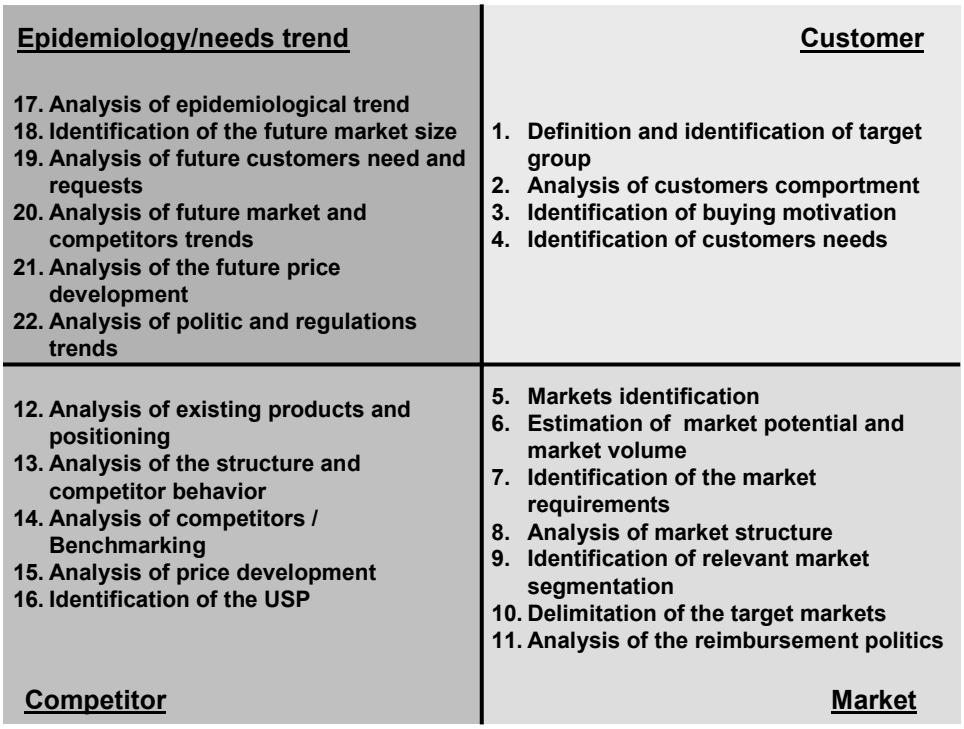

Figure 7: Third loop – quantification, with 22 tasks

MODEL VALIDATION

The model has been tested in two use cases: semiautomatic robot for coronary surgery and the pre-study phase of a system for the automation of clinical laboratories. In both cases, the project members experienced the guideline as easy to use and to understand. The third loop (quantification loop) is a little more difficult, complicated, and long for people without any business skills. The collection of tasks in three different loops to use in three different moments of the early stage was completed and approved, and the possible connection with the phase output has been found very interesting (first loop for scientific or growth business proposal, the second loop for draft requirement list, and the third loop for product requirements list and complete business proposal). The three loops help the project members better understand the repetition of some tasks in different points of the early stage. The feedback was very positive, especially for the second, quick and dirty, loop.

The three-loop guideline was presented to project members and leaders of eleven additional medical device projects. They did not completely implement the model, but rated it as easy to understand, helpful for planning the market analysis tasks, and—especially the first two loops—easy to provide. From all interviewed project members and leaders, the feedback was very positive, with the most frequently identified

benefit being the possibility to save important and expensive time during the project planning and while providing market analysis.

There is still a potential for improvement of the third loop. For non-marketing specialists, it was a little too complicated and intense.

KEY CONCLUSIONS

The spiral marketing guideline can be used in the early phases of a radical innovation project in the medical device sector. The results of the spiral marketing—a qualitative description and a rough quantification of the prospective market—are essential to user-university cooperation:

- to apply for research funding, and
- to convince manufacturing companies to cooperate.

This no-linear approach permits conducting the market analysis in different periods of the project, using loops containing tasks that—to a great extent—in terms of content, but not in terms of depth, are repetitions of tasks already completed. The user can use the information of the last loop to achieve the actual loop.

In any case the big problem, without market analysis specialists, is to find information sources. “Where can one find this information?” In the medical device sector, the lead user can be very helpful in identifying information sources. The spiral model can support cooperation between lead users and the person in charge to provide the market analysis. This is possible because the content of the spiral model is easy to visualize and to understand.

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