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Project initialization phase in target research project for medical device development

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Abstract

The embryo of a new product is always the product idea. In the Medical Device development after the idea process phase begins a pre-study phase. In many cases the pre-study phase is dedicated to develop a new technology or to adapt an existing technology. These two technologies development activities are focused on research for applied product functionalities. In the context of Medical Device development we will call these activities "target research". The target research extends significantly the duration of the pre-study phase. Many Medical Device pre-studies are complex cooperation project between different kinds of partners. The product idea that came from an industries (small or middle size) or a university (technical of medic), need in any case to be developed with one or more project partners for activities as technologies development or adaptation, for the development of device or for tests (animals or human trials with histological phases).

A simple pre-project became in this case a complex phase with target research. Therefore we propose to have an implementation phase before the pre-study phase. Start point of the project initialization is the product idea of the lead team. The initialization phase is structured in four main sub-processes: idea-refinement, concept and market exploration, partner identification and cooperation planning.

1. Introduction

Not long ago, internal R&D was viewed as a strategic asset and even a barrier to competitive entry in many industries. Only large companies with significant resources and long-term research programs could compete. Today the former leading industrial enterprises are finding remarkably strong competition from many new companies: these newcomers conduct little or no basic research on their own. The strategy is to acquire technology and innovation from other industries or universities through cooperation, acquisition or strategic alliances. Chesbrough (2003) explains the erosion factors that undermined the logic of Closed Innovation and assert the logic of the Open Innovation. The principles of Open Innovation are (Chesbrough, 2003):

- *"Not all the smart people work for as. We need to work with smart people inside and outside our company.*
- *External R&D can create significant value; internal R&D is needed to claim some portion of the value.*
- *We don't have to originate the research to profit from it.*
- *Building a better business model is better than getting to market first.*
- *If we make the best use of internal and external ideas, we will win.*
- *We should profit from others' use of our IP, and we should buy others' IP whenever it advances our own business model."*

Open Innovation is also an important trend for the Medical Device sector. The term Medical Device covers a vast range of equipment, from a simple plaster to a more complex pace-maker. The term Medical Device means any kind of instrument, machine, implant, in vitro reagent or calibrator, software or similar used (alone or in combination) for human beings. The European Union Norms for Medical Device classify all the Medical Devices in three main categories: actives implantable (90/385/EEC), general (93/42/EEC) and In vitro diagnostic (98/79/EC). The Medical Device Market is one of the biggest in the world with the estimated one and a half million different devices on the market and a market size of US$ 145 billion in 2000. With innovation and the rapid advancement of technologies, Medical Devices are currently one of the fastest growing industries, and the global market figure for 2006 is expected to exceed US$ 260 billion (WHO, 2003).
The Swiss Medical Device sector is a very interesting example for the Open Innovation paradigm because:

- In the Medical Device sector the lead partner (which generates the idea or which generates the most profit) in the cooperation project need support already in pre-study process during the approximate product conception, because only very big enterprises have all the capability (resources, core-competences and knowledge) to define all parts of the device.
- The network contributing to the Medical Device development is widespread: medicine institutes or enterprise, technical institutes or suppliers with software, hardware and electrical competencies.
- These diverse partners collaborate for longsome projects of 4-8 years development and 1-4 years histological phase. Some product ideas additionally need new technologies, which have to be developed first. The innovation process is interrupted after the idea generation phase and the pre-study phase is focused on the development of technology or even basic research. In this case the pre-study phase of the innovation process is a long and expensive research phase. The duration and the cost of the project have an influence on the cooperation needs: the longer and the more expensive the projects are, the more the sector tends to improve cooperation as knowledge winning process.
- The R&D expenditure for extramural cooperation project has fasted grown in the sector of Pharmaceutical, Medical Device and Medical Research-labors. This sector, in Switzerland, has in 2000 reached 69% of the total expenditures for extramural cooperations (1’215 of 1’760 Mio. CHF) (Bundesamt für Statistik 2000).

In the Medical Device and also in all other sectors there are not only successful cooperation projects. Following Littler (1995) *“over 40% of the respondents expressed their view that, in their experience, collaboration makes product development more costly, more complicated, less efficient, more time consuming, and more difficult to control and manage”*.One key to improve the success of cooperation projects is a suitable process. Therefore we propose to add an additional phase in the Medical Device innovations process, the “Project Initialization” phase.

2. Objectives of this paper

In this paper a guideline for the Project Initialization phase will be developed. We propose this Project Initialization phase to precede every long-term pre-study including target research for Medical Device development. The guideline is dedicated to support the project management to better plan, estimate and define the long pre-study process with a strong focus on the technology

development. For this type of projects a guideline is particularly needed, because business and organizational skills are not always present in medical research teams. The guideline to be developed contains the main tasks and most important methodologies to perform for the pre-study phase. Thereby it ensures the integration of cooperation management activities.

3. Research Methodology

The development of the guideline for the project initialization in target research project for Medical Device development is based on an extensive literature survey on Open Innovation, cooperation in R&D and technology development (see literature list).
Additionally input for the development of the guideline came from the observation and analysis of four Medical Device development projects between four different industries, with different Medical Devices (dental equipment, active implantation, cardiac stents and defibrillators) and the ETH Zurich. Before the development of the guideline R&D processes of 14 medium and big sized companies (9 of the medical sector and 5 technology enterprises from different sectors) have been analyzed, in collaboration with another project at Center for Product Design of ETH (Front End - Integrative Methods for the early stage in Product Innovation processes).
The guideline was tested and refined by using it in the decision process of two actual Medical Device research projects of Swiss National Science Found, The National Centre of Competence in Research (NCCR) Co-Me: the development of a semiautomatic robotics for coronary anastomosis and monolithically integrated tactile sensor supports for blood pressure measurement. Three different technical universities institutes, a surgery research institute and two enterprises (component suppliers) collaborate in these two projects.

4. Survey on innovation processes in literature and practice

We state that in Medical Device development extensive pre-studies (including target research and cooperation) should be preceded by a project initialization phase including: idea-refinement, concept and market exploration, partner identification and cooperation planning.
This project initialization should be started just after the idea generation. Before we develop the guideline we have a close look to existing models in literature and practice.

4.1 Innovation processes in literature

A standard process for Medical Device development is difficult to identify because the regulation of Medical Devices is a vast and rapidly evolving field that is often complicated by legal technicalities. The World Health Organization (WHO) develops through the Global Harmonization Task Force regulatory tools. They identified “conception and development” as the first phase of the Medical Device life cycle (figure 1).

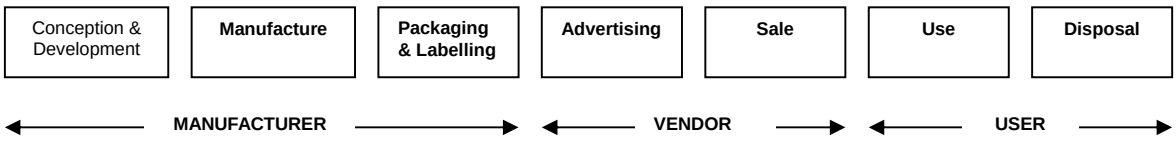

Figure 1: Medical Device life cycle: common stages of government regulations (WHO, Medical Device Regulations, 2003)

The International Organization for Standard (ISO) detailed the Quality Systems ISO 9001:2000 with the special standard for Medical Devices ISO/DIN 13485:2003, *Quality Systems - Medical Devices - Particular Requirements for the Application of ISO 9001*. An important element for the Medical Devices categories "General" and "Active Implant" is the use of a special risk management model (*Quality Systems - Medical Devices - Application of risk management to Medical Devices*, ISO 14971:2000). ISO standards do not suggest a particular process for Medical Device development, but give the requirement for the application in this sector of the ISO 9001.
Another reference model is provided by the Medical Devices Bureau of Health Canada, and used by U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health (figure 2). The model is a Waterfall Design Process with application of Design Controls. The Waterfall Design Process is adopted in a lot of Medical Devise enterprises that manufacture products with an important software component, because this model can easily be adapted to the software development processes (Waterfall and V-Model).

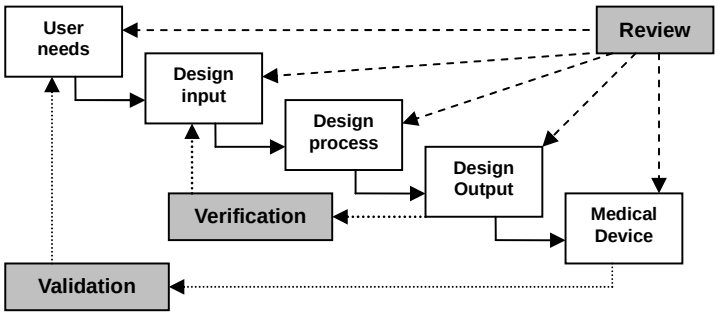

Figure 2: Application of Design Controls to Waterfall Design Process (Medical Devices Bureau of Health Canada)

The literature does not give a detailed innovation processes specific for Medical Device development, there are only reference and general models of innovation processes. The mentioned general descriptions of innovation process for Medical Device do not give relevant input about the pre-study phase or idea collecting and refinement phase.

4.2 Innovation processes in practice

If we look to the industries and to the more operative processes, it is nearly the same picture. The processes are not detailed and especially not for the early stage of the product innovation process.
We analyzed the innovation processes of 14 medium and big sized enterprises (9 of the medical sector and 5 technology enterprises from other sectors, 9 medium sized) regarding the existence and detailed description of:

- an idea process,
- idea process output,
- early stage market analysis
- cooperation management.

The observations were:

- Only 5 processes have a detailed description of the early stage "idea process", only 3 give a structure and describe the content of the output of the idea process.

- Only 6 processes check the market with some market analysis in the early stage before the start of a pre-study phase. The majority of enterprises absolve the market study in other contexts, for example directly in the marketing department. This kind of market studies aren't in correlation of a product innovation project but eventually only as separately initiation process.
- In 8 enterprises exists a cooperation management. 5 describe this with a process and in only 3 enterprises exists a "protocol" that describe the procedure for cooperation in innovation projects with partners, suppliers and universities (Another 2 enterprises have something similar but only for the cooperation with universities).
- The cooperation with universities is for more enterprises a procedure that improves with the operating experience. The participation of small and medium sized enterprises in research with universities depends more on personal acquaintances than on established procedures.

An example of analyzed processes is the process of a Swiss medium sized Medical Device, a stage gate process for the Medical Device development (figure 3).

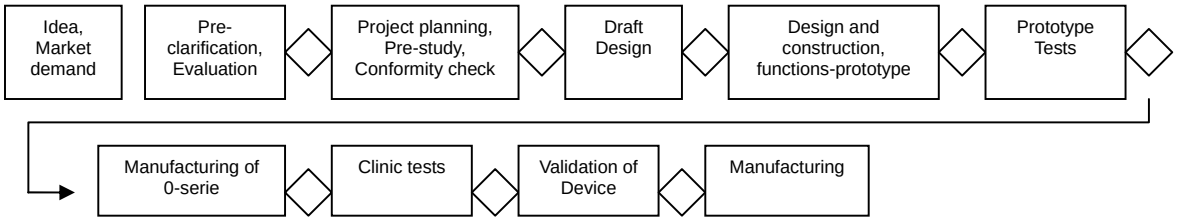

Figure 3: Medical Device Development stage gate process, a real and operative case in a Swiss middle size enterprise.

Interesting in this process example is the introduction of Norm's analysis (check of conformity) in the pre-study phase and the presence of different market analysis tasks before the first stage gate. Our guideline suggests too the analysis of norm and market in the project initialization, before the start of the pre-study.

4.3 Summary of survey

All the analyzed processes in literature and practice are designed for Intramural development. We did not find any relevant innovation process with integrated cooperation management. The literature does not differentiate the case of innovation process with target research. The development or adaptation of technologies for specific device functionality (for us Target Research) is considered as another process, in the majority of cases as technology development.
If this process "runs" parallel during the innovation project, in the same enterprise (other department) or with partners, we speak in any case of collaboration. This separate or integrate development muss to be planed before the start of the project.

5. Guideline for project initialization phase

For Medical Device innovation with both project characteristics cooperation and target research we propose an additional project phase, the "project initialization" phase. This phase should take place between the idea phase and the pre-study phase (see figure 4).

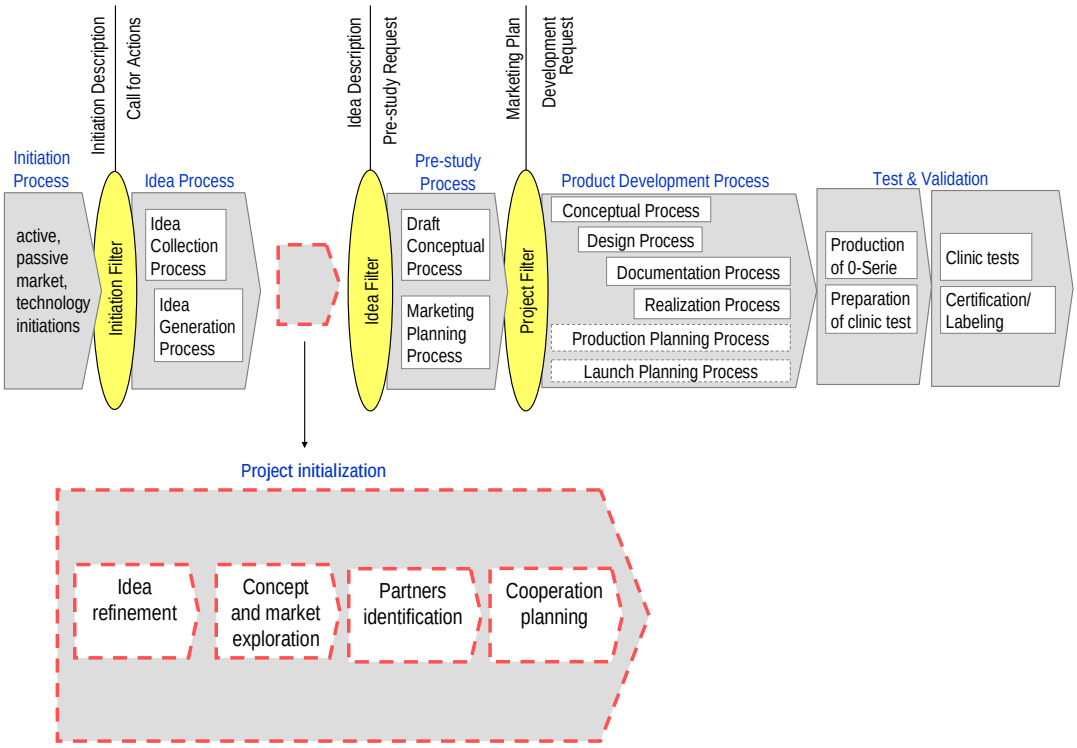

Figure 4: Adaptation of Reference Product Innovation Process of Centre for Product Design, ETH Zurich, for Medical Device Development and with Project Initialization Phase.

The following sectors elaborate on the four sub-processes of the project initialization: idea refinement, concept and market exploration, partner identification and cooperation planning.

5.1 Idea refinement

The Idea refinement is a sub-process with three tasks (fig. 5).

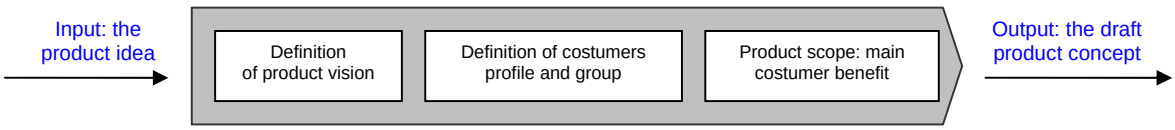

Figure 5: Sub-process Idea Refinement of project initialization phase.

The “Product vision” contains the most important preliminary information about the product. This information are for example the main product functionalities and depending on their relevance also size, weight, price segment, main utilization process or utilization field. After a first definition of the product it is important to identify the costumer/user profile or group. In the Medical Device sector this is not an easy task because it is difficult to define who decides on buying. For example the surgeon decides which kind of Pace-Maker the patient has to use (user is the patient, costumer is the surgeon). After the definition of the costumer profile and group it is

important to identify the main costumer benefit (the USP proposition of the product on the market). The result of these three tasks is the draft product concept. The draft product main contains the most important main objectives for the product. Another idea selection filter can be placed at the end of Idea Refinement sub-process.

5.2 Concept and Market exploration

The feasibility and the first market orientation analysis are the core element of the concept and market exploration (fig. 6). The objective of this sub-process is to define the size of the market, to estimate the project duration (time-to-market), and to estimate the market situation at the end of project (size and players).

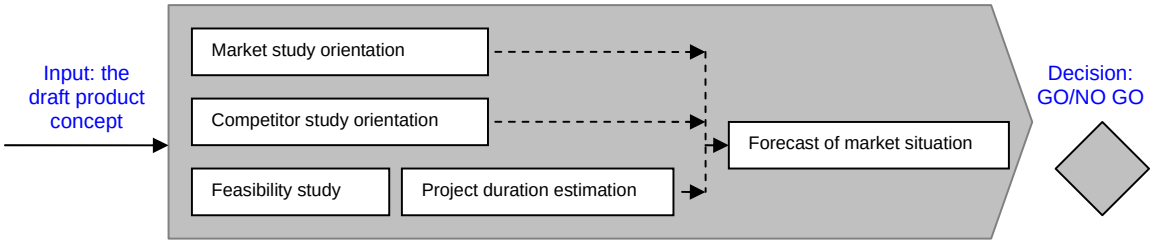

Figure 6: Sub-process Concept and Market exploration of project initialization phase.

These preliminary types of Market and Competitor Analysis have the name “orientation” because the objective of these two tasks is only to analyze the size of the present product market. Later, during the Pre-study phase the team can deduce the potential market share of the product respective the competitor’s products. The name of this second und later market analysis is “market analysis quantification”. The project with “target research” has the characteristic of a long duration. It’s important to identify the size of the market today with all the influencing factors. For example in the development of a coronary anastomosis device it is important to know the epidemiology factors (smoking, cholesterol, diabetics, blood pressure, overweight, alimentation, physical activities) and their trend. The most important question to answer at the end of concept and market exploration is “Will there be a sufficient market at the end of the project?”. The task “Feasibility Study” is important to estimate the “Project Duration”. Objective of the feasibility study is to identify of all important product functionalities. Are there technologies or solutions for all functionalities? If not: how big is the development or adoption effort? What are the potential influences on the final product (risk, complexity, difficulty and importance for the product). Portfolios methodology can be used for the evaluation of functionalities as for example Complexity/Difficulty vs. Importance. This classification can help to plan a first and rough technology development or adaptation roadmap and than estimate the duration of the project. Project duration, present market situation and trend of influencing factors (histological factors) are the basis for the forecast of market situation at the end of project (product market entry). For the “Forecast of market situation” we suggest to use an integrated methodology of Scenarios (Gausemaier, 1996) and Delphi that we have developed and actually tested (fig. 7).

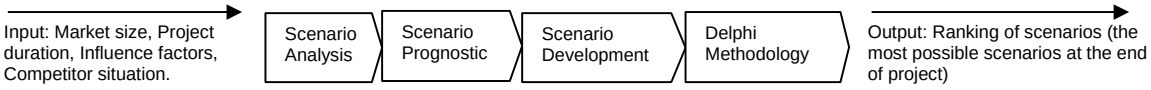

Figure 7: Integration of Scenarios technical with Delphi Methodology for long term market forecast.

In the example of the coronary anastomosis device experts in market are different from expert in epidemiology factors that for the two elements two different scenarios and Delphi have to be implemented (fig. 8).

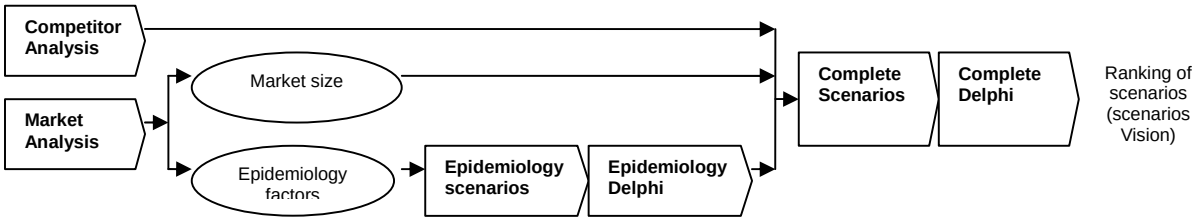

Figure 8: Integration of Scenarios with Delphi Methodology for coronary anastomosis device.

At the end of the concept and market exploration the management can decide if the potential market is attractive enough compared to the risks and resources needed. If yes, the next step is to identify and contact eventual project partners and plan the collaboration.

5.3 Partner identification

The objective of the "Partner Identification" is to build a basis for the selection of the best partner for all different points of view (strategic, cultural and organizational). Important in this phase is the identification of the competencies needed (Marxt, 2000) (fig. 9). The identification happens with to sub-tasks: "Identification of Product Requirements" and "GAP Identification". The result of this task is a Competence-Portfolio (Competence Breadth vs. Competence Depth) of Marxt (Marxt, 2000). After the identification of the intern competence weakness the next task is the design of the partner profile. The partner profile contains the competencies needed, the cultural and organizational requirements.

The search of the partner happens frequently through research in internet, publications and databases, sector experts, costumers, suppliers, personal connections, association, etc.

The partner selection is basically the comparison between the partner profile and the researched real candidates.

The last task is to get in contact with the possible partner and to check of the real possibilities. This can only be successful if the two parts explain the real intention and can the potential future partner through Due Diligence.

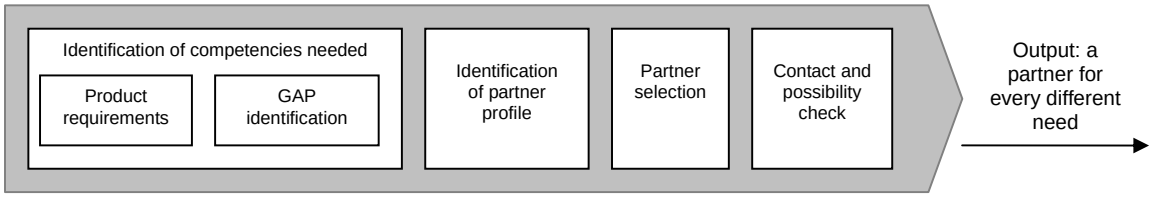

Figure 9: Sub-process Partner Identification of project initialization phase.

5.4 Cooperation planning

The most frequent problem during product innovation project is that in the middle of the project the partners discover that their objectives are incongruent. This is a typical case when industries cooperate with universities. The main academics objectives are research results and publications yet for the industries are economic benefit and secrecy. It's for this that after project objectives identification and personal objectives declaration, we suggest implementing a common IP strategy for the outcome of the project (Fig. 10). This can help to clarify the conflict objectives "Publications vs. Secrecy/Patenting". If this common basis about project and personal objectives exists the cooperation can be sealed with a juristic agreement.
The cooperation planning ended with the project definition (leaders, teams and teams leaders, structure, resources, etc.), project plan (we suggest to separate the tasks in different tasks thematic in the same project plan, as for example device development, market-studies, clinic tests, and if needed utilization variants of outcome) and the cooperation rules (communications and information model, procedural justice, secrecy protocols, etc.).

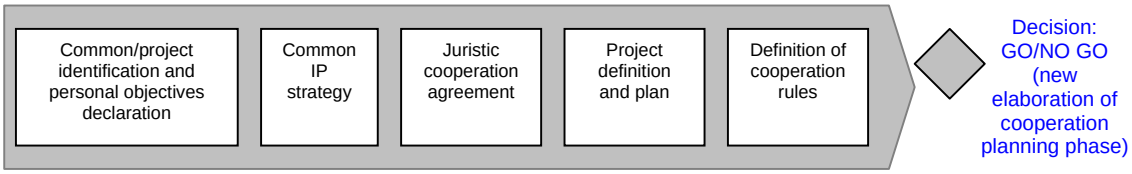

Figure 10: Sub-process Cooperation Planning of project initialization phase.

6. Use cases

The guideline was tested and refined by using it in the decision process of two actual Medical Device research projects of Swiss National Science Found, The National Centre of Competence in Research (NCCR) Co-Me: the development of a semiautomatic robotics for coronary anastomosis and monolithically integrated tactile sensor supports for blood pressure measurement. Three different technical universities institutes, a surgery research institute and two enterprises (component suppliers) collaborate in these two projects. In the analyzed project use cases the frequent problems during the pre-study phase and design phase are the underestimate tasks contained in the project initialization and not implemented as for example and specially a superficial partner identification, the absence of personal objectives declaration, the absence of market situation forecast, and the to later market analysis. Problem in cooperation relationships activate consistent delayed because the project muss resolve for example infinite conflict about patents, problem with the network transparency and knowledge credibility or absence of trust between the teams, etc.
The absences of market analysis before the start of an expensive pre-study (with target research) can delay the abortion of an expensive project without a market.
In all these cases the result of the implementation of a complete project initialization phase brought remarkable cost reductions and higher success possibility rate.

7. Conclusion

The guideline for project initialization focused on the Medical Device development because every project needs three categories of partners: technical, marketing and medical. Only big size

enterprises can have all these competences. A small or medium size enterprise can't have all this competencies and muss cooperate with other entities as enterprise, research labors or universities. The project initialization phase is indicated for small and medium size enterprises that have to innovate but do not have all the competencies to do target research alone.
The guideline is indicated for project where the product idea came from team that don't have any competencies about marketing, innovation management or cooperation management as for example an medicine research institute or a technical university institute. The utilization of the guideline can reduce or eliminate errors because it gives the consciousness about theses themes.
The different tasks of the guideline are actually under development. In this paper we presented the project initialization phase in a rough form.
Our ambitious research objective is to create a complete an in-depth guideline to simplify the transfer and sharing of research results between universities (research and teaching) and industries through cooperation in innovation projects.

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