

ADmed: An Adaptive Technical Process for the Agile Development of Medical Devices

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Abstract: Agile project management is an established approach in software development and over time has also been adapted to different fields of work. While there are proven advantages for an agile development process, not all branches have incorporated agile methods in their project and development practices yet. One of these branches is the medical device industry. They often fall back on traditional, plan-based process models due to regulatory and normative requirements because of perceived conformity. ADmed is a process model that combines agile and plan-based processes while still adhering to the necessary regulatory requirements. In order to make it more accessible and approachable for a wide range of users it also incorporates adaptive elements, which are adjusted based on the user context.


1 INTRODUCTION

In everyday life, medical devices support and improve the quality of life in different ways (Austromed, 2018) – ranging from daily products for fitness diagnostics to high end devices for medical operations. The medical device industry covers a wide field of different products. This leads to diverse industry, which in Germany alone generates sales of over 34 billion Euro in 2021 (BVMed e.V., 2021). Sales have been steadily rising over the last few years and with an aging society the demand is expected to rise even further. It is clear, that the medical is an important economic factor not only in Germany but worldwide. Despite this the industry is also facing new challenges (BVMed e.V., 2021). Like in most other branches, digitalization is currently one of the main topics in developing new medical devices. While it may require new ideas and expertise on the developer side, it is also an opportunity to create new and innovative products (Dispan, 2020). Companies have realized this challenge and currently about 9% of the generated turnover is reinvested into research and development. The industry is splitting their efforts between developing new products and further improving existing medical devices (BVMed e.V., 2021). As

medical devices are usually very close to patients or users, there is always a strict focus on the safety of every person involved, which includes the product safety and also the product usability (Donaldson et al., 2021). Both of these aspects can be achieved by traditional, plan-based project management, but they are also perfectly achievable with an agile development approach. Especially the iterative, incremental approach and the involvement of different stakeholders ensure not only the usability but also that the critical functionality is often tested multiple times due to the iterations. While agile methods can provide valuable advantages during product development, there is still hesitation from developers to employ them. This is mainly caused by caution as they want to guarantee compliance with the strict regulations, specifications and guidelines to which they must adhere. So they trust their established methods instead of incorporating new and possibly beneficial methods. However, many manufacturers desire more agility in management and execution of medical device projects (Jonnalagadda et al., 2019). The innovative, flexible process model *ADmed* (Agile Development of Medical Devices) was developed in response to this desire for more agility and demonstrates how the compatibility of plan-based and agile development with the specifications of regulations and standards can be realized (Schidek and Timinger, 2022). The model offers insight in how agile methods in the development of medical devices can be achieved. However, it re-

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quires developers and project managers to understand agile methods in order to be able to use it. As agile methods are rather new in the field of medical device development, the knowledge about them on the practitioners side is on an early level. To alleviate this drawback, the ADmed model could be reconstructed as an adaptive process model that supports and guides its user throughout the tailoring of the process model.

2 ADmed MODEL

This section describes the structure of the ADmed Model with respect to its functionality and the roles that take part in the process model.

2.1 Structure and Functionality of ADmed

2.1.1 Top Level

Figure 1 provides an overview of the basic structure of the process model ADmed. It consists in parts of traditional, plan-based project phases, which makes the model rather easy to understand. The main phases are initialization, project design, realization and extra phases especially for a final verification and validation, and the design transfer of the medical device. In the realization phase, the model offers a potentially iterative way of working. The top level of the process model ADmed is in line with the medical device regulation of the European Union, detailed in the harmonized standard EN ISO 13485, chapter 7. As more details on each phase are required, beneath the more detailed level of each phase is presented.

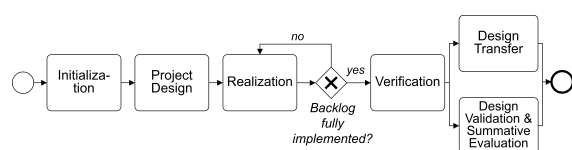


Figure 1: Main structure of the flexible process model (Schidek and Timinger, 2022).

2.1.2 Detailed Level

In order to show the relevant activities for the process as well as the agile building blocks that were specifically set, the process model was expanded by a more detailed level, shown in Figure 2, in addition to the top level and is explained in the following.

Even before the actual project start, the process model begins with the *initialization*. According to the traditional understanding of project management, this

phase is regarded as an orientation to obtain a rough overview of the project and its scope. Checking the necessary resources in the company is also part of this step. After the official project release, the *project design* begins. In this phase, the framework conditions for the implementation of the project are defined. Starting with the definition of the user needs (as well as the superior intended use of the medical device), the first agile building blocks are used here. Requirements are defined together by the entire project team – and in particular by the relevant stakeholders – on the basis of user needs, in the form of user stories, use cases or similar. By involving relevant stakeholders, requirements can be gathered qualitatively without expecting quantitative details from them, which often cannot be formulated directly at the beginning of the project. In order to find concrete user needs as early as possible, this process can take place in an iterative form and in collaboration with the stakeholders. Various creative methods and techniques can be used for this purpose. The formulated user needs are recorded in the backlog in a way that is comprehensible and accessible to the entire project team. Parallel to this step, the risk management process according to EN ISO 14971 can already be started here and the first cycle can be run through. For the sake of clarity, the risk management activities are not shown in the rest of the process model. These are considered to be a prerequisite with the start of the risk management process and should be carried out in parallel with the development. In the next step of the project design, further framework conditions for the implementation of the project are set by the project manager. These include prioritizing the backlog and defining the associated definition of "done", assembling the project team on the basis of the required competencies and defining the time box for the iteration and the activities defined therein. Only when these factors have been set, the next phase can begin. The *realization* is executed iteratively and incrementally. For this purpose, user needs prioritized in the backlog are first transferred into quantitative requirements during iteration planning and an iteration target is defined jointly by the project team and recorded in the iteration backlog. The requirements definition is taken over directly by the developers – similar to scrum – in order to strengthen the necessary understanding and commitment. Planned activities for verification and validation of the set requirements are also already defined.

To focus on implementation and to improve communication within the project team, short daily stand-up meetings are conducted. They also help to communicate the upcoming work of the day of each team member and to address potential impediments. As

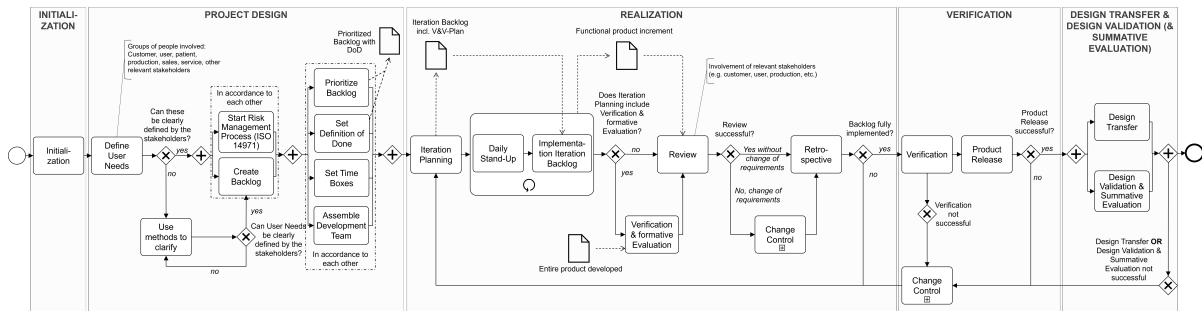


Figure 2: Detailed view of the defined activities within the individual phases (Schidek and Timinger, 2022).

a result of the implementation of the iteration backlog, a functional product increment is created, which is then evaluated by the entire project team and compared with the specified definition of "done" in the subsequent review. At this point, relevant stakeholders can make possible change requests. However, the EU regulations require that changes must not accidentally introduce additional risks or changes of the intended use of the medical device.

For this reason, potential changes follow a well-defined change management process. Approved changes are documented in the backlog in a traceable manner, as required by EN ISO 13485. Another quality assurance activity in the realization is the usability check during development in the form of a formative evaluation. This can be defined at certain intervals in the iteration planning and carried out after the implementation of the iteration backlog. Typically, agile development processes end with a retrospective, to reflect one's own work and processes. Through open communication, processes can be reflected and optimized, and problems can be directly addressed and solved.

After the retrospective, it is possible to start the planning for the following iteration. The activities of the realization phase are executed iteratively as often as open user needs are listed in the backlog.

Once all user needs of the backlog have been implemented, the final *verification* of the developed medical device can start. According to EU regulations, the verification has to be performed in a separate development phase. Test cases for the verification have already been collected in the iteration backlogs and can now be executed and documented.

As the final phase, the medical device can now be transferred to production in the *design transfer*. In the *validation* phase, the fully developed medical device is tested by comparing it to the intended use and the user needs. Similarly, the usability of the medical device is also finally tested by means of the summative evaluation in accordance with IEC 62366.

2.2 Roles

In order to fulfill the regulatory requirement for defined responsibilities according to EN ISO 13485, the project team consists of three persons (groups) who perform defined tasks: project manager, developer, and customer (representatives). The roles described below act on an equal level to enable the most open and direct communication and action possible. Traditional project management tasks, such as defining the framework parameters in the project design, are performed by the *project manager*. Maintaining the backlog of requirements is also one of the project manager's tasks. As a link between stakeholders and developers, the project manager ensures that the project runs efficiently and effectively.

The project is implemented by the *developers*. They act and work according to the agile values in an interdisciplinary and (mostly) self-organized way. The active involvement of the developers throughout the process promotes identification and motivation with regard to the development of the project object. Various activities, such as the daily stand-up or the retrospective, also require direct communication channels. This open communication and regular reflection on one's own actions and processes ultimately benefits not only the project itself, but the entire company. The last relevant group of people is the group of project-relevant stakeholders. In addition to the *customer*, these include, for example, users, suppliers, production or sales. All relevant stakeholders are involved throughout the entire development process. Beginning with the collaborative definition of user needs through to validation and design transfer, the stakeholders are actively involved and can introduce change requests according to a well defined change process at any time in order to create a medical device of highest possible quality and customer-specification.

One of the most demanding tasks in working with a reference model is to adapt it for a specific environment, especially for such a heterogeneous field like

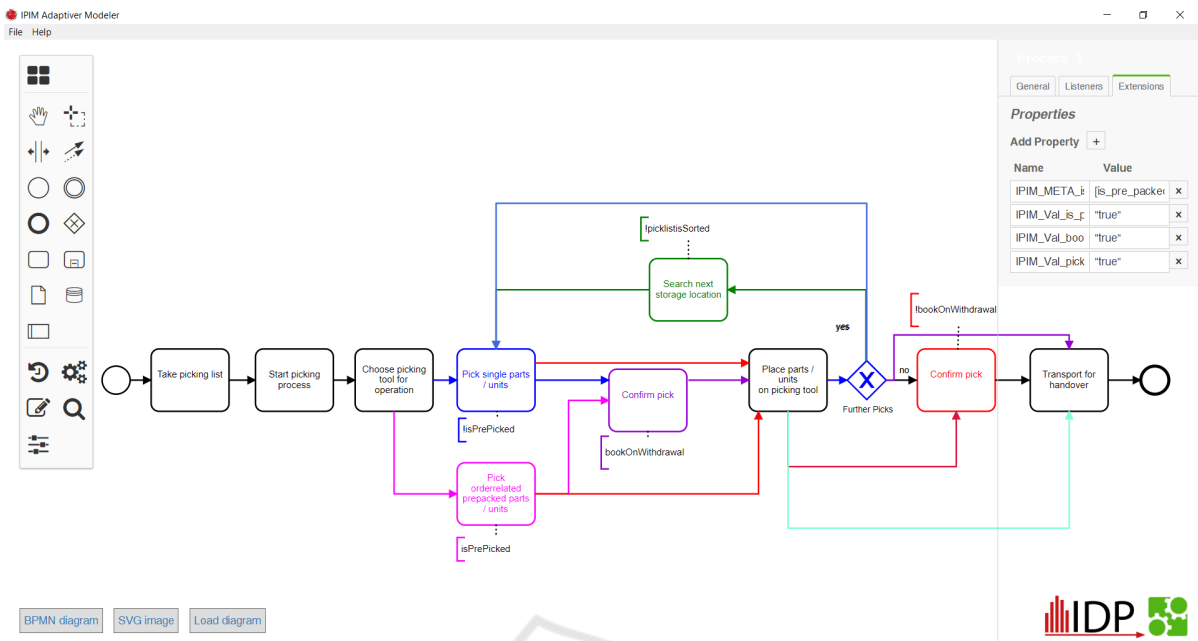


Figure 3: Screenshot of the ADAMO Modeler: The different colors of the model represent different adaptation options, which are later selected during process execution, dependent on the values of the specified parameters for adaptation.

medical devices are. To make it easier for users to apply the reference model for their specific case, it is beneficial to use an adaptive modeling technique. In this way the model also transfers knowledge about best practices on how to adapt it. First the ADAMO Modeler, a tool that enables adaptive modeling, will be discussed, followed by an example on how it could be used in the ADmed model.

3 ADAMO MODELER

Information modeling is a standard instrument of business informatics that is frequently used to model processes and company data (Seel, 2010). Currently, there are hardly any tools that provide sufficient functionality to both create and evaluate adaptive reference models (Seel et al., 2016). It is therefore necessary to extend an existing and established modeling language by the necessary elements (Hilpoltsteiner et al., 2019). For this reason, the ADAMO Modeler is being developed at the Institute for Data and Process Science at Landshut University of Applied Sciences (Institute for Data and Process Science Landshut, 2020). This not only enables processes to be modeled in conformity with BPMN 2.0, but also extends its meta-model to include parameters and variables. While parameters are available globally throughout the process and can thus be evaluated in all terms, a term is always linked to a BPMN ele-

ment in the process (Hilpoltsteiner et al., 2018).

Once the process model has been created, the ADAMO Modeler also offers the possibility of evaluation. First, the user is asked to enter values for all parameters required in the model. These values, then, automatically replace all parameters in the terms of the process model. Subsequently, all terms are evaluated using the values. On the basis of these terms, the model can later decide to remove unneeded parts of the model (according to the logic), thus suggesting the user an implementation of the process based on his parameters. An example what the tool looks like can be seen in Figure 3.

3.1 Boolean Decision Making

A previous release of the ADAMO modeler was solely based on Boolean logic as described by Becker (Becker, 2002) and Delfmann (Delfmann, 2006). Each element, like tasks, flows, events, or others could be assigned with a Boolean term. The most central piece, as with any term, were the variables that can be used. As the possible use cases should be as broad as possible, we opted for an open approach with the following data types: numeric values, texts, and truth values. As the software is based on an open source project in JavaScript, this corresponds to the data types of Number, String, and Boolean. A term, however, can not only contain string variables, the whole term itself is also saved as a string (e.g.,

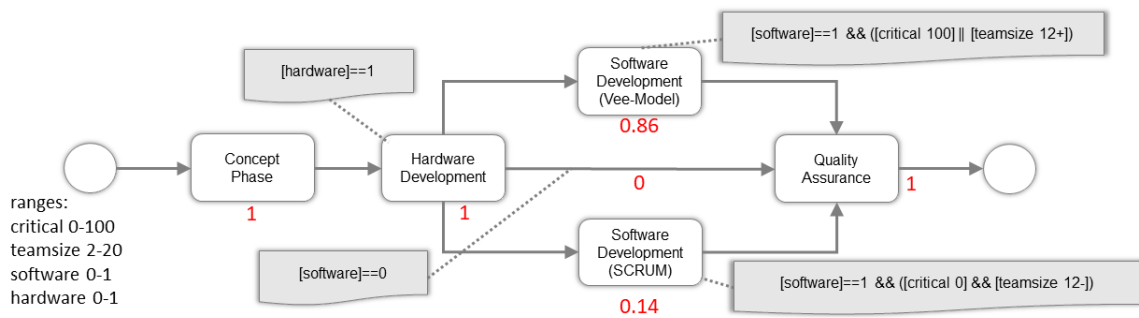


Figure 4: Example of the fractional 0-1 Decision Making approach.

variable names are strings). Hence, it is important to make variables clearly distinguishable. For this reason a delimiter is defined that allows to mark a variable as such. This delimiter may not use operators or limit the possible content of text variables. While staying within these technical limitations, the goal was also to keep the term as readable as possible for humans. In order to fulfill this criteria, square brackets are used as delimiter. As the evaluation logic of JavaScript does not consider them as commands this works out well. A possible term looks like the example below.

```
[participants] <= 12
```

In this case [participants] represents the variable name, which can be substituted with the variable value by implementing a simple search and replace algorithm before the evaluation takes place. In order to separate between text strings and decimal variables, it is important to introduce various identifiers. Within an ADAMO term, character strings must be introduced and terminated by quotation marks to enable a safe evaluation.

3.2 Fractional 0-1 Decision Making

While the approach with Boolean variables is enough to satisfy basic use cases there are also some types of decisions that are less clear-cut and require a more gradual decision-making process. The Boolean approach will by definition always result in a clear true or false for an element to stay in the reference model or not. While this may work for some decisions, other problems require a more gradual approach in the output (Schmidner et al., 2021). For example, in project management, Scrum is generally attributed to be usable by small teams. If small teams are defined as less than 12 people, in the Boolean approach Scrum immediately becomes useless for teams with 13 or more people, as it is a clear decision between "more than 12" or not. However, this does not reflect reality, because Scrum is not unusable with 13 people

albeit it becomes less attractive the more people join the team or it requires additional structures for large scaled Scrum.

Also users of reference models often would like to prioritize certain aspects in regard to their individual project. For example, a project may value the personnel or culture parameter as far more important than the actual team size. Both of the aforementioned reasons make simple Boolean terms unsuitable for an approach where the user wants a less clear cut for variables or wants to weigh the parameters differently.

Today, thus, ADAMO offers another solution which is based on the Boolean logic but enables an even more user specific evaluation. To reflect this, the fractional 0-1 approach allows for the full spectrum in between. A solution becomes gradually less attractive the more the values differ from their optimum. So we do not have one point that suddenly reverses the decision whether the element is deleted from the model but instead we have a numerical evaluation how good the element fits the variables based on the attached term. To explain this new interpretation of parameters, at first the variable [participants] is reconsidered, which settles in the range between a minimum of 2 and a maximum of 20. Now we need to define the optimum for a specific approach. In case of the aforementioned Scrum example, a participant number of 12 or below would be best suited for this approach. In this case, the following term can be defined to the relevant elements in the model.

```
[participants 12-]
```

This will lead to a score of 1 if the parameter for [participants] is equal to 12 or below and gradually decreases towards 0 the further the parameter exceeds 12. At 20 participants, the score is 0. As we now have a numerical value on how good an element fits into the model, we must make a decision on which elements to keep and which to remove. Therefore each path along the process model is analyzed and the values of all elements along the path are multiplied. The path that has the closest value to 1 after all calculations is the

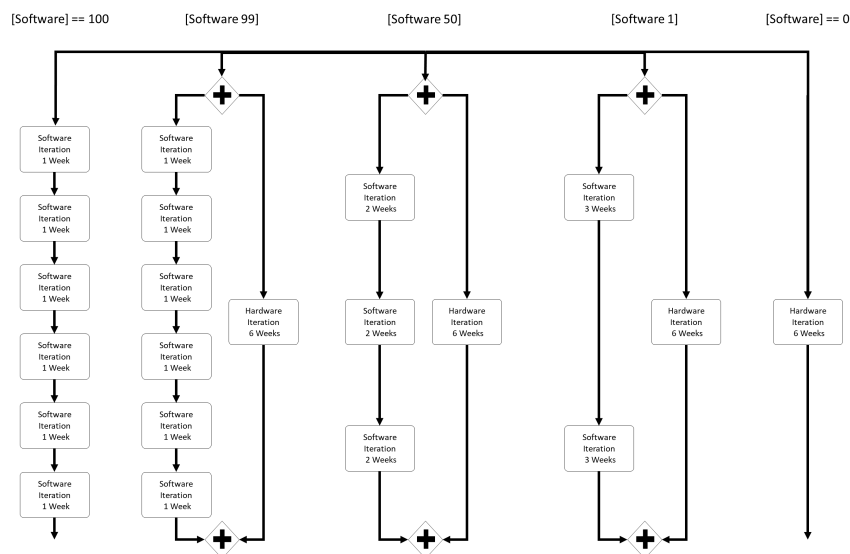


Figure 5: Adaptive ADmed Example.

one most suitable for the given parameters. This is, therefore, recommended to the user as the final process.

An example for this can be seen in Figure 4. In that simple example we have three possible paths throughout the model. The model is defined with 4 parameters ([software] and [hardware] ranging from 0 to 1, [teamsize] ranging from 2 to 20 and [critical] with a range from 1 to 100). The user selects the parameters as follows: [critical] = 0.86, [software]=1, [hardware]=1 and [teamsize]=12. The first path using the Vee-Model is calculated with a score of 0.86, the second path is to have no software development calculated with a 0 and the third is with Scrum and a calculated score of 0.14. According to the values given, the Vee-Model path is suggested to the user.

4 ADAPTIVE ADmed EXAMPLE

If we now apply the possibilities ADAMO offers to the ADmed model it enables recommendations to be given to users on how to best tailor the model to their specific needs. An example is the tailoring of the duration of iterations, depending on how much software in relation to hardware is part of the specific project. The idea here is that the more software-oriented the project is, the shorter should be the iteration to collect feedback. If the project leans more toward hardware orientation, the software iterations can take more time to match up with the hardware development speed, which typically is slower than that of software. To model this, we define a parameter [software] that can

range between the values of 0 and 100 (see Figure 5 for an illustration). The user can then choose to input a value depending on how much software development is needed in the project under consideration. 100 denotes a pure software development project. 0 denotes a pure hardware development project. If the user chooses a value in between, the reference model calculates the approach of closest distance to its optimum and suggests this as the final process.

Initially five alternative paths are present in the ADmed process model. In case the user specifies a pure software development project (value equal to 100), the leftmost part with six one week intervals receives a score of 1, while the path to its right ([Software 99]) has a score slightly below 1, because the given value 100 is (only) very close to 99, where that path would be optimal. All other paths are even further from 1, ending at the rightmost path with a score of 0. Hence, the leftmost path is recommended to the user as the most suitable process for the project. If, on the other hand, the user specifies a value of 0 to the variable [software], it is a pure hardware project and with the reverse argumentation the rightmost path without any software development is recommended. If the given value is in between, meaning in the range of 1 to 99, the process model recommends the path [Software 99] ("Hardware Project with Software"), if the given value is closer to 99 than to 50 or 1, [Software 1] ("Software Project with Hardware"), if the given value is closer to 1 than to 50 or 99, or [Software 50] ("Hard- and Software Project"), if the given value is closest to 50. Please note, that this simple example focuses only on one part of the ADmed Process

Model with only one variable. The logic can be formulated much more in depth with additional variables and if the best path along the whole model is calculated it may come to a different result, depending on the other parameters involved.

5 CONCLUSION AND OUTLOOK

If the ADmed Process Model is reconstructed as an adaptive model, it will provide benefits for users tailoring it to their needs. This is especially true for the targeted audience group of medical device project managers. The adaptive model supports the individual configuration of the development process while ensuring compatibility to the regulatory requirements which are unavoidable for the development of medical devices. The combination of plan-based and agile process models in ADmed facilitates a great degree of flexibility. ADmed is also suited to guide inexperienced managers through the development process of medical devices. However, there remain open tasks to be solved in the future: In order to further implement the adaptive model, the relation between influencing parameters and required processes must be examined and modeled in more detail. This also includes the acquisition of knowledge about suitable ranges of the values of the parameters. For this, expert interviews and observations are planned in order to complete the model. Additional case studies will, then, help to evaluate and further refine the model.

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