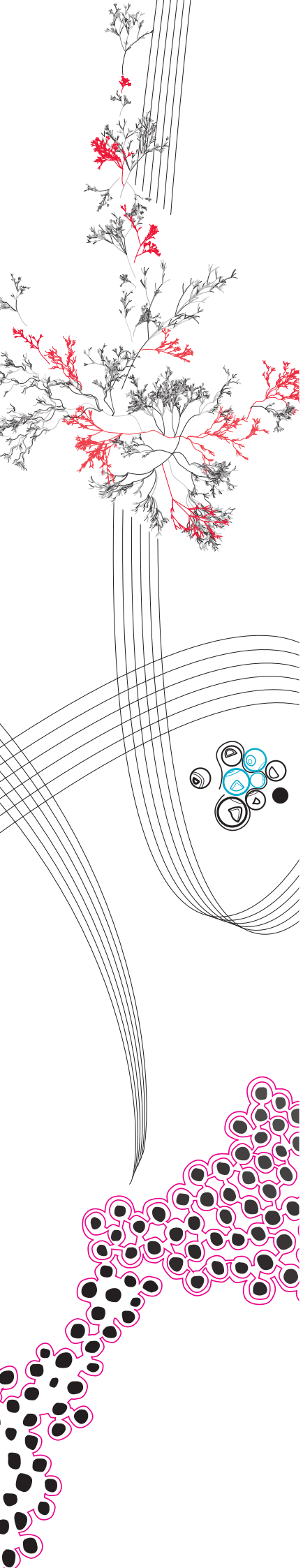

Master assignment Health Sciences

DESIGN OF A DECISION MAKING MODEL TO AID IN THE DEVELOPMENT OF MEDICAL TECHNOLOGY

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Abstract

The world moves forward with innovation, which requires time and money. Research groups can invest time, but often lack the finances needed. Therefore, groups need to apply for funding in order to carry out research. With funding received, the question remains if the medical technology being created will prove successful upon completion/market introduction. The failure rate of new products, not MT specific, is being estimated at $35\% - 40\%$. Within the current practice of funding elicitation, creation and assessment of medical technology a trend of inefficiency and non-specificity can be noted;

1. The method for handling the creation of research proposals is **inefficient** and therefore time consuming.
2. Models currently used for assessing the feasibility of the technology are **non-specific** and **inefficient**.
3. By not including certain stakeholders, a **low**er (direct) customer satisfaction and a possible **decrease** in (future) sales is expected.

The goal of this research is to develop *a structured assessment method to standardize, speed up, and support the decisions made by the R&D-team creating new MT and allocate knowledge in a more efficient way.*
Via the analyse of several research proposals, a model predicting whether or not a still to be submitted proposal regarding MT will receive funding was created. The analysis preceding the model creation allowed for the set-up of a template helping and advising in writing research proposals.
Based on the acquisition model of the ZGT Hengelo, a focus on a single purchasing stakeholder to be implemented in the Health Technology Assessment type Assistive Decision Making Model (ADMM) is made. Working from this acquisition model solutions for/indicators of/ assessment of problems identified, were created. The resulting elements were connected in a flowchart model. The element order is based on the (future) working methods of RaM.

The current version of the model supports the decisions made by the team itself by a standardized route expected to speed up the project by a more efficient knowledge allocation. The ADMM is presented as a flowchart divided into several phases, this flowchart should be interpreted as an example of how to connect these phases together, whilst the actual result of this research is a set of building blocks to implement within the design process.

Contents

1. Introduction

The world moves forward with innovation, which requires time and money. Research groups can invest time, but often lack the finances needed. Therefore, groups need to apply for funding in order to carry out research. To receive funding as a research group, a simple application has to be filled in, a so called *research proposal*.

Typically, several months of work, with no real output, is needed when applying for a funding. Simultaneously, there is a chance to end up empty handed whilst having invested substantial amounts of time and money. Figure 1.1 shows the trend of successful proposals of the last 11 year as stated by Technology Foundation STW (STW), an example of a funding agency. This gives a failure rate of $\approx 50\%$ for 2015, totalled for two of their programs [53].

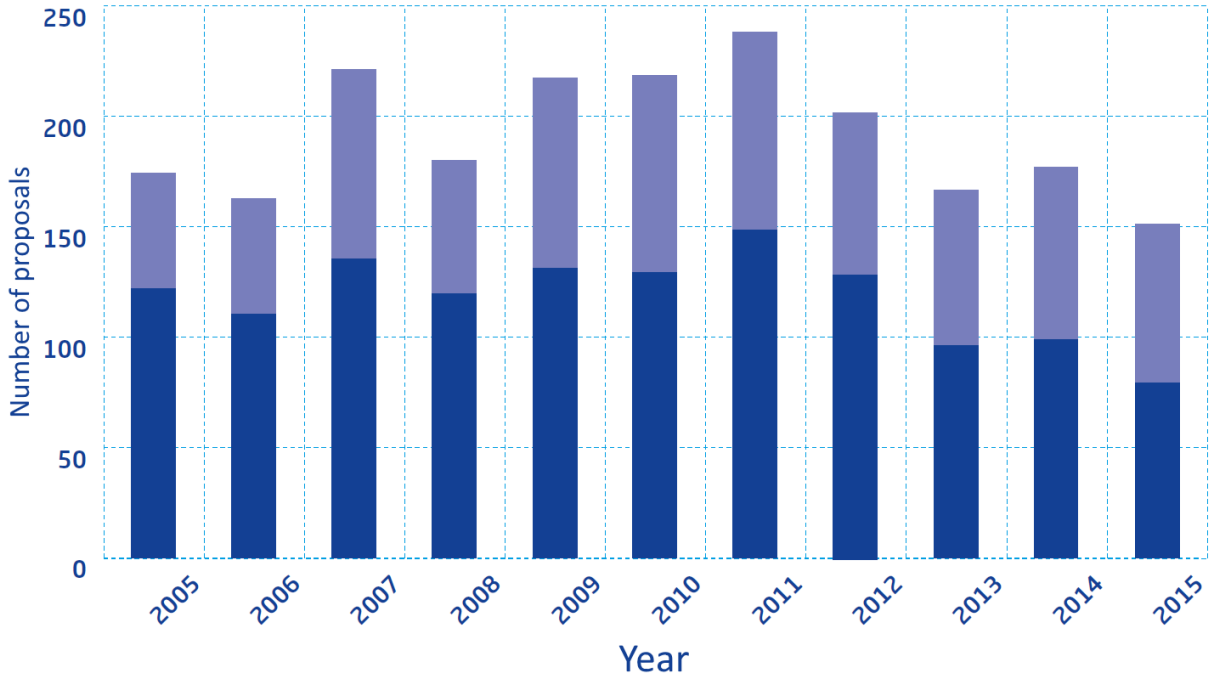


Figure 1.1.: **Number of proposals and the yearly success rate of these proposals submitted to STW of the past 11 years totalled for two of their programs [53].**
In dark the portion of rejected proposals is shown.

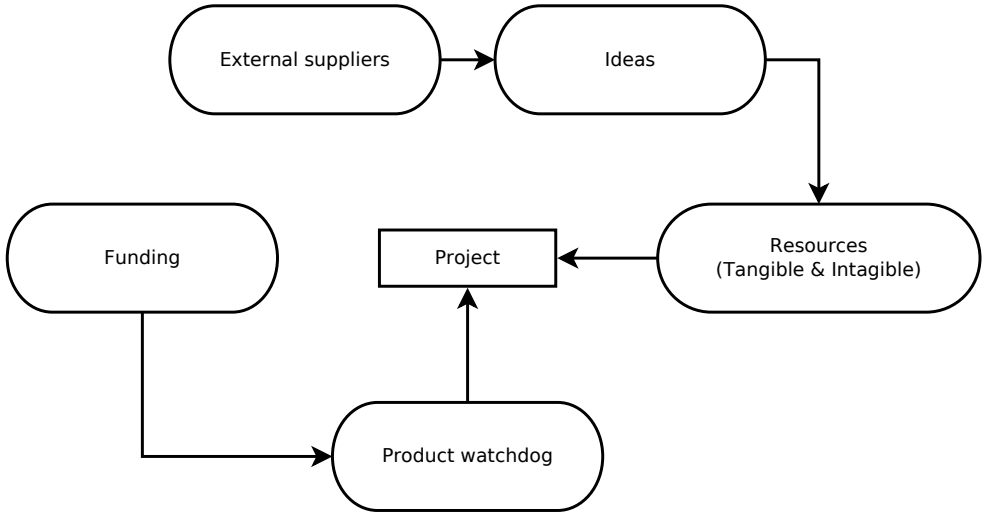
Continuing the uncertainty whether or not the funding is granted, the question remains if the medical technology (MT) being created will prove successful upon completion/market introduction. The failure rate of new products, not MT specific, is being estimated at $35\% - 40\%$ [13, 17, 28].
The development of MT stands out from other product design processes due to the time horizon of projects. Typically, a 15-year investment is required to bring a product to the market. A way to predict feasibility and success of MT, preferably early in the process, is missing [23]. These problems are apparent for university style (research) groups "too small" to internally financially support the design process of MT. 15 out of the 128 research groups at the University of Twente (UT) are directly involved in the development of MT. This shows that at this university alone $\approx 12\%$ of the researching groups suffer from the above mentioned problem [56].
As it seems, the application of a research proposal is not all that simple, and even with funding safely secured in ones back pocket, market success is not guaranteed.

1.1. The problem

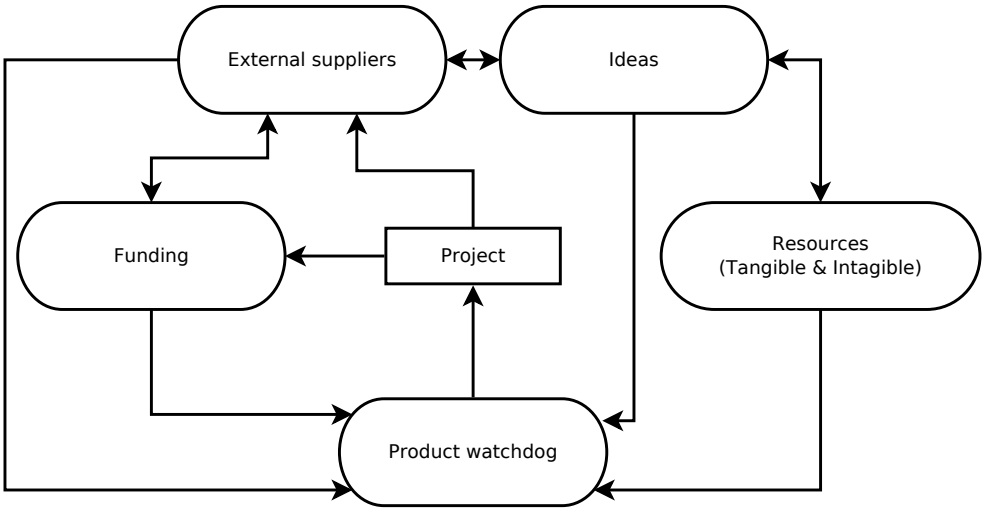
Within the lengthy projects, the main problem is that the *researchers* and *scientists* who make up the (research) groups, however trained in developing and making a case for MT, lack time and knowledge to fulfil the other requirements needed to successfully create the new MT [23]. Alongside this, the development of a method that is able to predict the feasibility and the success of MT has been put forward [23]. For this research the following bottlenecks have been identified via project meetings with designing parties and within literature [23, 29, 40, 57, 60].

1. Receive funding (with a process that is as efficiently as possible).
2. Adjudicating the feasibility of the MT as efficiently and/or early as possible.
3. Interaction with stakeholders as to increase the feasibility of the MT.
4. Solid decision making, with regards to the design choices made, within the design process of the MT.

By placing five standard design process elements, linked to the four points mentioned above, alongside the "Project" in Figure 1.2a, an illustration of interactions between these elements emerges. This is in no sense a complete representation of the current practice, but the limited amount of interaction between these problem elements can be seen. At the end of this research, hopefully connections as suggested in Figure 1.2b are reached. So solving the problems within the elements. To better understand these issues, each of the problem(s) within the four elements is discussed further in Chapter 2.



(a) **Example of current process element connections [23, 29, 40, 57, 60]**



(b) **Example of improved process element connections [23, 29, 40, 44, 43, 57, 60]**

Figure 1.2.: **Example of design process element connections experienced within research groups and a proposed improved connections [23, 29, 40, 44, 43, 57, 60]**

1.2. Research goals

The goal of this research is to develop *a structured assessment method to standardize, speed up, and support the decisions made by the R&D-team creating new MT and allocate knowledge in a more efficient way.*
To achieve this, a set of sub-goals can be set up.

- Provide MT-creator with increased insight in how to manage their decision making process surrounding MT, to increase product success
  - by means of a structured way of operations/a model.
  - by increased insight in dealing with the steps leading up to the creation of a research proposals.
- Provide MT-creators with increased insight in how stakeholders, restricted to those described in Chapter 4, wish to purchase MT.
- Provide MT-creators with a standardized way to write their research proposals.

During the project, the issue of *"We don´t know what we don´t know."* was brought forward by the supervisors. Whilst not being the (main) focus of this research, the information gathered here will contribute to lifting a piece of the veil surrounding the field of medical technology purchasing.

1.3. Purposed research

To reach these goals, a(n Early) Health Technology Assessment type Assistive Decision Making Model (ADMM) will be created to help MT-creators hone their decision making process. This enables the socio-economic factors important to the relevant stakeholders to be taken into consideration as early as possible. Ultimately giving the products a higher chance of success on the market. These factors will be extracted from literature, meetings with the epistemic parties within the UT and the Ziekenhuis Groep Twente Hengelo (ZGT Hengelo) department of radiology and will flow from an analysis of several proposals submitted to STW. The feasibility of the presented model will be tested by a single run of the McRobot project, this project will be introduced in Section 4. Inversely the McRobot project will also be assessed in accordance with the ADMM.

As a secondary benefit, the initial steps in the creation of ADMM provides the opportunity to create a Funding Proposal Model (FPM) that assesses the success chance of, and assists in writing research proposals. With this the amount of time and effort required for these applications can be decreased by pinpointing the, most of the time, hidden requirements of (governmental) funding agencies and providing standardized format for the actual proposal.

2. Method

The goal is to develop a model to guide the uncertainties in the development and decision making process regarding medical technology.
In order to develop this model, first a method for the elicitation of funding is created. This will be done based on a literature study of current best practice, extending this into a model structuring the creation and assessment of research proposals and thus the elicitation of funding. A validation will occur based on a sample of case studies. This Funding Proposal Model (FPM) will serve as input for the (Early) Health Technology Assessment type Assistive Decision Making Model (ADMM).
For this ADMM, development also started with a literature study. The study will again be extended into a model designed to structure the development, decision making process and assessment of medical technology. The case study used to test the feasibility of this ADMM is the McRobot project of the Robotics and Mechatronics group (RaM), see Section 2.1.

To create a model that advises in the development of new MT, a clear understanding of; the socio-economic factors valued by relevant stakeholders; knowledge of the decisions concerning purchasing by these stakeholders; and the general design and decision making process within RaM, is needed [23, 26, 29, 40, 57, 60]. The here mentioned points are selected because:

1. Indexation of the stakeholder
    a) With indexation of the relevant stakeholder the scope of the research can be narrowed greatly. This consequently increases the specificity of the model(s).
    b) With indexation of the relevant stakeholders the points mentioned below can be performed.
2. Socio-economic values
    a) The socio-economic values not only indicate what stakeholders want, but are also an indicator of the values and virtues deemed important by society as a whole. Products that can capitalize on these values can so become, and are allowed to become, successful [26];
    b) By fulfilling these societal needs, projects will become more/totally applicable for (governmental) funding elicitation. These agencies greatly prioritize benefit for society [43, 44];
3. By knowing the purchasing behaviour of the customer, the product can be designed to not only fit the needs of the user but also be (more) directly suited for sales [26].

A major pitfall of product design is the thought that the costumer is always the user and vice versa. In the case of medical products, where the hospital buys the products whilst the medical staff uses them, this is almost never the case;

4. An overview of the working methods of RaM makes clear where and how this model could be implemented in practice.

As introduced, the research will be split into two major sections, that of the FPM and the ADMM. The first will tackle the understanding of the socio-economic factors valued by all relevant stakeholders. This FPM will also lead to *increased insight in dealing with research proposals* and eventually lead to *a standardized way to write research proposals*. The latter charts the design and decision making process within RaM. Within the ADMM all the puzzle pieces, of which the FPM is one, will be put into place. These separate method descriptions for the two sections will be presented in Chapters 3 and 4 respectively.

2.1. Robotics and Mechatronics group

The research will be conducted for the Robotics and Mechatronics group at the UT. Being a university based research group, this group can be used as a starting point and will function as a representation of the population giving useful insight in the workings of relevant research groups.

"The Robotics and Mechatronics group deals with application of modern systems and control methods to practical situations. Focus is put on robotics, as a specific class of mechatronic systems. The research is embedded in the CTIT and MIRA institutes. The research of the group is application oriented. The main goal is to investigate the applicability of modern systems, imaging and control methods to practical situations in the area of robotics.

Robot application areas we investigate are: inspection robotics (UAVs, UGVs, UUVs); **medical robotics** (assistance to surgeons, diagnostics) ..."

RaM website
UT
01-06-2016

2.2. Current practice

The bottlenecks presented in Chapter 1 will be analysed via a State of the Art (SotA) literature search.

2.2.1. Receiving funding

To create technology, on a very basic level the 5 steps listed below need to be taken [26].

1. Create idea
2. Develop idea into new MT
3. Test new MT
4. Redevelop new MT
5. Sell new MT

All these steps take up financing from the (research) groups. Because one is not dealing with major corporations such as Phillips, Siemens or Johnson & Johnson, but rather with groups that do not have their own financial buffer, a form of external funding is needed. This is especially apparent with fundamental research being performed at university-like institutes. Although other factors for success are applicable: the means available; selection of the correct sales market; size; growth and the competitiveness within this market, the financial health of the project remains an absolute condition [14, 23, 29].

For most of the research groups housed within a university, the usual route for receiving this financial support is the application to a funding agency via a research proposal. STW is part of the Dutch organisation for Scientific Research (Dutch: Nederlandse organisatie voor Wetenschappelijk Onderzoek (NWO)) that hands out indirect government funding for scientific research under the Open Technology Programme (OTP) and is an example of such an external financier [44].
STW connects people and resources to develop technology with economic value that contributes to the societal challenges by bringing scientific researchers and potential users together and by funding excellent research in the applied and technical sciences [44]. The focus will be put on this STW because the McRobot project of RaM, see Chapter 4, will apply for funding within this OTP.

Most of the researchers lack expertise in the area of funding elicitation, and there is always the chance of rejection by the funder [23]. By writing a research proposal, accompanied by the preliminary research needed, valuable time and money is invested by a non-expert leaving work that he/she is (optimally) suited for. All this is invested into a project that might still fail due to rejection of funding, or to have it fail when creating a prototype, or even when the product is put on the market. But before a proposal can even be written, the applicants have to wade through many available funding programmes to select one that

is most suited to them.
Even by diminishing the amount of funding to choose from, applying for funding still proposes a challenge. For the writing of the proposals, no real help besides the guidelines provided by the agencies is available.

Overall this leads to an inefficient method for the creation of research proposals.

2.2.2. Adjudication of feasibility

As a part of the funding application the feasibility of the MT has to be judged. After receiving funding, during the design process, the MT still needs to be followed and assessed with respect to its feasibility and expected commercial success. By doing so, potential unsuccessful projects can be terminated early in the process. This type of assessment is being practised in the field of Health Technology Assessment (HTA) and proves an excellent vantage point.

(Early) Health Technology Assessment

The aim of Early Health Technology Assessment (EHTA) and HTA is to inform development decisions and, ultimately, decrease the failure rate by selection of projects that are most likely to become successful by assessment at different decision moments within the development process [18]. It does so by trying to decrease the failure rate at each stage of the development process, and enhancing the efficiency of R&D and resources [18, 37]. Figure 2.1 shows different HTA stages of the development for a MT. On the bottom, the decreasing amount of uncertainty concerning the design of the MT is illustrated.

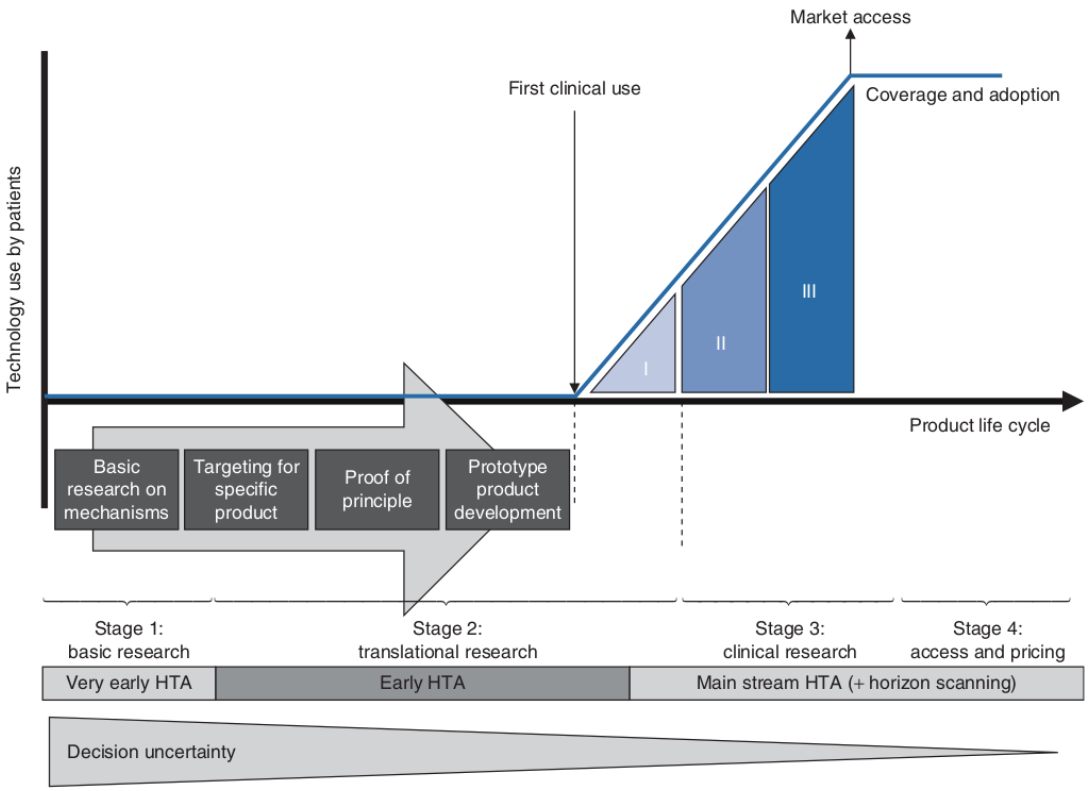


Figure 2.1.: **Simplified flowchart of the stages in medical technology development [37]. The decreasing amount of uncertainty is illustrated at the bottom of the figure.** [30]

Coupled with the uncertainty expressed via the triangle in Figure 2.1, there are several additional reasons for failed device development. One of these factors is the late evaluation of the potential that a MT holds within the healthcare practice. This evaluation is usually performed after a prototype design is finalized [37]. With such a late evaluation, it is very likely that, having a large uncertainty present in the earlier stages, an un-beneficial decision has already been executed.
Alongside this, the early phases of development are loaded with enthusiasm of the design team and the desire to pioneer. But with the large amount of uncertainty this can result in false judgement based on insufficient information [5, 37]. At these early stages of the process a lot can be gained by providing more security about the factors assessed to be important by the relevant stakeholders the project, decreasing the chances for the continuation of unsuccessful projects.

Because there is a large amount of models available that approach the problem from either of the two sides, feasibility and expected commercial success, all fulfilling $\leq 50\%$ of these tasks, a more detailed SotA-analysis/description will be given of the *NewProd System* and the *EUnetHTA - HTA Core Model*®. The choice for these models is made because the

NewProd System has been around for a long time, still being viewed as valid, and is in some sense an archetype model for the adjudication of (the feasibility of) new products in general [7, 29]. On the other side of the spectrum stands the *EUnetHTA - HTA Core Model*®, a large European project attempting to reach a goal quite similar to this research, providing a model that is specifically created for the assessment of MT and one of the most widely used sets of guidelines on how to perform such an analysis [42]. Because the healthcare sector is such a niche, a model targeted towards this sector provides an excellent vantage point.

NewProd System

The NewProd System fulfils its screening/assessment task by separating probable successful products from the unsuccessful ones. It does this with $\approx 84\%$ certainty by basing on the premise that the desirability, attractiveness, and eventual success can be predicted by the examination of the project profile [14].
Being a scoring model type of analysis, the NewProd System is plagued by the accompanying difficulties [50]. Models like these rely on subjective ratings leading to a discussion of the reliability of the input. When analysing anything at these early stages, such subjective ratings are often the only source of data. Combining ratings from several evaluating parties consequently increases the reliability for each of the inputs [50].
A scoring model remains a good screening tool when taking several intrinsic characteristics into account [14]. A big advantage is its property to make highly judgemental decision somewhat more objective and delivers an easy to understand, use and applicable model. This objectivity is jeopardized by the danger of possible oversimplification and the bias and/or error within the question and weights selection in which certain items are possibly present in duplicates [14, 25, 50].
The NewProd System distinguishes itself from other scoring models by being derived from a large number of past new product successes and failures [14]. These were however not MT specific, coupling this with the general issues present in a scoring model, there is still a large gap present before implementation within MT projects can be achieved here.

EUnetHTA - HTA Core Model®

The EUnetHTA - HTA Core Model® is a methodological framework for collaborative production and sharing of HTA information [54].
It contains, among other things, an extensive list of generic questions and elements for assessment divided into nine domains, that can be used during a EHTA or HTA [42, 54]. With this it provides a standard format for the output of such HTA projects [42, 54]. The main goal of enabling international collaboration in HTA information creation and achieving efficient sharing of these results is tackled as to avoid redundant overlap in work within different regions and countries [54].

Content, quality and focus of HTA varies significantly, making structuring research difficult [54]. Because the model contains "only" generic questions, a large element of un-specificity overshadows the model [54]. Even if the model states to address these problems with its design originally developed through applications of medical and surgical interventions, the connection with the actual design process still lacks. These hospital-based HTA products should be in line with the needs of the head decision maker within the hospital, but the overlap between the EUnetHTA - HTA Core Model® and the informational need of hospital decision makers is currently unknown [42].

The assessment of MT with either of these models would be inefficient because many assumptions and alterations with regards to the non-specific models are needed to use the models correctly in MT-project situations.

2.2.3. Stakeholder interaction - Expertise interaction

To create a successful product, stakeholders need to be taken into consideration. Stakeholders are all parties involved with the design and finished product. This is nothing different when dealing with MT. Even within the own education of the UT, the model illustrated in Figure 2.2 is put forward. Here the red rectangle, shown in the top right corner, indicates how early stakeholders become involved with the process. In the case of MT the most apparent stakeholders are the medical staff, consisting from medical specialists and nursing staff, and the patients. However, meetings with medical staff point out that most of the design teams systematically choose to only incorporate preferences elicited from medical specialists, and not other users such as the nursing or technical staff [57, 60]. Because these factions also influence the purchase of new MT within the hospital, this is extremely unbeneficial for the selling party [57].

Excluding relevant stakeholders from the design process leads to a lower user satisfaction and a possible decrease in (future) sales.

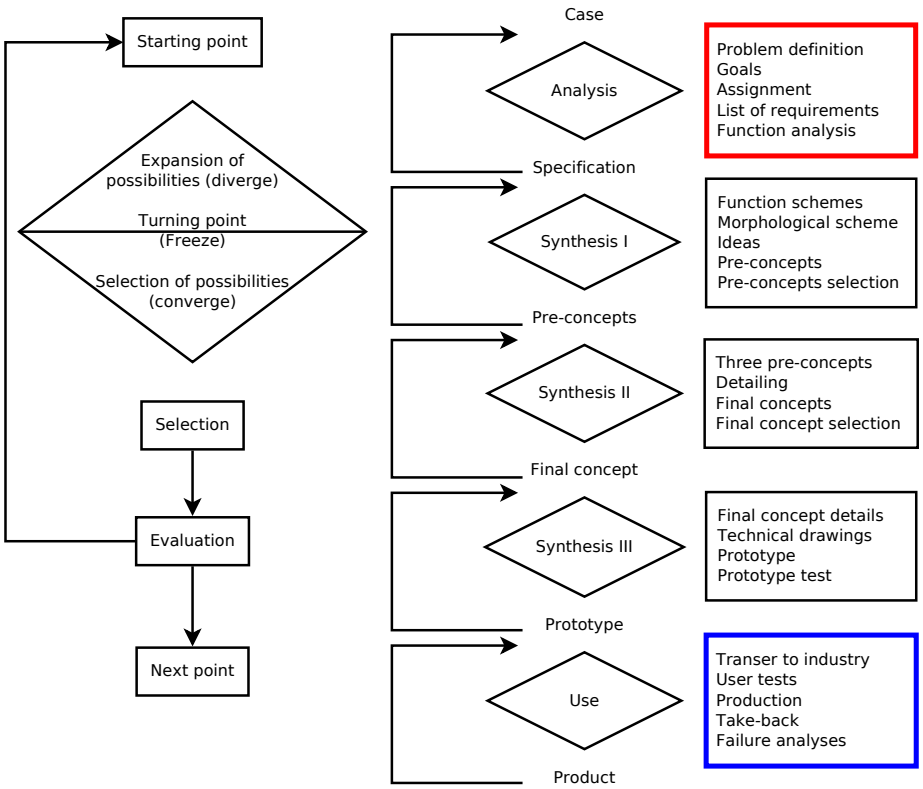


Figure 2.2.: **Methodical process for designing biomedical products [26].**
The red rectangle, top right corner, indicates how early in the process stakeholders become involved.
The blue rectangle, bottom right corner, shows that the product is subjected to "user tests".

2.2.4. Solid decision making

One of the starting reasons of this research was the expressed need for "solid decision making" with regards to the design choices made, within the design process of the MT [23]. When a decision between option A and B needs to be made, the R&D-team often bases its choice on gut feeling/personal preference [23]. This problem stands at the core of the ones previously discussed.
Returning to Figure 2.2, the blue rectangle shows that the product is subjected to "user tests" as one of the final steps within the design process [26]. Meaning that these decisions, greatly affecting the course of the project and product, should always be based on the effect they have on stakeholders associated with the product [23, 26]. By utilizing such decision making, development will conclude in an easier selling product with a higher quality [26].

Making unjustified design decisions leads to a lower user satisfaction and a possible decrease in (future) sales.

2.3. Chapter conclusion

Within the current practice of funding elicitation, creation and assessment of MT a trend of inefficiency and non-specificity can be noted;

1. The method for handling the creation of research proposals is **inefficient** and therefore time consuming [23].
2. Models currently used for assessing the feasibility of the MT are **non-specific** and **inefficient** [14].
3. By not including certain stakeholders, a **low**er (direct) customer satisfaction and a possible **decrease** in (future) sales is expected. [23, 26].

When designing products, any element of inefficiency means unnecessary drainage of funds. The lack of finances and constraints of a budget are one of the key issues leading to this research [23]. Thus when such a negative loop is present, this will only decrease the (fundamental) output of the research groups and thus halting development of other technologies.
With this the global section of literature study is concluded. Now the first steps towards the actual development of the FPM and the ADMM can be taken.

3. Method: Funding

This first step being the indexation of the socio-economic values. These socio-economic values, to be referred to as *points of interest*, will be extracted through creation and analysis of the FPM. They are the foundation on which the ADMM will be build and are quite abstract to define, but they (help to),

- indicate where societal preferences lie.
- indicate where societal interests lie.
- indicate where governmental preferences lie.
- indicate where governmental interests lie.
- indicate where the preferences of the epistemic community lie.
- indicate where the interests of the epistemic community lie.
- etc.

During the analysis, initially only used as a first step in the creation of the ADMM, it became clear that its results could serve a secondary benefit. It facilitates the creation of the Funding Proposal Model (FPM) which can be used to predict the success of the proposal and can be directly implemented into the ADMM.
To implement the information extracted from this FPM the following step are taken.

1. Analyse successful and unsuccessful research proposals
    a) Create framework
    b) Validate framework
2. Extract input from proposal analysis for ADMM
3. Implement FPM into ADMM

STW research proposals

To come to the points of interest, 6 successful STW proposals were compared alongside the STW/OTP guidelines. The proposals are listed in Table 3.1.
The points of interest are partially extracted from proposals because these funding agencies possess "market knowledge". In the case of STW, being a government representative, besides this market knowledge there is also an amount of societal and administrative information hidden within their judging procedure. When scoring proposals, STW will check each of these points. By implementing these into the ADMM, the model will not only

use this knowledge, but also be on par with the STW procedures, increasing proposal application success and help in creating successful research proposals.

As previously stated, a focus is put on STW because this is the program the McRobot project will elicit funding from. Furthermore STW is a Dutch organization which helps keeping the research scope to remain on a (Dutch) national level as defined by the inclusion of the ZGT Hengelo.

Table 3.1.: **Overview of research proposal used to set up the FPM.**
Proposal 7 was only used in the validation part of the model.

	Project title	Involved group(s)	Institute	OTP	Granted
1.	Reflex leg	Electrical Engineering	University of Twente	no	yes
		Biomedical Engineering Advance Robotics			
		Rehabilitation medicine	Roessingh		
2.	Heath2Control		Eindhoven University of Technology	yes	yes
3.	RObot SEnsors	Mathematics and Natural Sciences Industrial Technology and Management	University of Groningen	no	yes
		Electrical Engineering	University of Twente		
4.	State of the art mechatronics for the design of a next generation haptic feedback enhanced robot system for minimally invasive surgery	Mechanical Engineering	Eindhoven University of Technology	no	yes
5.	Instruments for Minimally Invasive Techniques Interactive Multi-Interventionals Tool	Biomechanical Engineering	Delft University of Technology	no	yes
		Precision and Microsystems Engineering Electronic Instrumentation			
		Biomedical Engineering	Erasmus University medical Center Rotterdam		
		Dept. of Cardiology Biomedical Imaging Group Center of optical Diagnostics & Therapy Clinical Electrophysiology			
		Biomedical Engineering & Physics	Academic Medical Center		
		Dept. of Physics	VU University Amsterdam		
		Control Engineering	University of Twente		
		Obstetrics and Fetal Medicine	Leiden University Medical Center		
		Inst. of Animal Sci, Exp. Zoology group	Wageningen University & Research Center		
6.	MÖBIUS: Additive Manufacturing of Complex Precision Flexure Mechanisms	Interactive Mechanisms and Mechatronics	Delft University of Technology	no	yes
		Mechanical Automation & Mechatronics	University of Twente		
7.	Pipe Inspection Robot for small diameter pipes	Robotics and Mechatronics	University of Twente	no	no

3.1. Creating the FPM

To develop the model, a seven-step guideline that is proposed within literature is followed [14].

1. Develop a reasonable set of screening items or questions.
2. Identify a sample of past successes and failures within the corporation.
3. Request one or more evaluators to rate each of the projects based on the criteria.
4. Derive a subset of key underlying dimensions and a success equation.
5. Validate the model.
6. Develop the computer software to handle the evaluator´s inputs.
7. Establish a procedure within the firm to facilitate the use of the model.

From these only the first four points will be implemented within this research. Due to a limited amount of time and resources (available research proposals), only a small step towards the validation of the model will be taken.

3.1.1. Develop a reasonable set of screening items or questions

To create the screening items and questions an iteration of the NewProd model, as described in Chapter 2, is used [14]. The original model describes how to screen new products in order to define the probability of success for these new products on the market and is intended to screen non-MT products [7, 14].
The iteration used was created as part of a yet to be published paper within the Health Technology and Services Research group within the University of Twente (HTSR) and is MT specific. This altered version can be found in Appendix A.
The section division and relative weights of the sections are slightly altered to, again, be more specific for this utilization. The existing lists are supplemented with several new questions and given a typical five-level Likert scale answering options, denoted with 5Ls. Several of these questions will have a five-level Likert scale with a "pass or fail" coding, denoted with 5Ls-pf, to indicate a direct expected failure of the proposal when answered with a "Fail". See Table 3.3 for the Likert scale answer options. The normal procedure of the NewProd model states a ten-level Likert scale [7]. Because rating items is found difficult by respondents, the switch to a five-step Likert scale is opted [58]. With this condensation the answer coherence is expected to increase [58].
Additional there are several open questions (OQ) placed to help answer these 5Ls and 5Ls-pf questions.

Table 3.2.: **Answers and corresponding scoring system of the FPM for the two types of questions.**

	Score	
	5Ls	5Ls-pf
Strongly disagree	2	Fail/No
Disagree	4	Fail/No
Neither agree nor disagree	6	Fail/No
Agree	8	8
Strongly agree	10	10

Screening questions

Using roughly the same division as in Appendix A, the screening questions are listed. These questions are created based on the NewProd model by Cooper and are supplemented with questions based on literature and interviews with staff at ZGT Hengelo, UT and RaM [14, 15, 23, 29, 40, 57, 60]. To indicate the origin of the question, the following notes are used.

Note	Meaning
[1]	Directly taken from NewProd System iteration presented in Appendix A.
[2]	Altered from NewProd System iteration presented in Appendix A.
[3]	Newly implemented based on literature and epistemic information.

	Section A Weight of 16%(≈ 0.15625) **Medical technology superiority/quality in comparison to the SotA**	
1	The state of the art has been thoroughly investigated.	5Ls[3]
-	What is, scientifically speaking, the starting point of the research?	OQ
-	What is the SotA lacking?	OQ
-	What needs to be added to the SotA.	OQ
2	It is possible to create that what is missing.	5Ls-pf[3]
3	The technology address clinical need better.	5Ls[1]
4	The technology offers unique features for users.	5Ls[1]
5	The technology has a higher quality than the SotA.	5Ls-pf[2]
6	The technology performs an unique task for users.	5Ls[1]
7	The technology reduces buyer their costs.	5Ls[1]
8	The technology is innovative.	5Ls[3]
9	The technology brings clear health benefits to society.	5Ls[2]
10	The technology will increase potential user satisfaction.	5Ls[1]

	Section B Weight of 9%(≈ 0.09375)	
	Economic advantage to future users in comparison to the SotA	
1	The technology is priced lower than competing technologies.	5Ls[1]

In question section C, questions 1a trough 1g will be counted as one. This because not each of the statements needs to be true for a real world problem to arise.

	Section C Weight of 16%(≈ 0.15625)	
	Advantages to future users with respect to disease characteristics	
-	What is the real world problem?	OQ
-	Why is this a real world problem?	OQ
1a	There is a too high mortality rate.	5Ls[3]
1b	There is a too low 5-year survival rate.	5Ls[3]
1c	There is a too high Incidence rate.	5Ls[3]
1d	The costs per patient are too high.	5Ls[3]
1e	There is a too high severity of disease./There is to little QoL.	5Ls[3]
1f	There is a scientific relevance to this research.	5Ls[3]
-	What are the socio-economic consequences to the disease?	OQ
2	The disease causes removal out of workforce.	5Ls[3]
3	The disease causes removal of direct family out of workforce.	5Ls[3]
4	The disease causes a decrease in consumer spending.	5Ls[3]

	Section D Weight of 16%(≈ 0.15625)	
	Company-project fit for this project	
1	RaM has the necessary engineering skills.	5Ls-pf[2]
2	RaM has the necessary other expertise.	5Ls-pf[2]
3	RaM has the necessary intellectual property revision.	5Ls-pf[2]
-	Does RaM have suitable applicants?	OQ
-	Does RaM have expertise/is capable within the subject area?	OQ
4	RaM has the necessary R&D resources.	5Ls[1]

	Section E Weight of 9%(≈ 0.09375)	
	Marketplace	
1	Buyers have a need for the technology.	5Ls[1]
2	Size of the target population is adequate for distribution.	5Ls[2]
3	Buyers are willing to pay for the technology (willingness to pay).	5Ls-pf[1]
4	The technology is set in a fast growing market.	5Ls[1]

	Section F Weight of 3%(≈ 0.03125)	
	Market competitiveness	
1	There is no intense price competition in the market.	5Ls^2
2	There are clear health benefits.	5Ls^1
3	There are no changing user needs.	5Ls^2

	Section G Weight of 6%(≈ 0.0625)	
	Medical technology scope	
1	It is a market derived idea.	5Ls^1
2	It is a new technology idea.	5Ls^2

	Section H Weight of 9%(≈ 0.09375)	
	Healthcare compatibility fit of the technology	
1	It adheres to healthcare market regulations.	5Ls^1
2	It has no a learning curve when used.	5Ls^2
3	It fits in with existing work procedures.	5Ls^1
4	It poses no financial burden for patients.	5Ls^1
5	It adheres to the reimbursement scheme.	5Ls^1
	There exists a willingness to accept the technology	
6	* by medical staff.	5Ls-pf^2
7	* by patients.	5Ls-pf^2
8	* by others.	5Ls-pf^2
9	Healthcare specialists were involved during the design.	5Ls^2
10	Healthcare staff was involved during the design.	5Ls^3
11	It has trail possibilities.	5Ls^1

	Section I Weight of 16%(≈ 0.15625)	
	Utilization (proposal)	
-	What is the proposed utilisation?	OQ
-	How to realise this proposed utilisation?	OQ
	* What will each user (group) benefit?	OQ
	* How will the end product reach the user?	OQ
	* How big is the chance that the proposed utilisation will occur?	OQ
1	The proposed utilization is achievable.	5Ls-pf^3

3.1.2. Identify a sample of past successes and failures within the corporation

Identification of past successes and failures has already been performed as to create the above criteria. See Table 3.1 for an overview of the research proposals identified and analysed. These proposals will again be used in the validation process in Section 3.2.

3.1.3. Derive a subset of key underlying dimensions and a success equation

The weights of each of the questions stated in Section 3.1.1 were derived from the existing weights in Appendix A. Combining these weights and the scoring system seen in Table 3.2, the maximal and minimal scoring possibilities can be calculated via Equations 3.1 and 3.2, denoted in Table 3.3.

$$Section_{max} = n_{questions} * score_{+} * \frac{score_{w}}{n_{questions}} \tag{3.1}$$

$$Section_{min} = n_{questions} * score_{-} * \frac{score_{w}}{n_{questions}} \tag{3.2}$$

with

Unit	Name	Description
$n_{questions}$	Number of questions	Number of questions within the relevant section
$score_{+}$	Score highest	Highest score per section in correspondence with Table 3.2
$score_{-}$	Score lowest	Lowest score per section in correspondence with Table 3.2
$score_{w}$	Weight	Weight of each section

Table 3.3.: **Maximal and minimal scoring possibilities of the FPM.**

Section	Equation	max	Equation	min
A	$10 * 10 * \frac{16}{10}$	160	$Fail$	$Fail$
B	$1 * 10 * \frac{9}{1}$	90	$1 * 2 * \frac{9}{1}$	18
C	$4 * 10 * \frac{16}{4}$	160	$4 * 2 * \frac{16}{4}$	32
D	$4 * 10 * \frac{16}{4}$	160	$Fail$	$Fail$
E	$4 * 10 * \frac{9}{4}$	90	$Fail$	$Fail$
F	$3 * 10 * \frac{3}{3}$	30	$3 * 2 * \frac{3}{3}$	6
G	$2 * 10 * \frac{6}{2}$	60	$2 * 2 * \frac{6}{2}$	12
H	$11 * 10 * \frac{9}{11}$	90	$Fail$	$Fail$
I	$1 * 10 * \frac{6}{1}$	90	$Fail$	$Fail$
Total		930		$Fail$ (68)

Combining the calculation method of Table 3.3 and the scoring system introduced in Table 3.2 the theoretical lowest score of a proposal without a "Fail" can be calculated with Equation 3.3, as seen in Table 3.4.

$$\text{Lowest score without a "Fail"} = \frac{((n_{questions-pf} * score_{-}) + ((n_{questions} - n_{questions-pf}) * score_{-}) * score_{w}}{n_{questions}} \tag{3.3}$$

with

Unit	Name	Description
$n_{questions-pf}$	Number of questions "Pass/Fail"	Number of 5Ls-pf questions per section

Table 3.4.: **Theoretical lowest score of a proposal without a "Fail" of the FPM.**

Section	Equation	Lowest "Pass"
A	$((2*8)+(8*1)) * \frac{16}{10}$	38
B	$((0*8)+(1*1)) * \frac{9}{1}$	9
C	$((0*8)+(4*1)) * \frac{16}{4}$	16
D	$((3*8)+(1*1)) * \frac{16}{4}$	100
E	$((1*8)+(3*1)) * \frac{9}{4}$	25
F	$((0*8)+(3*1)) * \frac{3}{3}$	3
G	$((0*8)+(2*1)) * \frac{6}{2}$	6
H	$((3*8)+(8*1)) * \frac{9}{11}$	26
I	$((1*8)+(0*1)) * \frac{6}{1}$	56
Total		279

Hypothesis

With this a first iteration of the success equation, Equation 3.4, can be created.

$$\begin{aligned} \text{if} \quad & Total \geq 279 \quad \& \quad Total \neq \text{Fail} \\ & \qquad\qquad\qquad\qquad Successful \\ \text{elseif} \quad & Total < 279 \quad \& \quad Total \neq \text{Fail} \\ & \qquad\qquad\qquad\qquad Unsuccessful \\ \text{elseif} \quad & Total \geq 279 \quad \& \quad Total = \text{Fail} \\ & \qquad\qquad\qquad\qquad Unsuccessful \end{aligned} \tag{3.4}$$

3.2. Validation

To perform the validation of the model and its success equation, the proposals number 1 and 4 from Table 3.1 will be evaluated according to the FPM. These are chosen for their (bio)medical nature and proposal type. Because the number of proposals is rather small, no real validation can be made. However, this will be a good initial indication of the first iteration of Equation 3.4.

Table 3.5.: **Scores per section and total score of proposals 1 and 4, see Table 3.1, of the FPM.**

Project number	A	B	C	D	E	F	G	H	I	Total	Prediction	Conclusion
1.	75	4	28	48	32	22	16	86	8	682	Successful	Correct
4.	88	2	28	48	32	22	14	82	8	675	Successful	Correct

With these outcomes one can only state Equation 3.4 still stands for these two proposals, and that the total score of 675 indicates that the actual threshold of an unsuccessful proposals is < 675.
Within the pool of available research proposals there was only one non-successful proposal. Sadly, this research proposal is about a non-MT product. This means that validation of the model is not possible by use of this proposal. It however may prove interesting to see how the model deals with a non-successful proposal. When using the FPM and Equation 3.4 on proposal 7, the following results, presented in Table 3.6, are obtained.

Table 3.6.: **Scores per section and total score of proposal 7, see Table 3.1, of the FPM.**
Note: Proposal 7 is not a MT proposal.

Project number	A	B	C	D	E	F	G	H	I	Total	Prediction	Conclusion
7.	82	10	30	40	30	26	11	52	8	686	Successful	Incorrect

For a non-MT product/proposal the FPM shows a score of 686 for a non-successful proposal. This is well above the predicted 279 threshold. Due to the fact that the listed questions are MT specific, multiple scoring questions needed to be interpreted differently, again no conclusion can be connected with regards to the validation process.

3.3. Input for ADMM - points of intrest

With this the secondary goal of this "funding analysis" is completed. From this analysis, its results and the MT-Cooper model questions, the *points of interest* mentioned at the

start of the chapter are extracted. These can be split up into two categories. That of the **socio-economic relevance** and **future utilisation**.

Socio-economic relevance
When a ... is present, a higher chance of receiving funding is present due to the high socio-economic relevance.

- High burden of disease
- Low Quality of Life (QoL)/High severity of disease
- Negative reports and Ratings of (quality of) health care
- High costs of state of the art
- Low 5-year survival
- High mortality
- High incidence rate
- Poor Incremental Cost Effectiveness Ratio (ICER)

Future utilisation When ... holds true, a higher chance of receiving funding is present due to the well thought out future utilisation.

- There is a clear understanding of what is missing in the SotA
- It is possible to create this missing information/technology
- There is a real world problem to be solved
- There is a scientific problem to be solved
- The MT-creator possesses the necessary
  - managerial skills
  - engineering skills
  - expertise
- Buyers have expressed a need for the technology
- The target population size is adequate
- There is no price competition in the market
- The proposed utilization is achievable

3.4. Template

The questions stated in Section 3.1.1 and the analysis of the proposals in Table 3.1 allowed for the development of a template that can be followed to more easily create a research proposal. This template can be found in Appendix B.

3.4.1. Advice when writing a proposal

Besides the template, several points of advice when writing a research proposal/applying for funding can be given. These were extracted from the analysed proposals, the STW guidelines, and several meetings with researchers familiar with submitting proposals. The points are split up into a set of general and a set of specific points. The general points concern themselves more about structure and format, giving general advice for writing. The specific points show four points that are specifically important for RaM when constructing a proposal.
Note:
1. These points are not the *points of interest* mentioned.
2. Sounding rather arbitrary, these points are emphasized by STW themselves as well as experienced by several researchers when submitting proposals [23, 43, 44, 59].

General points

- Follow the format set by the funder.
- Have the appropriate main and co-applicants. This will also help to show that the needed expertise is present within the group.
- Only ask for that what is allowed within the format. For OTP this is for example.
  - Don't ask for more than €750.00, excluding Dutch VAT, or €1.000.000 when considering projects that require more than €250.000 in equipment costs, per project.
  - When the total project costs are larger than €500.000 have the 25% of the amount exceeding co-funding pledge(s) signed.
  - Plan projects so that their duration falls below 6 years.
- Have the division of sub-project leaders ready.
- Have the user committee already set. The guiding principle will be to ensure that the composition of the user committee maximises the likelihood of the results being applied and that the interchange of ideas, including confidential information, remains possible [44].
- When writing, split points into different (sub)sections. When finished, combine these into one piece of text. This will decrease the likelihood of forgetting points.

Specific points

- The STW will adjudicate application based on two equal important grades given by the jury. These grades are in accordance with Appendix C [43, 44]. On completion of the proposal the authors should re-evaluate themselves as objectively as possible

using the same question and grading scheme. When results are (too) high, a lower score is better, an alteration of the research proposal should take place.

- Furthermore the proposals are judged based on the following $2 * 6$ questions [43, 44].

  Scientific quality

  1. To what extent is the proposed research original and how would you rate the innovative elements?
  2. What is your assessment of the design of the project, including the goals, hypotheses, research methods, and scientific feasibility?
  3. What is your assessment of the coherence and time schedule of the proposed lines of research?
  4. Is the research group competent enough to carry out the research? Does the group have a relevant position in the international scientific community? Is the available infrastructure adequate?
  5. Are the number and category of requested personnel, budget for materials, investments, and foreign travel adequate?
  6. What are the strong and weak points of the scientific part of the proposal?

  Utilisation potential (the application of the results of the research by third-parties)

  1. What is your assessment of the description of the commercial and/or societal potential impacts of the research given in the proposal?
  2. What is your assessment of the contribution and commitment of the users and the proposed composition of the user committee?
  3. Do you expect the application of results to be hampered by commercial propositions, existing patents, eligibility or societal acceptance?
  4. What are the prospects for collaboration with the industry and knowledge transfer, assuming the project is successful? Please address both aspects.
  5. What is your assessment of the research group's competence regarding the transfer and application of research results?
  6. What are the strong and weak points of the utilisation plan?

- Research proposals from a medical faculty or university medical centre should have, just like other applications, potential users. At least one of the users should be a company. It is not sufficient merely state "the patient" or "a clinic" as user [44].
- The final composition of the user committee is still subject to the same conditions as other STW projects [44].
- Under several types of programmes, of which OTP is one, the proposal will also be judged by a non-epistemic jury. This makes the readability and understandability of the abstract of great importance [51].

With part of the points of interest analysed with creation of the FPM, in Chapter 3, the next step in the creation of the ADMM can be made.

3.5. Chapter conclusion

Via the analyse of several research proposals, a model predicting whether or not a still to be submitted proposal regarding MT will receive funding from the relevant agency was created. The funding agency selected is STW for the fact that the McRobot project that will be used in the feasibility testing of the ADMM will elicit here. Because the number of available research proposals was small, the model could not be validated. The analysis preceding the model creation allowed for the set-up of a template helping and advising in writing research proposals.

4. Method ADMM

When starting with this research concerning the ADMM specifically, the following reasoning was to be implemented.

- Create a decision making model
  - What is the normal design process of medical technology?
    - Strong points of the normal process
    - Weak points of the normal process
  - What goes wrong during the normal design process?
    - Why does this happen?
    - Where should alterations take place?

But it became clear quite early within this process that within RaM there is no real "normal" design process [23]. Combining this with that what such an model will bring to the other stakeholders, described in Section 4.1, this strengthens the need for standardization. Because the method described in Section 3 used for the creation of the FPM was also not suitable route, for all the points important information is missing, a different approach was needed to create this ADMM.
By first indexing the stakeholders connected with the creation and/or market introduction of MT, the problems mentioned within the previous chapters could be specified. This specification step was done based on literature and meetings with several relevant epistemic parties. With this information solutions for/indicators of/assessment of these problems could be created. The resulting elements were connected in a flowchart model, the (Early) Health Technology Assessment type Assistive Decision Making Model. The element order is based on the (future) working methods of RaM.

4.1. Stakeholders to be implemented

In the list below, a selection of the most important and apparent stakeholders generally involved with the creation of MT is shown. Those concerned with, for example, the transportation of the finished product, are not included here. The impact of these users on the decision making process is not as big and apparent as those listed because they fall outside the categories of *primary*, *secondary* and *tertiary users* [26, 39, 45]. Due to this effect not

every stakeholder needs to be represented within the R&D-team when the effect of the product on them is considered [26, 39, 45].

1. Government
    - European Government
    - National Government
    - Regional Government
2. Insurance Companies
3. Hospital
4. Medical staff
5. Patients/Society
6. Applicant/Researchers and Developers
7. Investors
8. Medical industry

The creation of the ADMM aims to provide some direct possible benefits to these stakeholders, examples of these are stated in Table 4.1. Again indicating the need for, and the value of such a ADMM.

Table 4.1.: **Examples of possible benefits experienced by stakeholders [23, 26, 29, 37, 40, 42, 54].**

	Expected benefit
1.	Earlier (as soon as possible) termination of unsuccessful projects.
2.	Simplified creation of research proposals.
3.	Possible decrease in design time due to knowledge elicitation and standardized design process.
4.	Clearer understanding of the needed product functions leading to less iterations within the process.
5.	Improved and more effective final product due to improved/correct stakeholder implementation.
6.	Easier and higher product sales.
7.	Decrease in time between idea and implementation in practice.
8.	Easier exchangeable data between projects.
9.	Less chance of forgetting steps within the design and/or decision making process.
10.	Easier creation of a time schedule.
11.	Overall decrease in costs.

How these benefits are linked to the specific stakeholders is seen in Table 4.2. The three types of government are grouped here.

Table 4.2.: **Examples of possible benefits experienced from Table 4.1 linked to specific stakeholders.**

	Stakeholder ↦	Applicant	Patient/Society	Medical staff	Hospital	Insurance company	Government	Medical industry	Investors
	Benefit								
1.	Early termination	X							X
2.	Easier proposal	X							
3.	Decrease time	X	X						X
4.	Clear functions	X	X	X				X	
5.	Improved design	X	X	X	X	X	X	X	X
6.	Product sales	X							X
7.	Faster implementation	X	X	X	X	X	X	X	X
8.	Exchangeable data	X							
9.	Structured steps	X							X
10.	Time schedule	X							X
11.	Decreased costs	X	X	X	X	X	X	X	X

From these, several stakeholders can again be removed to narrow the scope of the research. Even though they are involved in the product, their influence in the decision making is small in comparison with the remaining stakeholders.

Even though the **European Government**, in the form of the European Union (EU), holds legislative power over its Member States, in the case of medical products and practice this is mostly restricted to soft law legislation in the form of guidelines or prohibition of products that do not adhere to certification such as ISO or the Conformité Européenne standards as described in the Council (of European Communities) Directive 93/42/EEC [16]. This advisory and certification standpoint of the EU means that decision making trickles down to the national level. This means that the Netherlands can continued to be taken as the field of operations within the research given the involvement of RaM, STW and ZGT Hengelo.

The **Hospital** and **Medical staff** can be combined into one stakeholder. The procedure of acquiring new MT is something that starts with a medical specialist stating a need, and the need being assessed by a multitude of levels, see Figure 4.1 [40]. The McRobot project, see Chapter 5, does have interventional radiologists, a medical specialists, as its end user [46]. So these will be grouped under **Hospital**.

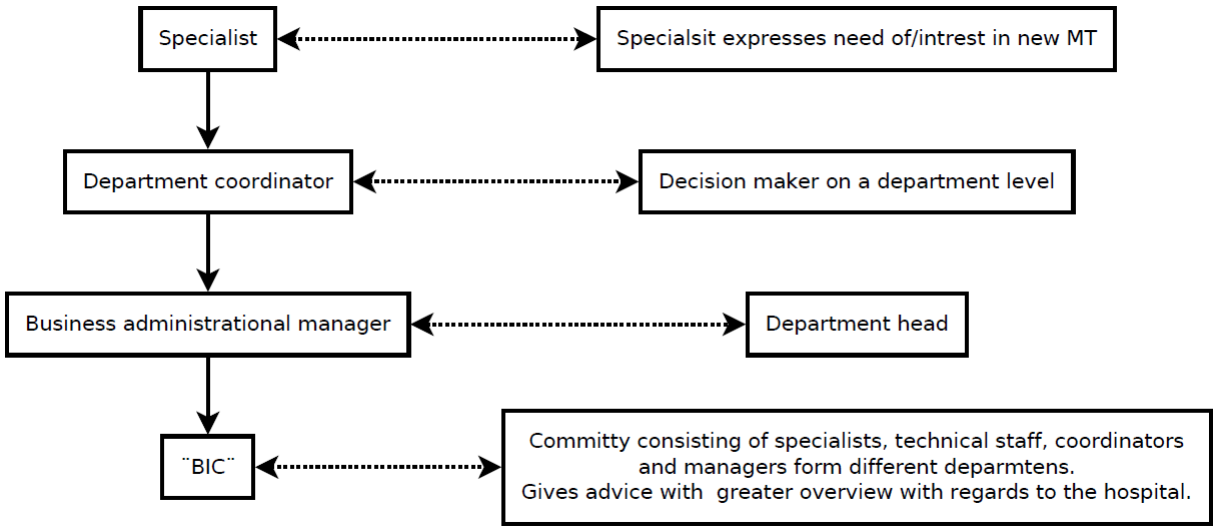


Figure 4.1.: **Procedure of acquiring new MT based on personnel "levels" within ZGT Hengelo [40, 60].**

Even though healthcare centres around **Patient/Society** care, most, if not all, of these individuals are a poor judge of what they need in terms of MT. Even with the current trends of patient-centred care and patient-reported outcomes, they generally lack the knowledge, and are too focused on individual care to make these choices [6, 29]. This does not mean that their input and/or requirements are to be ignored, but more that these are (most likely) better assessed by medical staff treating them. So these will again be grouped under **Hospital**.

Whilst **Investors** play an important role in supporting the project, their requirements are clearly stated, in the case of an institute like STW, or too diverse/specific, in the case of a private funder, to be discussed here. This combined with the fact that in Chapter 3 an analysis of several STW proposals and the OTP guidelines has been performed leads to the removal of the **Investors** as a direct stakeholder.

The influence of **Medical industry** will be both a positive, a company manufacturing MRI-compatible needles will experience an increase in sales with the introduction of a product like the McRobot, and a negative, in the form of competition, one. Because the business model of RaM is taken as a given input, no further steps will be taken towards this stakeholder.

To translate the remaining stakeholders into usable information, their requirements will be reduced into a single core question and answered.

- National Government
  What does this stakeholder look for when deciding to allow the use of the product within its country?
- Insurance Companies
  What does this stakeholder look for when deciding to reimburse the use of the product?
- Hospital
  What does this stakeholder look for when deciding to purchase the product?

Dutch Government

In the Netherlands, the Ministry of Public Health, Welfare and Sport (Dutch: Ministirie van Volksgezondheid, Welzijn en Sport (VWS)) is tasked with the adjudication of medication, medical technology and medical applications to give approval for use within the Netherlands.
More specific, the government body Health Care Inspectorate (Dutch: Inspectie voor de GezondheidsZorg (IGZ)) performs this task for them. The IGZ monitors and advises on the quality and accessibility of health care. Besides advising the ministers, it also advises and stimulates health care professionals, supervises institutions, companies and solo health care providers [41]. The IGZ can, in the case of medication, give permission to use a non-registered medicine for an individual patient, but a doctor´s statement is essential [31].

What does the Dutch government look for when deciding to allow the use of the product within its country?

Simplistic saying, the Dutch government allows all technologies that adhere to the set norm. The verdict will, depending on what class of medical technology, be given by IGZ or a third party. These classification can be found in Appendix D. The McRobot project will fall under Class IIb in accordance with 93/42/EEC Annex IX rule 3.1.

Insurance Companies

Insurance companies play a vital role in the availability of health care to the public. They do so by providing service packages and reducing the variability of the incomes of those insured by pooling a large number of people and operating on the principle of large numbers [10]. By entering into such a pool arrangement the individual loss distribution is replaced with the average loss distribution of the group [10]. This enables individuals to undergo expensive treatments [10]. The insurance companies have influence by offering or not offering these procedures.

However, they will have much less, or even no, impact on the allowance of the more peripheral device type of projects within RaM because the hospitals will purchase the MT themselves rather than forwarding these costs to society [29]. The McRobot project is one such a project. This renders the question of:

What do insurance companies look for when deciding to reimburse the use of the product?

to be irrelevant in this case.

Hospitals

For smaller purchases the acquisition of new technology will be discussed within the department of the requesting specialist, but bigger expenses will still have to be communicated with the acquisition committee of the hospital [60]. This leads to the structure shown in Figures 4.1, 4.2a and 4.2b. The height of this tipping point could not be discussed. As such it is denoted as a within Figure 4.2a.

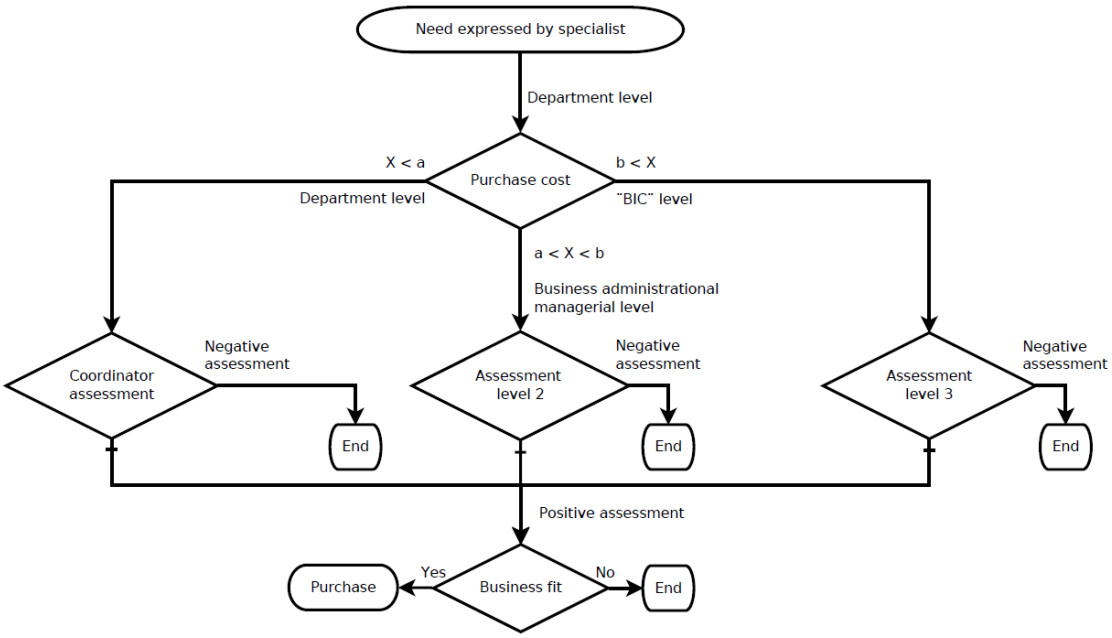
What do hospital purchasers look for when deciding to purchase the product?

Before a new technology enters the hospital, two things need to happen. A medical specialist must show interest in the technology. This means that he or she would like to implement this within the ward. Secondly, the new technology must fit within the hospitals business plan. It may be strange to view something as a hospital needing a business plan, but this refers questions like the following [40, 60].

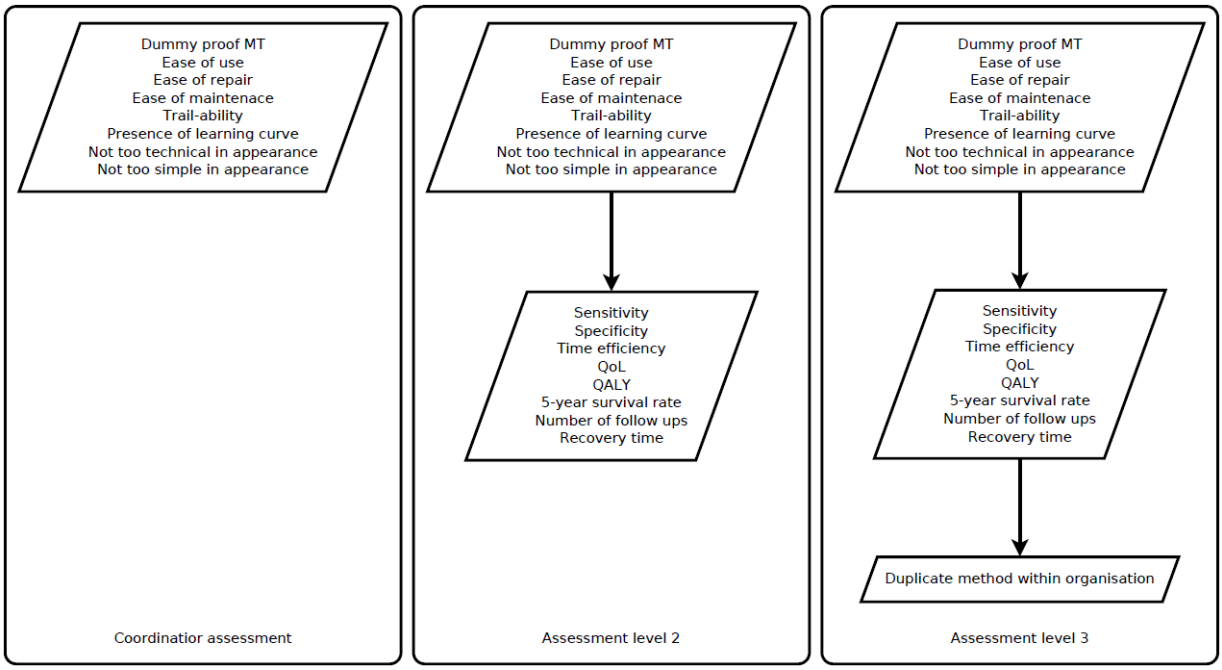
- Does this technology replaces an existing technology/device (within the hospital) or will this be an additional one?
- Does this mean we can perform extra or fewer types of procedures?
- Are these new type of procedures desirable considering the demography?
- Does this mean we can perform a greater or smaller number of procedures?
- Do we have funds available for this?

From the three here mentioned stakeholders, the focus for the model creation, will be put on the **Hospitals**. **Note:** that these also contain the **Medical staff** and **Patients/Society**.

With the knowledge gap identified, the socio-economic values indexed and the relevant stakeholder(s) stated the development of the ADMM can begin.



(a) **Impression of the decision making model implemented within the ZGT Hengelo for the purchase of new MT [40, 57, 60].**



(b) **Examples of assessment items per level used within Figure 4.2a [23, 29, 40, 44, 43, 57].**

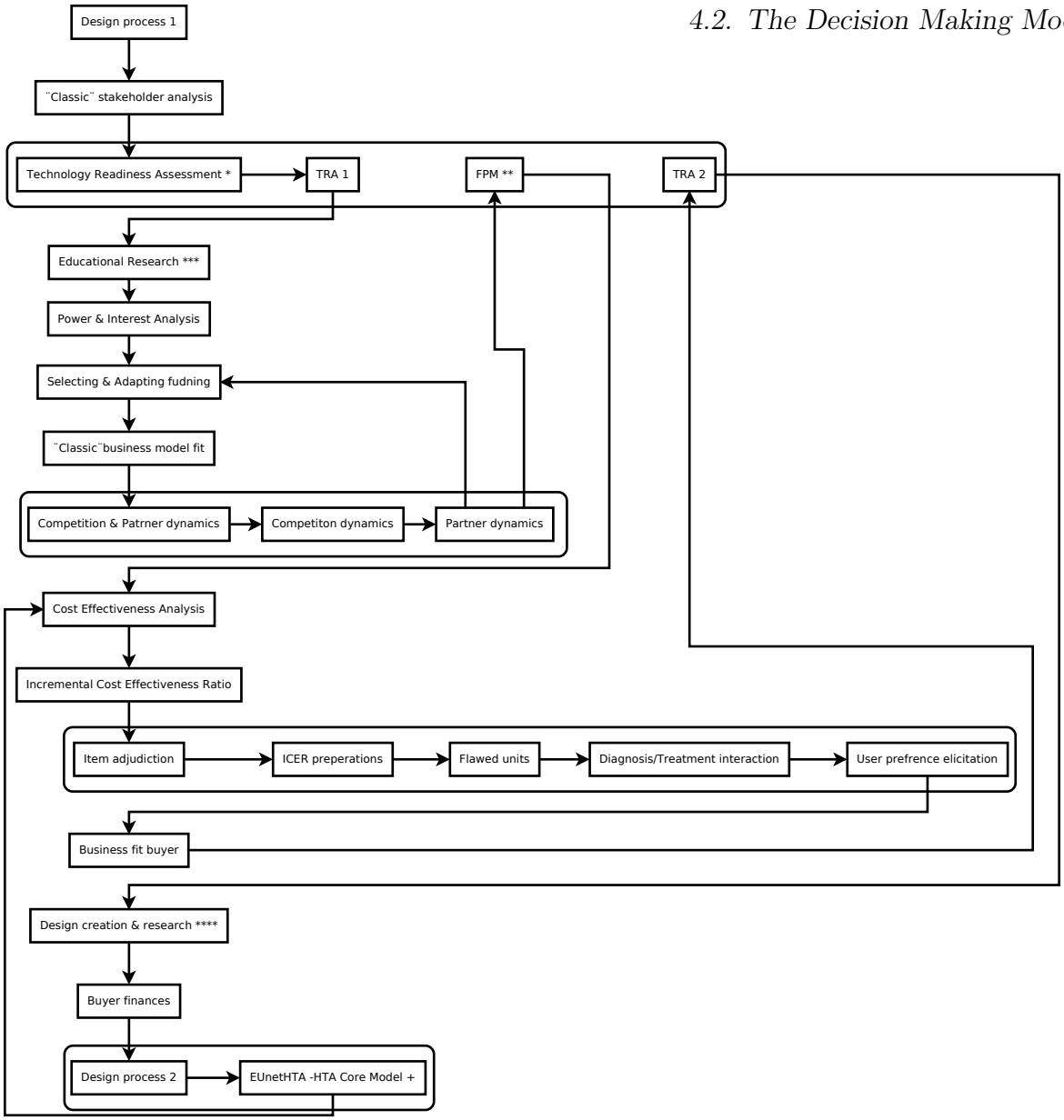
Figure 4.2.: **Impression of the decision making model implemented within the ZGT Hengelo for the purchase of new MT and examples of assessment items per level [23, 29, 40, 44, 43, 57, 60].**

4.2. The Decision Making Model

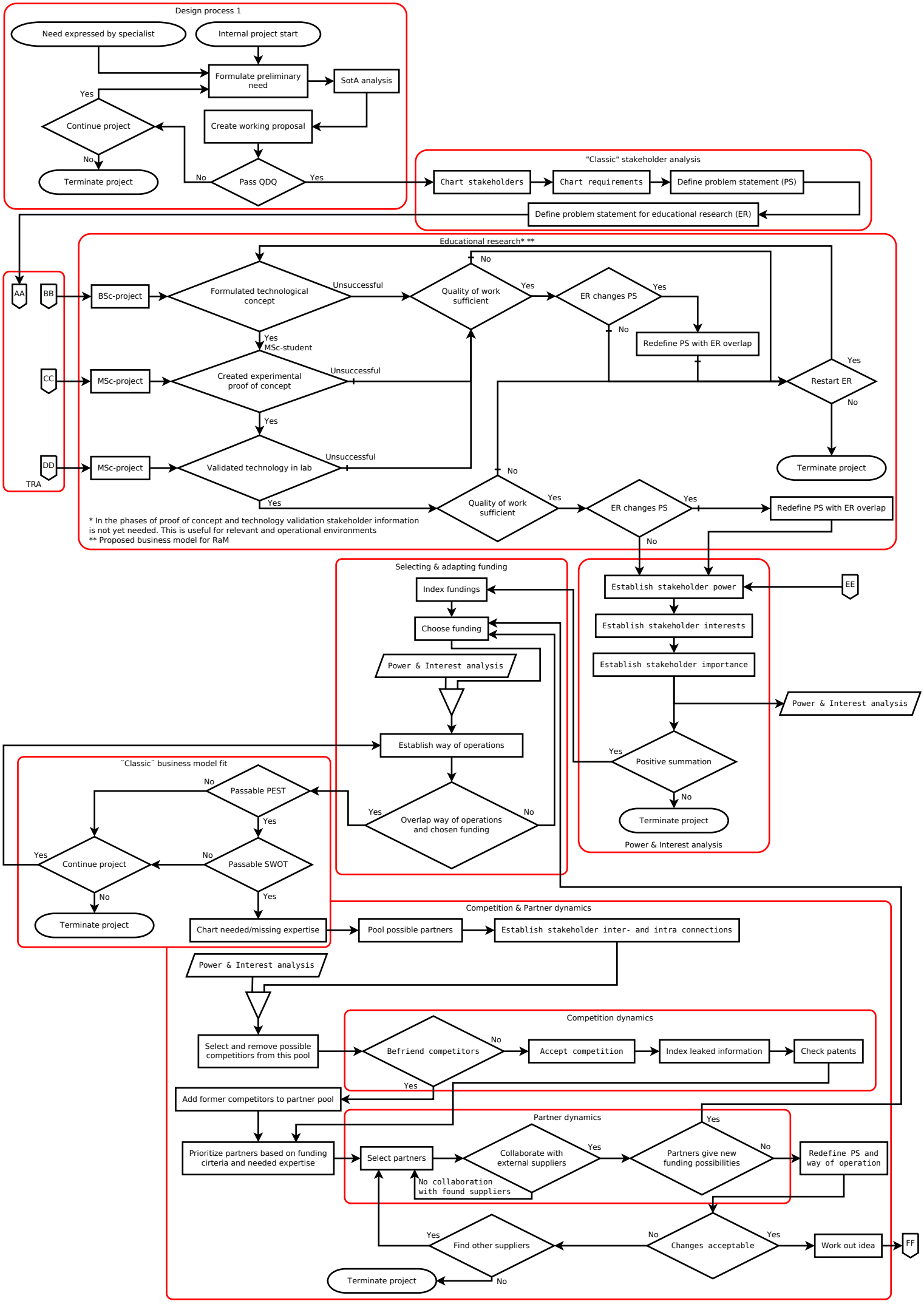
On the following pages the ADMM is presented. In Figure 4.3 a legend with the flowchart symbols used and their precise meaning is shown. The model will be explained in the upcoming sections where each of the red boxes, denoted as phases, will be discussed individually. Each of the phases consists of
a *What*-section, describing the general function of the phase in a couple of sentences,
a *Why*-section, describing the need for the phase and
a *How*-section, in which the opted solution is explained. Here *italic* text will indicate an action box/decision box/in- output/endpoint. Whereas **bold** text shows the connecting (downstream) phase of the ADMM.

Table 4.3.: **Diagram legend of the ADMM.**

Name	**Discription**	**Symbol**
In accordance with ISO 5807-1985(E) [32]		
Start/End point	Denotes the start/end point of the model	
Input/Output	Input or output of the model	
Action box	Denotes the noted action	
Decision	Denotes a choice	
Altered with respect to ISO 5807-1985(E) to increase readability [32]		
Parallel set	Downstream path occur simultaneously	
Merge branches	Downstream path is taken only when all upstream paths are filled	
In accordance with DIA protocol		
Off page connector	Connects similar denoted off page elements of the model	
On page connector	Connects similar denoted elements of the model throughout the page	



* Using the 9 level Horizon 2020 TRA discribed and stating that only at TRL 9 the MT can be sold.
** The FPM is placed here based on (proposed) RAM buisniness model.
*** In the phases of proof of concept and technology validation stakeholder information
is not yet needed. This is useful for revlevant and operational environments.
**** Will not be explained.


Design process 1
Need expressed by specialist
Internal project start
Formulate preliminary need
SotA analysis
Yes
Continue project
Create working proposal
No
Terminate project
No
Pass QDQ
Yes
"Classic" stakeholder analysis
Chart stakeholders
Chart requirements
Define problem statement (PS)
Define problem statement for educational research (ER)
Educational research* **
AA
BB
BSc-project
Formulated technological concept
Unsuccessful
Quality of work sufficient
Yes
No
ER changes PS
Yes
No
Redefine PS with ER overlap
Yes
MSc-student
CC
MSc-project
Created experimental proof of concept
Unsuccessful
Yes
Restart ER
Yes
No
Terminate project
DD
TRA
MSc-project
Validated technology in lab
Unsuccessful
Yes
No
Quality of work sufficient
Yes
ER changes PS
Yes
Redefine PS with ER overlap
No
* In the phases of proof of concept and technology validation stakeholder information is not yet needed. This is useful for relevant and operational environments
** Proposed business model for RaM
Selecting & adapting funding
Index fundings
Choose funding
Power & Interest analysis
Establish way of operations
Overlap way of operations and chosen funding
Yes
No
Establish stakeholder power
EE
Establish stakeholder interests
Establish stakeholder importance
Power & Interest analysis
Positive summation
Yes
No
Terminate project
Power & Interest analysis
"Classic" business model fit
Passable PEST
No
Yes
Continue project
Yes
No
Passable SWOT
No
Yes
Terminate project
Chart needed/missing expertise
Competition & Partner dynamics
Pool possible partners
Establish stakeholder inter- and intra connections
Power & Interest analysis
Competition dynamics
Select and remove possible competitiors from this pool
Befriend competitors
No
Accept competition
Index leaked information
Check patents
Yes
Add former competitors to partner pool
Partner dynamics
Prioritize partners based on funding cirteria and needed expertise
Select partners
Collaborate with external suppliers
Yes
Partners give new funding possibilities
Yes
No
Redefine PS and way of operation
No collaboration with found suppliers
Yes
Find other suppliers
No
Changes acceptable
No
Yes
Work out idea
FF
Terminate project

4.2.1. Design process 1

After beginning the project at either of two terminals, a working proposal is created based on the formulated preliminary need and a SotA analysis. The fit of this working proposal and the project within RaM is directly assessed via a set of Qualitative Design Questions (QDQ).

By directly assessing the project, even at such an early stage, an as high as possible fit between the project and the R&D-team can be created. If such a fit is not possible, or when the SotA analysis points out no new MT is necessary, the project can be tweaked or terminated. Again, as soon as possible to safe time, money and effort.

Either the project is started by a *need expressed by a medical specialist* or *started as an internal project* within RaM. Now a *preliminary need* has to be formulated. Even though the medical specialist has expressed a need already, this is more than often already formulated as a proposed solution for a still underlying problem [26]. With a *SotA analysis* a quick overview of the currently available technology that tries to/possible solves the expressed need is given. With these pieces of information, a working proposal can be created. This overview is the direct input for the QDQ.
Such a set of qualitative questions can be used to determine the viability of the project and its eventual product(s) within RaM and the market before quantitative analyses are needed. These questions are stated in the list below and are partly familiar to any product designer. If one of these questions cannot be answered or has a negative outcome, it is likely that the project holds little relevance and viability within the group/company or even the market.
It is natural that each member of the project has his or her own skill set. This means that the introduced questions could be weighted according to this expertise to achieve optimal effectiveness. A first step towards this can be found in *Future work* found in phase 8.

QDQ category **Project**

1. What is the expressed need/formulated problem?
2. What is the output of the project?
3. Will it be a(n) (assistive) diagnostic or (assistive) therapeutic type product?
4. Will it fulfil a specific function, a global function or a set of functions?
5. Will this product fulfil the expressed need?

QDQ category **Costumer**

1. To whom will the product be sold?
2. Why do these ... need this product?
3. How big is this expressed need?

4. How big is the group of costumers expressing this need?
5. Does this create a large enough sales market?

QDQ category **User**

1. Who will be the user of the product?
2. Why do ... need this product?
3. How big is this expressed need?
4. How big is the group of users expressing this need?
5. Does this create a large enough sales market?

QDQ category **Patient**

1. For what patient groups will the product be beneficial?
2. Why do ... need this product?
3. How big is this expressed need?
4. How big is the group of patients expressing this need?
5. Does this create a large enough sales market?

QDQ category **Management**

1. Does this project fits in with our skills [15, 43, 44]?
2. Do we expect to have the necessary skills for this project [15, 43, 44]?
3. Does this project fits within our current business model [15]?
4. Is the deadline set achievable?

QDQ category **Future project questions**

1. Do we have partners with the necessary/complementary skills for this project?
2. What are their interests?
3. What are our shared interests?
4. Who are our competitors [15]?
5. What are their interests?
6. What are our shared interests?
7. How will our decision influence competitor behaviour [15]?
8. What changes to the regulations are in the pipeline [15]?
9. Are similar/competing technologies about to be launched [15]?

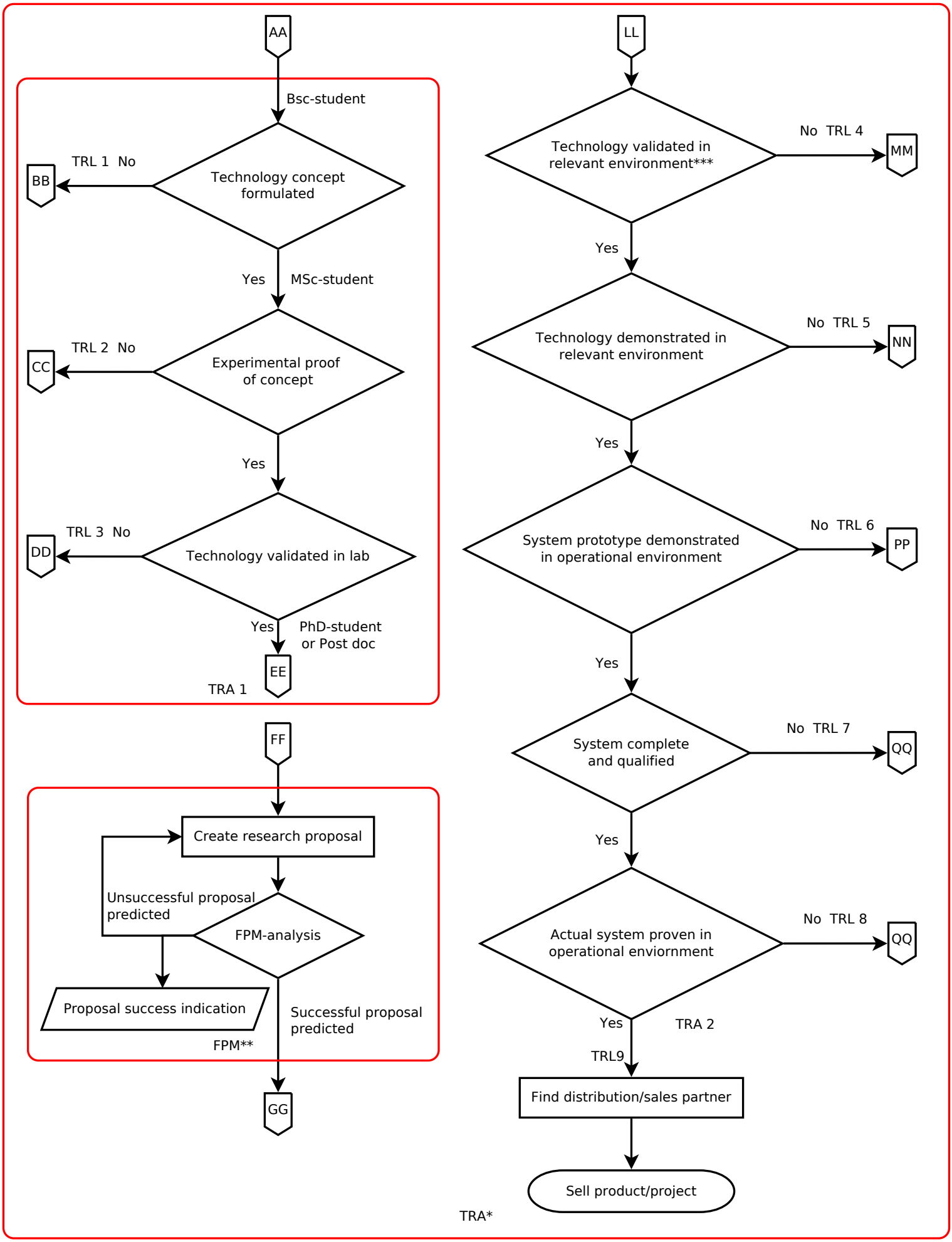
These questions will again give a good indication of the real world need, and thus the needed application, of the project, specifying what is expressed by the medical specialist. When these questions indicating a negative business/project fit, a decision to *continue the project* needs to be taken. When the project is continued, a new *preliminary need* has to be formulated, otherwise the project is *terminated*. With an positive indicated business/project fit, the model continues into the **"Classic" stakeholder analysis**.

4.2.2. "Classic" stakeholder analysis

A final project description needs to be defined [23, 26]. This is done by creating a problem statement following the indexation of the stakeholders relevant to the project and their requirements (and wishes).

To know what research needs to be conducted, a clear set of research questions is needed. These can be found within the problem statement. This process is common practice within many design projects and has already been mentioned in Figure 2.2.

By *charting the stakeholders* involved with the project a clearer indication of the shape of the final product can be made [23, 26]. Via the *charting of the requirements* (and wishes) of the stakeholders a so called design brief can be created. The design brief is a check list used to determine if the (finished) product meets the set requirements. With all this information a *problem statement* can be defined as a definite project description and to indicate, on a more detailed level than a SotA analysis, what the knowledge gaps are that need to be filled. Before continuing to the next stage within the model, the problem statement is re*defined for educational research.*
A possible option to fill these knowledge gaps is the integration of BSc, MSc and PhD-students and their assignments carried out within RaM into the projects. For this the problem statement has to be altered to such an extent that the information to be extracted via these assignments is on par with the level of the respective student. This distribution will be made via a **Technology Readiness Assessment**.



* Using the 9 level Horizon 2020 TRA discribed and stating that only at TRL 9 the MT can be sold.
** The FPM is placed here based on (proposed) RaM buisniness model.

4.2.3. Technology Readiness Assessment

To determine at which point of its life cycle a project currently resides and how it will be distributed across the three levels of students, a categorization according to its Technology Readiness Level (TRL) is made.

This allows for a more effective assessment of, and communication regarding the maturity of new technologies. It can also give a clear (over)view of the past, present and future of projects. [36].

Via an off page connector the **Technology Readiness Assessment (TRA)** is reached. This TRA is again divided into three phases as a result of the different off page connectors used. Here the Horizon 2020, the biggest EU Research and Innovation programme, Technology Readiness Level (TRL) division will be implemented because of its relevance to the Dutch market [21].

TRA levels as defined by Horizon 2020 [20]

TRL 1 Basic principles observed
TRL 2 Technology concept formulated
TRL 3 Experimental proof of concept
TRL 4 Technology validated in lab
TRL 5 Technology validated in relevant environment
TRL 6 Technology demonstrated in relevant environment
TRL 7 System prototype demonstration in operational environment
TRL 8 System complete and qualified
TRL 9 Actual system proven in operational environment

After this introduction the model flow can again be followed.

TRA 1

Starting with the decision if *the technology concept is formulated*, corresponding with TRL 2, a negative conclusion will lead to a BSc-student performing this task. A positive conclusion will continue the process within the TRA and leads to the decisions corresponding with TRL 3 and 4. The negative conclusions will lead to a MSc-student performing one or both of these tasks. A continuation of the TRA will place the project into the PhD or post doc research. Generally speaking, BSc and MSc-students already fall under the responsibility of a PhD-student who again falls under that of a post doc. The three negative-outcome off page connectors, connect to their corresponding connectors within the phase of *Educational Research*. The "EE" connector will connect to an action box reached upon completion of a

formulation of a technological concept, *experimental proof of concept* and a *laboratory validation* also present in this Educational Research. This links to the **Educational research** in Section 4.2.4.

FPM

Via a off page connector the next step to be taken in the *creation of the research proposal*. This first draft will be scored by the FPM introduced in Chapter 3 and will have to be rewritten if the proposal is predicted to fail. Otherwise the model can continue into the **Cost Effectiveness Analysis** in Section 4.2.9. It will prove beneficial, much like discussing the QDQ within Section 4.2.1, to have the assessment performed by multiple project members to have a more objective result [50].

TRA 2

This part of the TRA follows the same set-up as **TRA 1**. This time TRLs 4 to 9 are discussed. Here the four connectors, "MM", "NN", "PP" and "QQ", will connect to an action box *developing the MT further* present in **Design creation & research** and this again will flow into the **Buyer finances** phase in Section 4.2.13.

4.2.4. Educational research

Continuing the distribution of work over BSc and MSc-students, the MT goes through a technical/experimental proof of concept phase. The work done here is checked for correctness and overlap with the set problem statement.

The research conducted by the students needs to be checked based on its scientific/practical value and correctness. But besides this, a comparison between these results and the previously stated problem statement shows if the project is still on the right track.

From one of three off page connectors within the **TRA** either of three corresponding decisions is made. Is the *technological concept formulated*, has an *experimental proof of concept been created* and/or is the *technology validated in the lab*? Again these correspond with TRL 2 to 4, by which each positive outcome allows for the increase of a TRL concluding in a check if the *quality of the work is sufficient*. If so, the model continues. Returning a unsuccessful outcome, the *quality of the work* is also graded *sufficient* or not. If so, does the *educational research changes the problem statement*? When this is the case, a *redefinement of the problem statement* is in order to change the course of the project. The research indicates that the missing information initially defined by the problem statement cannot be created. Based on this new statement the *educational research starts over* or the *project is terminated*. A similar route is taken when educational research is completed "successfully". Only here no restart option is present due to the fact that the results match the initial problem statement. The flow of the model continues into the **Power & Interest analysis**.

4.2.5. Power & Interest analysis

This phase describes how to objectify the normally subjective process of identifying the power and interests of stakeholders in the project and its market. With this analysis again an attempt of early success indication is made.

By assessing both the power with regard to and interest in the project and/or finished product and/or product market, the design team can identity the more important stakeholders connected to the project. This importance directly relates to these levels of power and interest. Consequently, a focus can be put on the stakeholders maximizing product success chances.

Every *stakeholder can be assessed on power*. Access to resources increases the influence on the process. Resources can be divided into tangible (e.g. votes, finance, infrastructure and members) and intangible assets (e.g. legitimacy and expertise, access to mass media, networks and political decision makers) [8]. Power can be a result of interaction between structure and agency, authority, level of access to knowledge, personality, and individual wealth [8].
Assessing every stakeholder on the level of commitment, interest and position will determine how they will implement their resources. Determining what their interest are can be difficult. Often it is the expected economic effect gained by the project [8]. Positions are also not easily determined as they may be concealed or because public opinions may be different from private ones [8]. The impact of an issue on the interest of stakeholders determines their position. Sometimes the stakeholder is not certain because they do not yet know how the project might affect their interest [8].
Historically this kind analysis is represented in a **Power map**, an example can be found in Figure 4.3.

High Opposition	Medium Opposition	Low Opposition	Neutral	Low Support	Medium Support	High support
A			B		C	D
			E		F	G
			H		I	

High power
Medium power
Low power

Figure 4.3.: **Example of a Power map style of Power & Interest analysis for stakeholder A to I with respect to project X.**

But a new approach could be taken. By setting an extra step *the stakeholder importance is established*. Because each of the indexed stakeholders is taken into account during the design phase of the project, time can be saved by only focusing on the "more important" stakeholders. Combing this information results in the *Power & Interest analysis*. This could be the endpoint of this phase. However, taking another step by trying to objectify these results leads to the development of Equation 4.1 where the power (in the field of the new MT), importance (within the design process of the new MT) and interest (in the new MT) of $stakeholder_j$ to form the weight of $project_i$.

$$W_i = \Sigma_j P_{ij} In_{ij} Im_{ij} \tag{4.1}$$

with

Unit	Meaning	Lower range	Upper range
W	Weight of the new MT	-	-
P	Power of stakeholder in the field of the new MT	0	1
In	Interest of stakeholder in the new MT	-1	1
Im	Importance of stakeholder within the design process of the new MT	0	1

If W_i results in a positive summation of the power, importance and interest of each of the stakeholders, the project is stated to be able to be successful. To achieve this, the units receive a $\forall$ -1 to 1 scale for In and $\forall$ 0 to 1 for P and Im. Where $P_j = 1$ means that the power of $stakeholder_i$ in the field of the new MT is very high in a positive way, not a competitor for example, for the project.
Whereas $In_j = -1$ means that $stakeholder_i$ has little interest in the new MT, even a reasonable aversion against it. Actual implementation of the ADMM will show if these scales prove valid. With this equation the continuation or termination of the project can be quantitatively expressed via a *positive summation* to the **Selecting & Adapting of the funding**.

Note: The three input variables are still subjective. This being a new concept introduced within the ADMM still extra work has to be done. The equation will be discussed in Chapter 8.

4.2.6. Selecting & Adapting funding

With the selection of a funding programme, the project and its team composition can be adopted/finalized to fit the criteria set by the funder.

As described in previous sections, the need of funding is apparent. Before applying, an indexation of all possibilities and a definite choice for a specific funding programme has to be made. Based on the chosen programme and the corresponding criteria, the business model of RaM can be strengthened or altered.

By *indexing the available funding programmes* the possibilities for a possible funding become clear. In this process a selection based on the working proposal and the problem statement can already be made to exclude non-relevant funding programmes. *Choosing a funding programme* will determine as what kind of project group the R&D-team will ultimately operate. Some of these criteria will directly flow from the requirements set by the funding programme [23, 43, 44]. The *establishing of the way of operations* of the R&D-team will further be influenced by the results of the *Power & Interest analysis*, and of course all previous information within the model. Before continuing, *the overlap between the way of operations and the chosen funding programme (criteria)* have to be assessed. This might prove necessary due to the fact that an excising business model/way of operations was previously in play and was merely adopted for this project. A good fit with the funding programme (criteria) cannot be assumed. If there is no/not enough overlap present the *funding has to be (re)chosen* [23, 43, 44]. With sufficient overlap, the flow continues towards the **"Classic" business model fit**.

4.2.7. "Classic" business model fit

With increased knowledge, the fit between the (current shape of the) project and the R&D-team can be re-adjudicated. This time the business model fit will also be included in this assessment.

Using the classic PEST and SWOT analyses the business model can be finalized. This gives a clear understanding of the needed fit between the project, R&D-team and possible partners.

In Section 4.2.1 the fit between the project and RaM/the R&D-team has already been made using the QDQ. With the increased amount of information, a new round of fit testing can be performed. This will be done by means of a Political, Economic, Social and Technological analysis (PEST) and Strength, Weakness, Opportunities and Threat analysis analysis (SWOT). Because these are excising and proven concepts, this model phase has been given the prefix "classical".
Both represented by a 2x2 matrix table, the PEST uses its four key perspectives to help understand market growth or decline. This can be done for the position, potential and direction for a business and can also, like SWOT, be used to review strategy, position and direction of ideas and concepts [11]. That said, a PEST and a SWOT are used to look at an idea/concept from two different perspectives [11]. The PEST looks at the market, including the competitors, from the standpoint of a particular proposition or a business leading to a better market position. Whilst a SWOT is an assessment of a business or a proposition and will lead, in the case of RaM, to a stronger project foundation [11].
As PEST factors are essentially external, completing a PEST is helpful prior to completing a SWOT in which a PEST helps to identify SWOT factors [11, 12]. Because of this the overlap between a PEST and a SWOT exists. The four quadrants within both analyses vary in significance depending on the type of business. For example, social factors are more relevant to consumer businesses, whereas political factors are more obviously relevant to a global supplier [11]. The four dimensions used are a useful extension of a basic two heading list of pro's and con's used in decision making [12].
In addition to this, a SWOT is also a widely recognized method for gathering, structuring, presenting and reviewing extensive planning data within a larger business or project planning process [12].

See Appendix E for a template and progressive scheme of how to perform both the PEST and SWOT .

Note: "If you use SWOT Analysis as a 2x2 matrix method, then technically Strengths and Weaknesses are internal factors (generally the case anyway), whereas Opportunities and Threats are external factors (this can be more difficult, since it requires you to ignore internal threats and opportunities). The SWOT 2x2 internal/external matrix method

thus only considers external threats and opportunities [12].“

The two decision boxes with the questions if *the PEST is passable* and if *the SWOT is passable* suggest that these two analysis generate a ”pass or fail“ outcome, this is not the case [12]. As explained above, these give an indication of (the location of) strength, weakness and market position of the product/company/project/idea. A negative outcome here, what will have to be assessed by the R&D-team/analyst themselves, gives the possibility to re-assess these results and *re-establish the ways of operations* accordingly. Whilst a passable outcome lets the model continue into the **Competition & Partner dynamics** phase.

4.2.8. Competition & Partner dynamics

Based on the given funding programme criteria and needed expertise, external project partners will be added to the R&D-team/project.

To continue the project, the R&D-team undoubtedly needs external suppliers providing the expertise missing, needed to complete the project. By keeping the inter- and intra-stakeholder dynamics/connections in mind, the most optimal partners can be chosen.

At this stage of the project it will have become clear that the R&D-team misses certain expertise to further develop the MT. By *charting the needed/missing expertise* and *pooling possible partners* it becomes clear which external supplier can provide RaM with this expertise. This pool still contains a set of competitors. From here the *inter- and intra-stakeholder connections can be established*. Figure 4.4 illustrates, via a Fenn-style diagram, the dynamics of these relationships.

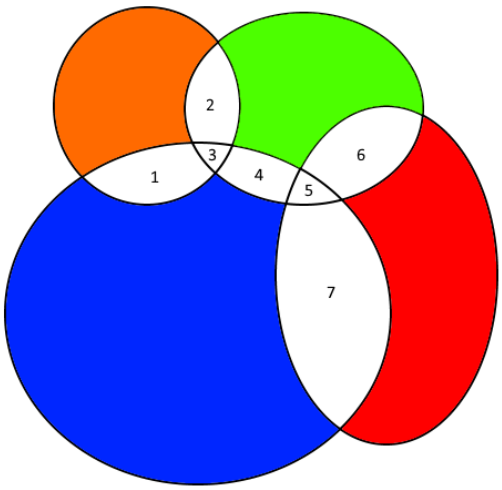


Figure 4.4.: **Fenn-style diagram showing the inter- and intra-connections, via overlaps 1 to 7, of the four main globalized stakeholders in the design process.**
Requesting party - Bottom left
Designing party - Bottom right
External supplier - Top right
Competitors - Top left

The difference with the stakeholder analysis in Section 4.2.2, is that the pool created there can be (re)categorized over the four globalized stakeholders, showing the (market) connections between those stakeholders. Based on this information a more in depth indexation of stakeholders can be made to select partners and indicate competitors.

Figure 4.4 shows a very globalized analysis which centres the four main globalized stakeholders. The stakeholders listed in Chapter 4.1 nest under one of these four groups which are the **Requesting party**, **Designing party**, **External suppliers** and the **Competitors**. Starting with the expressed need, RaM tries to accommodate in this need. as seen in overlaps 5-7, but does not have all the needed expertise. An external supplier might be beneficial to increase the knowledge, overlaps 3-4, increasing the total knowledge span to 3-4-5-7. But not only RaM will try to accommodate in this need, but also competitors, overlaps 1-3, will do so. These competitors might also have need for external suppliers, overlaps 2-3. And this external supplier will have its own interests in the the expressed need, overlaps 3-4-5. This example shows the level of complexity already present with only four stakeholders and gives an indication of how to think when choosing external partners. Here the external suppliers could choose to cooperate with the designing party rather than the competitors, based on the premise that overlap 7 is larger than overlap 1.
With this knowledge these *possible competitors can be selected and removed from the pool* to approach them as to *befriend them.*

Competition dynamics

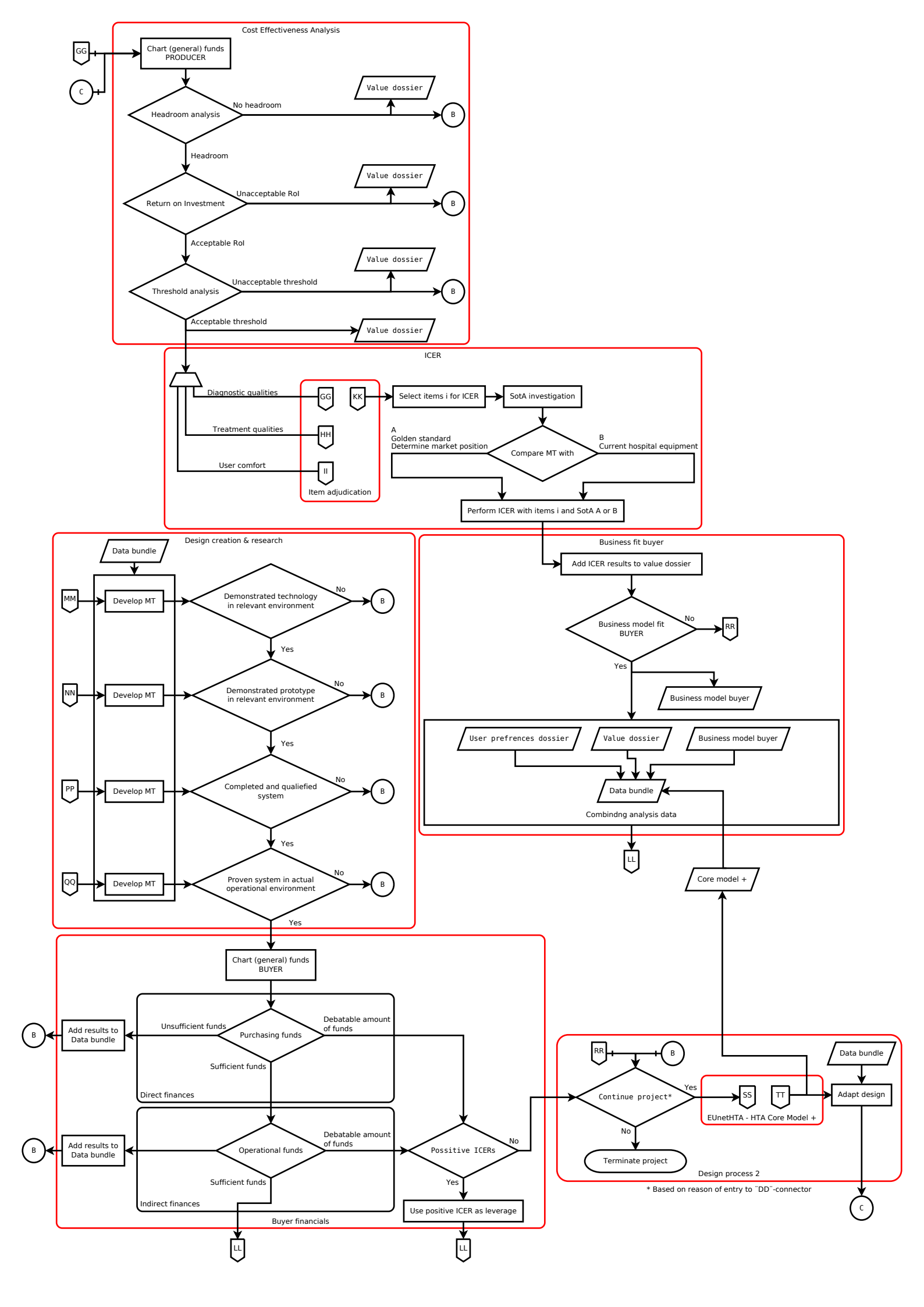
If either RaM or the approached parties declines this cooperation, the possible competitors become actual competitors. The R&D-team will have to *accept the competition*, *index the project information leaked during negotiations* and *check patents hold by these parties.* This last step is normal practice, but after presenting competing parties that hold relevant patents with your project it is most likely that they will have a heightened focus on the project than when it was presented to them. If the negotiations as to *befriend the (possible) competitors* are successful, these parties can be *re-added tot to (possible) partner pool.*

Partner dynamics

The selection of partners will depend on the *needed expertise*, as they need to fill the current knowledge gap present within the R&D-team. However, as mentioned in Section 4.2.6, the chosen funding programme will also set requirement regarding the team composition flow from the requirements set by the funding programme [23, 43, 44]. *Do the selected external supplier agree with a collaboration effort?* If no, a *reselection of partners* needs to be made. If so, *the selected partners perhaps give new funding possibilities* to which the R&D-team was not eligible during the *choosing of the funding* in Section 4.2.6. If this is not the case the model can be continued without an iterative loop.

With the introduction of these external parties, supporting or not, the *problem statement and way of operation* stated at the start of the project will have to be *redefined* to accommodate the external parties. If these *changes are acceptable*, based on the design

brief, funding criteria and other points, will determine if the R&D-team will opt for *other suppliers* (replacing the current selection) or terminate the project. If the *changes are acceptable* the model continues into the **FPM** presented in phase 4.2.3.


Cost Effectiveness Analysis
GG
C
Chart (general) funds PRODUCER
Headroom analysis
No headroom
Value dossier
B
Headroom
Return on Investment
Unacceptable RoI
Acceptable RoI
Threshold analysis
Unacceptable threshold
Acceptable threshold
ICER
Diagnostic qualities
Treatment qualities
User comfort
GG
HH
II
Item adjudication
KK
Select items i for ICER
SotA investigation
A
Golden standard
Determine market position
Compare MT with
B
Current hospital equipment
Perform ICER with items i and SotA A or B
Design creation & research
Data bundle
MM
NN
PP
QQ
Develop MT
Demonstrated technology in relevant environment
Demonstrated prototype in relevant environment
Completed and qualified system
Proven system in actual operational environment
No
Yes
Business fit buyer
Add ICER results to value dossier
Business model fit BUYER
RR
Business model buyer
User prefrences dossier
Value dossier
Data bundle
Combindng analysis data
LL
Core model +
Chart (general) funds BUYER
Purchasing funds
Unsufficient funds
Debatable amount of funds
Sufficient funds
Direct finances
Add results to Data bundle
Operational funds
Possitive ICERs
Indirect finances
Use positive ICER as leverage
Buyer financials
RR
B
Continue project*
Terminate project
SS
TT
EUnetHTA - HTA Core Model +
Adapt design
Design process 2
* Based on reason of entry to ¨DD¨-connector
C

4.2.9. Cost Effectiveness Analysis

With the (possible) funding amount known, a business economic assessment of the product is in order to know if market success, on an economic level, is possible.

Within the **Design process 1** and **"Classic" business model fit** phases, see Sections 4.2.1 and 4.2.7, the market need and the fit with RaM/the R&D-team have been assessed to see if market success is possible. With the amount of funding (to be) received clear, the outgoing costs can be planned, this is done within the research proposal, and laid down next to the expected sales to see what has to be done to enable profit for the project.

With *a knowledge of the (general) funds of the producer* received or to receive via the applied funding, a business economic assessment of the product is in order to know if market success is possible. Using three types of cost-effectiveness analysis (CEA) the needed product quality (increase) and the maximal production costs are calculated. More generally speaking, a CEA is one of the tools to rank the desirability of using an alternative, an alternative MT, in comparison with current practice. With its many similarities with the more economical cost-benefit analysis, most prefer to use CEA because it does not, on the foreground, places a monetary value on the health outcomes [15, 38].
If either of the three, *Headroom analysis*, *Return on Investment analysis* or *Threshold analysis*, presents the R&D-team with a non-desirable outcome, the model redirects the flow via connector "D" to **Design Process 2** presented in Section 4.2.14.

Cost-effectiveness: Headroom analysis

Cost-effectiveness is typically modelled using parameter estimates obtained from randomized controlled trails (RCT). Note that these parameter data are still estimates.
In the case of a technology that is in an early stage of its life cycle, or even yet to be developed, the nature of the product is unclear [38]. However, instead of taking the route were the leading question is

How cost-effective will the project be?

containing the above described amounts of uncertainty, another question can be used.

Would it be cost-effective if the project develops as thought?

The use of this question allows for an estimation of the effectiveness gap present between the SotA and the level the purposed technology and a calculation of the corresponding incremental costs of the project to the point where it is still considered to be cost-effective. This way the *headroom* of the project is calculated, hence the term headroom analysis (HA) [38].

If there is too little headroom, when the net cost of using the product could not realistically be held below this level, investment of resources should be allocated elsewhere [38].
Note that the reverse not holds true, the new technology might still fail despite an adequate estimated amount of headroom. The project might turn out to be less effective or more expensive than initially estimated or alternatives may emerge [38]. Taking this in consideration, a well preformed HA can lower the risk of embarking on a project [38]. This type of analysis will be suited for most of the projects presented by RaM, is given below.

Equation 4.2 results in the amount of incremental Quality Adjusted Life Years (QALY) the new technology will provide [38].

$$\Delta QALY = (1 - \Delta QoL) * n[38] \tag{4.2}$$

with

Unit	Name	Description
$QALY$	Quality Adjusted Life Year	Life years weighted by quality of life
QoL	Quality of Life	Scale where 1 signifies perfect QoL and 0 represents death
n		Amount of years
$ICER$	Incremental Cost Effectiveness Ratio	Extra cost per unit of benefit when comparing one treatment, technology or programme against another [15]

The incremental QALYs are to be converted into monetary terms when enough certainty is present, to offset the financial costs of the treatment, to arrive at a net health benefit for each treatment via a scenario analysis [1, 18]. Using Equation 4.3, $\Delta Costs$ expresses the headroom the project has based on the Willingness to Pay (WTP) of the specific region, the maximum additional cost of the new treatment over the comparator for the new treatment, to be [15, 38].

$$\Delta Costs = \Delta QALY * WTP[38] \tag{4.3}$$

with

Unit	Name	Description
WTP	Willingness To Pay	Amount society is willing to pay for an increase of 1 QALY for an individual

Often this $\Delta Costs$ is taken further to calculate the ICER as can be seen in Equation 4.4 and will be discussed in more detail in Sections 4.2.10 and 4.2.11.

$$ICER = \frac{\Delta Costs}{\Delta QALY}[15] \tag{4.4}$$

with

Unit	Name	Description
$ICER$	Incremental Cost Effectiveness Ratio	Extra cost per unit of benefit when comparing one treatment, technology or programme against another [15]

Cost-effectiveness: Return On Investment

When an acceptable amount of headroom is present for the project, continuation of development and investment would appear to be justified. When looking from a (purely) business perspective, a viable company must have adequate volumes to repay the Return on Investment (RoI) [15].
Development costs will play a part in the decision to continue or abandon projects. These factors will be largely based on internals of the organisation rather than the technology itself [15]. As these fall outside the scope of this research, they are not discussed here.

Using the introduced Equation 4.3, the amount of revenue that, given the estimates, can be generated can be calculated with Equation 4.5 [15]. Note that revenue refers to business income in general and is not the same as profit [15].

$$R = (\Delta Costs_{max} - C') * V[15] \tag{4.5}$$

with

Unit	Name	Description
R	Revenue	Income from normal business activities
C'	Expected costs of production	Annual production costs
V	Amount of cases per year	Effective sales market indication

Using Equation 4.5 the needed QoL present in Equation 4.2 can be reversely calculated by changing from

$$R = ((((1 - \Delta QoL_{max}) * n) * WTP) - C') * V \tag{4.6}$$

to

$$QoL_{needed} = QoL_{SotA} + (-\frac{\frac{(\frac{R}{V}+C')}{WTP}}{n} + 1) \tag{4.7}$$

giving the needed QoL of the MT as a result. With this Equations 4.5 and 4.6 venture into the Threshold analysis described below and in Equation 4.8.

Cost-effectiveness: Threshold Analysis

The estimated amount of revenue, in combination with the calculated headroom, shows whether the MT could be profitable with the stated amount of funding.
Alternatively, a more formal value of investment analysis testing might be needed. This involves testing a more realistic, effectively speaking this will result is a less optimistic, estimate of the increased effectiveness ΔQoL [15].
The analysis gives an effectiveness threshold as to where further investment of capital and time must stop.
The threshold analysis is an iterating variant upon the headroom analysis presented in Section 4.2.9 and Equation 4.3 where single value of ΔQoL will be replaced by a range of possible effectiveness. This determines at what point the new technology will no longer be cost-effective from a development perspective. This being the case when Equation 4.8 does not hold true.

$$Margin_{Profit} < ((((1 - \Delta QoL) * n) * WTP) - C') * V \tag{4.8}$$

With all this information a *Value dossier* can be created. This will set clear goals for the designers as where to aim for when taking the next iteration in the design process. The next step is the construction of the actual **Incremental Cost Effectiveness Ratio**.

4.2.10. Incremental Cost Effectiveness Ratio

With the creation of an ICER, the assessment of the increased quality of the new MT in comparison with the SotA is possible to use as a sales pitch instrument rather than an analysis tool.

To convince buyers to buy the new MT being developed or, in earlier stages of development, peak their interests, a method of comparison is needed. An ICER shows the increase in (cost) effectiveness of the project in comparison with the SotA and is one of the most commonly used methods in doing so.

A CEA describes an intervention in terms of the ratio of incremental costs per unit of incremental health effect, using the QALY as the standard unit within CEA [24]. In some instances, this changes the name from CEA into a cost-utility analysis. These calculations can also be seen in Equation 4.4 and are explained in Section 4.2.9. As mentioned, the calculation of an ICER is often a next step in the process. Whilst the previous equations show whether the project should continue or not, this ICER is an excellent tool to show the "quality" of the MT in comparison the other (competing) devices.
Typically the results of an ICER analysis are represented as points in one of the four quadrants of the cost effectiveness plane shown in Figure 4.5. Most new technologies lay within quadrant b., being more effective but also costing more than their comparator. Here the WTP line comes into play. The WTP, which is country and sometimes even disease specific, is the amount society is willing to pay for an increase of 1 QALY for one individual. This is, in most cases, the line to which governments and insurance companies abide when deciding on reimbursement questions. Meaning that a product estimated to be below and to the right of the blue line will be reimbursed. This is normally used for medication and medical technology that is eventually paid by society itself. However, it can be connected to the later distribution to the Dutch market of technologies of which the purchase will fall on the shoulders of hospital or medical institutions. Because this effect is an in depth effect of insurance systems, this will not be discussed further. In Table 4.4 the new newly adopted WTP values, based on the experienced burden of disease, for the Netherlands are shown. When presenting this in the cost-effectiveness plane from Figure 4.5, not one, but three lines are present [29].
Because RaM deals with the more peripheral types of MT, the insurance company allowance of the MT is less important, see Section 4.1. In most cases, the hospital itself will be responsible for the purchase and no insurance plan type of funding is present for them. Meaning that the ICER will primarily be used as a sales pitch instrument within RaM.

Table 4.4.: **Dutch WTPs based on burden of disease per 2015 [49]**

Burden of disease (disutilities)	WTP
0.10 to 0.40	€20.000/QALY
0.41 to 0.70	€50.000/QALY
0.71 to 1.00	€80.000/QALY

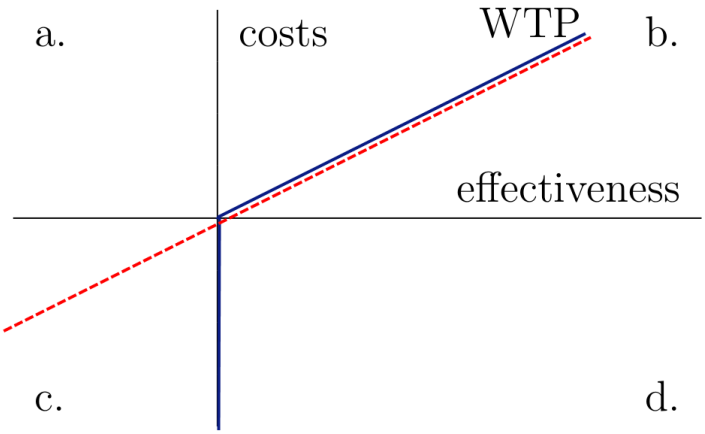


Figure 4.5.: **Cost-effectiveness plane used in CEA to compare different medical technologies with eachother. With in dotted red the WTP and in blue the reimbursment line.**

Still several problems remain present within CEAs, of which three are listed below [24].

Indirect costs
Indirect costs typically consist of lost wages due to being taken out of the general work force.

There is no uniformly accepted standard practice of incorporating such costs [24]. If implemented by calculation of actual monetary value, the ADMM would become extremely more complicated. Alternatively, a simpler variable, the difference in indirect costs (ΔIC) between comparators, can fulfil the same function [24].
When $\Delta IC < 0$, patients are back to work faster than when using the comparing technology. When implementing, this reasoning has to be reversed by showing that patients will need/are estimated to need less recovery time, leading to $\Delta IC < 0$ [24].

Future medical costs
Simply the extra medical costs the, for example, patient, insurance company and government will experience by the patients prolonged life caused by the new technology [24].

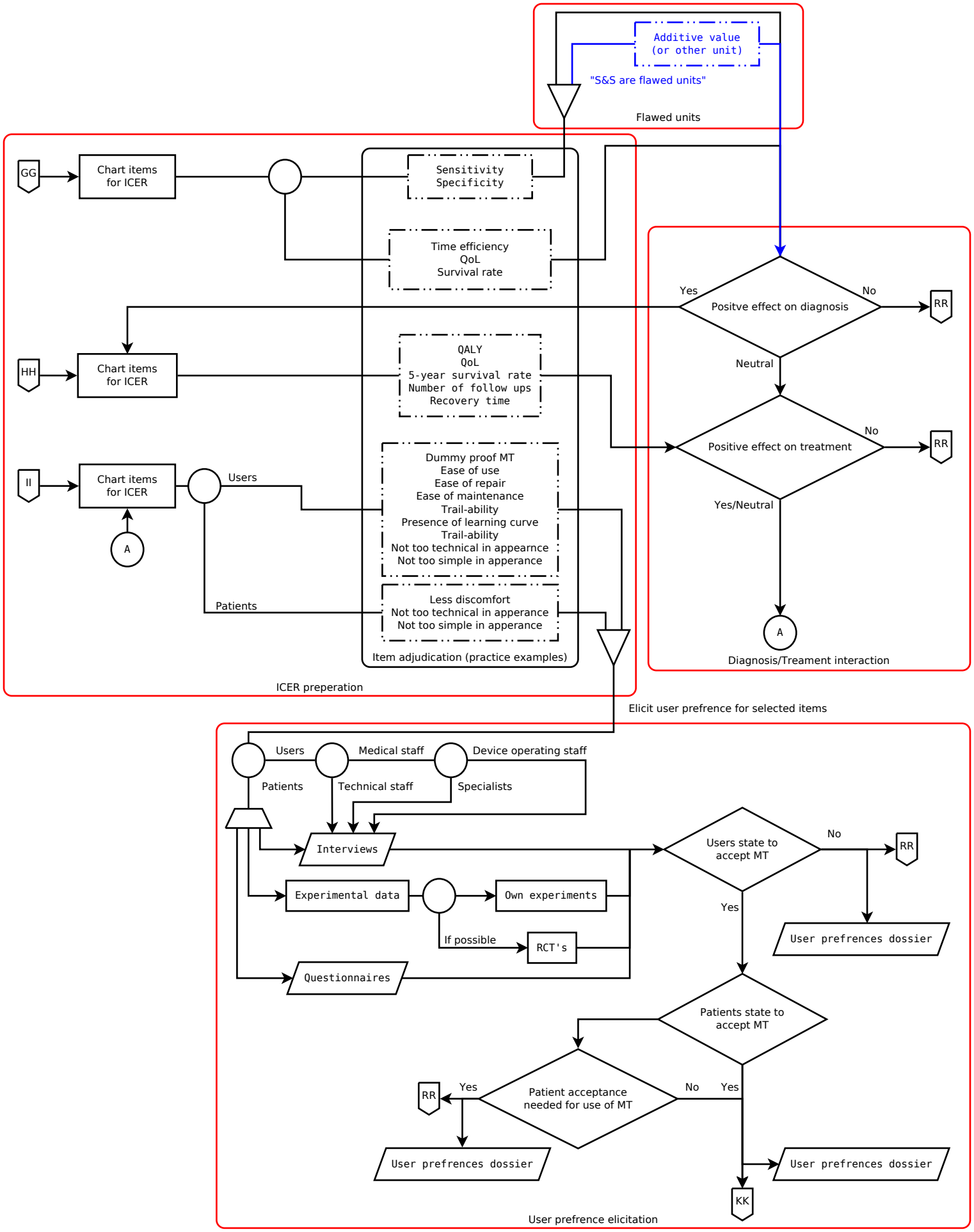
This is not something to be taken into consideration for two reasons. First of all, this

is a logical consequence of improving medical technology [24]. This is being complemented by a longer living population [24].

Age bias
When describing the benefit of new technologies in terms of QALY or life years saved, a question arises. Are these methods intrinsically bias against the elderly?

The answer to this question, in most cases, is "yes" [24]. But in most cases the outcome is again weighted based on age categories. This bias is also less relevant in the field diagnostics where new technology is purchased for a multitude of patients in comparison to single patient purchases in the case of medication, meaning lower relative costs for hospitals [24].

To fill in the cost effectiveness plane for the new MT a selection of items that are to be compared is needed. For this the possible items are divided into the *Diagnostic qualities*, *Treatment qualities* and *User comfort* of the product and will be selected in the **Item adjudication** phase of the model, see Section 4.2.11. With the *items selected* a more thorough SotA investigation will allow for a *ICER to be created*. This can be done by either *comparing the new MT with* the golden standard. This will also determine the market position of the product. In the early stage of the project it is perhaps more useful to compare it with the equipment used by the hospital of with the specialist expressed need originates persuading a *specific* hospital in purchasing the MT [29].


Additive value
(or other unit)
"S&S are flawed units"
Flawed units
GG
Chart items
for ICER
Sensitivity
Specificity
Time efficiency
QoL
Survival rate
HH
Chart items
for ICER
QALY
QoL
5-year survival rate
Number of follow ups
Recovery time
II
Chart items
for ICER
A
Users
Patients
Dummy proof MT
Ease of use
Ease of repair
Ease of maintenance
Trail-ability
Presence of learning curve
Trail-ability
Not too technical in appearnce
Not too simple in apperance
Less discomfort
Not too technical in apperance
Not too simple in apperance
Item adjudication (practice examples)
ICER preperation
Yes
Positve effect on diagnosis
No
RR
Neutral
Positive effect on treatment
No
RR
Yes/Neutral
A
Diagnosis/Treament interaction
Elicit user prefrence for selected items
Users
Medical staff
Device operating staff
Patients
Technical staff
Specialists
Interviews
Experimental data
Own experiments
If possible
RCT's
Questionnaires
Users state to
accept MT
No
RR
User prefrences dossier
Yes
Patients state to
accept MT
Patient acceptance
needed for use of MT
Yes
RR
User prefrences dossier
No
Yes
User prefrences dossier
KK
User prefrence elicitation

4.2.11. Item adjudication

The items that will be used within the ICER analysis are chosen within this phase.

Such an ICER analysis can become complicated very quickly. Therefore, performing the analysis with only certain/several comparing items can be used to perform the analysis quicker or to draw attention to a certain aspect of the new MT.

Continuing de division of *Diagnostic qualities*, *Treatment qualities* and *User comfort* the model enters the **ICER preperation**.

ICER preparation

At each of the three tracks, the *items that can be used with the ICER analysis are charted*. In the case of *User Comfort* again a division concerning *Users* and *Patients* is made. For each of the four categories, a set of item examples extracted from literature and practice is given [23, 29, 40, 44, 43, 48, 57, 60, 42]. Because the QoL and its variations have already been discussed a set of other useful items will be explained in more detail.

A low 5-year survival, high mortality and incidence rate are useful to RaM as indicators were opportunities for improvement are present [61]. Besides this, the three measures can also be used to show the successfulness of a new technology [43, 44, 61].
Although 5-year survival is a valid measure for comparing cancer therapies in a RCT, research shows that changes in 5-year survival over time bears little relationship to changes in cancer mortality rates [61]. Instead, they appear primarily related to changing patterns of diagnosis [61].
Even when new screening and treatment strategies are ineffective, comparing former cancer patients with palpable tumours at the time of diagnosis with patients with now diagnosable microscopic abnormalities, a drop in 5-year survival would be expected.
To avoid the problems introduced by changing patterns of diagnosis, observers have argued that progress against cancer be assessed using population-based mortality rates [61].
This combined with the need for RCTs and/or population-based statistics, leads to the advice to use these rates as indicators were opportunities for improvement are present [43, 44, 61].

"Flawed Units" - Sensitivity and Specificity

Following the *Diagnostic qualities* we arrive at the *Sensitivity & Specificity*. By classifying patients into groups based on the results of an investigation, sensitivity & specificity are two of the simpler diagnostic tests [2]. Most of the times this is based on the presence or absence of a positive outcome of the test. To state how good a scan, test or investigation

is in this classification, the proportions of patients who received a correct classification can be calculated [2].
This leads to the terms *positive* and *negative* to refer to the presence or absence of the condition of interest. Both terms can be subdivided to be a *true* - or a *false* -, meaning an actual presence/absence or a falsely attributed presence/absence leading to the abbreviations TP, TN, FP and FN [2]. When applying these within Equations 4.9 and 4.10 the sensitivity and specificity of the test can be calculated [2]. These outcome measures represent how good the investigation is in correctly determining affected and unaffected patients respectively [2].

$$Sensitivity = \frac{TP}{(TP + FN)} \tag{4.9}$$

and

$$Specificity = \frac{TN}{(TN + FP)} \tag{4.10}$$

Sensitivity and specificity are one approach to quantifying the diagnostic ability of the test and are an accepted outcome measure to show the quality of a procedure [2]. In clinical practice, however, the test result is all that is known [2]. Even so, when comparing patient A to patient A at a later moment in time, physiologically speaking they differ. This leads to the trend of researchers and doctors disliking these values and the introduction of new ones [22, 23, 60, 61]. For this reason, if sensitivity and/or specificity are found to be flawed, another unit could be used [22, 23, 60, 61]. Presented within Future Work, see Section 8, is the suggestion of Additive value.

Diagnostic/Treatment interaction

Continuing the *Diagnostic qualities* track, the decision whether or not *a positive effect on the diagnosis (quality) can be seen* is taken. If this is not the case, a redesign is in order. This is represented by the off page connector. If a positive effect can be measured, than a choice of *Treatment qualities* items should be investigated and a *positive effect on the treatment* **should** be reported [29]. If there is only a positive increase of the diagnostic quality by adding the new MT, there will be no increase in ICER and a redesing is needed [29].
Example: Disease A can only be diagnosed earlier/more clear/with higher accuracy. But if this does not lead to an increase in a measure of treatment quality, the experienced overall effect will be non-existing [29].
From here the model re-connects to the *User comfort* part of the model en continues into the **User preference elicitation**.

User preference elicitation

Because a large part of the sales success within the hospital depends on user satisfaction this part of the model is reached by all three of the ICER-tracks [40, 57, 60]. Here the users of the product are further/again split into four categories. This split shows how each of these categories is linked to three ways of eliciting (user) preferences, see Table 4.5.

Table 4.5.: **User categories and their elicitation methods.**

	Eliciting methods		
	Interviews	Experimental data	Questionnaires
Globalized users			
Patients	X	X	X
Users			
Technical staff	X		
Specialists	X		
Device operating staff	X		

Not only will these elicitations give the practical interpretation of the MT by its end users, but the most important question of the design process can be asked here. *Will the users accept the MT (in its current state)?* If is this not the case this can be incorporated into the design via the *User preferences dossier*. Following a stated acceptance, the same question can be stated to the patients. And only if their *acceptance of the MT (in its current state)* is important a possible redesign is in order. With the items for the ICER analysis selected the model can go back to the **ICER** and complete the analysis.

4.2.12. Business fit buyer

Assessing the current state of the new MT, the quality of the business fit for the buyer can be expressed.

Whether or not the MT provides a business fit for them is the core of the purchasing process within the hospital.

The most important question the hospital asks concerning new MT, is *if the new MT provides a business fit for them* [40, 57, 60]. It might be strange to think of a hospital as a business. Examples of questions to indicate if such a fit is present with the current state of the project are listed below.

- Is this/comparable MT already present in one of our other branches. (ZGT Hengelo for example consists of multiple hospitals in the region of Twente.)
- Is this/comparable MT already present within our operating area?
- Will this MT improve current interventions?
- Does this technology replaces an existing technology/device (within the hospital) or will this be an additional one?
- Does this MT fit in within our current specialization? (Many hospitals specialize themselves within a certain medical field.)
- Are these new type of procedures desirable considering the demography?
- Will this MT make new types of interventions possible?
- Does this mean we can perform a greater or smaller number of procedures?
- Do we have funds available for the purchase of this new MT?

With a positive outcome a bundling of the *User preference dossier*, *Value dossier* and the *Business model buyer* creates a *Data bundle*. This bundle will act as a direct input for the design phases. Even though a flowchart model uses the previously generated information anywhere downstream, these pieces of information are assessed to be so important that they are used as direct input. Now the third phase of the TRA, **TRA 2**, is entered. This is again described in Section 4.2.3.

4.2.13. Buyer financials

Assessment of the funds of the buyer available to purchase the MT being developed. Tactics how to cope with these funds are also presented.

Not only does the buyer (hospital) must have interest in the MT, expressed by a positive business fit, but the possibility to actually purchase the product also needs to be present.

By indexing, as far as this is possible, or *estimating the available funds within the buying party*, this is very much linked to trying to sell the product for the first time to a (set of) hospital(s), the price of the product can be assessed. These direct costs are for example determined by:

- the length of the project;
- the amount of paid employees within the project;
- the size of the sales market;
- the materials used within the final product;

If these *purchasing funds* prove insufficient, this *outcome is added to the Value dossier via the data bundle* and the flow constitutes to the **Design process 2**.
With sufficient purchasing funds available, the indirect costs of the product need to be assessed. These operational costs are the costs needed to keep the MT in working order. Example of operational costs are the:

- costs of disposables;
- costs of medical staff needed to operate the machine;
- costs of maintenance;
- costs of required power;
- costs associated with follow ups needed due to diagnostic/treatment failure;
- costs associated with follow ups needed due to diagnostic/treatment success;

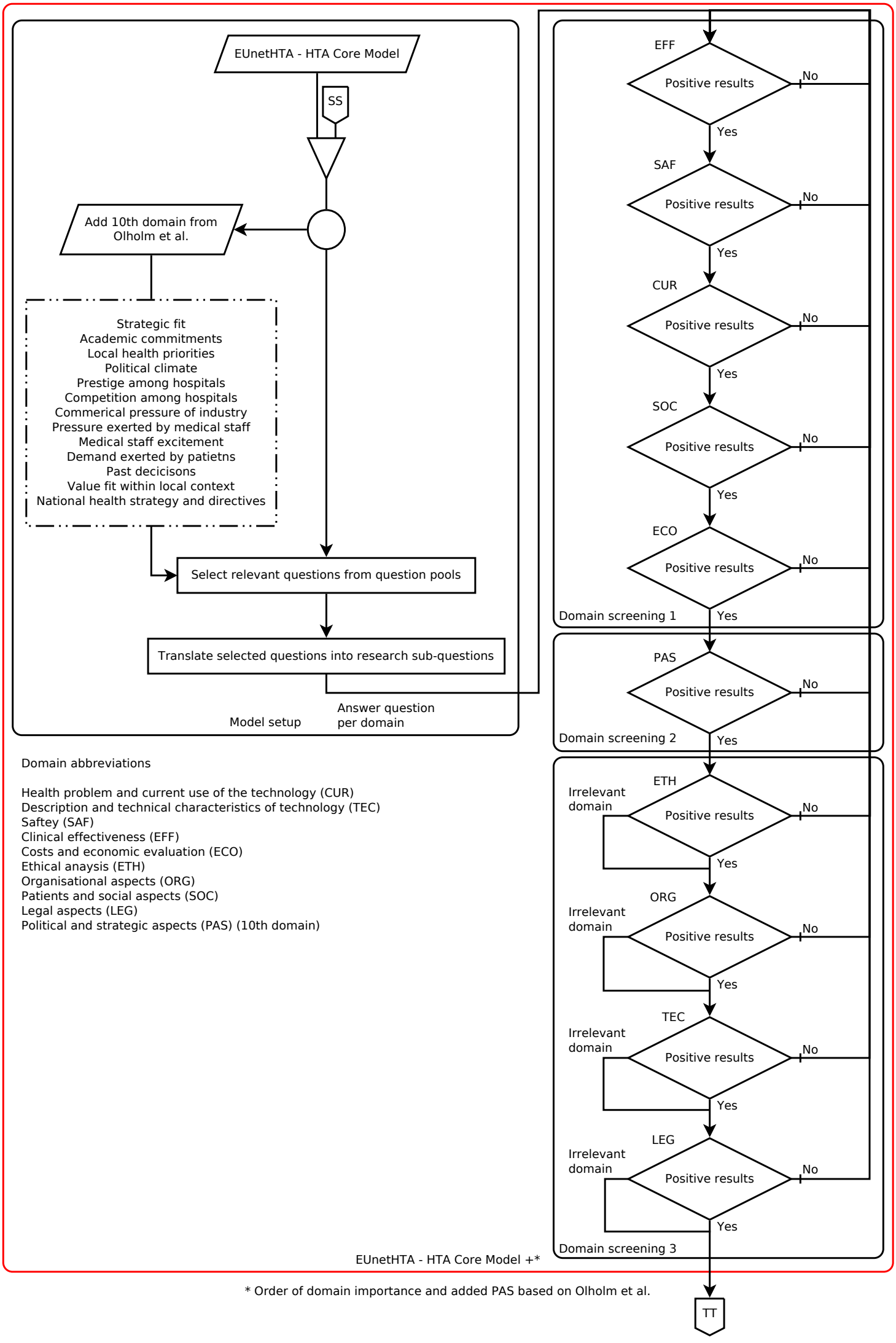
If these *operational funds* prove insufficient, this *outcome is added to the Value dossier via the data bundle* and the flow constitutes to the **Design process 2**.
However, if one of the funds is in a grey area, the calculated *positive ICER outcomes* can act as a *way to persuade* the hospital to buy.

4.2.14. Design process 2

Inputting collected data into the redesign of the MT after the ADMM has predicted that the current iteration of the project will be unsuccessful.

A design adaptation is in order when any of the previous questions/analyses conclude in a negative outcome.

Via (off page) connectors this phase is reached. Based on the origin of this connector the decision *whether or not to continue the project* is made. This leads to either a *termination of the project* or an *analysis via the* ***EUnetHTA - HTA Core Model®***. The goal of this analysis, the EUnetHTA - HTA Core Model® is explained in Section 4.2.15, is to give increased insight as why the project "ended up" here. The outcome of this analysis is added to the Data bundle. This bundle will also be the direct input got the *design adaptation*. From here the model is looped back towards the *Cost Effectiveness Analysis*, this being the first location where a link to the **Design process 2** can occur. If the fault was present at a later phase, these upstream lying phases can be skipped.



Domain abbreviations

Health problem and current use of the technology (CUR)
Description and technical characteristics of technology (TEC)
Saftey (SAF)
Clinical effectiveness (EFF)
Costs and economic evaluation (ECO)
Ethical anaysis (ETH)
Organisational aspects (ORG)
Patients and social aspects (SOC)
Legal aspects (LEG)
Political and strategic aspects (PAS) (10th domain)

EUnetHTA - HTA Core Model +*

* Order of domain importance and added PAS based on Olholm et al.

4.2.15. EUnetHTA - HTA Core Model®

As mentioned in Section 2.2.2, the EUnetHTA - HTA Core Model® contains, among other things, an extensive list of generic questions and elements for assessment divided into nine domains that can be used during a EHTA or HTA [42, 54].
This model is placed relatively late within the ADMM to act as a gatekeeper. It will be used to determine as to why the ADMM adjudicated the MT as unsuccessful during one of the earlier analyses. By introducing a new set of screening question, the R&D-team cannot fall into the pitfall of skipping over the failed analyses already performed when testing the new iteration of the product (design) due to eagerness or frustration.

To the nine domain already present within the EUnetHTA - HTA Core Model®, a tenth domain is added. Literature assessed that the items present within this *Political and strategic aspects* are found to be valued by hospital managers when dealing with health technology investments [42]. With the introduction of this new domain an equally new set of question categories is introduced within the *model set-up*. From this pool of ten domains *relevant questions are selected* and *converted into questions*. These questions could also be used in the beginning of the project as a replacement of or supplement to **Design Process 1**, but are used here to fulfil the gate keeping function. Continuing the model a set of three *Domain screening* boxes where the questions are tested per domain are presented. In *Domain screening 1* and *Domain screening 2* the options are either a positive outcome, continuing downstream, or a negative outcome, looping back to the beginning of *Domain screening 1*.
In *Domain screening 3* the option of "irrelevant domain" is added. The order of domains is based on the information most preferred by hospital managers when dealing with health technology investments [42]. Here the domains ethical aspects, organisational aspects, description and technical characteristics of technology and legal aspects where found to be unimportant [42].

With this the explanation of the building blocks forming the creation of the ADMM is concluded.

4.3. Chapter conclusion

Based on the acquisition model of the ZGT Hengelo, a focus on a single purchasing stakeholder to be implemented in the ADMM is made, the hospital. Working from this acquisition model, obtained via meetings with medical staff, medical specialists and members of the acquisition committee of the ZGT Hengelo, solutions for/indicators of/ assessment of problems identified in Chapters 1, 2 and 3 were created. The resulting elements were connected in a flowchart model, the (Early) Health Technology Assessment type Assistive Decision Making Model. The element order is based on the (future) working methods of

RaM. Within the next chapter a run of the model using the McRobot project as a case study will show the feasibility of the ADMM.

5. Results

As mentioned in Chapter 1, the completed ADMM will be tested with the "McRobot project" and this project will receive adjudication via the ADMM. This test is in no sense a validation of the model, but this first run will show strengths, weaknesses and the overall viability. This McRobot project (Mc-p) is a collaboration between RaM and the hospital ZGT Hengelo and can best be described by one of its supervisor.

McRobot project

"The burden of cancer is increasing every year. Since 2009, cancer has been the first reason of death in modern countries like the USA. Improvements in medical technology have reduced incident and mortality rates of many other diseases, leaving oncology as one of the most important fields for developments. Although cancer is an age-related disease and most of the incidences happen in old ages, it is also the main reason of death before retirement in almost all ages. In addition, medical industry has not kept up to the cancer growth and mortality rates of cancer-related diseases are rising significantly. On the other hand, modernism has declined birth rates in last decades, and many developed countries will struggle with lack of work force in near future. Governments, insurance companies and hospitals need to employ new technologies to cope with these upcoming problems.

Many technologies are being developed to overcome cancer-related diseases, including preventive, diagnostic and therapeutic technologies. Minimally invasive surgery, image-guided interventions and robot-assisted procedures are some of the very promising developments. However, each of them has difficulties when used separately. Conventional minimally invasive surgery elongates the surgeon's learning curve, lengthens surgery time and endoscopic pictures are inaccurate and limited. The capabilities of surgical robots are not explored to the maximum without digital feedback and image-guided interventions, and most of the operator´s precision is wasted with the current surgeon-in-the-loop solutions. Combining assisting robotic systems and medical imaging systems such as MRI, PET and CT can help the surgeons to see internal glands in details and reach the targets with the maximum possible precision. Robots compensate natural tremors, enhance human´s force and geometry abilities and keep operators far from any exposure and infection risk. The MRI-compatible assistant robot for image-guided minimally invasive interventions provides this solution. The most important application is for minimally invasive cancer diagnosis and treatment.

Procedures like biopsies, brachytherapy, cryotherapy, thermal ablation and drug delivery are some possible applications.

In the last decades many groups have tried to combine robots and imaging systems for minimally invasive surgery but none of them was ever successful to sell to the market. Many of these project appear to be technology driven where the work flow and boundary conditions of the surgical application/environment are not taken fully into account. The resulting systems do not fit well within the clinical work flow, and are therefore not capable of passing the other hurdles before successful clinical introduction (e.g. surgeons apprehension with respect to autonomous robotics legal issues, and FDA resistance) safety issues, sterilizibility, human compatibility and user-friendliness are some of the main issues which will be solved in this project.

The McRobot project started in 2006 in Iran with the objective of creating an affordable and versatile MRI compatible robot. Several research and proof-of-principle set-ups were created to test and analyse critical functions and possible design solutions of components. The primary investigator moved in 2014 to the RaM of the UT. Work on the McRobot project is now continued under the supervision of prof.dr.ir. Stefano Stramigioli. The goal of this project is to achieve all objectives that the McRobot project started out with. A researcher and one MSc student are working on the project with a Total Design and market oriented approach. *(At the time of writing.)* We are designing a system that can work during real-time MRI. It must be compact and fully MRI compatible. Compensating of the human body motions, fast needle insertion, needle rotation control and automatic specimen removal are some of our innovations. Every radiology site can buy McRobot with a reasonable price to extend applications and promote its medical efficacy.“

ir. Foad Sojoodi Farimani
RaM
30-10-2014

Ziekenhuisgroep Twente Hengelo

ZGT Hengelo is the Hengelo branch of several Dutch hospitals. The ZGT Hengelo is involved with the Mc-p via interventional radiologist Jeroen Veltman. He provides epistemic information and allows the design team to experience the procedures for which the McRobot is being designed.
For this research dr. Veltman and colleagues provided insight into the workings and reasoning of the purchasing within the ZGT Hengelo and how they as medical staff tend to be involved in the decision making and design process of new MT.

5.1. McRobot analysis

Because both the Mc-p and the ADMM itself are still in early stages of development, a complete project analysis or model test is not possible. The Mc-p, when comparing it to the ADMM structure, stands at the brink of the **Cost Effectiveness Analysis**. The ADMM shows several completely new key concepts and some excising concepts new to the general design of MT. To illustrate these concepts, four of the phases that would have been used on the Mc-p if the project would have implemented the ADMM, were used to analyse the Mc-p and test the current version of the ADMM. See Figure 5.1 for the (sub)phases analysed and where the stand within the model structure.

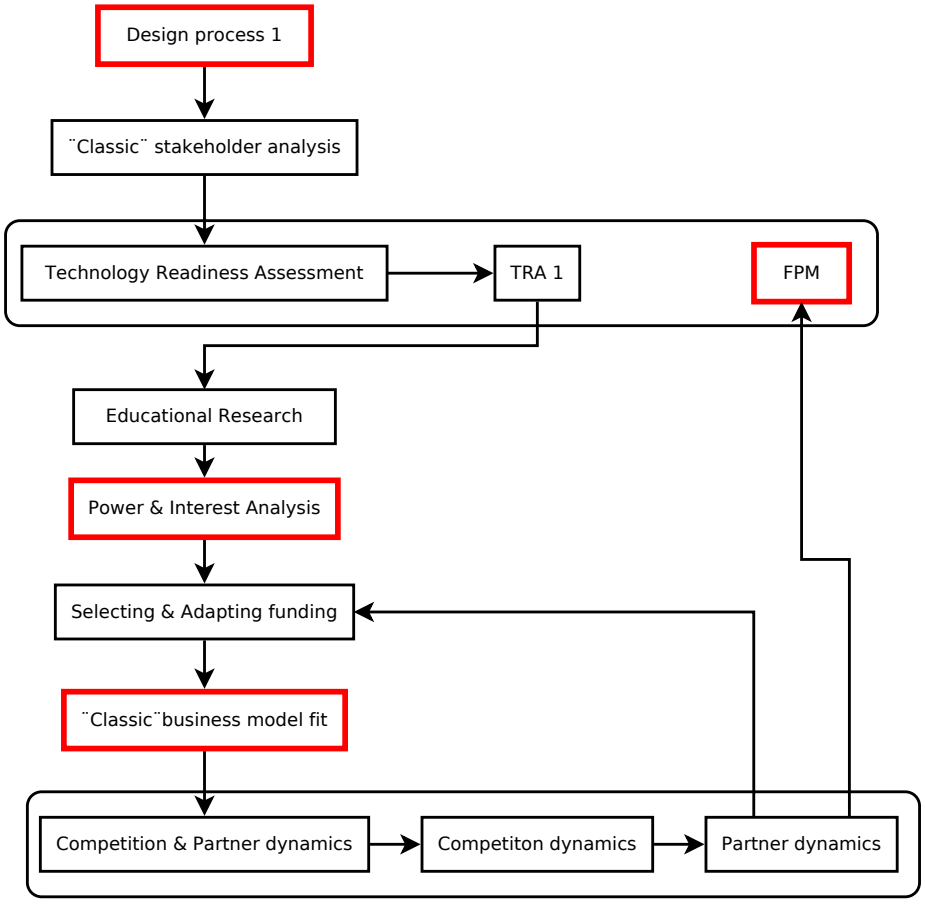


Figure 5.1.: **Overview of the part of the ADMM applicable for the McRobot analysis.**
In bolded red the (sub)phases of the model being analysed and presented in this chapter.

5.1.1. Design Process 1: QDQ

The first of these phases is also the starting phase of the model. Within this phase only the QDQ, one of these new key concepts, used to determine the continuation of the project, is performed. For this the qualitative design questions are repeated and answered below. The answers are based on the written research proposal and answers given by the project supervisor [23, 46].

Project

- What is the expressed need/formulated problem?
  There are three levels of needs expressed as the basis of this project. Firstly is the improvement of medical imaging in general. This is followed by a need for the inclusion of medical automation within these imaging modalities. Via the McRobot the specific need of improving MRI guided interventions is tackled.
- What is the output of the project?
  The output of the project is a multi-modality-compatible assistant MRI compatible robot for image guided minimally invasive interventions.
  More generally the output of the project is the widely implementable MRI compatible modulus to enable further development by others.
- Will it be a(n) (assistive) diagnostic or (assistive) therapeutic type product?
  The Mc-p will enable all of these to be developed.
- Will it fulfil a specific function, a global function or a set of functions?
  The Mc-p will fulfil a global function/set of functions.
- Will this product fulfil the expressed need?
  Together with the medical specialists, it was determined that the proposed McRobot can fulfil the expressed need.
  The modular approach is also believed to be a good stepping stone to enable the rapid improvement of medical image modalities.

Costumer

- To whom will the product be sold?
  The product will be sold to hospitals with a (sufficiently large) radiology department.
- Why do these ... need this product?
  Hospitals with a (sufficiently large) radiology department need this product because it will enable increased performance and an improved working environment within the ward.

- How big is this expressed need?
  Believed to be sufficiently large to have started the project.
  This could not be expressed in numbers.
  Within the world there are approximately 36,000 MRI machines, at present, about 2,500 MRI imaging units are sold worldwide every year [35]. This number can be carried over to the upcoming (unanswered) questions.
- How big is the group of costumers expressing this need?
  Believed to be sufficiently large to have started the project.
- Does this create a large enough sales market?
  The fast growing use of MRI is estimated to surpass the use of even CT in 2040 [22, 23]. This is sufficient to believe such a sales market exists.

User

- Who will be the user of the product?
  The end user is currently set to be interventional radiologists.
- Why do ... need this product?
  Interventional radiologists need the McRobot because it enables to perform better in an easier working environment.
- How big is this expressed need?
  Believed to be sufficiently large to have started the project.
  This could not be expressed in numbers.
- How big is the group of users expressing this need?
  Believed to be sufficiently large to have started the project.
  This could not be expressed in numbers.
- Does this create a large enough sales market?
  The project is discussed with several (interventional) radiologists, all assessing the need present large enough.

Patient

- For what patient groups will the product be beneficial?
  At the smallest scope of the project this product is beneficial for patients undergoing lung biopsy. At the largest scope, this will extend to all patients undergoing any kind of image guided intervention.
- Why do ... need this product?
  Patients need the McRobot because it will increase the overall user comfort across the board.
- How big is this expressed need?
  Believed to be sufficiently large to have started the project.
  This could not be expressed in numbers.

- How big is the group of costumers expressing this need?
  Believed to be sufficiently large to have started the project.
  This could not be expressed in numbers.
- Does this create a large enough sales market?
  Believed to be sufficiently large to have started the project.
  This could not be expressed in numbers.

Management

- Does this project fits in with our skills?
  The creation of robotic devices stands at the core of RaMs capabilities.
- Do we expect to have the necessary skills for this project?
  With the pledge of cooperation by the ZGT Hengelo, the in house knowledge regarding MT and image modalities and the given robotic expertise within the group itself, RaM expects to have the necessary skills for this project.
- Does this project fits within our current business model?
  Do to shifts within RaM this is something that could not be investigated.
- Is the deadline set achievable?
  The project has not been granted funding, so no deadline is present at this time. However, the Mc-p is already, when viewing via the ADMM, halfway through the model. This gives reason to assume that the deadline of six years set by OTP should be achievable.

Future project questions

- Do we have partners with the necessary/complementary skills for this project?
  The ZGT Hengelo and in house expertise regrading MT and image modalities already provide RaM with the necessary/complementary skills for this project.
- What are their interests?
  Both parties share the same interests, that of creating the technology so it can be used in a hospital setting.
- What are our shared interests?
  See answer given at the previous question.

The questions that could not be answered are removed from this list.

5.1.2. Power & Interest analysis

In contrary to the Design Process 1 phase, all the sub phases in this second phase are new concepts within the design process and will therefore be discussed step by step.

Before performing this Power & Interest analysis (P&IA), explained in Section 4.2.5, the set of stakeholder used as input must be defined. For this the stakeholder listed in Table 4.1 is used, see also the list below. Note that within the creation of the ADMM the used stakeholders were condensed to only include the **Hospital**. Within the analysis of the Mc-p all the mentioned stakeholders were implemented.

1. Government
2. Insurance Companies
3. Hospital/ZGT Hengelo
4. Medical staff/Radiology department of the ZGT Hengelo
5. Patients
6. Applicant (used as the benchmark)
7. Investors
8. Medical industry

Using a set question when assessing P, In and Im for each of these seven stakeholders, all three variables are set at 1.00 for the *investors*, helps to rate them as similarly as possible. Here the leading question is straightforward.

"Do I, the stakeholder, want the McRobot to be available to me and others? "

Because the concept of a P&IA is a new one for most of the R&D-team members, the process can be simplified by first creating a power map, see Section 4.2.5 for an example, using the same leading question in Figure 5.2.

High Opposition	Medium Opposition	Low Opposition	Neutral	Low Support	Medium Support	High support
			Government		Hospital	Insurance companies
			Investors		Medical industry	Medical staff
					Patients	Applicant

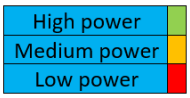


Figure 5.2.: **Powermap for the Mc-p.**
Leading question: "Do I, the stakeholder, want the McRobot to be available to me and others? "

The placement of the stakeholders is justified and introduced towards the P&IA as followed.

Government
In most cases the In of government is either extreme or neutral. This neutral stance is taken when the SotA is acceptable [8]. This acceptance can also be a product of ignorance. With no extreme interests taken in the Mc-p or the alteration of the current interventions, the government is stated to be neutral.
As discussed in Section 2 both the European and Dutch governments pose no threat to the market introduction of more peripheral types of MT that adhere to the set safety standards leading to a P of 0 [8].

Hospital
The hospital is stated to have a medium support of the product. Even though the project promises an increase in cost effectiveness, the stakeholder is placed here for two reasons. Not all hospitals have the same level of specialisation with regards to radiological interventions. The stakeholder here is representing a pool of hospitals, therefore reducing the overall interest. This effect is strengthened by the uncertainty concerning the actual amount of cost effectiveness increase.
Being the main costumer of the McRobot, their acceptance of the product is critical for the project success. This gives them a P of 1.00

Insurance companies
For the insurance companies a similar reasoning exists as mentioned for the hospitals above. Only here the effect of an unknown amount of cost effectiveness is nullified by the large(r) amount of savings that are experienced by the companies by reduced costs for the patients they insure even if the increase in cost effectiveness is small [10].

As discussed in Section 2 the purchase of peripheral types of MT is generally financed by the hospitals themselves. However, if the insurance companies accept the MT within their service packages, increased sales might follow raising their power within the availability aspects of the project. This leads to an overall P of 0.50.

Investors
Most of the investing instances are non-commercial enterprises. They fund those whose research proposal indicates the most chance of project success and thus have no interest other than stated by their funding criteria. Leading to a neutral stance.
Being the core of this research, the importance of finical health within the project has been made clear stating a P of 1.00.

Medical industry
Not the McRobot itself, but its components are predicted to be beneficial for the growth of MT in general. Therefore, the want of the medical industry will also be present. Due to the presence of competitors the pooled interest is set at a medium support.
Here the dynamics explained in Section 4.2.8 come into play. Because positive and negative external parties are present within this stakeholder pool, a P of 0.50 is assessed.

Medical staff
The Mc-p is focused on improving working conditions for the medical staff. This statement is enough to assess the In of the medical as that of a high support.
In the case of the ZGT Hengelo (part of) the medical staff generally makes a case for the purchase of new MT. Because their acceptance is key for the market success of the project, they are assessed with a high P. However, the hospital (management layer) will still make the decisions regarding purchasing, leading to $P_{hospital} > P_{staff}$.

Patients
Besides the improvements for the users, the Mc-p can lead to increased patient satisfaction. However, not all patients will benefit for this new technology. Leading to a total of a medium support
The patient pool is assessed to have little power within the acceptance process of the McRobot. This because the product will be a "back stage" type of instrument. This means that patients will have little to no knowledge physical existence of the product so aversion against or preference for the product dot no hold influence. This leads to an overall P of 0.50.

Applicant
Standing at the core of the project, the applicants wish for the product is the greatest. Consequently, their In is the benchmarking 1.00.
They also have the greatest power to make the end product available, leading to a P benchmarking 1.00

This power map will be supplemented with the Im of each of the stakeholders and is shown, alongside the results of the P&IA, in Table 5.1

Table 5.1.: **Power & Interest analysis performed for the Mc-p. Leading question: "Do I, the stakeholder, want the McRobot to be available to me and others? "**

$Stakeholder_i$	P	In	Im	W_i
Applicants	1.00	1.00	1.00	1.000
Government	0.00	0.00	0.50	0.000
Hospital	1.00	0.75	1.00	0.750
Insurance companies	0.50	0.90	0.00	0.000
Investors	1.00	0.00	0.80	0.000
Medical industry	0.50	0.75	1.00	0.375
Medical staff	0.95	1.00	1.00	0.950
Patients	0.50	0.50	0.50	0.125
$W_{McRobot}$				$2.2(+1.000 = 3.2)$

5.1.3. "Classic" business model fit

For the third phase the approaches written in Appendix E on how to perform both the PEST and the SWOT are followed. Both these state the need or a fixed situation being analysed. The situation for both analyses is *"implementation of the McRobot into the (Dutch) hospitals"* and is chosen as an example for the fact that it stands at the core of the success of the project.

Table 5.2.: **Example results of the PEST using the fixed situation: "Implementation of the McRobot into the (Dutch) hospitals".**

Political	**Economical**
Adherence to (medical) safety rules	Reasoning for buying new MT by costumer
Adherence to funding programme criteria	Product interest by costumer
	Product interest by user
	Product interest by patient
	Long project span
Social	**Technological**
Development of target group	Obsolete-ion cycle
Viewpoint on medical robotics by costumer	Competing technology development
Viewpoint on MT by costumer	Competing patents
Viewpoint on medical robotics by user	Intellectual property issues
Viewpoint on MT by user	
Viewpoint on medical robotics by patient	
Viewpoint on MT by patient	

The PEST results in Table 5.2 indicate the following points that are important business model/way of operation parameters to be considered when continuing the project. These points are also fairly universal and will not only prove important for the Mc-p, but also almost all of these points are explained and dealt with in the research proposal. The results regarding the viewpoints of the costumer, user and patient with respect to MT and robotics are known by the current project members.
Several of these PEST results will again be seen in Table 5.3 during the SWOT.

Table 5.3.: **Example results of the SWOT using the fixed situation: "Implementation of the McRobot into the (Dutch) hospitals".**

Strengths	**Weaknesses**
Adherence to (medical) safety rules	Product interest by costumer
Medical advantages	New protocol adaptation
Reputation of RaM in field of robotics	Long project span
Experience of RaM in field of robotics	Unknown vulnerabilities
Innovative concept	
Demand is practice generated	
Opportunities	**Threats**
Development of target group	Obsolete-ion cycle
Viewpoint on medical robotics by costumer	Competing technology development
Viewpoint on MT by costumer	Competing patents
Viewpoint on medical robotics by user	Intellectual property issues
Viewpoint on MT by user	Long project span
Viewpoint on medical robotics by patient	Viewpoint on medical robotics by costumer
Viewpoint on MT by patient	Viewpoint on MT by costumer
Current lifestyle trends	Viewpoint on medical robotics by user
	Viewpoint on MT by user
	Viewpoint on medical robotics by patient
	Viewpoint on MT by patient

The SWOT results in Table 5.3 indicate the following strengths and pitfalls within the Mcp. The here mentioned *strengths* are not yet advertised within the research proposal, the template found in Appendix B as part of the FPM does mention to do so. Of the identified *weaknesses* only the dangers of the long project span associated with the development of MT are discussed. The same goes for the *threats* in which the obsoletion cycle of the McRobot is something to investigate further.

5.1.4. TRA: FPM analysis

Lastly, by using the current version of the research proposal of the Mc-p the FPM analysis was performed. The results of the analysis by a single respondent per question are seen in Table 5.4. Table 5.5 shows an overview similar to the results in Chapter 3.

Table 5.4.: **Total overview of the results scored per question in the FPM by the Mc-p [46].**

	Question											
Section	1	2	3	4	5	6	7	8	9	10	11	Section score
A	6	10	8	10	8	10	4	8	4	8		122
B	2											18
C	10	8	8	6								128
D	10	10	8	8								144
E	6	8	8	8								68
F	2	8	8									18
G	6	10										48
H	10	6	8	8	8	8	8	8	10	6	6	70
I	8											48

Table 5.5.: **Scores per section and total score of the Mc-p of the FPM [46].**

Project	A	B	C	D	E	F	G	H	I	Total	Prediction
McRobot project	76	2	32	36	30	18	16	86	8	663	Successful

6. Discussion

To discuss the conducted research, again the division present within the report is continued.

6.1. The FPM

The FPM was created with only STW proposals. This, being a funding agency very suited for RaM, increases the amount of specificity of the ADMM. With specificity the focus on an individual subject is meant. However, the applicability of the FPM is also lessened by this specificity because STW is not the only agency that provides a good fit with the group. If the FPM is too focused, especially when lifting the scope from a (Dutch) national level to a European level, is a question that can only be answered by the usage of the model itself. But it is likely that the trend of focus/points of interest identified within the proposals in Table 3.1 will continue in supra national levels and for other agencies.
Even though the amount of proposals analysed, combined with the fact that only half of these were MT specific, was small ($n = 6$), a clear trend was identified. For this reason, the FPM does not show to be any weaker than if it would have been created with more (MT specific) proposals. The implementation of $n = 4$ non-MT proposals within the FPM, what is designed to be a MT specific model, can be justified by the relative small differences between these proposal types in comparison with the global (writing) trend that needed to be identified [52]. This trend resulted in the *points of interest* (socio-economic values) [52]. From this point onward, a MT specific route is taken where the questions presented in Section 3.1.1 were created.
As previously stated, the amount of proposals is significantly too small to perform an actual validation. The fact that the same input proposals were used in the validation, strengthens the needs for adequate validation. How to perform a more sufficient validation is explained in Section 8.
The scoring system used within this model can said to be still subjective. However, the adjudication process within the funding agencies is a subjective one and the amount of subjectivity can be further reduced by running the FPM with different project members. Taking this into consideration, the current version of the FPM already succeeds in making a highly subjective process, that of the writing and checking of an own research proposal, more objective.

6.2. The ADMM

The completed ADMM is a first step. Many of the here mentioned point of discussion are linked to this fact. For such a first step simplifications had to be made. Instead of looking at purchasing behaviour of "all" of the possible purchasing parties associated with MT, a focus has been put on a single stakeholder, the hospital. Within this research the stakeholder is represented by the ZGT Hengelo. By this, the research is pinned at a Dutch national level. This focus enables the model to have a high level of specificity. The specificity also ignores the interaction between stakeholders. The combination of insurance company and hospital being a classic example, mentioned throughout the report, of an ignored interaction.
To test the ADMM, the current version of the Mc-p was run through the model and the findings of this analysis are stated below.

If the ADMM were to be implemented within RaM in its current state, a change in working method is required. This is an issue that will influence the success of the model greatly. Transition can be smoothed by the fact that using the model will not take up much time per respondent. As mentioned, an increased quality of the results is expected when (sub)phases, such as the QDQ, P&IA and FPM, are performed by multiple respondents. Consequently, this will increase the workload drastically when viewing from a project level. However, by using several of the model phases during the McRobot analysis, the usage of the ADMM shows to be straightforward and not so taxing. On top of this, both of the issues, that of acceptance and the time constraints, can be solved by the fact that each of the newly introduced key features can still be implemented even if the flowchart approach is not accepted as new working method. The features will retain their ability to estimate the viability of the MT being developed and assist in securing finances to span the investment needed when used outside of the ADMM.
This being said, placement of two of the phases within the ADMM may seem strange. The FPM, and with that the application for a funding, is situated relatively late within the flow, with the Educational Research placed in front. By following this order, a lot of work is done before the financial health of the project has been secured, seemingly strengthening the problems mentioned at the start of the report. However, the proposed flow allows for the possibility of performing several project and product success predictions, one of which is the entirety of the Educational Research phase, giving much information about whether or not to continue the project. This enables the R&D-team to terminate unsuccessful projects before even having to invest in writing the proposal. Ideally, the preliminary phases lead to all the information needed for the research proposal, what now only needs to be combined in a report.

Furthermore, throughout the model several of the phases show to have overlap with other phases, this is shown in Table 6.1. This is not a bad property of the model because overlap, without doubling the work, can provide extra depth within and extra connection between

the phases. This for example within the CEA phase of the model. By connecting this to the ICER and Item Adjudication phases, a more in depth explanation of the material and a broader overview was created.

Table 6.1.: **Overview of phases of the ADMM and overlap between phases**

	Phase	Overlap with				
1	Design process 1	2	5	7	12	16
2	"Classic" stakeholder analysis	1	8			
3	Technology Readiness Assessment					
4	Educational Research	13				
5	Power & Interest Analysis	1				
6	Selecting & Adapting funding	7	8			
7	"Classic" business model fit	1	6			
8	Competition & Partner dynamics	2	6			
9	Cost Effectiveness Analysis	10	11	14		
10	ICER	9	11			
11	Item Adjudication	9	10			
12	Business fit buyer	1				
13	Design creation & research	4				
14	Buyer finances	9				
15	Design process					
16	EUnetHTA - HTA Core Model +	1				

The title of the research speaks of a *decision making model*, indicating this to be the core. The created ADMM could be viewed as such, but should be seen as more of a decision supporting model. Each of the decisions present in the overall process of MT creation should still be made by R&D-team, R&D-manager, etc. The ADMM enables them to perform solid decision making easier and standardizes this process to help them not miss any important steps.

6.3. McRobot project analysis

Performing the analysis gave good insight with regards to the quality and ease of use of the (used phases of the) ADMM. During the analysis the four phases were redefined to facilitate easier analysis and were more tailored towards RaM. These are also the versions found in Chapter 4. This indicates that the ADMM, certainly the not yet used phases, is still too global with regards to MT and RaM, and will need refinement with respect to this as well as to the "rough edges" considering the user friendliness.

Before any conclusions about the Mc-p results in Chapter 5 can be made based on this analysis, there are several important differences present between the analysis and the proposed route. The QDQ questions were answered by a single person. As mentioned in Section 4.2.1 the questions should be answered by multiple project members. These members ideally represent different skill sets as to maximize the value of the answers. Consequently, the introduced questions could be weighted according to this expertise to achieve an even higher effectiveness. To answer the QDQ questions, information from the present research proposal was used. Following the ADMM structure, this would not be possible and could have led to answers normally not given.
Within the justification of the placement of stakeholders within the power map, and thus the P&IA, there was mention of the pooling of different internal stakeholders. This leads to a less extreme output being observed in the results of the P&IA, see Table 5.1. To remove this dampening pooling effect, to some extent, the stakeholders used in the P&IA can be specified in more detail. However, this effect will always be present and is not necessary a negative factor within the analysis due to the fact that within each set stakeholder, there will be negative and positive voicing.
As with the answering of the QDQ questions, the proposal adjudication using the FPM was also performed by a single person. More intrinsic points are mentioned in the FPM section itself.

The points of discussion mentioned in Sections 6.1 and 6.3 and their respective rebuttals are also to be included in the discussion of the ADMM itself.

6.4. Literature placement

Because the created model is rather large, the literature placement is limited to the phases providing concepts new to the current design and decision making process (within RaM). These phases, and the completely new concepts, can be seen in Figure 6.1 also illustrating where in the ADMM these are located.

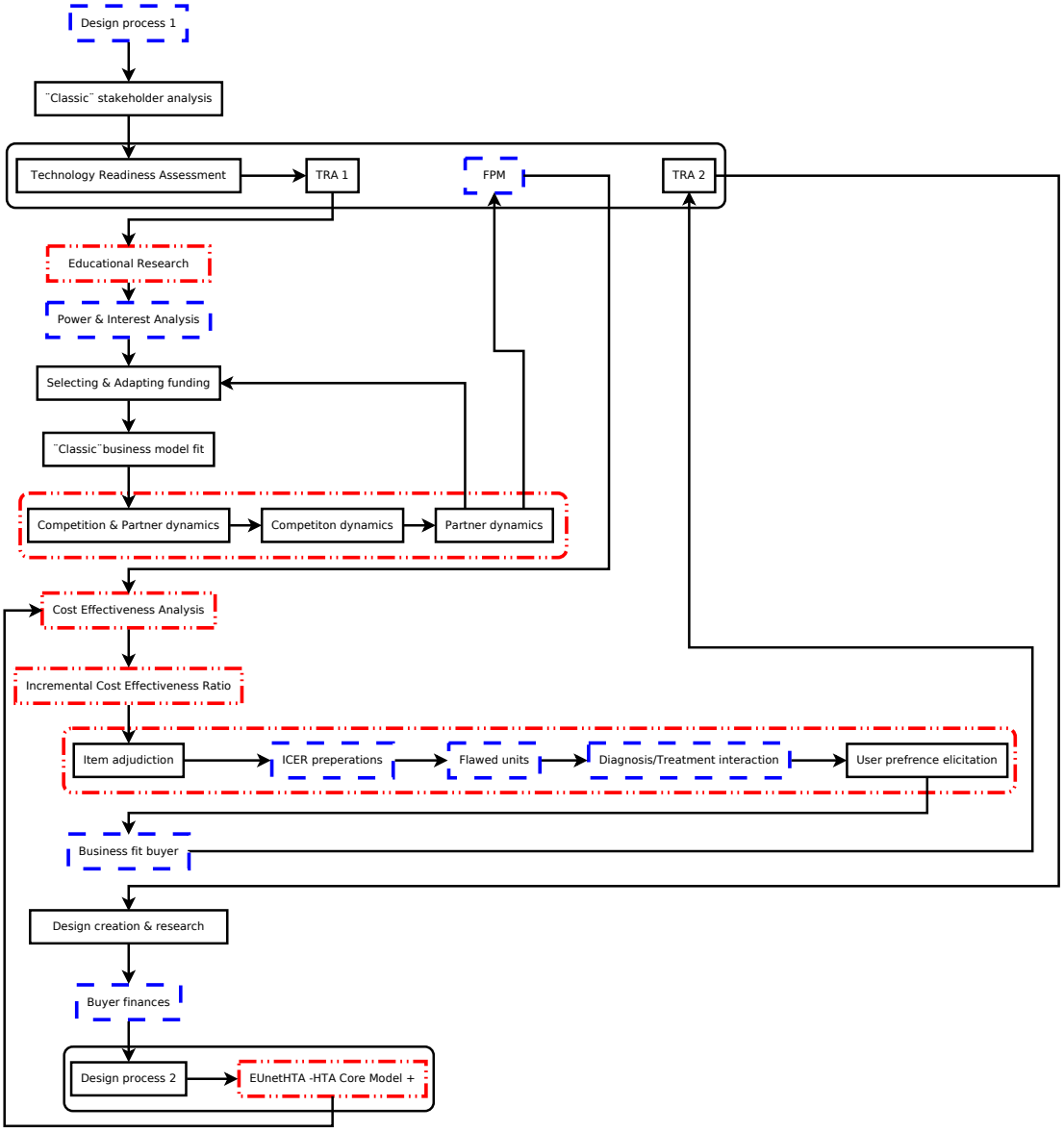


Figure 6.1.: **Overview of the ADMM with outlined in:**
striped blue the phases added to the design process using concepts created by this research.
striped and dotted red the phases added to the design process using excising concepts.

6.4.1. Qualitative methods

Within several of the model phases a qualitative approach, rather than answering qualitative, when making design decisions is taken. This is most apparent at the first phase of the model in which a sub phase called *Qualitative* Design Questions is presented.
Elegant technical solutions are not, in themselves, sufficient to drive investment [15]. When being situated in the early stages of technology development, here sometimes the nature of the end product is unknown, making a realistic estimation of its effectiveness difficult [15, 23, 26]
Literature states the following; "An organisation needs to begin by asking itself questions such as the following: Does this technology fit with our skills and strategy? Who are our competitors? How will our decision influence competitor behaviour? What changes to the regulations are in the pipeline? Are similar / competing technologies about to be launched [15]?"
These questions are therefore integrated within the QDQ. For the structuring of this process, there are already existing management tools. Examples of this are the PEST and SWOT [15]. Whilst others are available, these two analyses were chosen for their relative high ease of use while they still provide clear information. About this information, these qualitative analyses in general may do no more than formalizing existing knowledge [15]. But by doing so they give rigour to decisions and exclude low success projects [15]. However, an effect of qualitative questions, often forgotten by the more quantitative orientated engineers linked to the design of MT, is the "eye opening" factor of not only the answers, but also the questions themselves [15, 23]. Summing these effects, the "qualification" of certain model phases can prove very useful.

6.4.2. Power and it´s mapping

As a concept copied for the field of health policy, the implementation of a power(map) within the design process may seem as the odd one out. This field handles the explanations of power, its distribution in society and how governments make decisions [8]. Normally, this shows the interaction between society and government, often represented by policy and law. It is used to explain why decision making is not only a rational process, but eventually the result of power struggles between competing groups of actors [8]. Here again the qualitative factor comes into play. The way of thinking implemented in health policy can be transferred to the field of medical product design. Surely, here "(power) struggles between competing groups of actors" are also present. Not only can the position of actors, within the design field known as stakeholders, with regards to the project/MT give the R&D-team new insights, knowledge of the interaction between technology and policy, something that is not addressed in depth within this research and therefore not implemented in the model, is of major importance when creating MT that stands at the edge of regulations.

6.4.3. Cost Effectiveness Analysis

Within Chapter 4 some constraints regarding CEA have already been mentioned. But why is chosen for this CEA? In the economic appraisal of technology using health states the following connections are presented, see Figure 6.2. This figure shows several methods of measuring the health improvement provided by a newly implemented health programme [55].
This can be done by route *E*, measuring units natural to the programme or tackled disease. Route *B* assesses the economic benefits linked to the health improvements as a result of the health programme. The third route, *V*, measures the value of the improvement based on its value for the patient, family, or society. This is regardless of any economic consequences [55].

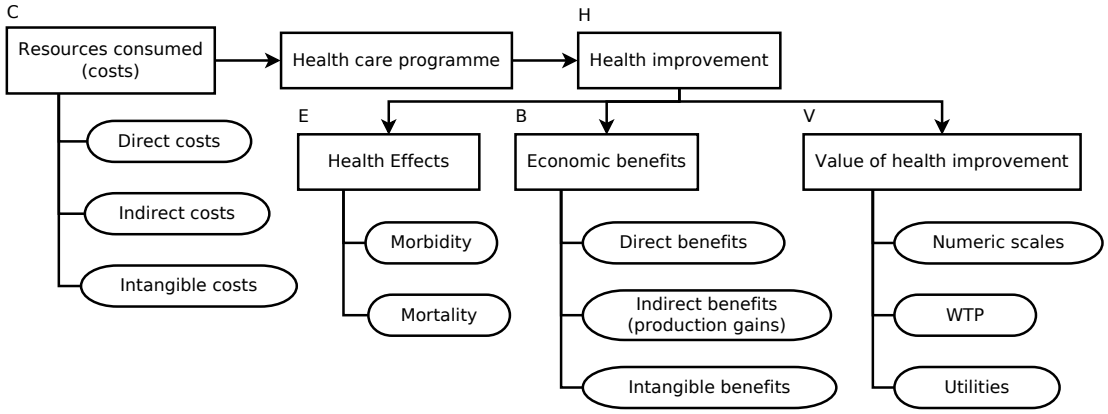


Figure 6.2.: **Components of economic appraisal of medical innovation [55].**

From here several combinations of *C*, *E*, *B* and *V* can be made, leading to a *Cost-effectiveness analysis*, a *Cost-benefit analysis* and a *Cost-utility analysis*. From these routes the CEA is chosen, in the phase **Cost Effectiveness Analysis** which is supplemented by a Cost-utility analysis (approach) within the **Incremental Cost Effectiveness Ratio** phase of the model.
Whilst the Cost-benefit analysis uses the simpler Equation 6.1 to calculate the net social benefit of the programme (NSB) [55].

$$NSB = B_1 + B_2 - C_1 - C_2[55] \tag{6.1}$$

Where a $NSB > 0$ means that the project is cost-beneficial and should be implemented, the analysis is seriously flawed because of this equations B_2 term [33]. By including these *indirect costs* as product gains, the analysis favours programmes targeted (more) to those who work and earn [55]. A strong point of the analysis, when dealing with the B_2 term

correctly, is the fact that it needs no comparator during decision making [55]. The presence of this comparator is however likely in the case of RaM. Showing increased benefits/effectiveness/experienced utilities in comparison with the SotA only strengthens the sales pitch. For these reasons the Cost-benefit is analysis is not used within the model.
The C_1 and C_2 terms are also found in the **Buyer finances** phase, where a similar reasoning towards purchasing, rather than appraisal, is taken.

6.4.4. Business model ZGT Hengelo

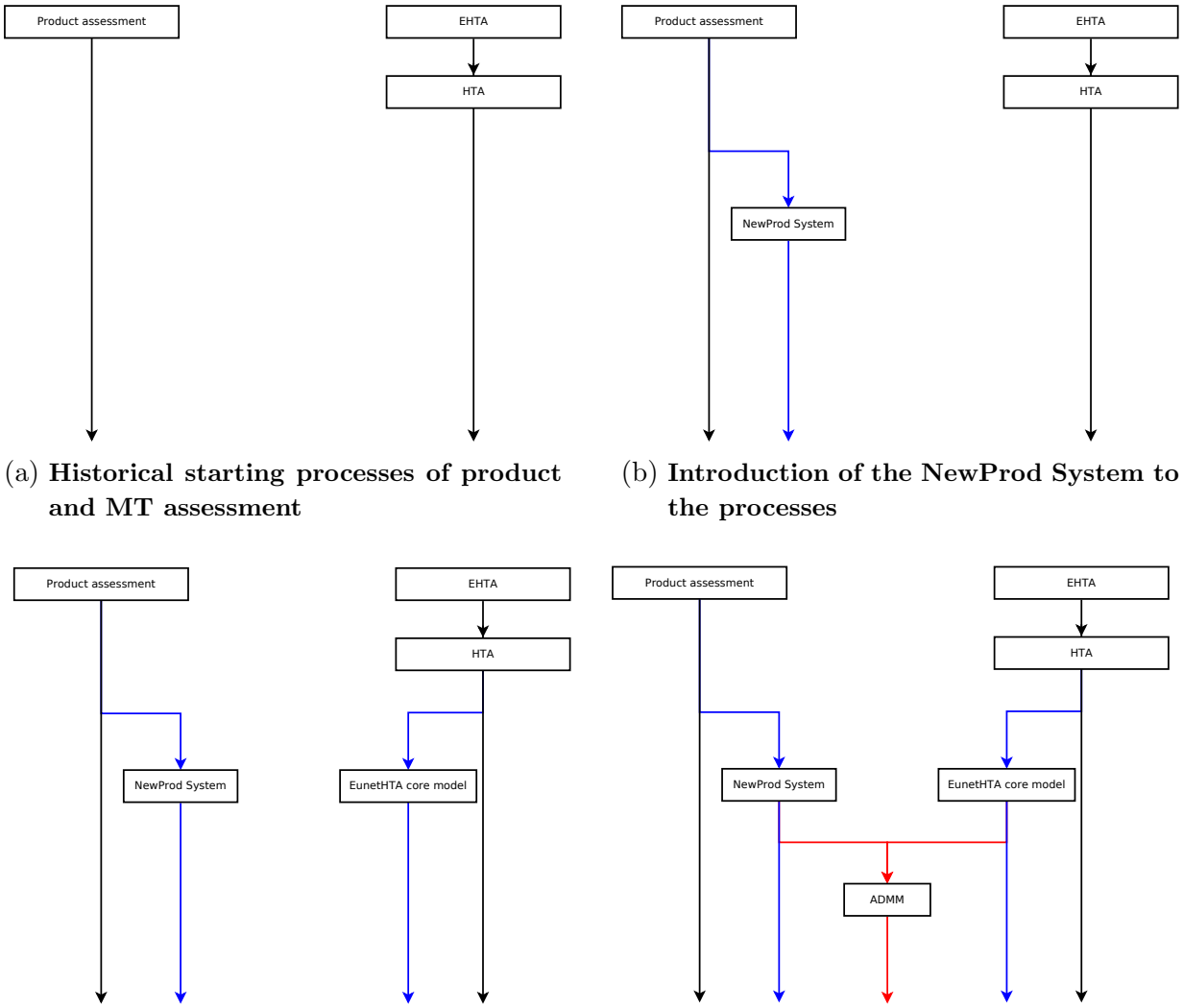
It is difficult to compare the business model and acquisition process, represented in Figure 4.2, for correctness. Even if is created based on meetings with those involved, there is always chance of withholding information, be it intentional or unintentional, for strategic purposes. The location from which the data is extracted is also highly specific.
By taking a step back within the process, a literary justification can be made. Using research concerning the adoption of technology among nursing staff and hospital managers, the items brought forward within the phase **Item adjudication** through **Business fit buyer**, see Figure 6.1, can be justified.

Nursing has been care orientated without any real concerns with regards of applying advanced technology, requiring nurses to make decisions [48]. Modern nursing however must take the explosion of new technology into consideration [48]. Because the nursing staff represents the largest group of technology users in health care organizations, their acceptance is vital in success of new MT [27]. It is advised, as this is also the most applied evaluation method of the implementational success of computers systems in health care, that acceptance relies on the nursing staff their individual decisions to adopt it or not [19, 27, 34]. Via Rogers innovation-diffusion model, it is stated that technology boasts characteristics defining its appeals to the individual. These are *relative advantage* to the SotA, *compatibility* with existing values, *complexity*, *trail-ability* and *observability* of the technology [47]. These key aspects are for $\frac{4}{5}$ identical to the aspects stated throughout the relevant model phases [23, 29, 40, 44, 43, 57, 60]. These are again underlined by the raking of the domains of EUnetHTA - HTA Core Model® model based on the hospital managers´ need or information when decision making for health technology investments is in order, as can be seen in the top five listed below [42]. Several of these can be directly linked to (sub-)phases of the ADMM.

	Domain	(sub-)phase
1.	Clinical efficacy/effectiveness	Cost Effectiveness Analysis
2.	Safety	
3.	Quality of evidence	
4.	Disease severity	QDQ and FPM
5.	Impact on healthcare costs	FPM and Buyer finances

6.4.5. Model combination

The goal of this project, when condensing the research goals, is a success indicating HTA/EHTA type model. Therefore, the choice of models that perform one of these tasks is not strange. The decision to use these two model specifically has been explained in Chapter 2.2.2. In this SotA analysis both models were deemed to be too general/global/unspecific and fulfilling only $\leq 50\%$ of the tasks needed from the ADMM. Sadly, a simple unification of the two process, see Figure 6.3, does lead to the ADMM but does not result in a 100% implementable ADMM.



(a) **Historical starting processes of product and MT assessment**

(b) **Introduction of the NewProd System to the processes**

(c) **Introduction of the EUnetHTA - HTA Core Model® to the processes**

(d) **Introduction of the ADMM to the processes, unifying them into one process**

Figure 6.3.: **Evolution of the product and MT assessment processes towards the proposed goal by combining the two basic schools.**

To get to this 100%, lifting both routes to reach the next step in assistive decision making, not only this research but the recommendations presented in Chapter 8 are needed.

7. Conclusion

Does this research result in the creation of a decision making model to aid in the development of medical technology? The answer to this question is, "no". Nowhere within the ADMM does the model makes a decision for the R&D-team. By structuring the assessment method, it supports the decisions made by the team itself. This is done by a standardized route expected to speed up the project by a more efficient knowledge allocation.

The ADMM is presented as a flowchart divided into several phases, this flowchart should be interpreted as an example of how to connect these phases together, whilst the actual result of this research is a set of building blocks to implement within the design process. The answers given within the QDQ sub phase of the ADMM are an excellent indication of the usefulness, and need, of the model. Even a project leader, a person who has been spear pointing the project for over 10 years, could not directly answer all questions. He underlined and understood then, the effect such models can have besides the objectification and support of decision making. It helps project members to think about their project. This shift in thinking and focus is one of the powers of the decision supporting model.

By combining the *NewProd System* and the *EUnetHTA - HTA Core Model*® the gap between two ways of product assessment has been bridged. When the recommendations are implemented within the decision supporting model, the next step in assistive decision making can be made.

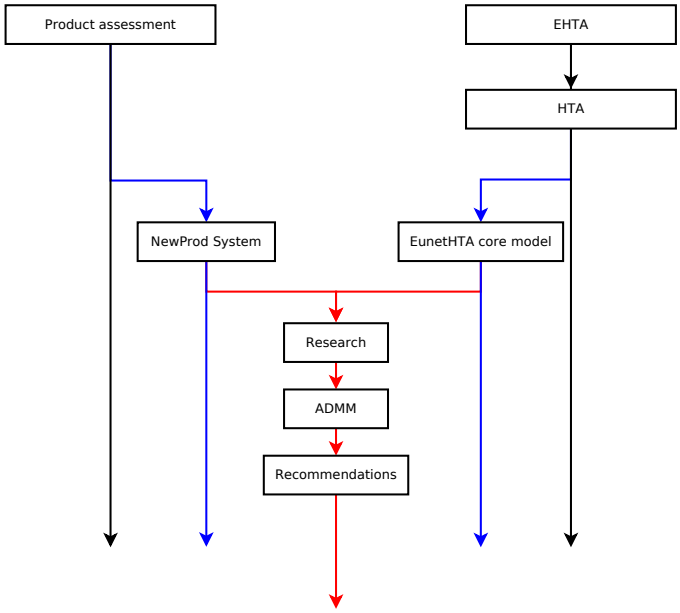


Figure 7.1.: **Lifting the current assitive decision making to the next level.**

At the start of this research, the term "veil" has been mentioned. This has led to the mantra like approach of: *"We don't know, what we don't know."* After lifting a piece of this veil, the following question can be concluded from this research.

How do stakeholders react to the (possible) market introduction of new medical technology?

From this single sentence a multitude of underlying research questions can be extracted.

How do **stakeholders** react to the market introduction of new medical technology?

1. Who are the stakeholders involved in the (possible) market introduction of new medical technology?
2. Which of these stakeholders are important and why?

How do stakeholders **react** to the market introduction of new medical technology?

1. What is the reaction of an individual stakeholder to the market introduction of new medical technology?
    - Reaction and/or interaction with respect to sales/purchase/funding blocking/allowing/investing in/funding
2. What is the interaction between multiple stakeholders when reacting to the market introduction of new medical technology?
    - Reaction and/or interaction with respect to sales/purchase/funding blocking/allowing/investing in/funding

How do stakeholders react to the (**possible**) market introduction of new medical technology?

1. At what level should innovation in the field of medical technology become public?
2. When should innovation in the field of medical technology become public?

How do stakeholders react to the **market introduction** of new medical technology?

1. What is the best sales market/costumer (for RaM) when introducing new medical technology?
2. How should this market introduction take place?

How do stakeholders react to the market introduction of new **medical technology**?

1. What is the stakeholder´s opinion towards medical technology?

7.1. Conclusion McRobot analysis

While taking the discussion points and conclusions regarding the research, ADMM and FPM into consideration, a conclusion about the McRobot project can be drawn. Note that the project did not follow the proposed structure from the ADMM and that information was used that would normally not have been available (as such).

With the answers given within the Qualitative Design Questions sub phase, even with the presence of the unanswered questions, the choice of continuation of the McRobot project is deemed to be justified.
In accordance with the success formula of $W_i > 0$ the Mc-p with a score of $W_{McRobot} = 2.2$ the project is advised to continue because there are no hindrances expected at this stage of the ADMM/the choice of continuation of the Mc-p is deemed justified.
The PEST showed no un-discussed points meaning that continuation the Mc-p is deemed justified.
The SWOT did show several weaknesses that were not yet discussed within the research proposals. By adding these extra weaknesses to those already identified, a stronger project position/foundation can be achieved. This shows that the choice of continuation the Mc-p thus far seems justified.
With a resulting score of 663($\gg$ 279) the research proposal is, according to Equation 3.4, deemed to be successful when submitting this to a relevant funding programme. The score is also on par with successful proposals 1 and 4, see Table 3.1, scoring 682 and 675 respectively.

Summing up these separate results leads to a positive verdict with regards to the further continuation and even the submittal of the research proposal with the OTP programme.

8. Future work

After completion of the research there are several points that are left unfinished or stand wanting. The first five of these points were already mentioned within the report, redirecting the reader´s attention towards this chapter. These points are all (sub) phases of the ADMM.

8.1. Validation FPM - mentioned in Chapter 3

At the core of the FPM stands the hypothesised success equation, Equation 3.4, repeated below.

$$\begin{aligned} \text{if} \quad & Total \geq 279 \quad \& \quad Total \neq \text{Fail} \\ & \qquad\qquad\qquad\qquad\quad Successful \\ \text{elseif} \quad & Total < 279 \quad \& \quad Total \neq \text{Fail} \\ & \qquad\qquad\qquad\qquad\quad Unsuccessful \\ \text{elseif} \quad & Total \geq 279 \quad \& \quad Total = \text{Fail} \\ & \qquad\qquad\qquad\qquad\quad Unsuccessful \end{aligned}$$

This equation was validated by the use of only two research proposals. These proposals were even part of the same pool used to create the equation. This must be improved upon when the equation, and so the FPM, is to be implemented. For improved validation a larger pool of research proposals regarding medical technology needs to be scored with the FPM. Each of the proposals also will be scored by multiple project members. With this new information Equation 3.4 can be changed into Equation 8.1 as to creep up to value X. Each proposal entered into the validation round will specify the actual threshold with more (experimental based) certainty rather than the theoretically calculated threshold of 279. By pooling the scoring results of different project members, the spread of answers can be averaged out increasing the reliability of the conclusion [50].

$$\begin{aligned} \text{if} \quad & Total \geq X \quad \& \quad Total \neq \text{Fail} \\ & \qquad\qquad\qquad\qquad Successful \\ \text{elseif} \quad & Total < X \quad \& \quad Total \neq \text{Fail} \\ & \qquad\qquad\qquad\qquad Unsuccessful \\ \text{elseif} \quad & Total \geq X \quad \& \quad Total = \text{Fail} \\ & \qquad\qquad\qquad\qquad Unsuccessful \end{aligned} \tag{8.1}$$

8.2. Weighted QDQ - mentioned in Section 4.2.1

The Qualitative Design Questions are presented in six categories. These are *Project*, *Costumer*, *User*, *Patient*, *Management* and *Future project* questions. Diversity between these categories suggests that not each of the project members is equally qualified to answer these questions correctly. It is not likely that R&D-team member "A" tasked with patient satisfaction will be as informed about the total managerial requirements with respect to the entire project as its project leader. To level the difference between the respondents, much like with the FPM, response from multiple members will increase the reliability of totalled answer [50]. To achieve this there are two options available.

1. Each of the project members answers each question. Because the output of these questions is a non-numeric value, a weighted system is difficult to implement. Rather than actual numeric weights, the given answers are taken more or less into account based on the respondent´s role within the project using the insight of the supervising analyst.
2. A specific project member role is assigned to one or multiple of the QDQ categories. With this the relevant expertise is present within the given answers. This again by-passes the need of a numeric weighted system.

8.3. Validate Power & Interest analysis - linked form Section 4.2.5

Just like the FPM, the P&IA´s conclusion is based on a success equation. When combining this Equation 4.1 with the success conditions we arrive at Equation 8.2.

$$\begin{aligned} \text{if} \quad & \Sigma_j P_{ij} In_{ij} Im_{ij} > 0 \\ & Successful \\ \text{elseif} \quad & \Sigma_j P_{ij} In_{ij} Im_{ij} \leq 0 \\ & Unsuccessful \end{aligned} \tag{8.2}$$

Again there is no certainty if the presented threshold holds true. Unlike with the FPM, it was not theoretically calculated but rather theorized based on the mathematical relation between the scales set for each of the three variables. To validate Equation 8.2, only implementation of the ADMM, or this specific part of the model, is possible. During this validation period as many projects as possible need to be run through the P&IA to creep up to the actual threshold. From this validation effort several results may arise.

1. The set threshold of $W_i > 0$ is incorrect
2. The scales set for P, In and/or Im are incorrect
3. The variables P, In and/or Im are incorrectly linked to each other
4. The variables P, In and/or Im are incorrect/incomplete
5. A combination of the points listed above

8.4. Flawed units - mentioned in Section 4.2.11

Within the explanation of the ADMM, the reasons for assessing units as flawed has been mentioned. Further discussion during the research has led to the following argumentation [22, 23].

All of the statistical units compare groups of patients that are not the same people, that are not within the same society or suffer from the same disease. During these different comparisons variable time spans are used, pulling the comparators even further apart [22, 23, 60]. Taking a look at the highly integrated sensitivity and specificity, Equations 4.9 and 4.10, it already is clear that these measures strongly depend on the statistical population, prevalence distribution and the way the TN, FN, TP and FP factors are calculated. At the core of the "distrust" stands the *false negative uncertainty*. In epidemiology the calculation of the term FN generates the most disgruntlement. All of the mentioned uncertainties converge when the term is calculated via comparisons between the initial test and the follow up. This problem is illustrated in Figure 8.1 showing that it does not take into account the natural progression/stage of the disease [22, 23, 61].

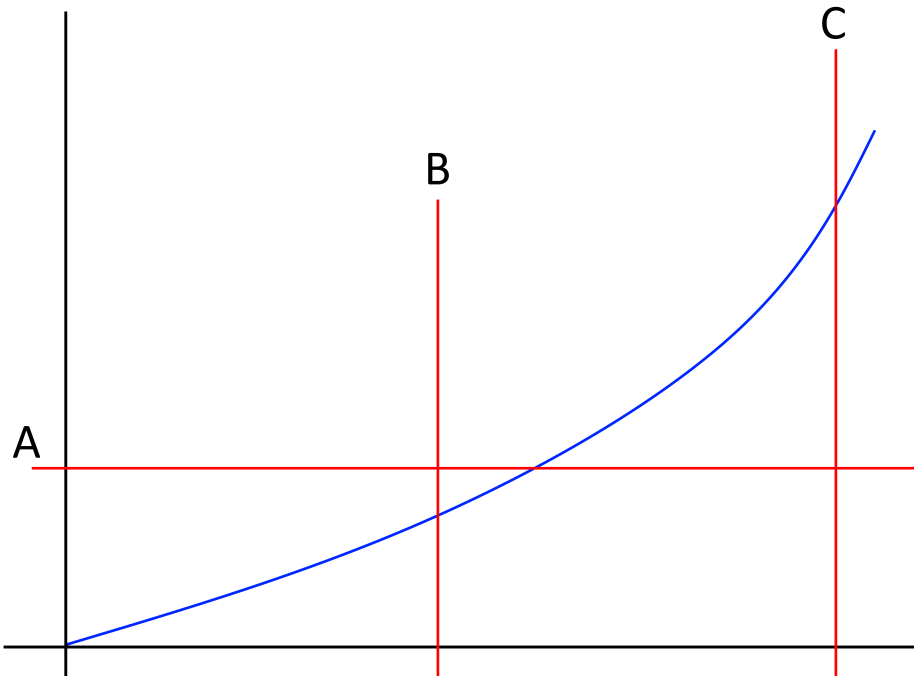


Figure 8.1.: **Graphical representation of natural progression of a disease, blue line, between intial testing, B, and the follow up, C.**
Line A represents the threshold for defining the patient to have contracted the disease.
This shows the *false negative uncertainty* in practice.

From this the Equations 8.3, 8.6, 8.11 and 8.12 were constructed by ir. Farimani. Because these provide an excellent stepping stone, and are linked with the ADMM via phase **Incremental Cost Effectiveness Ratio**, they will be discussed shortly within the upcoming sections as how they might be implemented within further research.

8.4.1. Additive value

At the beginning of this discussion stood the term additive value. Using this value instead of sensitivity, the uncertainness of the terms TN, FN, TP and FP are to be removed. With the use of Equation 8.3, the added value indicates the detection ratio of new technology A with respect to technologies B and C.

$$AV = \frac{\text{detected only by A}}{\text{detected by all}} [22] \tag{8.3}$$

with

Unit	Name	Description
AV	Additive value	Added value of technology

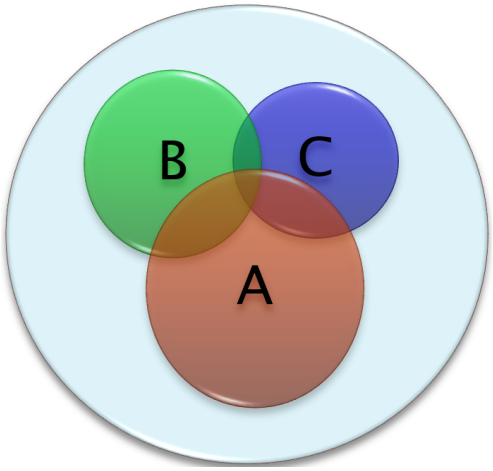


Figure 8.2.: **Graphical representation of the introduced term AV in Equation 8.3.**

Using the old terms, this calculation would still be comprised of FN, TP and FP, being the components of a detection of i. This leads to Equation 8.4.

$$AV_{j\,for\,i} = \frac{(FN_i + TP_i + FP_i)}{(FN_{SotA} + TP_{SotA} + FP_{SotA})} \tag{8.4}$$

When comparing this to the set definition of sensitivity,

$$Sensitivity \equiv \frac{TP}{(TP + FN)}$$

there seems to be an added term. Possible introducing more uncertainty in Equation 8.3 than already present in Equation 4.9. Further research must show if this holds true or if this new unit, and the way it is calculated, will solve the above mentioned points of concern. Ideally this will change Equation 8.4 to Equation 8.5 [23].

$$AV_{j\,for\,i} = \frac{TP_i}{TP_{SotA}} \tag{8.5}$$

Before this research has taken place, it is advised to call this new unit *Possible additive value*.

8.4.2. Deterioration

Continuing to Equation 8.6 the term deterioration (D) is created. D show the ratio between the diseased life expectancy (LE) and the normal life expectancy [22, 23]. Here $D = 0$ leads to $LE = LE_{max}$. This whilst $D = 1$ deems the person to die at the spot [22, 23].

$$D \cong 1 - \frac{LE - LE_{min}}{LE_{max} - LE_{min}}[22] \tag{8.6}$$

with

Unit	Name	Description
D	Deterioration	Life expectancy ratio
LE	Life expectancy	Expected length of life in years

Equation 8.6 is a step at incorporation of the disease stage into the statistical units.
The concept of deterioration can however also be used much like the 5-year survival, mortality and incidence rate suggested in Section 4.2.11 to indicate where the creation of MT can have a big impact. For this Equation 8.6 is changed to Equations 8.7 and 8.8 elevating them both from a individual to population level.

$$D_i \cong 1 - \frac{LE_i - LE_{min}}{LE_{max} - LE_{min}} \tag{8.7}$$

$$D_{mean} \cong 1 - \frac{LE_{mean} - LE_{min}}{LE_{max} - LE_{min}} \tag{8.8}$$

If $D_i = D_{mean}$, Equation 8.9, patients suffering from disease i enjoy a LE equal to that of the average population.

$$1 - \frac{LE_i - LE_{min}}{LE_{max} - LE_{min}} = 1 - \frac{LE_{mean} - LE_{min}}{LE_{max} - LE_{min}} \tag{8.9}$$

If D_i rises above D_{mean} at any given moment the patient group suffering from disease i is assessed to be in need and a market for MT_i opens up. After simplification of Equations 8.7 through 8.9 the simple disease interest indicating equation, Equation 8.10 is created.

$$\begin{aligned} \text{if} \quad LE_i &> LE_{mean} \\ &\text{Act} \\ \text{elseif} \quad LE_i &\leq LE_{mean} \\ &\text{Do not act} \end{aligned} \tag{8.10}$$

Further research can focus on two steps with regards to the D. The first being the investigation towards and the validation of the concept of Deterioration and Equation 8.6. Within this research, special attention towards the fact that D makes use of the unit LE should be taken. It is advised to investigate if this life expectancy is not also flawed when calculated. Following this, a closer look at possible benefits that the concept of D holds for the ADMM, or medical purchasing in general, can be taken.

8.4.3. Survival rate

Continuing the route of D, Equation 8.11 uses this new concept to calculate the survival rate (SR) based on the age of the person and his/her deterioration [22, 23].

$$SR = \frac{\frac{1}{\pi}tan^{-1}(\pi(1 - \frac{2t}{70(1-D)})) + 0.5}{\frac{1}{\pi}tan^{-1}(\pi) + 0.5}[22] \tag{8.11}$$

with

Unit	Name	Description	Scale
D	Deterioration		$\forall D = 0 \text{ to } 1$
t	Time	Age in years	$\forall t = 0 \text{ to } 70$

Within Figure 8.3 this equation is plotted showing the inclusion of the disease stage [22, 23].

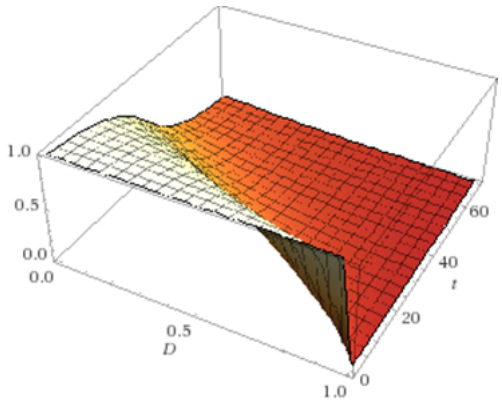


Figure 8.3.: **Graphical representation of Equation 8.11 showing the SR [22].**

Because SR makes use of D, all of the recommendations made concerning this unit also hold true for Equation 8.11.

8.4.4. Man years saved

The introduction of the concept of assessing technology by calculation of the number of man years saved (MY) when the MT is implemented is a course that fits in very well within the created model and HTA in general [22, 23]. Within the FPM this subject is already touched upon lightly. But Equation 8.12 does so by more quantifiable means, by combining the concepts of AV, D and SR.

$$MY = \int_0^{+\infty} (\int_0^1 ((\frac{d}{dD} A\nu(D)_{A,B} - \frac{d}{dD} A\nu(D)_{B,A}) \frac{dP(\ acD)}{dD} (SR(D,t) - SR^*(D,t)))dD)dt [22] \tag{8.12}$$

where

$$\frac{d}{dD} A\nu(D)_{A,B} - \frac{d}{dD} A\nu(D)_{B,A}$$

represents AV

$$SR(D,t)$$

the survival rate after t at a certain D at the start of a specific treatment whilst

$$SR^*(D,t)$$

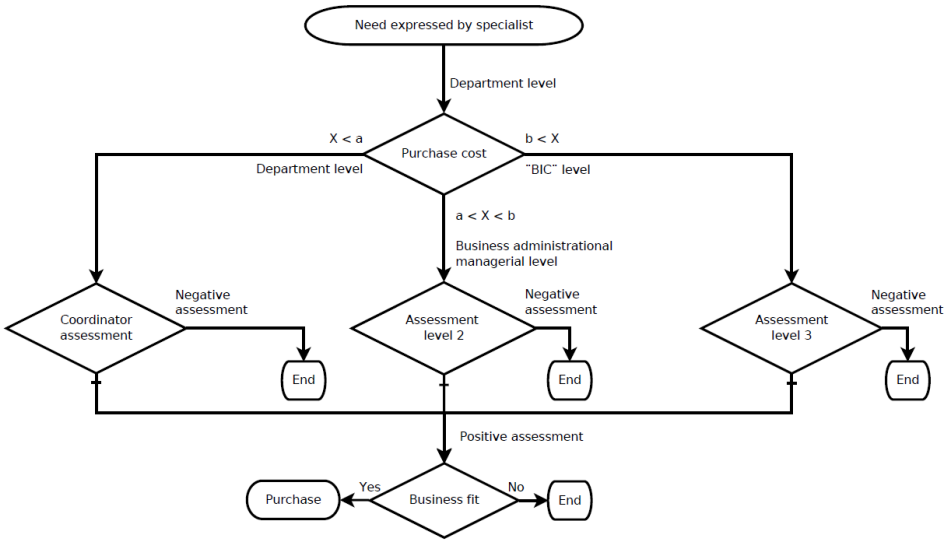
does the same when no treatment is presented.

Within this research much effort has been made to make measures used within EHTA, HTA, product design, decision making and medical purchasing more objective. Equations 8.3, 8.6, 8.11 and 8.12 are again a good example of this urge. However, this need is very much experienced by engineers such as present within for example RaM. Before starting research in this direction, research towards the expected acceptance by the field, and if these numbers are truly as objective as thought, is necessary. Are these MY, SR, D and AV not as reliant on the "flawed units" making use of LE and TN or is the worry expressed unjustified because all the comparisons suffer from the same uncertainties nullifying the overall effect?

8.5. Other

With these specific points the conducted research can already be lifted towards a higher level. To add to these, presented here are some other, more general points of recommen-

dations concerning the model and the research are given.
The ultimate next step for the ADMM would be validation of its workings. For this several projects should be run through the model. This will not only show the usefulness of the flowchart, but also indicate where the need for fine-tuning is present. As stated in Chapter 2, part of the model is based on Figure 4.2a, repeated below, which in turn was based on the acquisition procedure from the ZGT Hengelo.



Impression of the decision model implemented within the ZGT Hengelo [40, 57, 60].

A small step toward the mentioned validation is the inclusion/comparison of more hospitals acquisition procedures to see if the used flow is representative. By doing so, also this part of the model can truly be said to reside at a national level.
From this point on, two strategies can be adopted. Widen the model by implementing more stakeholders but remain on a national level, or heighten the model by lifting it into an international, European, or supra-national level. If more stakeholders are to be implemented, so widening the ADMM, it is advised to fist incorporate the **Insurance companies**. As can be seen within this report, there exists a strong connection between the implementation, availability and purchase of medical items and the interaction of insurance companies and hospitals, at least within the Netherlands. Even though this effect is less influencing with regards to the peripheral medical devices produced by RaM, the inclusion of this stakeholder will give the ADMM a whole new layer of decision supporting qualities with regards to the sales angle of the product.
When lifting the model out of the Dutch national level, a focus on two points is needed.

1. Is the hospitals acquisition procedure on which the ADMM is based still representative?

2. What kind of health system is present within the new country, and how does this influence
    a) general acquisition of medical technology? (With this, one already ventures into the area of insurance (companies) for most European countries.)
    b) general acceptance of medical technology? (It the ADMM proves to be correctly developed and implemented, this will also be tackled, be it late in the design process, in phase of **User preference elicitation**)

With these points in mind it is still difficult to suggest a first country to incorporate within the model. Figure 8.4 shows the difference between different European health systems. Based on this both Belgium and Germany are suitable first candidates because both their *dominant revenue stream*, the way health care is financed, and the *delivery of care*, the nature of heath care deliverance, are the most comparable with that of the Dutch system. Because the current version of the model focuses on acquisition decisions via the hospital internally, **Belgium** could be preferred because their delivery of care lies closest to that of the Netherlands.

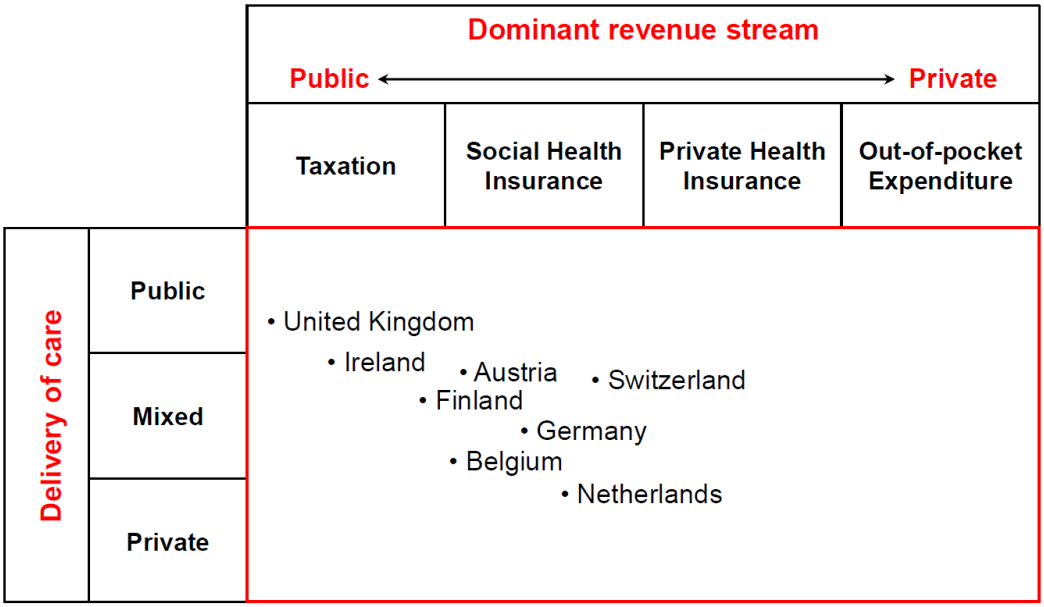


Figure 8.4.: **Different European health systems based on their *dominant revenue stream* and *delivery of care* [9, 10].**

With both of the strategies, it is likely that **interaction between policy, regulation and design** will present when creating new MT. This issue will be especially noticeable when the technology being created can be labelled as "ground breaking" or "at the edge of modern science", to name a few expressions. Because of the new territory being explored, there is not a lot of regulation present to dictate the technology´s development. This however, is a completely different field of expertise and should be therefore be investigated by

experts. Because of this, no real advice as how to possibly research this can be given.

Using the ADMM will have to show, as mentioned in previous chapters, if the model will be accepted as a flowchart system. Even if it is implemented within RaM, future research could be used to see if a pool of the introduced phases, so the project members can choose to perform any analysis at any time in the process, proves more beneficial within the designing of medical technology. Even if this nullifies one of the key aspects stated in the research goals, that of a structured method, this could be a more accessible approach with regards to its implementation.

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Abbreviations & Nomenclature

Abbreviations

5Ls five-level Likert scale

5Ls-pf five-level Likert scale with a "pass or fail" coding

CEA Cost-Effectiveness Analysis

CT Computed Tomography

DIA DIA Diagram Editor - Open source flowchart editor

ADMM The (Early) Health Technology Assessment type Assistive Decision Making Model framework used for implementing EHTA in the design process

EHTA Early Health Technology Assessment

EU European Union

FDA Food and Drug Administration

FN False Negative outcome measure

FP False Positive outcome measure

FPM framework used for the success prediction of funds elicitation

HA Headroom Analysis

HTA Health Technology Assessment

HTSR the Health Technology and Services Research group within the University of Twente

IGZ Inspectie voor de GezondheidsZorg

ISO International Organization for Standardization

Mc-p McRobot project

MRI Magnetic Resonance Imaging

MT Medical Technology

NWO Nederlandse organisatie voor Wetenschappelijk Onderzoek

OQ Open Question

OTP Open Technology Programme

PEST Political Economic Social and Technological analysis

PET Positron Emission Tomography

P&IA Power & Interest Analysis

QDQ Qualitative Design Question

RaM the Robotics and Mechatronics group

RCT Randomized Controled Trial

R&D Research and Development

RoI Return on Investment

SotA State of the Art

STW Technology Foundation STW

SWOT Strength Weakness Opportunities and Threats analysis

TN True Negative outcome measure

TP True Positive outcome measure

TRA Technology Readiness Assessent

TRL Technology Readiness Level

UT University of Twente

VWS Ministirie van Volksgezondheid Welzijn en Sport

ZGT Hengelo ZiekenhuisGroep Twente Hengelo

Nomenclature

AV Additve value

C' Expected costs of production

D Deterioration

$score_+$ Highest score per section in correspondence with Table 3.2

ΔIC Change in indirect costs

$ICER$ Incremental Cost-Effectiveness Ratio

Im Importance of stakeholder within the design process of the new MT

In Interest of stakeholder in the new MT

LE Life expectancy

$score\_$ Lowest score per section in correspondence with Table 3.2

MY Man years saved by implementation of the MT

n Amount of years

$n_{questions-pf}$ Number of 5Ls-pf questions per section

NSB Net social benefit of a health programme calculated via a Cost-benefit analysis

P Power of stakeholder in the field of the new MT

$QALY$ Quality Adjusted Life Year

QoL Quality of Life

R Revenue that can be generated

SR Survival rate

$score_w$ Weight of each section

t Time in years

V Number of cases per year

W Weight of the new MT

WTP Willingness To Pay

A. Cooper (inspired) factors for commercial success

This altered version was created as part of a yet to be published paper within the HTSR group and is a medical technology specific iteration of the NewProd System of Cooper discussed in Section 2.2.2 [14].

Weight	Sub-weight	Variables on Factors
0,25		**Medical device superiority/ quality**
	0,03125	Device address clinical need better
	0,03125	Device offers unique features for user
	0,03125	Device has higher quality than competitors
	0,03125	Device does unique task for user
	0,03125	Device reduces buyers their costs
	0,03125	Device is innovative (first of its kind)
	0,03125	Device brings clear health benefits
	0,03125	Device will increase potential users satisfaction
0,13		**Economic advantage to future users**
	0,065	Device reduces buyers their costs
	0,065	Device is priced lower than competing devices
0,13		**Company-project fit**
	0,01625	Managerial skills
	0,01625	Marketing research skills
	0,01625	Sales force/Distribution resources
	0,01625	Financial resources
	0,01625	Engineering skills
	0,01625	Expertise
	0,01625	R&D resources
	0,01625	Production resources
0,06		**Technological compatibility**
	0,02	R&D resources and skills
	0,02	Engineering resources and skills
	0,02	Intellectual property revision

0,06		**Newness to the company**
	0,0075	New device class to company
	0,0075	New device type to company
	0,0075	New competitors to company
	0,0075	New sales force/distribution
	0,0075	New type of users served
	0,0075	New buyers to company
	0,0075	New product technology to firm
	0,0075	New production process to firm
0,14		**Marketplace**
	0,035	Buyers need for the device
	0,035	Size of the target population
	0,035	Willingness to pay for the device
	0,035	Fast growing market
0,05		**Market competitiveness**
	0,00833333	Intense price competition in the market
	0,00833333	Highly competitive market
	0,00833333	Many competitors
	0,00833333	Many new devices enter the market
	0,00833333	Clear health benefits
	0,00833333	Changing user needs
0,04		**Medical device scope**
	0,02	A market derived new device idea
	0,02	Revenue market size (as opposed to one or a few buyers)
0,13		**Healthcare compatibility fit**
	0,01625	Healthcare market regulations fit
	0,01625	Learning curve
	0,01625	Fit with work procedures
	0,01625	No financial burden for patients
	0,01625	Reimbursement scheme fit
	0,01625	Willingness to accept device
	0,01625	Healthcare specialists involved
	0,01625	Trial-ability

B. STW OTP template

Details application

Title

Names and addresses of the Applicants

Applicants

Name	*Discipline*	*Institute*
...	...	...

Correspondence address
...

Embedding
The primary research partners in this project are ...

The project involves a collaboration with ...

The project is submitted to ... .

Other applications
...

Keywords
...

Duration of the program ...

Budget

Requested from STW
...
Contribution by others
...

Summaries

Because these must be clear for potential reviewers and the non-epistemic community make the two summaries understandable, concise and convincing. Jurors will base their verdicts based on the opinions of experts [43]. It might prove useful to already mention the expertise present in the project/group.

Research summary

1. Intro
2. Problem (will lead to the research question)
    a) Why is this a problem?
    b) For whom is this a problem?
3. Research question
4. State of the art
5. Proposed way of research
6. Expected results

Mention the key aspects of the new functionality of the purposed research/solution.

Example sentences [52]

- "The project is devoted to ... ."

Utilization summary

1. Real world problem
2. An utilization proposal that follows from the real world problem
3. Advantages (over state of the art)
4. How to realise the proposed utilisation
5. How big is the chance that the proposed utilisation will occur?

Example sentences [52]

- "The project team includes all the necessary expertise that is needed for such a development."

- "However, to further advance ... there is a need for innovations that ... ."
- "Limitations due to ... can be overcome by ..."

Composition of the research group

Mention the experts that are present within the group and why are specifically they suitable for this project.

Example sentences [52]

- "The applicants have a long track record for collaboration in the area of ... . "
- "Specific expertise resides in the ... ."

When proposing a PhD candidate, include an educational plan to strengthen possible weak points within his or her knowledge.

Specify role

1. Mention each relevant user (group)
2. Describe each relevant user (group) by at least mentioning their epistemic addition to the project.
3. Specify, in bold/a box/etc., their actual role within the project.

State current members of the different research groups that will participate in this ... year project.
Might be integrated within the *role specification* to save space.

Member	Group	Percentile involvement
PhD Student	Robotics and Mechatronics	100 %
...	...	... %

Scientific description

In contrast to the concise summaries, the information given here is for the epistemic community and should be so extensively as to convey the quality of the project.

1. Introduction
    a) Background

   b) Scientific relevance
   c) Objective
2. Problem (of state of the art)
3. Introduction of solution
   a) Name specific problems to tackle
   b) Name current shortcomings (of state of the art)
4. Proposed solution/research

Research contents/Introduction

Split this into three smaller sections in order to convey the message. Try to already point out the originality of the research.

Scientific starting points

What is, scientifically speaking, the starting point of the research and with which methods and techniques will the problem be tackled?

Available knowledge

What is the state of the art, and what will be added to the current knowledge obtain the (proposed) solution?

Instrumentation

What instrumentation will be used to obtain the (proposed) solution?

Existing infrastructure

Make clear that the proposed locations are suitable the perform the proposed research.

Time plan and division of tasks

Split this into three smaller sections in order to convey the message.

Research planning

Describe the research/project planning per task.

Deliverables

Describe the desired deliverables and divide these in *Tasks* (1 t/m x) and state milestones (A t/m x) within the project.

The planning and deliverables mentioned in Sections B and B can be illustrated via the following table.

Task/Month	1	2	...	PhD student	Other (technician, etc.)
1	X	X		1	
2		X		2	
...					
Milestones		A			

Management of the research project

Example sentences [52]

- "The project is managed by the applicant(s) and will be chaired by ... ."
- "The meetings will be discussed below in the order of frequency of occurrence."

Utilisation plan

Again, this should be made understandable, concise and convincing.

The problem and the proposed solution

1. Problem to be solved
2. For whom is this a problem
3. Socio-economic relevance/impact when unresolved
4. (Proposed schedule when results will lead to new products/processes/services)
5. Non-scientific utilisation

Example sentences [52]

- "User x has stated to want the research/product as soon as possible."
- "User x has stated that the research/product will enable them to make a huge step forward."

Potential users

1. What will each user (group) benefit?
2. How will the *end product* reach the user?
3. How will utilisation be "guaranteed"?
4. State/Show that all users have (already) agreed on working within the project via a *letter of support.*

Example sentences [52]

- " Whilst these concepts are possible in principle, several open questions exist in this phase concerning their actual performance and applicability, which will be investigated in this project."
- "In order to optimize the process of transferring the new technological concepts investigated in this project for actual future practice, the key users are involved in the project from the start."
- "The technological concepts proposed in this document will be investigated and the principles will be evaluated experimentally in collaboration with the users."
- "The concepts that will be proven feasible and have commercial potential will be protected by patents as far as possible, and subsequently transferred to interested commercial parties."

Past performance

Show capability within in subject area. Also include a list of (relevant) publication of the researchers or specifically refer to Section B.

Intellectual property

State all information relevant to the research proposal in relation to STW IP policy. Providing the requested information is compulsory [44].

Contracts

State whether there are any existing contracts (including material transfer agreements, licences, cooperation agreements) with third parties in relation to the subject of the research [44].

Example sentences [52]

- "A non-disclosure agreement has been signed between ... and the university of Twente to discuss potential research collaboration on the subject of... . This agreement does not transfer any right to ... regarding the ideas presented in in this research proposal."
- "The research proposed is high-risk and pre-competitive, therefore primary research funding is sought from STW.
- "There are no binding contracts at this moment."
- "Because ... will be based on a new concept, there are no patents obstructing the development of ... ."
- "Patents can stem from this project because of the new concepts applied."

Patents

1. Give a summary of patents held and/or patent applications made by intended parties to the project in the field of the research proposal. Indicate whether the patents and/or patent applications are in the name of the research institute(s) involved or in the name of third parties. If the research institutes involved have relevant patents, indicate whether agreements have been reached in this respect with third parties [44].
2. Indicate whether there are any patents and/or patent applications which obstruct the utilisation of the intended research results. If such an obstacle exists, explain whether there is still sufficient likelihood of protecting the intended research results by means of a patent [44].
3. If the patenting of research results is not expedient, explain why not [44].

Example sentences [52]

- "A patent search result is not necessary since it is clear from ... that our foreseen development on ... in this particular application field is new."
- "Because ... will be based on a new concept, there are no patents obstructing the development of ... ."
- "Patents can stem from this project because of the new concepts applied."

Positioning of the project proposal

Describe the extent to which the research proposal differs from ongoing research initiatives. Consider both the national and the international context. Also state the relevant collaborations with other national or international research groups [44].

Uniqueness of the proposed project

Indicate what it is that makes the research proposal original and innovative.

Example sentences [52]

- "first time "
- "major impact on ... development as ..."
- "From these insights ..."
- "(state of the art) is currently lacking ... "
- " to be first step"

Embedding of the proposed project

Provide further information on the embedding of the research plan described here within ongoing initiatives of the research group and/or section. Indicate whether the research proposal is part of or related to a research programme in which the applicant or applicants´ research institute is participating. If so, indicate the research programme in question [44].

Request for support elsewhere

State whether funding has been requested elsewhere for this research proposal or parts thereof. If so, indicate the grant provider(s) in question and the status of that application or those applications at the time of submission to STW [44].

Financial planning

Make a worst case/ exaggerated financial planning, and state this. This way the costs can only become lower, letting money flow back towards STW. Submit all *letters of support* as confirmation of the co-funding to be provided. Besides, or instead of, the in depth

explanation of costs required by STW the following table could be used (and placed on the front page to directly show the financial part of the proposal) [52].

	Year 1	Year 2	Year 3	Year 4	Total
# of PhD students					
Personnel costs					
Consumables					
Travel abroad					
Investments					
Total	**€...**	**€...**	**€...**	**€...**	**€...**
Contribution STW					
Contribution users					

References

Selection of key publications research group

State the key publications of the research group(s) in relation to the proposal. Also state any relevant published patents. Design and construction disciplines can, if so wished, provide an overview of designs realised (selected works) [44].

List of publications cited

State the publications cited. Identify those in which members of the research group(s) submitting the application are involved, by the use of a bold font. Design and construction disciplines can, if so wished, include a list of publications from other people about their designs [44].

Abbreviations and acronyms

It is important that both experts and jury members are able to read the proposal easily. Abbreviations and acronyms should therefore be explained at least once. This can be done in the text itself or in a separate list. Keep the use of abbreviations in summaries to a minimum [44].

C. STW-jury evaluation scales

Scientific quality

1. Excellent
   - An excellent researcher or outstanding research team.
   - A well-chosen problem.
   - The method is especially/pre-eminently effective and original.
   - Very urgent.
2. Excellent to very good
3. Very good
   - A competent researcher or competent research team.
   - A significant problem.
   - The method is original and effective.
   - An urgent approach is important.
4. Very good to good
5. Good
   - An average researcher or average research team.
   - A routine problem.
   - With the method, which has some original details, the project can be addressed, although other possibilities are conceivable.
6. Good to moderate

7. Moderate
    - It is far from certain that this work is within the capacity of the researcher and/or the research team: the proposal itself contains no obvious errors.
    - The problem is moderately interesting.
    - Whether the project can be successfully tackled with this standard method, is questionable.
    - The project may well be postponed.
8. Moderate to poor
9. Poor
    - The competence of the investigator or research team is inadequate.
    - The proposal contains serious errors or mistakes.
    - This old method is not good for this project.
    - Not to be executed, even if there is money left.

Utilisation

1. Excellent
    - This will certainly lead to important new techniques or to very important applications in industry, society and other sciences.
    - This research is urgently needed to make an estimate of the consequences of the use of this technology or technique.
    - The utilisation is very well thought out and the approach ensures the greatest likelihood of an effective use of the results.
2. Excellent to very good
3. Very good
    - This research will likely lead to important new techniques or to important applications in industry, society, or in other sciences.
    - This research is highly desirable to make an estimate of the consequences of the use of this technology or technique.
    - The utilisation is well thought out and the approach makes it plausible that the results of this work will be used well.
4. Very good to good

5. Good
    - This work will possibly lead to new technologies or applications that might be useful for industry, society, or other sciences.
    - This research will be needed to make an estimate of the impact of this technology or technique.
    - The utilisation is sufficiently thought through, it can probably be improved during the execution of the work. The results of this work will probably be used.
6. Good to moderate
7. Moderate
    - Technically this work could possibly be useful at some time or it is conceivable that in due course another science, industry or society or of the results could make use of it.
    - The results of this research are not exactly awaited, but they may be useful in the future if an evaluation is made of the consequences of using this technology or technique.
    - The utilisation is very unsatisfactory. This should certainly be improved, otherwise it is likely that the results of this work will not be used.
8. Moderate to poor
9. Poor
    - Technically the work is bad and redundant, i.e. different, better or similar techniques, which are cheaper are already available.
    - This study does not evaluate the consequences of using this technology or technique, moreover, it increases the confusion.
    - The utilisation is completely wrong.

D. European legislation concerning classification of medical technology (93/42/EEC)

Part of the Council of European Communities´ Directive 93/42/EEC concerning the classification of medical technology in to Class I, Class IIa, Class IIb and Class III [16].

ANNEX IX

CLASSIFICATION CRITERIA

I. DEFINITIONS

1. **Definitions for the classification rules**

1.1. *Duration*

Transient

Normally intended for continuous use for less than 60 minutes.

Short term

Normally intended for continuous use for not more than 30 days.

Long term

Normally intended for continuous use for more than 30 days.

1.2. *Invasive devices*

Invasive device

A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Body orifice

Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

Surgically invasive device

An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

For the purposes of this Directive devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

Implantable device

Any device which is intended:

— to be totally introduced into the human body or,

— to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

1.3. *Reusable surgical instrument*

Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out.

1.4. *Active medical device*

Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

1.5. *Active therapeutical device*

Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

1.6. *Active device for diagnosis*

Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

1.7. *Central circulatory system*

For the purposes of this Directive, 'central circulatory system' means the following vessels:

arteriae pulmonales, aorta ascendens, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachicephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.

1.8. *Central nervous system*

For the purposes of this Directive, 'central nervous system' means brain, meninges and spinal cord.

II. IMPLEMENTING RULES

2. **Implementing rules**

2.1. Application of the classification rules shall be governed by the intended purpose of the devices.

2.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.

2.3. Software, which drives a device or influences the use of a device, falls automatically in the same class.

2.4. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.

2.5. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

III. CLASSIFICATION

1. **Non-invasive devices**

1.1. *Rule 1*

All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

1.2. *Rule 2*

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:

— if they may be connected to an active medical device in Class IIa or a higher class,

— if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues,

in all other cases they are in Class I.

1.3. *Rule 3*

All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.

1.4. *Rule 4*

All non-invasive devices which come into contact with injured skin:

— are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,

— are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent,

— are in Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.

2. **Invasive devices**

2.1. *Rule 5*

All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device:

— are in Class I if they are intended for transient use,

— are in Class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I,

— are in Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.

2.2. *Rule 6*

All surgically invasive devices intended for transient use are in Class IIa unless they are:

— intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,

— reusable surgical instruments, in which case they are in Class I,

— intended to supply energy in the form of ionizing radiation in which case they are in Class IIb,

— intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb,

— intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class IIb.

2.3. *Rule 7*

All surgically invasive devices intended for short-term use are in Class IIa unless they are intended:

— either specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,

— or specifically for use in direct contact with the central nervous system, in which case they are in Class III,

— or to supply energy in the form of ionizing radiation in which case they are in Class IIb,

— or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III,

— or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IIb.

2.4. *Rule 8*

All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:

— to be placed in the teeth, in which case they are in Class IIa,

— to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III,

— to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,

— or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.

3. **Additional rules applicable to active devices**

3.1. *Rule 9*

All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb.

All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.

3.2. *Rule 10*

Active devices intended for diagnosis are in Class IIa:

— if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,

— if they are intended to image *in vivo* distribution of radiopharmaceuticals,

— if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.

Rule 11

All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa, unless this is done in a manner:

— that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class IIb.

3.3. *Rule 12*

All other active devices are in Class I.

4. **Special Rules**

4.1. *Rule 13*

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 65/65/EEC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III.

E. PEST & SWOT

PEST: Political, Economic, Social and Technological analysis

The Political, Economic, Social and Technological analysis (PEST) is a useful tool for understanding market growth or decline, and as such the position, potential and direction for a project [11]. An example of PEST template is found below.

How to perform a PEST

1. Set situation
   Set a fixed situation for the PEST being carried out by stating a leading situation being investigated.

2. Understand PEST Factors
   To perform a proper PEST, an understanding of each factor with respect to the situation is needed.

   - Political
     How do legal issues and government regulations affect the probability of product success? Issues include political stability, employment laws, safety regulations and trade regulations on the set scale of the project [4].

   - Economic
     Determine whether or not issues such as economic growth, unemployment policies, and business cycle of the country will play a role in the project success [11].

   - Social
     Normally this factor examines the cultural and demographic aspects to determine whether the business can compete in the market, helping to assess consumer need [11]. But because one is dealing with medical technology (MT) this factor becomes irrelevant by implementation of the **User preference elicitation** phase in the ADMM presented in Section 4.2.11. However, items such as age distribution, lifestyle changes and population ageing still remain relevant [4].

- Technological
  The SotA currently available can help improve the production level and/or enter into the market [4]. Therefore, items as government expenditure on technology, technological advancements, and the life cycle of the SotA can be taken into consideration [4].

3. Table completion
   Fill in the table according to the set situation of the PEST.
4. Identify opportunities
   Evaluate the table and identify if there are any economic, market or regulatory opportunities present on which to capitalize.
5. Identify threats
   Assess whether the identified opportunities, add to these the technological opportunities linked to the new MT, can undermine the project. Identifying these threats early within the project can prevent or reduce the amount and intensity of the threats [4].
6. Business plan
   Including the findings within the business plan/way of operations.
7. Repeat
   Possibly repeat the PEST for a different leading situation.

SWOT: Strength, Weakness, Opportunities and Threat analysis

The Strength, Weakness, Opportunities and Threat analysis analysis (SWOT) is a tool for decision-making in business and organizations. The SWOT provide a framework for reviewing strategy, position and direction of a business with regards to a project [12].
Note that SWOT is often interpreted and used as a SWOT Analysis 2x2 Matrix, especially in business and marketing planning [12]. An example of this SWOT 2x2 Matrix is found below.

How to perform a SWOT

1. Set situation
   Set a fixed situation for the SWOT being carried out by stating a leading situation being investigated.
2. Table preparation
   Prepare a 2x2 table by separating the positive factors, which are strengths and opportunities, from the negative factors, weaknesses and threats [3].

3. Table completion
   Fill in the table according to the set situation of the SWOT. When a PEST has been performed, may of the items identified here can be carried over to the SWOT categories.

4. Table analysis
   Having completed the table, analysis shows the building blocks, the strong points, necessary to create strategies enabling full potential [3]. This whilst the weak points show the holes within these blocks, indicating where to strengthen the structure [3].

5. Business plan
   Including the findings within the business plan/way of operations.

6. Repeat
   Possibly repeat the SWOT for a different leading situation.

PEST Analysis Template

Situation being analysed:

_____

PEST analysis (political, economical, social, technological) assesses a market, including competitors, from the standpoint of a particular proposition or a business.

criteria examples ecological/environmental current legislation future legislation international legislation regulatory bodies and processes government policies government term and change trading policies funding, grants and initiatives home market pressure-groups international pressure-groups wars and conflicts	**political**	**economical**	**criteria examples** home economy economy trends overseas economies general taxation taxation specific to product/services seasonality issues market/trade cycles specific industry factors market routes trends distribution trends customer/end-user drivers interest/ exchange rates international trade and monetary issues
criteria examples lifestyle trends demographics consumer attitudes and opinions media views law changes affecting social factors brand, company, technology image consumer buying patterns fashion and role models major events and influences buying access and trends ethnic/religious factors advertising and publicity ethical issues	**social**	**technological**	**criteria examples** competing technology development research funding associated/dependent technologies replacement technology/solutions maturity of technology manufacturing maturity and capacity information and communications consumer buying mechanisms/technology technology legislation innovation potential technology access, licensing, patents intellectual property issues global communications

SWOT Analysis Template

State what you are assessing here _____

(This particular example is for a new business opportunity. Many criteria can apply to more than one quadrant. Identify criteria appropriate to your own SWOT situation.)

criteria examples	**strengths**	**weaknesses**	**criteria examples**
Advantages of proposition? Capabilities? Competitive advantages? USP's (unique selling points)? Resources, Assets, People? Experience, knowledge, data? Financial reserves, likely returns? Marketing - reach, distribution, awareness? Innovative aspects? Location and geographical? Price, value, quality? Accreditations, qualifications, certifications? Processes, systems, IT, communications? Cultural, attitudinal, behavioural? Management cover, succession? Philosophy and values?			Disadvantages of proposition? Gaps in capabilities? Lack of competitive strength? Reputation, presence and reach? Financials? Own known vulnerabilities? Timescales, deadlines and pressures? Cashflow, start-up cash-drain? Continuity, supply chain robustness? Effects on core activities, distraction? Reliability of data, plan predictability? Morale, commitment, leadership? Accreditations, etc? Processes and systems, etc? Management cover, succession?
criteria examples	**opportunities**	**threats**	**criteria examples**
Market developments? Competitors' vulnerabilities? Industry or lifestyle trends? Technology development and innovation? Global influences? New markets, vertical, horizontal? Niche target markets? Geographical, export, import? New USP's? Tactics: eg, surprise, major contracts? Business and product development? Information and research? Partnerships, agencies, distribution? Volumes, production, economies? Seasonal, weather, fashion influences?			Political effects? Legislative effects? Environmental effects? IT developments? Competitor intentions - various? Market demand? New technologies, services, ideas? Vital contracts and partners? Sustaining internal capabilities? Obstacles faced? Insurmountable weaknesses? Loss of key staff? Sustainable financial backing? Economy - home, abroad? Seasonality, weather effects?

F. EUnetHTA JA2 WP8 DELIVERABLE HTA Core Model

Domain sections abstracts directly copied from the *EUnetHTA JA2 WP8 DELIVERABLE HTA Core Model Version 3.0 for the full assessment of Diagnostic Technologies, Medical and Surgical Interventions, Pharmaceuticals and Screening Technologies* [54].

Problem and Current Use of the Technology (CUR)

This domain describes the target conditions, target groups, epidemiology and the availability and patterns of use of the technology in question. Furthermore, the domain addresses the burden both on individuals and on the society caused by the health problem, the alternatives to the technology in question, as well as the regulatory status of the technology and the requirements for its use. Some of the topics considered relevant for this domain have generally been called "Background Information" in previous European projects or recommendations for conducting assessments.

Health Problem and Current Use of the Technology (CUR) covers the qualitative description of the target condition, including the underlying mechanism (pathophysiology), natural history (i.e. course of disease), available screening and diagnostic methods, prognosis, and epidemiology (incidence, prevalence), as well as the underlying risk factors for acquiring the condition as well as available treatments. A description of subgroups or special indications should be included especially in the case when the technology does not target the whole population [54].

Description and technical characteristics of technology (TEC)

The information given in this domain describes the technology (or a sequence of technologies) and its technical characteristics, i.e. when it was developed and introduced, for what purpose(s); who will use the technology, in what manner, for what condition(s), and at what level of health care. Material requirements for the premises, equipment and staff are described, as are any specific training and information requirements. The regulatory

status of the technology should be listed, where applicable.

The issues in this domain need to be described in sufficient detail to differentiate the technology from its comparators. Terms and concepts should be used in a manner that allows those unfamiliar with the technology to get an overall understanding of how it functions and how it can be used. It is important to distinguish between scientifically proven versus suspected mechanisms of action. Important terms should be defined, and a glossary or a list of product names provided. The section may include pictures, diagrams, videos, or other visual material, in order to facilitate understanding for persons who are not experts in the field.

The TEC domain contains 16 issues. The issues are related to the four main topics: (1) training and information needed to use the technology; (2) features of the technology; (3) investments and tools required to use the technology and (4) regulatory status. Table 1 below shows the topics and issues specific to this domain [54].

Safety (SAF)

Safety is an umbrella term for any unwanted or harmful effects caused by using a health technology. An HTA should include an assessment of safety both in order to benefit individual patients and to inform policy makers 1. Safety information, balanced with data on effectiveness, forms the basis for further assessments of the technology with regard to, e.g., costs and organisational aspects.

The diversity of various types of health technology draws with itself many different types of safety issues; due to this, legitimate differences can occur in the way one can undertake an assessment of safety. The authors of a core HTA should cover those safety issues that are important to patients, or otherwise likely to be important in guiding the decisions of health care providers and policy makers [54].

Clinical Effectiveness (EFF)

The effectiveness domain in a health technology assessment considers two questions: Can this technology work, and does this technology work in practice? This assessment commonly uses two definitions:

- Efficacy is the extent to which a technology does more good than harm under ideal circumstances.
- Effectiveness assesses whether a technology does more good than harm when provided under usual circumstances of health care practice. The research questions defined

within this domain aim at answering these questions, with emphasis on the second question.

Commonly, the focus of the evaluation of clinical effectiveness is to determine the magnitude of health benefits and harms or, in other words, of the net benefit (benefits minus harms) that are caused by a technology. The evaluation also focuses on determining the certainty of the evidence (3). As the harms are addressed in the core model in a separate domain (Safety - SAF) this domain focuses on the assessment of the health benefits and the benefit-harm-balance. In order to provide evidence of a causal relationship between intervention and health outcomes, the generally accepted standard is an appropriately designed and conducted randomised controlled trial (RCT), even without a need for a deeper biological theory as to why the intervention works or does not work.

Comparative clinical effectiveness research compares two or more alternative methods for preventing, diagnosing, treating and monitoring a clinical condition, or for improving the delivery of care. The two key elements of the research are that effective interventions should be directly compared and studied in patients who are typical in day-to-day health care settings5. The assessment of health benefits should primarily consider patient-relevant outcomes such as mortality, morbidity, and quality of life [54].

Costs and economic evaluation (ECO)

Economic evaluation has been defined as a comparative analysis of alternative courses of action in terms of both their costs and consequences. The aim of the Costs and Economic Evaluation domain (abbreviated as ECO) within HTA is to inform value-for-money judgements about health technologies with information about costs, health-related outcomes and economic efficiency. In this way, it often utilises evidence from the SAF domain and the EFF domain to make economic evidence available when allocating resources to emerging, new and existing health technologies.

In publicly funded healthcare systems, finite resources mean that not all technologies can be provided in every situation for all who may need or want them. The concept of opportunity cost is central to this area of health economics: choices have to be made between alternative, effective health technologies; a decision to fund one technology may mean that others cannot be funded, or that their use must be restricted. Economic evaluations of health technologies often focus on efficiency considerations in the production of health, with economic efficiency providing an indication of how resources should be allocated or utilised for maximizing health-related outcomes in an economic manner 4. Although societal objectives other than economic efficiency, such as equity of access, reduction of inequalities, and deontological considerations can typically be part of a full HTA report, they are usually not incorporated in economic evaluations and need to be considered separately by decision-makers.

The primary aim of this chapter is to encourage a more transparent and structured way of reporting evidence related to the costs and economic evaluation of healthcare technologies both in national (regional) HTA production and in collaborative projects aiming to produce core HTA information. The chapter identifies good research practices for dealing with aspects of validity and transferability, including analytic strategies and guidance for considering the appropriateness of transferring evidence to other settings. This domain does not aim at a global harmonisation of requirements or methods for economic evaluation. Instead, it highlights the importance of transparent and structured reporting (both in methods and results) so that the study users can assess the relevance of the information in their own setting or adapt the information to their own setting when needed.

Methodological guidelines on the methods for economic evaluation have been developed. The EUnetHTA guideline Methods for health economic evaluations - A guideline based on current practices in Europe acknowledges the possibility of variations in requirements for economic evaluations across countries or jurisdictions. This guideline aims to improve the usefulness of economic evaluations performed within EUnetHTA and move ECO closer towards the possibility of a common European framework for conducting health economic evaluations. One important, related objective of the HTA Core Model itself is to encourage the sharing of information between [54].

Ethical analysis (ETH)

The term "ethics" is broadly used to describe activities relating to the understanding and study of "the moral life". The term "morality" encompasses beliefs, standards of conduct, principles and rules which may guide personal and professional behaviour and the behaviour of institutions. Morals are standards that are widely shared, and that form some degree of social consensus.

The Ethical Analysis (ETH) domain considers prevalent social and moral norms and values relevant to the technology in question. It involves an understanding of the consequences of implementing or not implementing a healthcare technology in two respects: with regard to the prevailing societal values and with regard to the norms and values that the technology itself constructs when it is put into use. The moral value that societies attribute to the consequences of implementing a technology is affected by socio-political, cultural, legal, religious and economic differences. However, many ethical considerations are common to all countries and societies.

In addition to the ethical aspects of using technology, the domain also covers moral and ethical issues related to the consequences of performing the HTA. These are, for example, questions about the ethical consequences of choosing specific endpoints and about whether there are any ethical problems related to the economic evaluation. There are, however,

also various ethical considerations that should be taken into account when choosing what technologies to assess and when planning to conduct the assessment. This is to ensure that the assessments themselves are designed and conducted in such a way that key ethical principles are considered and respected. These types of consideration are not part of this domain but presented in the introduction to the Core Model.

The ETH domain includes six different topics, which together cover nineteen issues. The issues stem from the general values of the population, aims of the healthcare system and values arising from the use of a technology [54].

Organisational aspects (ORG)

The domain of Organisational Aspects (abbreviation: ORG) considers the ways in which different kinds of resources (e.g. material artefacts, human skills and knowledge, money, attitudes, work culture) need to be mobilised and organised when implementing a technology, and the consequences they may further on produce in the organisation and the health care system as a whole. Organisational issues include e.g. work processes and patient/participant flow, quality and sustainability assurance, centralisation, communication and co-operation, managerial structure, and acceptance of a technology.

There are three levels on which to consider organisational aspects: The first is intra-organisational (e.g. how information about a new technology is provided to the patients in the organisation), the second is inter-organisational (e.g. how the communication between different organisations occur), and lastly there is the health care system level (e.g. how to set national objectives). There are various stakeholders besides staff and patients/participants, at various levels, e.g. payers, providers and suppliers. These groups usually have different aims for and expectations of the technology.

The elements which constitute an organisation have been defined in many ways through different approaches; for example, the physical structure, social relations, technology and organisational culture. The structure of an organisation defines its assignment of tasks, reporting systems and the mechanisms of interaction and coordination. In addition, there are other elements of a society and its culture that influence an organisation and its function. There are also different types of organisations, e.g. the profit centre organisation, the matrix organisation and the network organisation.

One challenge which assessment of organisational aspects faces is the complexity of health care systems and processes. Due to the multiplicity of objectives and criteria in organisational analysis, this assessment is less pre-determined and more variable than for example economic and clinical effectiveness analyses. In addition, the findings are normally more context-dependent and less transferable than e.g. in the effectiveness and safety domains of an HTA. The choice of assessment areas should also be guided by the information needs

of HTA end users (e.g. regional health authorities' focus may differ from that of hospital managers). Furthermore, different health care systems and national rules for medicine prescription must be taken into account in order to deal with transferability issues. Since organisational aspects vary across countries, this could limit exportation of HTA information from one country to another [54].

Patients and Social aspects (SOC)

The Patients and Social Aspects (SOC) domain takes patients or individuals in whose care a health technology is used as a point of reference in an HTA. Patients Aspects relate to issues relevant to patients, individuals and caregivers. Patient refers to a person who receives (or has received) and uses (or used) health technologies and health services in the healthcare sector. The term individual is sometimes used synonymously with "patient", but it can also refer to a healthy individual, who receives health technologies, e.g. a person taking part in a screening programme. The term caregivers (sometimes referred to as carers) refers to family, friends and other persons from the patient´s/individual´s social network, who provide care to the patient and are in other ways involved during the course of the disease. It excludes those paid to give care, such as healthcare professionals. Social Aspects are related to social groups, that is specific groupings of patients or individuals that may be of specific interest in an HTA, such as older people, people living in remote communities, people with learning disabilities, ethnic minorities, immigrants etc.

Patients, caregivers or individuals can provide unique perspectives about experiences, attitudes, preferences, values and expectations concerning health, illness, service delivery and treatments that can inform HTA. Patients, caregivers and individuals will have a range of perspectives and an HTA should seek to gather as much evidence as possible to understand these wide ranging views. There may be some social groups that are particularly important to consider for a specific health technology or for which there is a policy imperative for special consideration (such as those with disabilities) or in which the value of the technology may be different (such as ethnic minorities) and these may need to be specified. Hence social groups are also important consideration in HTA [54].

Legal aspects (LEG)

The objective of the Legal Aspects (LEG) domain is to assist the HTA doers in detecting rules and regulations which need to be taken into consideration when evaluating the implications and consequences of implementing a health technology. Rules and regulations have been established to protect the patient´s rights and societal interests. The rules and regulations may be a part of patient rights legislation, data protection legislation, or health care personnel´s provisions, rights and duties in general. The market access authorisation

or -regulationprocesses have not been the direct focus of HTA earlier, but this may be subject to change in the future [54].