

Technical Report:

**Guidelines for the Project Initialization Phase
of Medical Device Development**

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Guidelines for the project initialization phase of medical device development

1 Introduction

The embryo of a new product is always its idea. Before the product development project is started, it is useful to conduct a pre-study to clarify the project goals, investigate the business plan, and check the technical feasibility. If the product idea is based on existing technologies and existing markets, the pre-studies are rather short and simple. In medical device development, the pre-study often includes the development of new technologies or the adaptation of existing technologies targeted to new product functionalities. In the context of medical device development, we call these activities *target research*. The target research significantly extends the duration and complexity of a normal pre-study phase. Many medical device pre-studies are complex cooperation projects with several different partners. Therefore, we propose starting the pre-study of a radical medical device product innovation with an extensive *initialization phase*, including *idea-refinement*, *concept and market exploration*, *partner identification*, and *cooperation planning*. The *initialization phase* is aimed at preparing the team in the best way for the individual project.

This technical report presents guidelines on how to conduct the *project initialization phase*. The guidelines have been developed and tested in the context of a case project with the objective of developing a semiautomatic tool for cardiac anastomosis (coronary bypass). The guidelines and each methodology have been validated by observing and analyzing 11 other radical innovation projects from the medical device sector (see Imelli, 2007).

Usually in this context, the idea generator and initiator of a radical innovation project is a lead user (e.g. a medical doctor at a research hospital) who possibly collaborates with a technical partner (universities). The guidelines are designed to build a trustful project network and avoid unsolved conflicts. For example, collaboration between engineers and surgeons, by reason of their completely different organizational and environmental cultures, has been, and still is, a significant challenge encountered by the project team.

Chapter 2 presents the *integration of the project initialization phase within the product innovation process*. The activities and tasks in the *project initialization phase* are introduced in Chapter 3. Two newly developed support methodologies are described in Chapter 4 (*spiral model for marketing research*) and Chapter 5 (*integrated methodology for long term forecast*). The guidelines allow the project team to prepare a successful radical innovation project.

2 Adoption of ETH innovation reference process for medical device development

The ETH innovation process model (see e.g. Meier, 2005) can be used in any industry or sector as a reference model. However, the process needs to be customized for concrete application. Figure 1 shows the reference model customized to the medical device sector. The orange (*project initialization process*) and green sub-processes (*trials*, *design control*, *test & validation*) are added because these aspects are especially important in the context of medical device development.

If the project involves the participation of partners and also involves target research, then a *project initialization process* is needed between the idea generation and pre-study phases. If the project is internal to a single entity (manufacturer or university), then *project initialization* can be a part of the *pre-study process*. *Design control* is a typical certification activity provided by the manufacturer. If the manufacturer enters the project only in the product development stage (for the critical engineering activities), we suggest beginning this important part at the

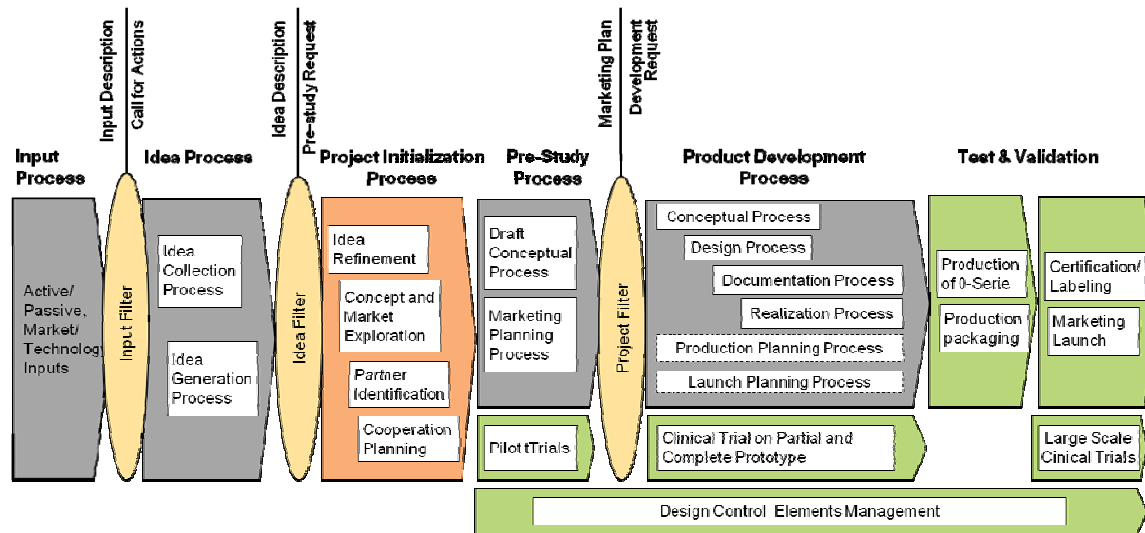


Figure 1: Innovation reference process for medical device development.

Source: Adaptation of the innovation process model of ETH Zurich (Meier, 2005).

same time as the pre-study process with a design control plan, a complete design input list, and a design history file.

In companies with portfolios of ideas and projects, the different *filters for ideas or projects* also represent the choices between competing ideas and projects. If we look only at one research project (e.g. an academic research project), these filters represent the choice between competing solutions or paradigms. Target research usually takes place during the idea and pre-project processes and during the pre-study project. When a project advances to the product development process, where the focus is on product engineering, the target research project becomes a radical innovation project.

3 Project initialization phase

3.1 Idea refinement

Idea refinement is the first sub-process of the *project initialization phase* with three main activities (Figure 2, left part): (1) *definition of product vision*, (2) *definition of customer profile and groups*, and (3) the identification of *product scope (main customer benefit)*. The goal is to enhance the *product idea*, moving toward a *draft product concept*.

The definition of product vision can be divided into four single tasks (Figure 2): (1) *product or service idea description*, (2) *definition of a project core-team*, (3) *definition of the product vision*, and (4) *identification of main product functionalities*. When the product idea is described, the project needs a core team to proceed. The core team should include the idea generator and, if he or she is not a lead user, should include a minimum of two lead users. The core team size should not exceed 6 to 8 members.

The next two tasks, *definition of product vision* and *identification of main product functionalities*, can be conducted in a workshop where the idea generator explains his idea and the user tries to draw the product vision. This motivates other project team members to ask questions about procedures and design ideas. After the identification of the product “vision”, lead users and other team members try to identify all main functionalities of the outcome. The core team members (alone or in the group) need several days to elaborate the results of this first workshop and enhance the idea. The objective is to transform an idea into a product vision with main functionalities.

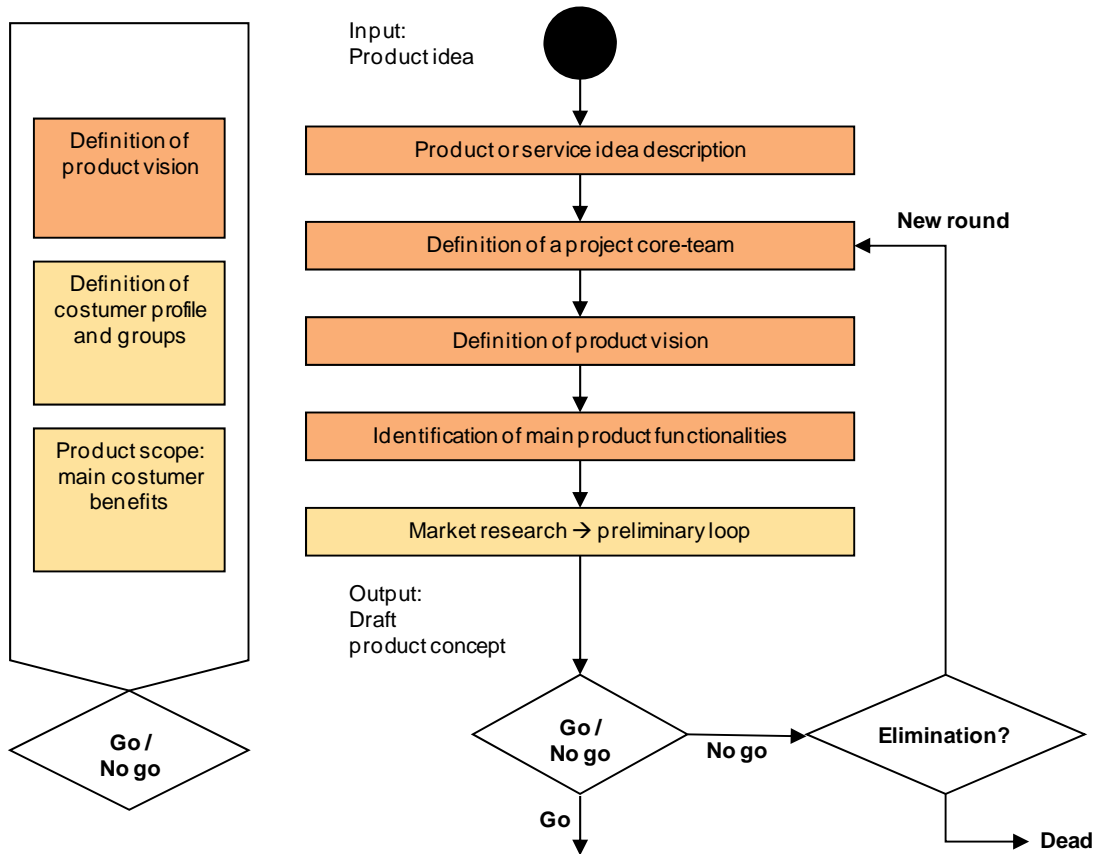


Figure 2: “Idea refinement” sub-process of the “project initialization” phase.

At this point, the team might begin to develop a first rough business analysis that contains the *definition of customer profile and groups* and the identification of the *main customer benefits*. In several project stages, the team needs market information to reach the next refinement level. Due to this repetition of marketing tasks, a *spiral model* with three repetition loops for the different project phases is utilized (Chapter 3). The two business-oriented activities of the idea refinement phase are described in the *first loop*, or the *preliminary loop* of the spiral model.

3.2 Concept and market exploration

The *market and customer orientation studies* and the *feasibility study* are the core elements of the sub-process *concept and market exploration* (Figure 3, left part). The objective of this sub-process is to *estimate the project duration* (time-to-market) and *forecast the market situation* at the end of the project (size and players). At the end of the *concept and market exploration*, the management can decide whether the potential market is attractive enough compared to the risks and resources needed.

The *market and concept exploration* can be split up into many tasks. *Market and competitor orientation studies* are integrated in the *spiral model* as the *second loop*, also named the *quick and dirty loop* (Chapter 3). The *feasibility study* is the central activity for the resulting project plan. During the *feasibility study*, the team must provide different tasks that help the project management estimate the duration of the project. These tasks are:

- *Identification and description of detailed functionalities*: Input for this task are the main functionalities identified during the *idea refinement phase*, and output is a detailed product functionality list with all the connections and interdependencies included. This list is an integral element of the *design control* that has to be provided later in the project.

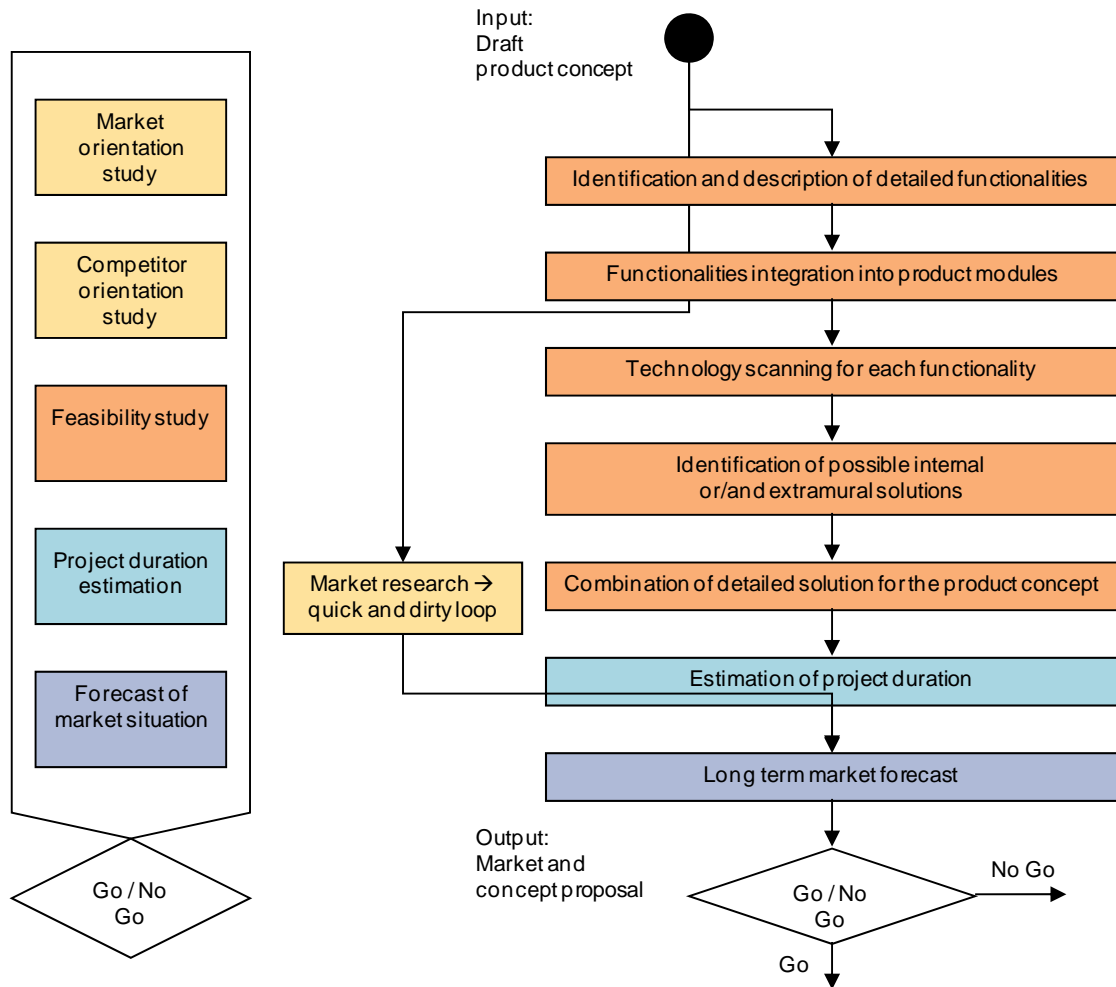


Figure 3: “Concept and market exploration” sub-process of the “project initialization” phase.

- *Integration of functionalities into product modules:* At this stage of a project, it is difficult to structure the product in different modules. However, we suggest engaging in this activity because it helps to identify possible work packages with different content.
- *Technology scanning for each functionality:* The objective of technology scanning is to identify which functionality can be implemented with already existing solutions and which still have to be developed. This activity is normally based on researching the technical literature and patent history, as well as on open discussions with technical sector experts. Patent research is important to identify which technology can be patented and which must be transferred from other entities (companies or universities). Technology screening is the basis for the next task.
- *Identification of possible internal and/or extramural solutions:* With this task, the team must clarify what can be internally developed and is then part of the project plan, and what can be transferred from outside. The extramural solutions can be transferred in the project through two possible actions: licensing or integration of a partner in the project.
- *Combination of detailed solutions for the product concept:* At this point, it is important to design different combinations of solutions, to evaluate them, and then to select a solution for the pre-study phase or, if enough resources are available, two competing solutions. We suggest using the morphologic boxes method, letting the lead user evaluate the potential solutions. The technical team supports the lead users during the evaluation through assisting with the understanding of different technical solutions.

At this point, with the combination of partial solutions and selection of the complete solution (or solutions), the *feasibility study* ends. During evaluation, the team gives a rating for different parameters of the solutions, and one of these parameters is the feasibility and risk of failure.

The next task is *project duration estimation*, which is performed by the project management and project members. This information is important for planning the project and estimating time to market. Project members tend, in many cases, to purposefully overestimate the time needed for each work package in order to avoid stress. In this case, the project manager may challenge and motivate the team by shortening the lead time. We suggest performing this activity in a plenum with all involved members because it is important to give a large consensus to this basic element of the project plan.

Projects with target research are usually of middle or long duration, and an important question at this point of any project is “Will this market exist at the end of the project?” This question has two objectives: the first is to assess the market chances of the project (and assure investments), and the second is to promote a future-directed thinking culture in the team. For these purposes, an integrated methodology of Scenario Technique and Delphi is used for medical device development in combination with the integration of scenarios of epidemiological factors (Chapter 4) which can be used to conduct the *long term forecast of the market situation*.

3.3 PARTNER IDENTIFICATION

The objective of the *partner identification* sub-process is to build a basis for selecting the best partner under all different points of view (strategic, cultural, and organizational). Important in this phase is the identification of the competencies needed (Figure 5, left part). Two sub-tasks are necessary for this identification: *identification of product requirements* and *gap identification*. After identifying the internal competence *gap*, the *partner profile* must be designed, including the competencies needed, and the cultural and organizational requirements. Based on this *potential partners* can be *selected*, *contacted* and *checked* for availability.

The *partner identification* sub-process can be divided into ten tasks (Figure 5, right side). The first task is *product requirement identification*. Product requirements have different origins:

- product idea and vision,
- market analysis (market and user needs) and competitor analysis,
- product functionalities,
- regulations, and
- utilization analysis (product and packaging).

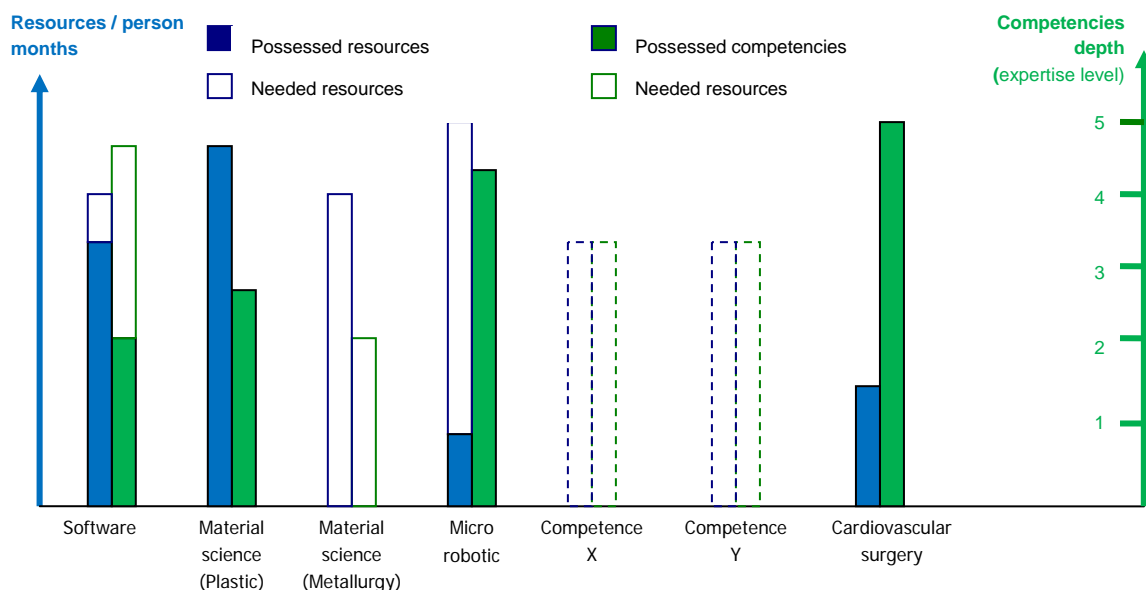


Figure 4: Diagram for the identification of competency depth and resources

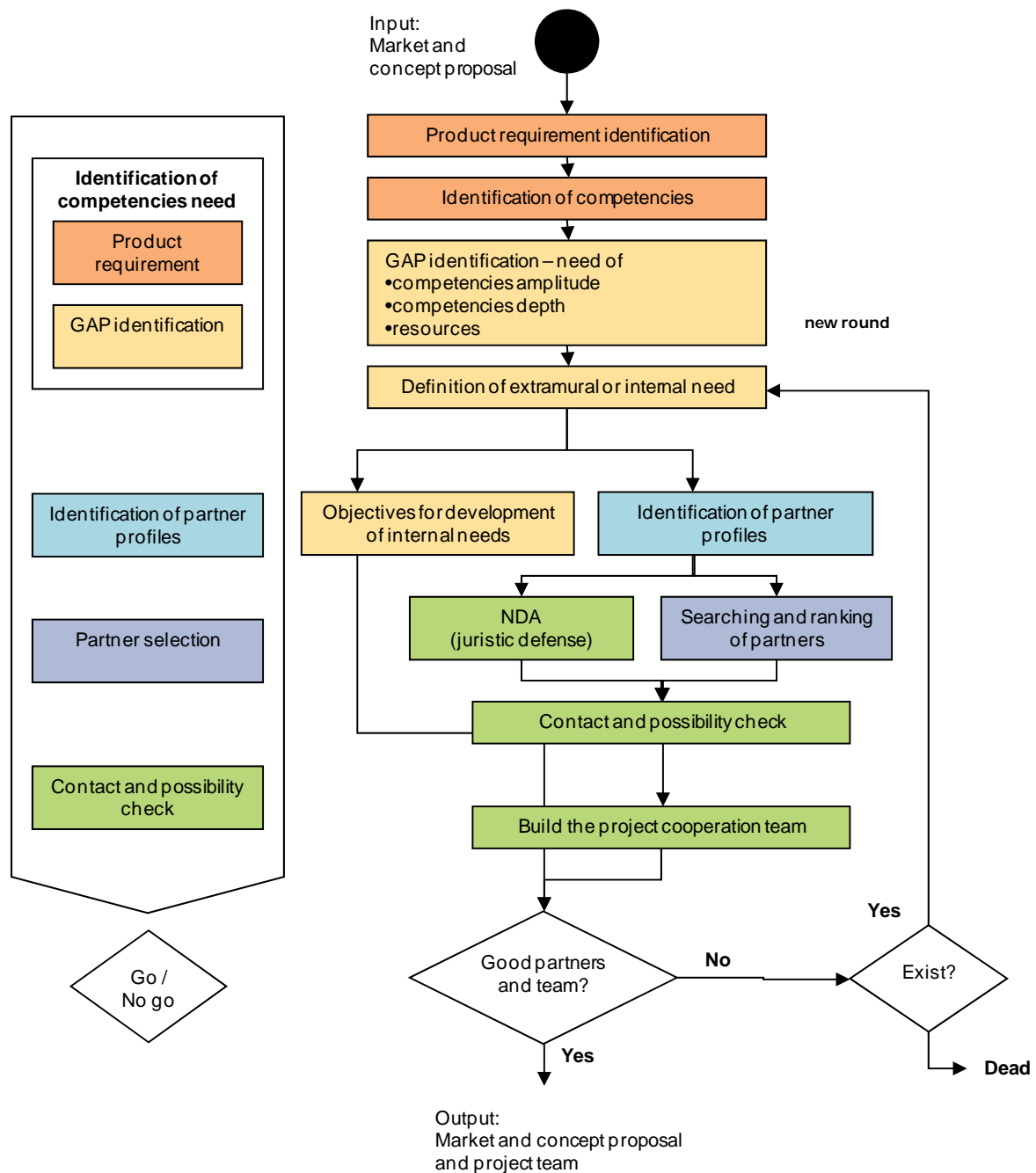


Figure 5: “Partner identification” sub-process of the “project initialization” phase.

For the identification of product requirements, the presence of lead users is necessary.

At this point, the team knows product functionalities, modules, and requirements, and can *identify all competencies needed* to absolve the project. The project competencies are checked in the next task with the objective of *identifying gaps* in the actual project team.

There are three types of competence gaps:

- *competence amplitude* – The team needs competencies not present in the core team members;
- *competence depth* – The team needs expertise in some topic; and
- *resources* – The team alone does not have the time resources necessary to complete the project.

If a competence needs a certain expertise level that is not possessed by the team, a partner is needed to perform the tasks linked with this competence. The same is true for resources: if resources in certain competence areas are too low in the team, then new members or partners are needed.

We suggest identifying the desired competencies using a diagram with three variables: the needed competencies (amplitude), the depth of the competencies, and the resources (Figure 4). The *definition of extramural or internal needs* can be dealt with based on this diagram. The decision is twofold:

- *Internal* – to develop a new competence level (competence depth) or enlarge the team (resources and competence depth).
- *Extramural* – to look for a new project partner.

The objective of this task is to fill all identified gaps with as few partners as possible. After verifying an eventual necessity for internal competence development, it is important to fix the objectives for this important parallel activity.

With the identification of the external competence and resource needs, the team should design a *profile for a potential project partner*. It is very important to develop a concrete profile before beginning the search. With this profile, the team *searches for partners and ranks the potential partners* in terms of the profile. The ranking is based on value factors that are assigned to every profile element. In addition to searching for and ranking potential partners, preparing a simple *NDA (juristic defense for the product idea)* with a legal expert is suggested. Clearly, after fulfilling these tasks, the project manager can *contact the partners* and *build the complete project team*.

3.4 Cooperation planning

In this pre-project phase, the complete team with all partners is ready to plan the cooperation actions during the pre-study as well as begin the product development process, including declaring objectives, defining the project and plan, building a common IP strategy, defining cooperation rules, and forming a juristic cooperation agreement (Figure 6, left part).

Cooperation planning ends with the *project definition* (leaders, teams and teams leaders, structure, resources, etc.), considering the *project plan* (we suggest separating the tasks in different topics in the same project plan, such as device development, market studies, clinical tests, and utilization variants of outcome, if needed) and *cooperation rules* (communication and information model, procedural justice, secrecy protocols, etc.).

3.4.1 Declaring objectives

The first activity, declaring objectives, is the most important part of the entire project, because it is the most frequent source of conflict in a cooperation project. *Analysis of the project situation*, *identification of project objectives*, and the *declaration of personal/single objectives* must be discussed in plenum to achieve a complete consensus. *Analysis of the project* needs considerable time, and is the basis for the *identification of the project objectives*. We suggest using the SWOT analysis methodology and investigating all elements of the *project system*, such as product requirements, team knowledge, communication and information exchange, and necessary technologies.

At the end of the analysis, the strengths and weaknesses of the project team/organization that can influence possible opportunities and threats appear in the four fields of the SWOT analysis (Strengths vs. Opportunities, Strengths vs. Threats, Weaknesses vs. Opportunities, and Weaknesses vs. Threats). Potential objectives of the projects can be found in the SWOT results:

- use strengths to take advantage of every opportunity (field strengths vs. opportunities),
- use strengths to reduce threats (field strengths vs. threats),
- reduce weaknesses to take advantage of opportunities (field weaknesses vs. opportunities), and
- reduce weaknesses to reduce threats (field weaknesses vs. threats).

After unanimous *identification of the project objectives*, every sub-team and team member must *declare personal objectives*. This is very important because personal objectives should not conflict with other personal or project

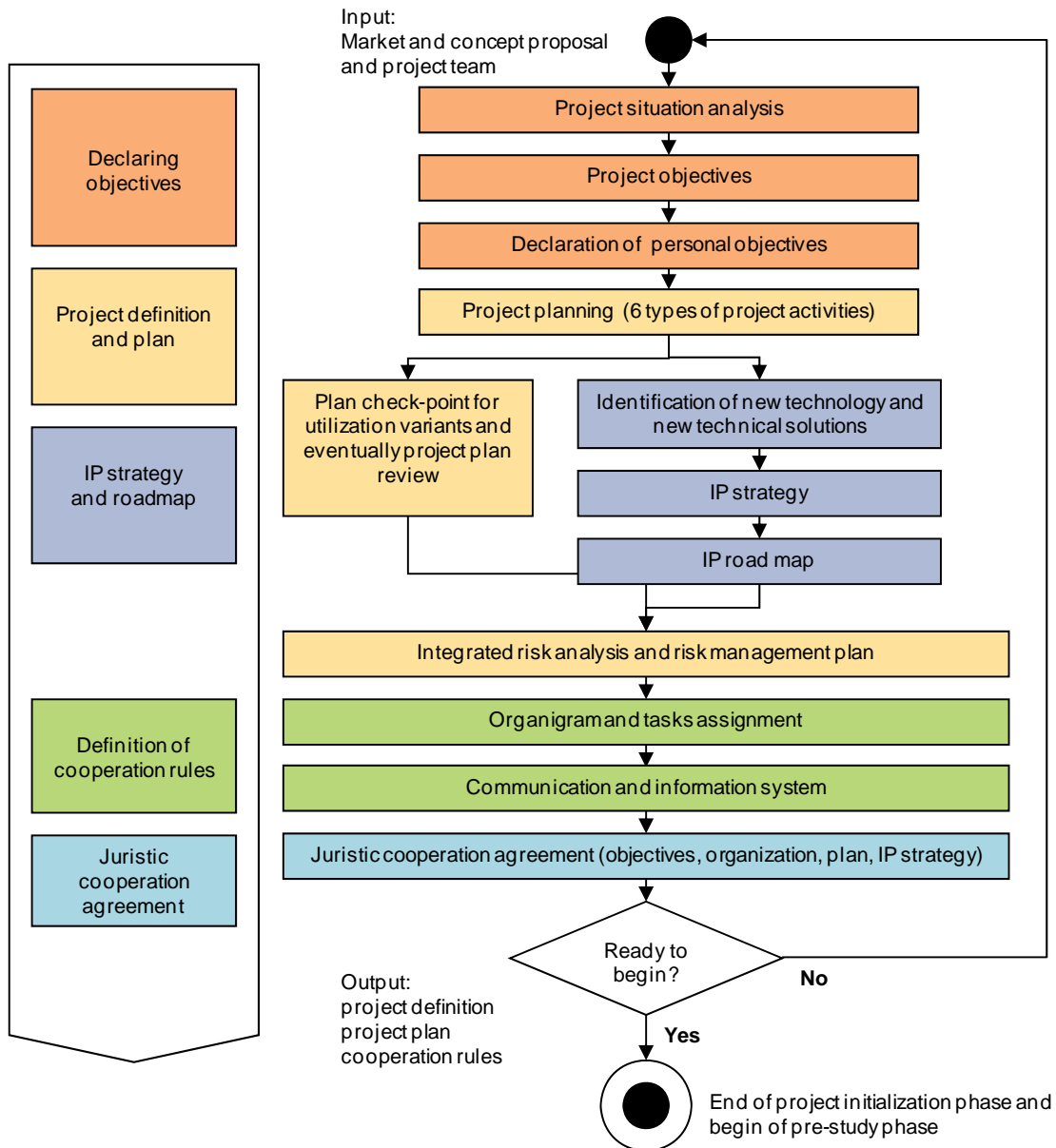


Figure 6: “Cooperation planning” sub-process of the “project initialization” phase.

objectives. Most conflicting situations during cooperative activities between universities and companies arise from incompatible objectives regarding secrecy versus publication strategies; whereas in projects involving only university partners, most conflicts concern the utilization of outcomes. For example, conflicts concerning the utilization of project outcomes can arise when part of a team wants to found a start-up while other members want to sell patents or licenses.

3.4.2 Project definition and plan

We have tested a very successful procedure to transform product functionalities and modules in a project plan within a single workshop. All project members participate in the workshop, which is composed of four main exercises. A skilled moderator facilitates the workshop so that complete consensus among project members is reached and the participants can take advantage of the day without disturbances (operative activities like phone calls). The four mentioned exercises are listed below.

1. *Complete list of functionalities:* Each member identifies the functionalities of the product and the interdependence of functionalities within or between product modules. The inputs of this exercise are the

main functionality list developed in the *idea refinement* phase and the *product requirement list* developed in the *cooperation partner identification* phase.

Starting with this list, the team members write down detailed functionalities and the corresponding activities or problems to solve for each functionality. As a result, a list of activities is compiled for each functionality. An example of this is an extract of this exercise from the Robotics in Cardiovascular Surgery project (Figure 7).

2. *Evaluation of every functionality and activity:* The project members are separated into two groups, which have different objectives. The first group, which includes the technical experts, evaluates every activity based on difficulty (engineering point of view), classifying them from 1 (very difficult) to 5 (very easy). The second group, which includes users such as experts in medical domains, evaluates every activity based on importance (user point of view) and, as before, classifies them from 1 (not important at all) to 5 (very important) (Figure 8)
3. *Insert the portfolio activities/problems in a portfolio based on difficulty vs. importance.* With this portfolio, the team identifies four classes of activities or problems to solve: easily solved and important, easily solved but not important, difficult to solve and important, and difficult to solve and not important (Figure 9). These four groups help the team to plan the project in the next exercise.
4. *Placement of activities/problems on a time axis (project duration).* Using the portfolio, the team first plans the activities that are *easy to do and important*. The choice to begin with easy (but important) tasks is dictated from the desire of the project manager to give motivation and satisfaction at the beginning of the project, and to test the collaborations while avoiding difficulties. In any case, the duration of an important but difficult activity can influence these planning rules. Our suggestion based on experiences in different projects is to plan with the following rules:

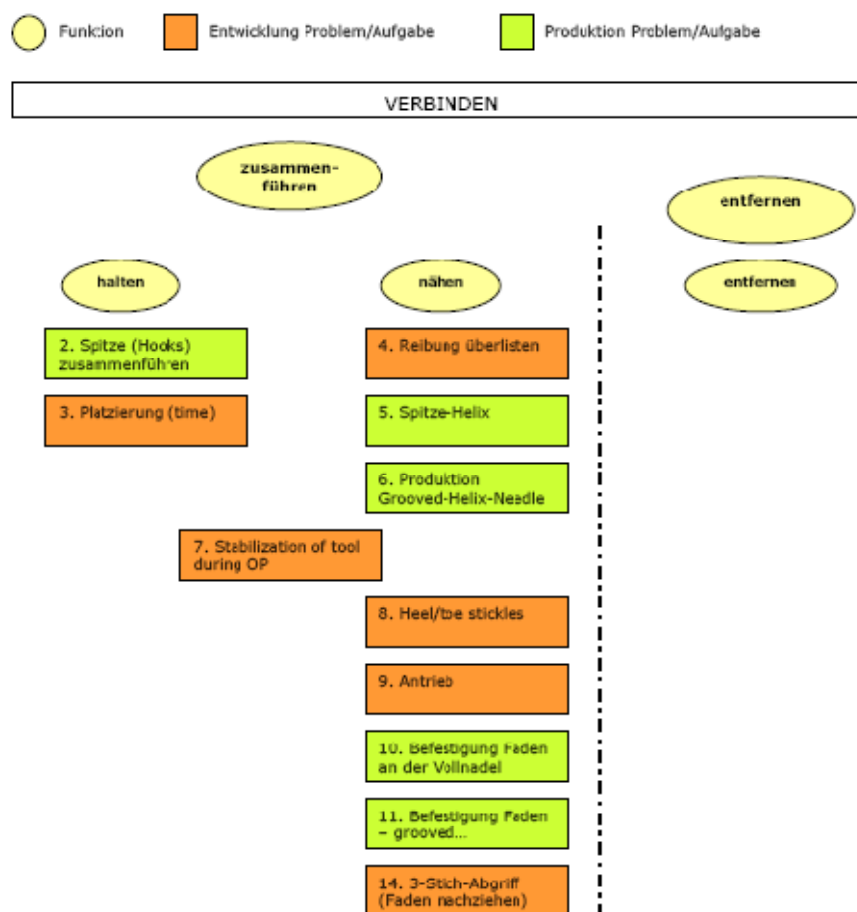


Figure 7: Activities or problems to solve for each functionality (in German).

Source: Diagram from the project Robotics in Cardiovascular Surgery.

Nr.	Problem/Aufgabe	Benutzer-Sicht	Ingenieur-Sicht
		Wichtigkeit (1 nicht wichtig - 5 sehr wichtig)	Einfach (1 sehr schwierig - 5 sehr einfach)
1b	Everten am lebenden gewebe	5	2
2	Spitze Hooks	5	4
3	Platzierung	5	1
4	Reibung überlisten	5	2
5	Spitze-Helix	3	3
6	Production grooved Helix needle	3	1
7	Stabil. of tool during OP	5	5
8	Heel/toe stickles	4	2
9	Antrieb	4	2
10	Befestigung Faden an der Vollnadel	3	2
11	Befestigung Faden-Grooved	3	3
12	Tool-Montage	1	1
14	3-Stich-Abgriff	4	2
15	Verpackung	1	5
16	Richtlinien + Normen	3	3
17	(6a) used of grooved Helix needle	4	2

Figure 8: Evaluation of activities or problems from the point of view of users and engineers (example in German).

Source: Diagram from the Robotics in Cardiovascular Surgery project.

- during the first main period, all *easy and important* activities and some *difficult but important* activities (the longest activities) have to be performed, with the objective of giving motivation and having more time for critical activities; and
- during the second main period, all *difficult but important* activities must be started, as the team has time to perform these activities and can count on the collaborative experience collected in the first period, and a deeper team culture has grown in the first period; and
- the third main period is utilized to complete important and long activities and perform *easy but not important* and *difficult but not important* activities.

The portfolio and timing rules should only be used for development and engineering activities, and not for activities in other domains, such as market analysis or clinical trials, because these have too much influence on the development status of the product.

In this context, we suggest using a Gantt diagram with six blocks of activities:

- *development activities* – planned with the portfolio and planning rules,
- *engineering activities* – planned with the portfolio and planning rules,
- *clinical trials* – planned depending on the development stage of the product (existence of partial or entire prototypes) and in function of important milestones,
- *design control activities* – planned depending on the development stage of the product and especially in function of the milestones, where typical tasks of design control are the management of the design history files, the design and approval of the product requirement list, and so on,
- *market analysis activities* – planned with the support of the spiral model (Chapter 3), and
- *intellectual properties and utilization of alternative planning activities* – planned in function of the development stage of the product and clinical trials, where typical activities of this group are screening of patents, patent road map planning, patenting, planning of outcome utilizations, and so on.

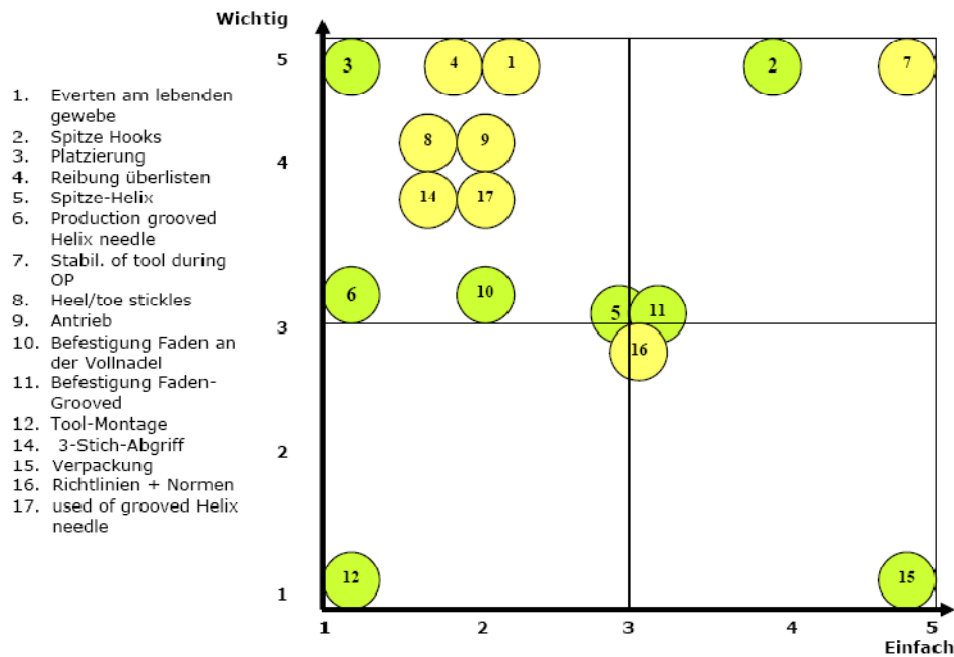


Figure 9: Portfolio for the visualization of activities and problems as a function of their difficulty and importance (example in German).

Source: Diagram from the use case Robotics in Cardiovascular Surgery.

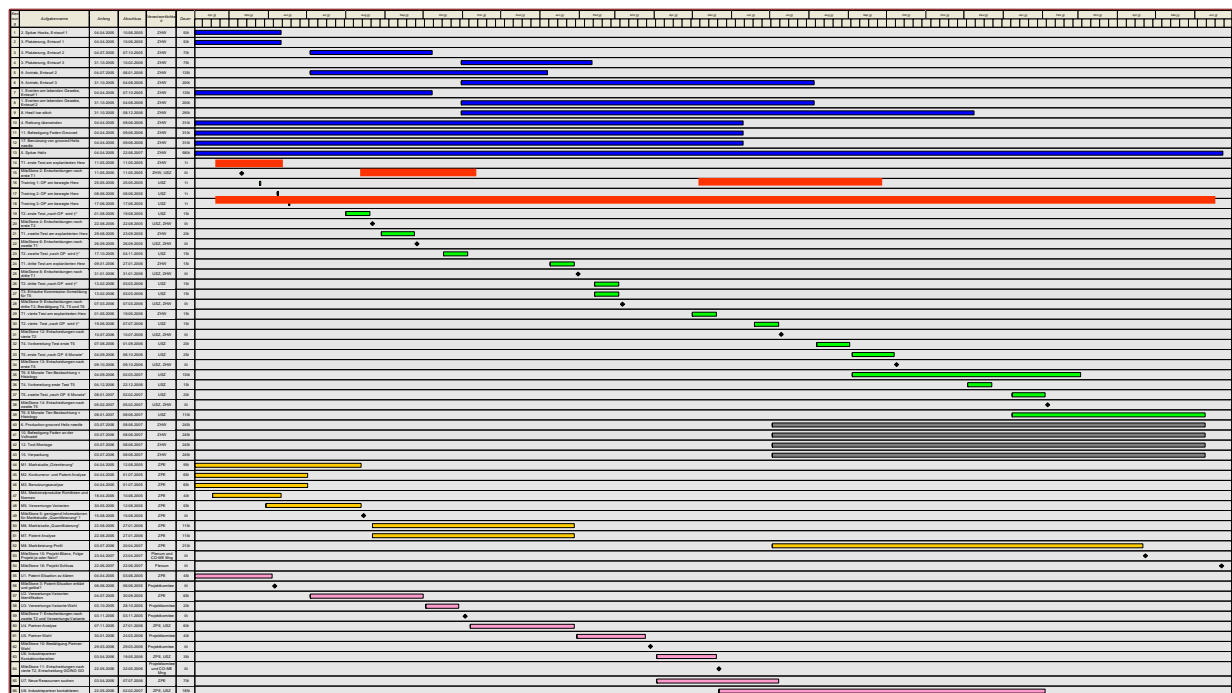


Figure 10: Project planned with GANTT-Diagram with 6 activity blocks (blue tasks: product development, red tasks: design controls, green tasks: clinical trials, gray tasks: product engineering, orange tasks: market analysis, and lilac tasks: IPs and utilization alternatives).

Source: Project plan of the project Robotics in Cardiovascular Surgery.

It is important for the project to include a plan for intellectual proprieties (IPs) and utilization variants. For IPs, the project manager must develop a strategy and create a road map to patent the newly developed technologies. These activities are an integral part of the project plan and are planned in function of important project milestones. The project manager must develop check points for utilization variants (Figure 10). During the project, and in function of the development and results status, the project manager must regularly assess whether the utilization of the project outcomes is in line with project possibilities and member wishes. Examples of these kinds of tasks are identifying, ranking, and contacting a manufacturer in order to sell a technology (licensing or patent sell) or to plan cooperative activities. These activities are strongly influenced by clinical trial activities, since in order to successfully contact a manufacturer the project team must present some clinical results. We developed a *utilization-alternatives barometer* (see Imelli et al., 2006a) to identify the best utilization possibility during the project (sell patents, licensing, cooperation, found a start up, etc.) and plan special project activities for this specific situation (search for an industrial partner, a buyer, funds or financing, etc.).

In most radical innovation projects, it is very difficult to respect the first designed project plan, and adapting and making changes are normal. In a radical innovation project, it is important to manage the project plan dynamically and to provide the right adaptations while not influencing the achievement of the most important objectives. All changes should be communicated to the team. Many times, the first draft of the project plan is not detailed and presents rough tasks. According to most project leaders and based on our experience, we suggest managing projects in the middle and long term with the project plan (main tasks and milestones), but in the short term (between two milestones or in proximity to an important milestone) it is better to plan and manage the team with an “open issues list”, with every single task, role, importance, responsibility, and deadline included, updating the list after each meeting.

3.4.3 Project definition and plan – Integrated risk analysis and risk management plan

Risk analysis is a central part of device approval by FDA as well as EC regulation. Risk analysis is not only an important element for meeting the different regulations, but can be a support instrument for the project manager.

FDA requests risk analysis in the early stages of development (Food and Drug Administration, 1996, Part 820, Subpart C-Design Controls, Section 820.30d). The finished design outputs must be documented in the pre-development phase in the DMR (Device Master Record), which includes the results of the risk analysis. EC regulations EN ISO13485:2003 (NBN Bureau de Normalisation, 2003) require certified development processes with risk analysis corresponding to the norm EN ISO14971:2001 (Asociacion Española de Normalizacion y

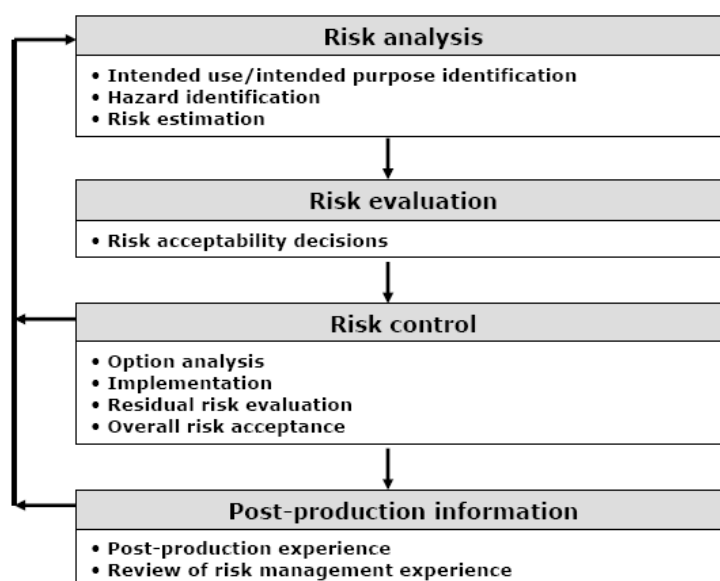


Figure 11: Application of risk management to medical devices, Source: ISO 14971:2001

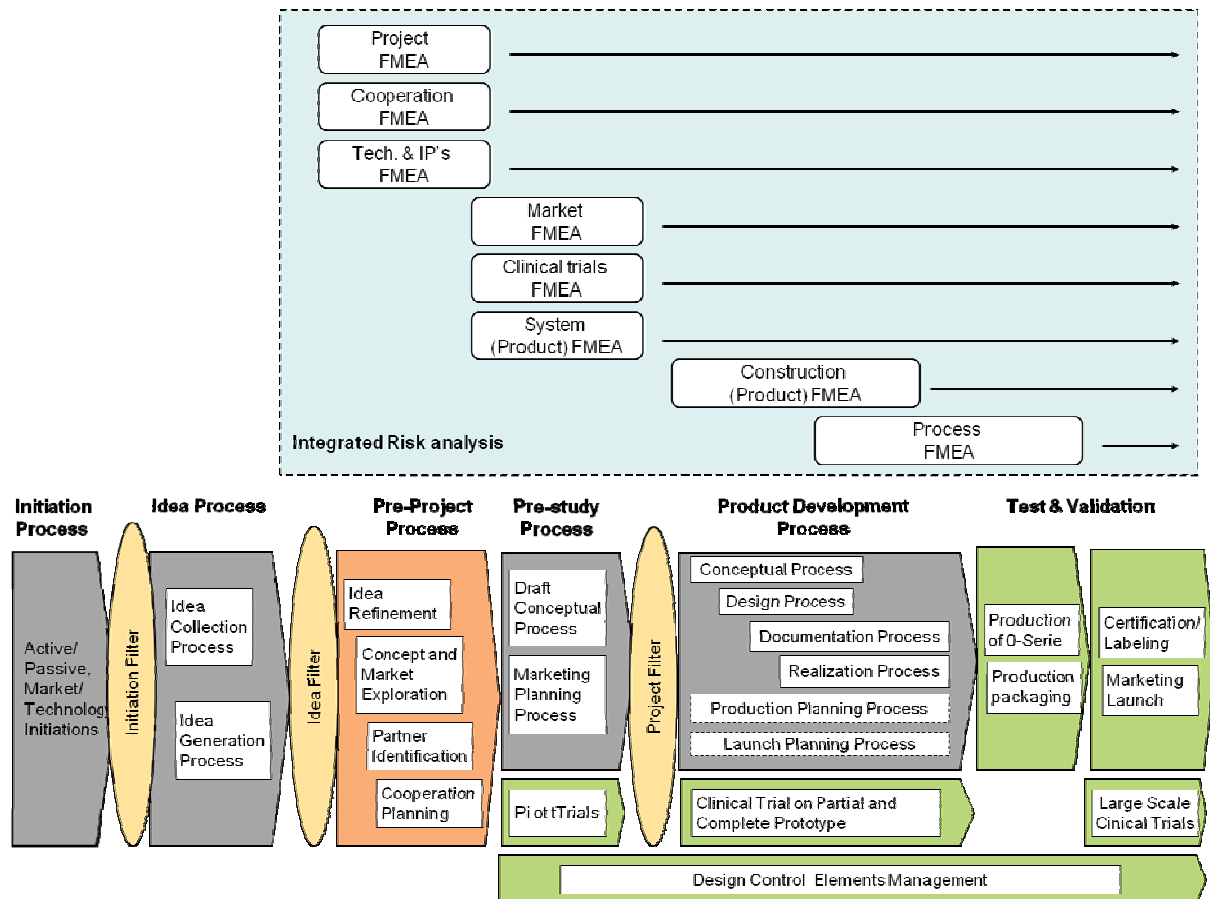


Figure 12: Eight modules of integrated risk analysis

Certification (AENOR), 2001) (Figure 11). This norm stipulates different types of risk analysis: product and process/components. Product risk analysis considers the risk related to the use of the device, while the process/components risk analysis takes into account the risks related to the choice of components and the manufacturing (and packaging) process. In the early stage, only product risk analysis is necessary, but we suggest implementing a single, complete, and integrated risk analysis in the early stages. This risk analysis should be based on different modules including all important elements that must be controlled during the complete project.

The best method to integrate different elements/modules from different domains (medical, business, technical, and so on) in a unique risk analysis, according to Nickel (1992), is FMEA.

The different elements/modules of the integrated FMEA are:

- *product risk module* – contains all possible risks related to setting-up the operation (preparation), utilization of the product (surgeon, doctor, etc.), and possible risks during the life-cycle of the product (pace-maker, stent, etc.);
- *technology and IP risk module* – contains all possible risks related to the development of new technologies, protection of inventions, acquisition of external technologies/knowledge, and so on;
- *project management risk module* – contains all possible risks related to the execution of the project (delay-related risks, costs explosion, lack of competencies, and so on);
- *cooperation management risk module* – contains all possible risks regarding the activities inside and outside the cooperation network (conflict between research groups, conflict between groups leaders, strong cultural difference between groups, etc.);
- *market risk module* – contains all risks related to the market, the market change/evolution, and the transfer of results into the market;
- *clinical trial risk module* – contains all risks related to providing clinical trials; and

- *process-/components risk module* – contains all risks related to the choice of components (suppliers or production processes), assembling, sterilizing, and packaging (risks related to engineering and producing a tool).

First inputs for the integrated risk analysis of the entire project are generated from the SWOT analysis (described above). The project manager should continuously check, up-grade, and dynamically adapt the risk analysis for each element, adding new elements to every module throughout the project. Measures to reduce risk should be taken after every risk check (Figure 12), and their effect measured. Different modules are integrated in different process stages (Figure 12).

3.4.4 IP strategy and roadmap

The project management should insert the patent road map in the project plan. The team must identify which kind of technologies can be patented (possibility and benefit), and in which period of the project. It is important to plan each patent application for the best moment, balancing protection, the need for publications, and costs. This road map influences the motivation of many project members, because research results should only be published and presented after patent application. The road map includes the go/no go decision points, patent preparation, and patent applications. This IP strategy is essential for reducing the possibility of conflicts between partners and project members, as well as the possibility of investing money in untargeted patents/technologies.

A difference in culture (medical vs. technical) among partners is often a source of conflict (e.g. regarding the definition of the inventor and the division of the holder-percent/costs). Therefore, the IP strategy should define the following items:

- *Who is the inventor* – In the hierarchical culture typical of many university institutes, especially in the medical domain, every team member must be included in a patent application as an inventor. If the team boss has any ideas about the content of the patent, he must be part of the inventors list. For research groups following a meritocracy system, this hierarchical approach is not acceptable. Therefore, the project patent rules should define the identification and choice of inventors in patent applications.
- *IP office* – Most universities and companies have a legal office with experts in the intellectual properties domain. We suggest choosing a single office for all partners leading the administration of the project IPs. The choice is difficult if two main partners are involved in the project. If a main partner exists (leading group), it is normal that the legal office of this university detains the lead. If there are two or more main groups, a choice between the main groups (with unanimous consensus) or the concession of the lead to a smaller partner as the impartial legal officer is necessary.
- *Patent holder* – In the IP strategy, the project partner must choose the holder percent of each partner for every possible patent. The participation costs of the partners for the total legal and patenting costs are distributed related to holder percent. The partner's holder percent does not necessarily reflect inventor presence in a single patent. We suggest defining a fixed percent among the partners for the holder's part of the patent, and letting the inventor's part be flexible depending on meritocracy.
- *Type of patent* – The type of patent (international, regional, or national) issued must be part of the IP Strategy. This decision is based on the depth of global market knowledge as well as on project resources. For instance, the application of a patent regarding only cardiology technology in Switzerland would not have good market coverage (the U.S. being the main market for cardiology instrumentation).

Figure 13 shows the main five tasks needed to compile the IP roadmap. The *first* task is *refining* the tasks absolved in earlier sub-processes, conducting an in-depth *screening* of existing technologies and in-depth patent research. The *second* task is based on *identifying target technologies/inventions* developed during the project that must be protected by patents. After identifying patenting possibilities, the team must identify the *development stage* (maturity points) of the different target technologies/ inventions and, where possible, begin to *decide on patenting* (third task). After identification of the development stages, the team can plan an *IP road map for each technology/invention* (fourth task). The *time point from which the publication* of results for each specific technology/invention is possible (fifth task) should also be included in the block, listing all activities concerning IP.

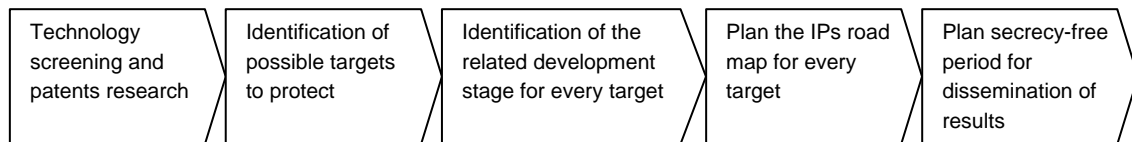


Figure 13: The five tasks to plan IP road maps.

3.4.5 Definition of cooperation rules and juristic cooperation agreement

At this point, all activities, project and product requirements, objectives, and strategies have been planned, but the following tasks still have to be performed:

- organizing the project, with a complete and definitive *organigram*;
- definitively *assigning each task*, with responsables and deadlines;
- defining a *communication and information system* between the groups and project members; and
- collecting the information in a *juristic cooperation agreement*, with objectives (product and project), organization, project planning, product vision, and IP strategy).

The organization of the project greatly depends on the culture within the different research groups. In a cooperation project, different cultures might coexist in the research groups regardless of whether the group is a complete flat hierarchical group (such as software development institutes) or a strong hierarchical group (such as surgical teams). There is no best structure for the communication and information exchange, because this depends on people involved in the project as well as on the geographical and cultural distance between the groups. However, if possible, the information should be hierarchically flat so that every project member receives information directly from every other member. In our project, we implemented a PDM system (Team-Center of UGS) to promote information exchange (with an online database) and communication (e-mail, chat, forum, and pop-windows), and also to have a single source for all documents and files. The Team-Center was optimal for the project management activities. The problem was implementing this system in the group of medical project partners. Surgeons, doctors, and nurses do not always use the same informatics infrastructure inside a hospital, and acceptance of new IT tools is very low (because little free time is available to learn to use new software). If the majority of members are able to use a software tool that can support the project management, data management, and communication, we suggest implementing such a tool. According to Moenaert et al. (2000), the organization of communication in a cooperation project for product innovation must fulfill the requirements listed below.

Efficiency requirements:

- *Cost* – The information flow between all members must be easy to enact and fast (reduction of time for communication and information exchange).
- *Secrecy* – Information and files must be available from every possible workplace (online), but complete safety in terms of external intrusion must be insured.

Effectiveness requirements:

- *Transparency of the communication network* – Transparency is defined as the point at which the communication network is sufficiently clear and accessible, in order to let everyone understand the inputs and progress made (Hamel, 1991). The transparency of a communication network decreases with increasing levels of complexity (Moenaert et al., 2000).
- *Knowledge codification* – Codification is defined as the individual and collective processes through which knowledge and experience may be structured and made explicit (Boisot, 1986). Problems with codification are not related only to tacit knowledge, but may also be observed with knowledge that is specific to a team, company, group to which a company belongs, or network of partners in which a group is embedded (Badaracco, 1991).
- *Knowledge credibility* – In a cooperation project, a reduction in the credibility of received information is often observed, and consequently the receptivity toward this information is lessened (De Meyer, 1991, Moenaert et al., 2000). Normally, this problem is based on a cultural difference (from an organizational

point of view) resulting from stereotypes, different professional origins, and scientific domain (medical and technical, for example).

The requirements for communication and information exchange between research groups in an innovation project encompass maximization of network transparency, knowledge codification, and knowledge credibility, and parallel the minimization of communication costs and maximization of secrecy and protection (Moenaert et al., 2000). Moenaert (2000) identified seven main communication and information exchange capabilities (cross-functional and inter-unit climate, communication infrastructure, goal congruence, core team, team leadership, team formalization, and procedural justice) for the achievement of these communication requirements, and in the end of the process for achieving the project objectives.

4 Spiral model for market research⁵

4.1 Three-loop process

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

The first loop is the preliminary loop. It is preliminary because, in this stage of the project, the team only has to demonstrate the existence of a potential market and eventually convince university government or other research funders to invest in this project. The second loop is quick and dirty, where the team collects all available information in the shortest time possible. The collected information is used for two purposes: (1) to deduce product requirements 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 analyzes the market in-depth to convince a potential investor or manufacturer at the end of the

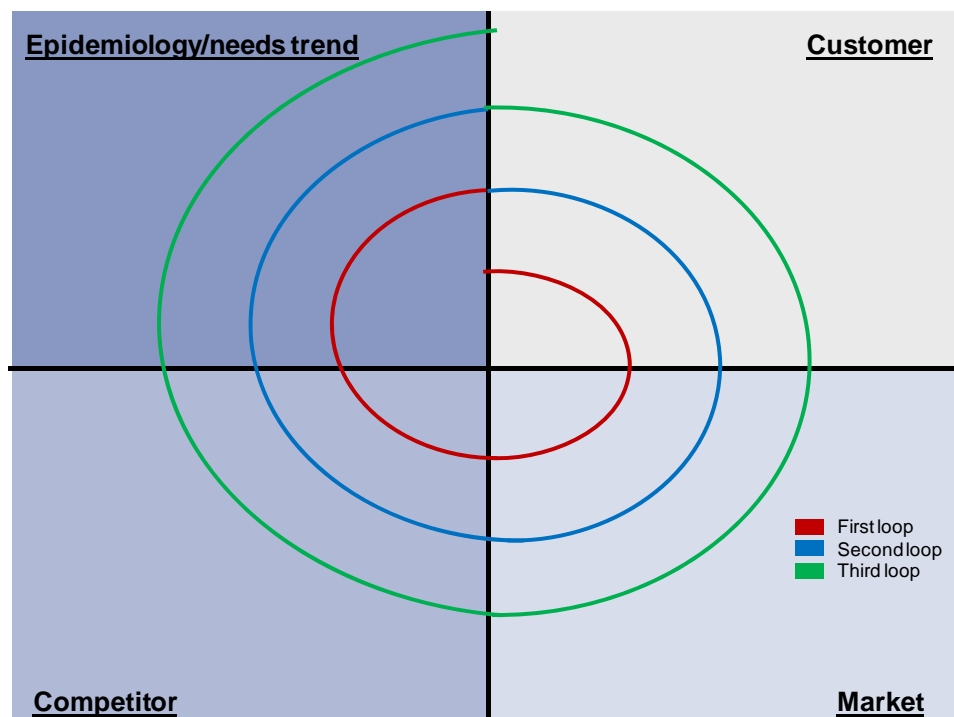


Figure 14: Spiral model for market research – Overview

⁵ Extracted from Imelli et al. (2007)

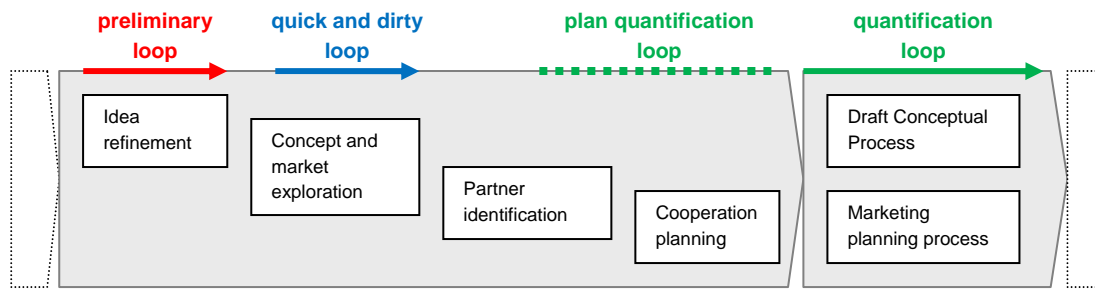


Figure 15: Placement of the single loops of the spiral model in the early stage

early stage to invest in a potential start-up, or to begin a cooperation project focused on the product development.

The three loop spiral proceeds through four main fields: customers, market, competitors, and epidemiological/need trend (Figures 14 and 15). In the *customers field*, the team analyzes 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.), while the *competitor field* includes all information about the products, market share, strategies, and so on 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 the tasks described, for example, in Pegler (2006) and Gerhards (2002), who identified more than forty marketing activities collecting four different categories of data: market, competitors, customers, and company.

4.2 First loop: Preliminary

The preliminary loop coincides with the *idea refinement* sub-process of the project initialization phase. The objective of the idea refinement process is the draft product concept, as it provides the basis for the decision to proceed in a deep market and begin concept exploration (next process step of the project initialization phase).

In this preliminary loop, the team answers the following market questions:

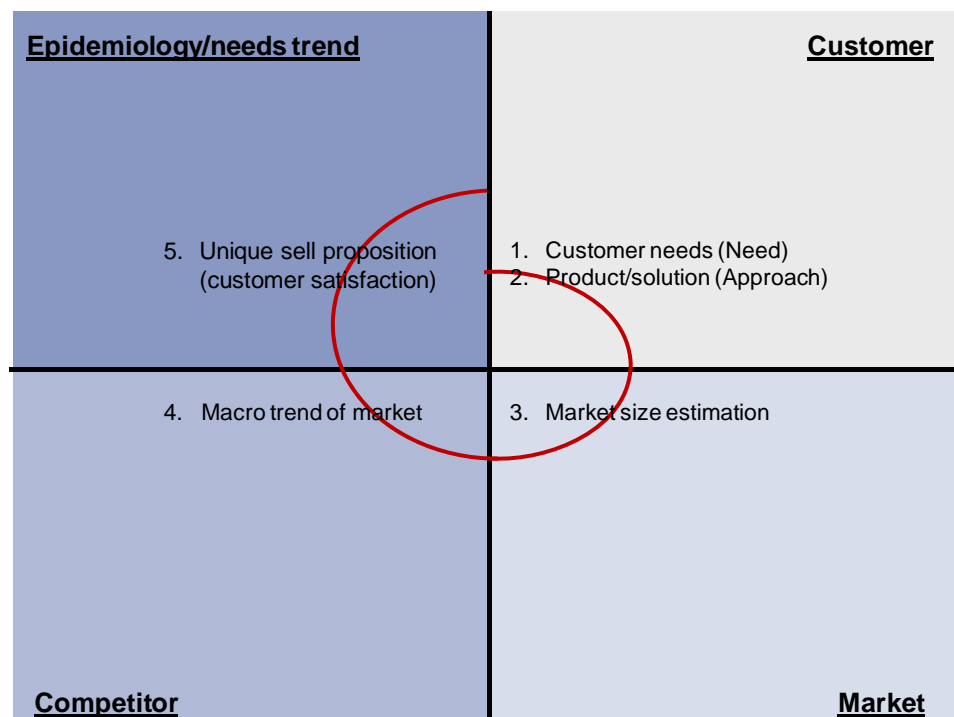


Figure 16: The first loop – Preliminary, with five tasks

- What are the customers' needs? (Need)
- What product or solution 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)

4.3 Second loop: Quick and dirty

The second market analysis loop contains many of the important aspects but, due to time and available resources, the team must absolve all tasks quite rapidly and not very deeply; therefore, we name the loop "quick and dirty." The objective of the *market and concept exploration* process 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, if so, its size. To obtain this information about the market, the questions to answer in this "quick and dirty loop" are:

- Market definition – What is the business? Is the business system easily described (product or service)?
- Definition and characterization of customers – Who is the customer? Is it the doctor/surgeon, the patient, or the government? What are the customers' needs? How does the customer decide? What are the customers' requirements concerning the core, formal, 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 the single geographical areas?
- Quantity of product sales in main geographical markets – How many products could be sold in the main geographical markets?
- Amount of sales in main geographical markets – How big is the market size in the main geographical market?

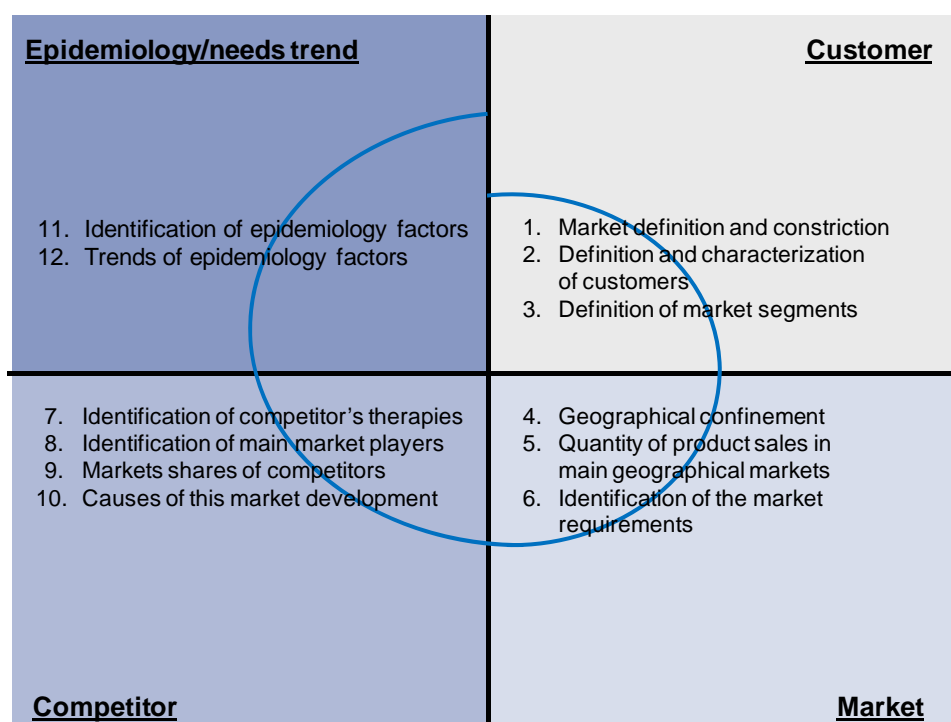


Figure 17: The second loop – Quick and dirty, with twelve tasks

- Identification of competitor therapies – Are there competitors or alternative therapies?
- Identification of main market and competitive therapy players – Who are the direct competitors? For which products? Who are the indirect competitors (competitive therapies)? For 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 causes the success or failure of competitors?
- Identification of epidemiology factors – Which kind of epidemiological factors define the development of the number of patients?
- Epidemiology factor trends – Does the trend of each factor decrease or increase? Do all factors move together? What is the trend regarding 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 has all information needed to start a long-term forecast of the system, integrating the market and epidemiological elements (see Chapter 5).

4.4 Third loop: Quantification

The third 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, the market, competitors, and trends. 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 will have some results from clinical tests. The team repeats almost all tasks from the first two loops, with the objectives being to analyze in-depth the market and quantify the potential of the tool. The quantification of the market can help the team to convince potential investors or companies to cooperate in a product development project. The third loop is surely more demanding, and the team needs to invest more resources here than during the quick and dirty loop. In total, 22 tasks are completed in this *quantification loop* (Figure 18).

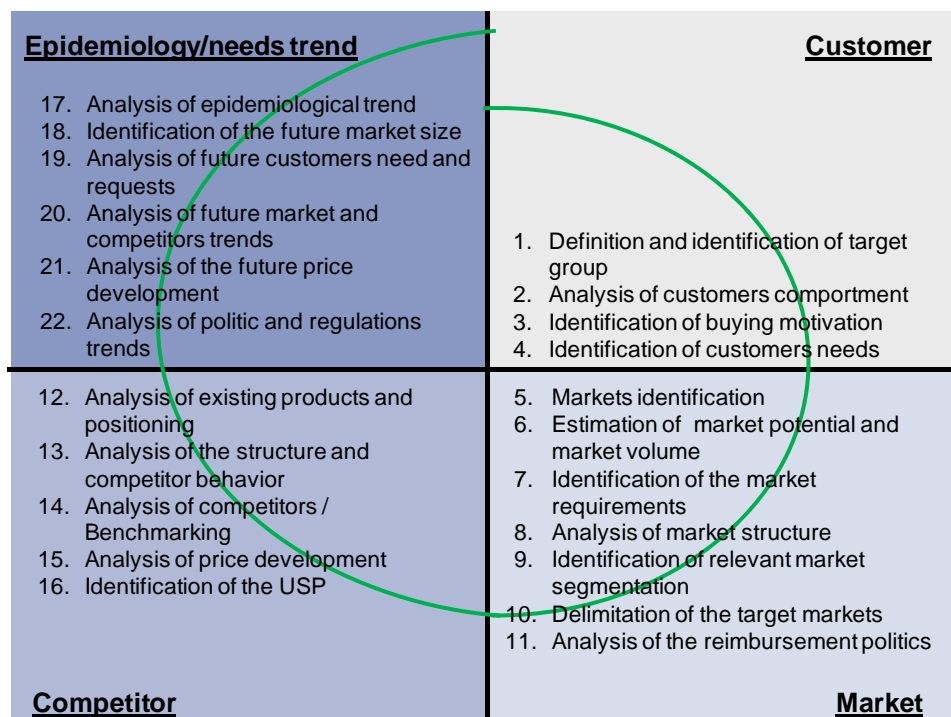


Figure 18: Third loop – Quantification, with 22 tasks

part):

- the Scenario Technique is used to identify all potential situations (Step 1 – epidemiological situation, Step 2 – market situation); and
- the Delphi Method is used to choose the most probable situations (Step 1 – epidemiological situation, Step 2 – market situation).

Figure 20 shows the whole process of scenario building and selection in the Delphi exercise for Step 1 (forecasting of epidemiological situation). It is an adaptation of Gausemeier's (1996) scenario process and the Delphi process of Fowels (1978). The main steps of the Scenario Technique (*analysis of scenario field*, *scenarios prognostic*, *scenarios generation*) are kept. The first step *scenario preparation* is replaced with the *identification of epidemiological factors* step, where the project team identifies which types of disease need the utilization of the device, and which types of epidemiological factors determine the disease. The *analysis of scenario field* step includes the analysis of each epidemiological factor and the identification of influence factors from the political, societal, demographic, social, and other trends.

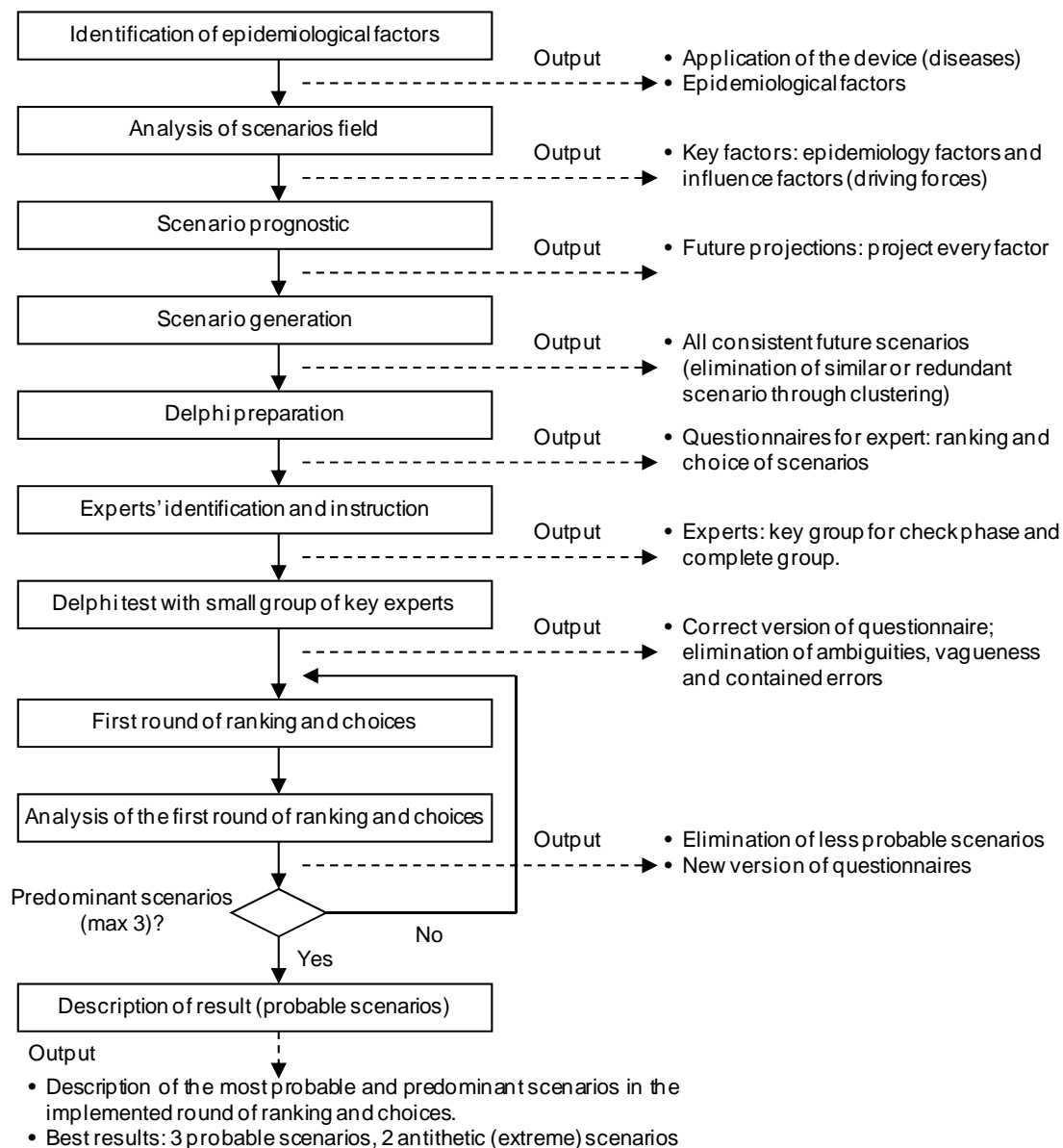


Figure 20: Integrated methodology of Scenario and Delphi methodologies.

Source: Combination of Gausemeier's scenario method (Gausemeier et al., 1996) and Fowles' Delphi method (Fowles, 1978).

The number of scenarios is limited by:

- the choice of most important epidemiological factors using Gausemeier's (1996) *Influence Matrix*,
- elimination of inconsistent scenarios using Gausemeier's (1996) *Consistence Matrix*, and
- Delphi exercises to rank the resulting scenarios in terms of probability.

The Delphi questionnaire contains 3 exercises:

- choosing the two most probable and two least probable scenarios (from the list of resulting scenarios; max. 15 scenarios);
- ranking the scenarios from the most probable to the least probable; and
- choosing the most probable from a selection of scenarios (repeated for approx. 30 different pairs of scenarios).

The Delphi exercise is repeated three or more times. The questionnaire is updated after each repetition (mainly to eliminate scenarios) but the structure stays the same. The answers from the expert panel help the project team identify 2 to 3 predominant scenarios. Two additional divergent scenarios complete the picture, and are used to test the robustness of the product concept and market forecast.

6 Resume

This technical report presents guidelines on how to conduct the *project initialization phase*, including:

- integration of the project initialization phase in the product innovation process (Chapter 2),
- activities and tasks in the project initialization phase (Chapter 3),
- *the spiral model for marketing research* (Chapter 4), and
- *the integrated methodology for long term forecasting* (Chapter 5).

The guidelines and each methodology were developed based on, and to be used for, radical medical device product innovation projects, but may also be helpful for other radical innovation projects with intense target research.

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