



# Medtech innovation guide: an empiric model to support medical technology innovation

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## Abstract

Innovation has become increasingly important for most industries to cope with rapid technological changes as well as changing societal needs. Even though there are many sectors with specific needs when it comes to supporting innovation, the medical technology sector is facing several unique challenges that both increases the lead-time from idea to finished product and decreases the number of innovations that are developed. This paper presents a proposed innovation guide that has been developed and evaluated as a support for the innovation process within medical technology research. The guide takes the unique characteristics of the medical technology sector into account and serves as a usable guide for the innovator. The complete guide contains both a structure for the process and a usable web application to support the journey from idea to finished products and services. The paper also includes a new readiness level, Sect. 4.2 to provide support both when developing and determining the readiness for clinical implementation of a medical technology innovation.

**Keywords** Biomedical engineering · Medical technology · Innovation · Medtech innovation guide

## 1 Introduction

The concept of innovation has been of great importance for introducing new technological solutions which have significant impact on society. There are many ways to describe innovation, e.g., as “doing things differently in the realm of economic life” [ , p. 84], “the commercial or industrial application of something new” [ , p. xix], or as “a radical act which is the introduction of a new element or a new combination of old elements” [ , p. 435]. It has, over time, become increasingly important to nurture the ability to break away from existing rules of the game to generate innovation and achieve success [1–4]. The concept of innovation often refers to “a change in technology” [ , p. 198], and can be defined as something original and more effective, and new,

that “breaks into” the market or society. Hence, in terms of a technological innovation, it needs both the technological invention and commercialization of the product or service.<sup>5</sup>

From a company’s point of view, innovation becomes important to cope with today’s highly competitive environment where quick and powerful strategic changes and moves by competitors have made it increasingly hard to gain and, foremost, sustain competitive advantages [1, 6–10]. Hence, innovation has become a way for companies to survive in “a world of continuous change, [and] companies need to maintain pressure constantly at the frontiers – building for the next round of competition” [ , p. 124]. This is even more common within industries that emerged from technologies that, today, has a great impact on society, e.g., software engineering, electronics, and computer engineering, where it is possible to observe fast technological innovation and a high frequency of new solutions [11, 12]. The medical technology industry is based on these foundations and is driven by innovations to make people’s lives better, but also to streamline existing care. There is, furthermore, a difference between larger, established, companies and SMEs regarding the support needed within the innovation process [13].

The definition of *medical technology* (medtech) is ambiguous. Often, the industry uses the term medical technology

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whereas the academy uses biomedical engineering and mean the same. Biomedical engineering is regarded to be the application of engineering principles and design concepts to medicine and biology for health care purposes. Sometimes the words *bioengineering* and *medical engineering* are used interchangeably with biomedical engineering and medical technology. On the other hand, medical technology is defined by the WHO as the “application of science to develop solutions to health problems or issues like the prevention or delay of onset of diseases or the promotion and monitoring of good health” [ , p. 777]. In this paper we also find the definition for medical technology to be the most appropriate regarding this area of research and development and it is the definition mostly used by the medical technology industry. Thus, hereafter we will use the term “medical technology” [14].

Research is an important foundation of innovation as emphasized by both the EU and the Swedish Government [15] during the last couple of years. One idea of applied research is to turn basic research into inventions and further into innovations. Thus, having processes that support commercialization closely linked to the research community has become increasingly important for both research institutes and universities globally.

For the individual innovator, the process from idea to product launch can be hard to follow and understand and get knowledge of. However, for most steps within the innovation process, there are tools that can be used to support the innovator regarding the different tasks to be carried out. Examples of these tools are e.g., Business Model Canvas [16], Lean Startup [17], and NABC (Need–Approach–Benefit–Competition) [18]. Different methods for structuring and framing the actual development process such as new product development [19] and design thinking [20, 21] provide brief guidance during the full length of the development. Furthermore, agile methods for product development (e.g., scrum), are complements to e.g., lean startup methods and design thinking, and there are great benefits to combine discovery methods and development methods that are lean and agile [22]. Even though these simple, but very effective, tools can support the user in the process they often not offer both an integrated and holistic view of the situation and the process. One example is the Business Model Canvas that gives only a simplified holistic view and ignores the competitive landscape [23].

There are also well-established methods to describe and understand the status of an innovation. For innovation projects, this can be in terms of applying for funding, attracting investors, or just for internal grading. There are many scales that are used for grading innovation projects depending on what part of the development process that is going to be ranked. Two of the more common scales are the Technology Readiness Level (TRL) [24], and Manufacturing Readiness Level (MRL) [25]. The TRL scale has been gradually

developed since the 1970s and the current 9-level scale was adopted in the 1990s [26]. Within the EU, the TRL scale is rated from *Basic principles observed* (TRL1) to *Actual system proven in operational environment* (TRL9). Hence, the scale can be used to more consistently discuss and evaluate the maturity of technology in general [27] and is still frequently used for grading product development. The MRL is a measure developed by the US department of defense to assess the maturity of a technology from a manufacturing perspective. There are also other scales that measure business readiness and innovation readiness, e.g., [28]. Furthermore, Benešová, Basl, Tupa and Steiner [29] give an overview over a wide range of maturity scales. All these scales are rough measures on the status of a technology, innovation, or business. Although these scales are important for evaluation and status, they do not provide guidance through the development or innovation processes.

The value of innovation is particularly evident in modern health care. Innovations are important in enabling a repertoire of highly specialized care. The health care industry that works in synergy with the health care systems is dependent on innovations, that can be commercialized, for its survival and expansion [30]. For example, Triple-Helix (academia, industry, society) methods to commercialize innovations from scientific research results [31] are well established in northern Sweden through the existing innovation system and for the health care system, through e.g., the Centre for Biomedical Engineering and Physics (CMTF). Smith et al. [32] emphasize the importance of early contact with clinicians to define needs and contribute to safety analyzes, but also important later in the commercialization process and the product launch.

The medtech field is inhomogeneous and ranges from rather simple devices to complex instruments that combine several advanced techniques. Since health care technology is used on humans, special demands and regulations need to be considered to ensure safe equipment [33]. This makes it challenging to succeed with inventions and innovation development [34]. It is challenging to navigate in the development process to quickly proceed from an initial idea to a certified medical equipment on the market. Several studies have shown that this process takes 10–15 years. For innovators and entrepreneurs in the health care sector, working with business models has become, not only increasingly important during the last 30 years but also more common. The specific needs in the health care sector have created a demand of customized tools and models to navigate the development process and provide support for innovation and development. There are organizations, e.g., The National Health Service (NHS) in the UK, that has a system to promote innovation with academic partners [35]. Today there are several different tools and models that offer this specific guidance to create a sustainable business around innovation within

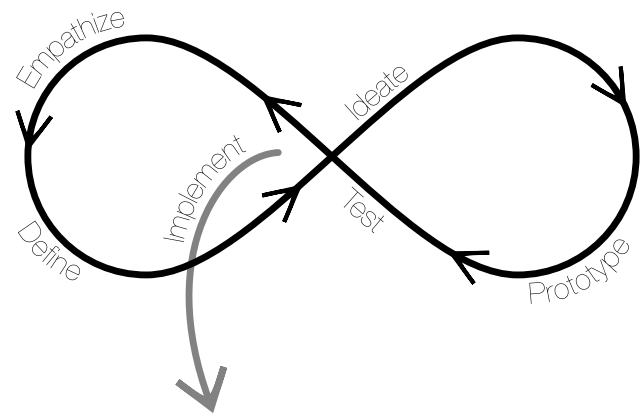
health care. These models have also gradually become more usable and give basic support to the users regarding the innovation process. The most well-known model that provide essential support within health care innovation, is the CIMIT-model (Consortia for Improving Medicine with Innovation and Technology) [36, 37]. This model aims at finding teams that can provide solutions to unmet needs by providing financial support, expertise, and guidance through the innovation process. For guidance, CIMIT proposes the Healthcare Innovation Cycle, which offers support to the clinical, market/business, regulatory, and technology development. The model provides support in 10 steps from initial clinical need to become a standard through invention (Need, Idea, and Proof of Concept), translation (Proof of Feasibility, Proof of Value, Initial Clinical Trials, and Validation of Solution), and commercialization (Approve & Launch, Clinical Use, and Standard of Care). The overall CIMIT-model offers a good support for health care innovation and is tailored by other institutions to create models to support innovation [38]. Another general model is the recent seven stage End-to-end Innovation Adoption Model [39], that combines specific requirements from the health care sector with the design thinking process and focuses on providing support for innovations that creates value and decreasing time-to-market. However, current models are mostly general and there is a need for an integrated and more hands-on guide to support researchers, innovators, and entrepreneurs within medtech research. A standalone guide to provide self-guidance in activities for the target group and give indications on support need from other actors, would serve as a tool to strengthen the control of the innovation process.

### 1.1 Objective

The aim of this work was to develop and evaluate an integrated guide to support the innovation process within medtech research. The proposed model combines general aspects regarding innovation with specific aspects related to the medtech industry with the purpose of providing an understandable and usable model with strong focus on the innovator and the journey from idea to finished product and service. The goal is to encourage innovation, prevent interruptions of the innovation process as well as reducing the time to market.

## 2 Method

To offer a structured method, the development and evaluation of the innovation guide has been framed within the ideas of design thinking using a co-creative methodology in cooperation with intended users of the guide (i.e., innovators and entrepreneurs in different stages of the innovation



**Fig. 1** The different stages of the design thinking process (based on [20, 21])

process) and has been gradually developed through prototyping with several iterations including feedback from testing and interviews with intended users. An overview of the development process of the innovation guide is described in the following chapter.

### 2.1 Design driven development of the innovation guide

Creative techniques, e.g., brainstorming [40], and ideas around creative engineering in the 1950s and 1960s [41, 42], have had great impact on the concepts around Design Thinking that has been increasingly popular as a development process in later years. Design thinking [20, 21] is an ideology of having a user-centered approach to development and problem solving. It is also a methodology that is used within many different fields for understanding, defining, and solving complex and multi-faceted problems regarding the development process. Design thinking is, in general, based on six different steps – empathize, define, ideate, prototype, test and, at the end, implement (Fig. 1).

As discussed in the introduction, there are many different models and tools for innovation and business model development. Understanding the actual need of the intended users (empathize) are of great importance to increase the value-in-use of the proposed model. The guide presented in this paper, the Medtech Innovation Guide, derives from both a theoretical standpoint on innovation combined with the actual need among a group of researchers and entrepreneurs within medical technology. The information and experience gathered among these researchers and entrepreneurs provided the foundation for defining the deficiency of current models and the idea for the Medtech Innovation Guide. In any product development process, prototyping is essential to focus the right amount of energy on the right things at the right time. According to Houde & Hill

[43], prototypes “provide the means for examining design problems and evaluating solutions. Selecting the focus of a prototype is the art of identifying the most important open design questions”. The development of the innovation guide has been based on the concept of an evolutionary prototype in conjunction with incremental prototyping. Using this method, different ideas have been added and gradually tested and the prototype has been refractured and expanded throughout the development process and some parts have been prototyped separately to guarantee high quality result.

### 3 Development process

Since the main foundation of the innovation guide has come from members of the medtech community, the innovation guide has evolved by involving potential users in early stages of the design process. The involvement of users in the development process has been discussed from the perspectives of the service innovation process [44] and the co-creation process [45, 46], that is common in dynamic and flexible product and service development today. This involvement and co-creative design method involving the intended users of the model has given insight into both the potential usage of the model and the needs that future users have. In general, the exchange of knowledge within the development process can assist in creating a high user value [47].

Early in the development process it became clear that to truly support the innovators, the guide should be integrated with a web application to increase its usability and availability. An illustration of the integrated development process of both the guide and the web application is shown in Fig. 2. The different stages of the design process have been connected to the activities below – *empathize* and *define* using expert groups, user interviews, and workshops, *ideate* using expert groups, brainstorming sessions, and workshops, *prototype* and *development* using evolutionary prototyping of the model and a combination of throw-away and evolutionary prototyping and development of the web application to increase usability, and *testing* using workshops and user interviews. The full development of the guide was carried out 2018–2021, Activities 1–3 were carried out in 2018, Activities 4–13 in 2019 and Activities 14–17 in 2020–2021 (Fig. 2). Due to funding of the research and development projects, the development process was divided into two parts – 2018–2019 with a focus on developing the guide and late 2020–2021 with a focus on refining the guide and developing the web application. All activities (Fig. 2) are described below.

### 3.1 Workshops

Workshops have been used during the development process. The workshops have been based on creative problem techniques, e.g., [40–42] with the aim to provide novel solutions to both the structure and content of the proposed innovation guide. Different steps in the design thinking process have been iterated and discussed in different groups of potential users.

### 3.2 Interviews and qualitative analysis

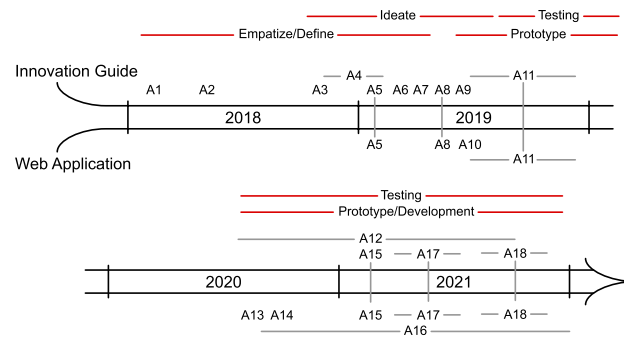
The process of designing the innovation guide has been iterative and data from testing has been, mostly, gathered by interviews [48, 49]. By using an approach with semi-structured interviews, an exploratory view upon the development of the guide has been kept. Every stage and data collection have contributed to further development of the guide, both in terms of e.g., brainstorming and testing. Structured and semi-structured interviews were used to give a possibility to compare data along with an opportunity for exploration of the potential use of the guide.

For the evaluation and extended development of the guide the qualitative data gathered during the interviews (i.e., the opinions of the interviewees) were analyzed and put into different themes using primarily an inductive approach, e.g., [50]. From the data, different important sub-themes emerged and became the basis for further development and evaluation of the guide and the supporting web application.

### 3.3 Evaluation-prototyping, testing

Prototyping is important in the development process to create usable results [51]. To both identify and satisfy the needs of potential users of the system, it has been designed using, foremost, evolutionary prototyping [52]. The system was split into two parts – the guide and its functions and the information before signing up. These two parts were created using the ideas around incremental prototyping and developed in parallel. As described in the previous chapter, there have been a continuous and iterative ideation, development, and testing of both the guide and the web application throughout the development process. Activities 9–18 (Fig. 2) have all been conducted for evaluation of the guide and the web application through prototyping and testing. The evaluation of the guide initially developed using input from regional innovation projects and experts was done on a national level. During Activity 15, Activity 17, and Activity 18 the developed guide and web application have been tested using surveys, interviews and live testing with national experts, researchers, and entrepreneurs. The evaluation was

**Fig. 2** Timeline of the activities (A1–A18) performed during the development process of the Medtech Innovation Guide and its web application



<p><b>A1: Forming expert group</b> An expert group was formed from a regional network of 12 research scientist, innovators, and entrepreneurs within medical technology.</p>	<p><b>A10: Prototyping the web application</b> The early user tests indicated a need for a supporting tool to make the guide usable during the innovation process. A first throw-away prototype of a web application was developed.</p>
<p><b>A2: Involving and understanding potential users</b> Five innovation projects with established industry contact currently in different TRL phases were carefully chosen to take part in the project as potential users of the final innovation guide.</p>	<p><b>A11: Feedback on guide and the web application</b> User feedback was collected both on the new version of the guide and a medium fidelity prototype of the web application.</p>
<p><b>A3: First structure model (workshop)</b> Originating from current scales and tools for measuring readiness regarding technology, business, and innovation, a first structure of the innovation guide was formed merging different readiness levels into one model.</p>	<p><b>A12: Continuous improvements to the guide</b> The guide was continuously improved with changes to themes and activities. To increase the usability of the guide and the web application, informative text was added to the guide.</p>
<p><b>A4: Continuous discussions regarding the guide</b> The model was continuously discussed in the expert group. Opinions and conclusions were collected.</p>	<p><b>A13: Specification for the web application</b> A specification of a web application to increase the usability of the guide was defined. A minimum of eligible functions of the web application were listed, together with a wish-list of future functions.</p>
<p><b>A5: Developing the 4-phase guide (workshop)</b> During a brainstorming session, the guide was restructured into a four-phase guide based on phases for product and service development.</p>	<p><b>A14: Prioritization of functions in the web application</b> Based on experience of the expert group and knowledge of design, desirable functions were rated according to feasibility and added value. The MoSCoW model [48] was used for prioritization.</p>
<p><b>A6: Feedback on the guide (user testing)</b> The innovation projects involved in the development process gave written feedback on the guide based on their needs and knowledge regarding the innovation process. The feedback was integrated into the guide and themes and activities were restructured and added to the guide.</p>	<p><b>A15: Integration of results from survey</b> The innovation projects evaluated usability and functionality aspects of the web application. The feedback was integrated in the web application and the guide.</p>
<p><b>A7: User interviews (user testing)</b> Interviews were carried out involving the expert group and the innovation projects for in-depth feedback on the innovation guide.</p>	<p><b>A16: Evolutionary prototyping of the web application</b> The web application was gradually developed using an evolutionary prototyping method involving feedback from the expert group.</p>
<p><b>A8: Final structure of guide – phases, themes, and activities (workshop)</b> A brainstorming session with the expert group was performed to integrate the collected user feedback into the guide. The brainstorming session led to a structure involving both the four phases and the activities put into themes regarding the different areas of importance within the innovation process. During this session, a theme regarding clinical readiness was proposed.</p>	<p><b>A17: Extended user feedback</b> Semi-structured interviews with 15 expert users were conducted over Microsoft Teams during a three-months period where each interview took approximately 60 minutes. The guide had been sent out to the interviewees before the interview and during the interviews, different parts of the guide and the usage of the web application were discussed. The expert users were recruited from the industry network Swedish Medtech among researchers, entrepreneurs, business incubators and representatives for medtech networks. Results from the interviews were thematized, analyzed and integrated in the web application and the guide.</p>
<p><b>A9: Developing Clinical Readiness Level</b> Clinical Readiness Level, an important theme for medtech was continuously developed throughout the project.</p>	<p><b>A18: Beta testing the guide and the web application</b> The guide and the web application were beta tested by letting five companies use the guide for a couple of months and, by structured interviews during 60–90 min, collect their experiences. This was incorporated into the development of the model and the web application.</p>

focused on the structure, content and usability of the model and the web application.

## 4 Results and discussion

The results can be separated into three integrated parts – the Medtech Innovation Guide, the Clinical Readiness Level, and the web-based application for making the guide accessible and usable for the target group.

### 4.1 Medtech innovation guide

According to the initial results from the emphasize and define stages of the design process, the goal was to provide a combination of a model that gives a clear general overview of the innovation process within medtech along with a web application to visualize and make the model usable for researchers, entrepreneurs, and financiers. Hence, the intention of the integrated model is to serve the users with guidance through the most common activities needed to take an idea to a tested product. This including a whole spectrum of different areas ranging from certification, company formation to technology development and sustainability. The aim has been to develop one guide to embrace it all and to encourage the initiation of several parallel activities to accelerate the innovation process. The Medtech Innovation Guide (Table 1) is structured as a matrix based on four different phases from concept to launch – *Conceptualization*, *Concept validation*, *Product development*, and *Product launch*. This is in accordance with current innovation models and guides for innovation support that guide the user through the different stages from idea to final product.

Vertically the guide embraces 10 different themes. Each of the four phases contain activities under these themes (themes are presented in no order of importance) – *Clinical validation*, *Technological development*, *Business development*, *Team*, *Gender equality and equal opportunities*, *Sustainability*, *Communication*, *Funding*, *Intellectual property rights*, and *Regulations and certification*. In accordance with other established models, e.g., CIMIT [36, 37], the themes and the corresponding activities have been selected and evaluated to provide a solid base of activities to support innovators from idea to commercialized product. Each activity is described according to common knowledge within the area and in some cases, links are supplied to access more information. Furthermore, the model extends the idea of only providing a snapshot of the innovation's status, which gives more information about the development project compared to the outcome using the established scales [e.g., 24, 25, 28].

Current innovation models and guides are often adopted to serve as support initiated from an incubator or other partners in the innovation system. These models are general and give both a more structured way to work through the innovation process and indications on steps that should be done. The Medtech Innovation Guide offers guidance for control over the innovation process and gives indication on support needed for accelerating the innovation process. The themes provide guidance in each phase, and it becomes easy to notice if important areas are not considered in the innovation process. Hence, the guide is more detailed than current common models. Furthermore, the integration with a web-based application gives an opportunity to tailor the model after specific needs.

The themes presented in the model have been developed to support innovation in the medtech industry. However, some of the themes are more generic when it comes to innovation. The most unique feature of the Medtech Innovation Guide is the theme *Clinical validation*, which is not found in other similar models or scales. The inclusion was motivated by the lack of a model within medtech for guidance through the most common activities, and in which phase to perform them. Including the theme was also motivated by the strive to decrease the time from idea to product launch, especially within medical technology, where the time spans often are prolonged, i.e., due to regulatory challenges.

### 4.2 Clinical readiness level

Regrading both product development and commercialization of innovations within the medtech industry, the clinical perspective is one of the unique factors that need to be considered. The ability to classify the readiness of medtech innovation and development projects required a scale that was missing. To further emphasize and strengthen the clinical perspective of the innovation process, the Clinical Readiness Level (CLR) was proposed (Table 2). This scale was derived from the Clinical validation theme, and its clinical perspective on innovation. The aim has been to support the understanding of innovation with clinical applications. Comparable with other scales, e.g., TRL [24], the CRL scale spans the development process from the first concepts to the finished product just before launch. Already in the first stage of a development project it is central to assure that there is a clinical need that the solution has potential to solve in a clinically feasible manner [32]. Usually there is also special demands for implementation of the innovation in the clinical environment.

Comparable with the pharma industry, the medtech industry has a complex innovation process associated with making safe products, e.g., [34]. In the sense of benefit versus risk, the development and innovation process for new medtech

**Table 1** Medtech Innovation Guide with Phases (horizontal) and Themes (vertical)

	Conceptualization	Concept validation	Product development	Product launch
<b>Clinical validation</b>	Secure clinical competence in the project Verify and define gap/need	Perform clinical tests in a lab environment Perform user studies	Validate product in a clinical trial Validate the product's usability	
<b>Technological development</b>	Develop basic concepts	Develop prototypes based on concept Carry out risk analysis Revise concept and prototype	Define requirements Develop the final viable product Verify the product in the relevant context Finalize product for launch	Develop plan for manufacturing
<b>Business development</b>	Agree on a working name Sign ownership agreements Formulate an initial business concept Conduct a competitive analysis Conduct stakeholder analysis Conduct a market analysis Conduct risk analysis Develop first draft of business model	Carry out in-depth analysis of market and competition Validate value proposition and customer base Revise business model based on user and customer needs	Choose the path of commercialization Manage business law Examine revenue and cost structure Conduct a health economics study Evaluate decision chains in public procurement	Develop final business model for launch Evaluate data security Monitor and respond to ongoing public procurements Develop post-market surveillance plan Identify potential changes for next version of product
<b>Team</b>	Form development team(s)	Evaluate development team(s)	Form team(s) for product development	Complement team with appropriate business skills
<b>Gender equality and equal opportunities</b>	Evaluate team composition Review governing values – be norm critical	Evaluate team composition Consider equality in the value proposition	Evaluate team composition Evaluate needs of the users Consider gender distribution in clinical studies	Evaluate team composition Evaluate gender-neutral accessibility of the product Consider diversity in marketing
<b>Sustainability</b>	Consider the global sustainability goals	Proactive or reactive sustainability work	Consider ecological sustainability Consider social sustainability Create circular flows	Review (public) procurement criteria Consider management system Consider economic sustainability
<b>Communication</b>	Create a communication plan Consider using social media	Contact relevant society Present the concept	Develop a marketing strategy Market the product based on the strategy Contact with early adopters	Collect data for marketing Launch the product Use recommendations from clinics Monitor (public) procurement channels Collaborate with investors
<b>Funding</b>	Investigate funding opportunities Discuss timing of incorporation Develop financing plan	Seek funding Make the project visible to potential investors	Prepare for due diligence Contact investors	
<b>Intellectual property rights</b>	Develop a strategy for IPR Sign ownership agreements Develop a publishing plan Conduct a Freedom to Operate analysis	Specify product protection strategy	Apply for patent(s) Register trademark(s) Register domain name(s) Apply for design right	Expand and manage IPR
<b>Regulations and certification</b>	Define preliminary intended use Formulate plan for certification work	Determine intended use Identify appropriate laws and standards	Review product requirements for certification Create documents for the product's technical file Verify certification of subcontractors Set up management systems Prepare company certification	Conduct relevant certification Establish plan for handling incidents Monitor changes in legislation

**Table 2** Clinical Readiness Level (CRL)**CONCEPTUALISATION****CRL1. Secure clinical competence in the project to complement the technical competence in the development process**

Determine how to achieve relevant clinical competence to facilitate clinical adoption of the technical product or method. Furthermore, identify an intended user (key opinion leader) in the environment who will be capable of pushing the idea forward. Assess the possibility of collaboration around validation of the clinical need and, further on, in the context of a pre-clinical and/or clinical study/trial.

**CRL2. Verify and define gap/need and risk analysis**

Verify that the product meets a real need within health care. Alternatively, the solution needs to be a relevant improvement of an existing solution. Perform a risk-analysis to determine user-safety classifications.

**CONCEPT VALIDATION****CRL3. Perform tests in a lab environment**

Test that a fully operational prototype provides the intended clinical functionality in a relevant laboratory environment, e.g., through a preclinical study.

**CRL4. Perform user studies**

Verify the need with the intended users and also assess how the proposed solution is received by relevant clinical environments.

**PRODUCT DEVELOPMENT****CRL5. Validate product in a clinical trial**

Validate prototype functionality regarding stability/repeatability (if applicable) and diagnostic or treatment performance in a relevant clinical environment. Also evaluate the prototype user friendliness with end users.

- Apply for ethical permission from the relevant authority.
- Apply relevant standards for study design.
- Aim for a high evidence level (e.g., by performing randomized, controlled multicenter studies, possibly using a double-blind approach with placebo control).
- Carefully consider all data that needs to be assessed in order to perform a health economic analysis.

**CRL6. Validate the product's usability**

Evaluate the product's user-friendliness and validate that the product meets the end users' needs and expectations.

products is similar to the drug development process [53]. These features are included in the clinical readiness level and subsequently in the innovation model proposed in this paper. Both processes start with an idea or discovery in a lab that has potential to diagnose, stop or treat a disease. Next step is to investigate the clinical need and then the potential benefit along with risks of adverse events and side-effects are analyzed. The risks and performance are, if possible, first investigated in a preclinical phase (in vitro). Subsequently, clinical studies are performed on different phases, with larger and larger patient populations, to assess safety, develop the technique (dosage) and ultimately to determine efficacy with respect to clinical benefit of the product (drug) as well as documentation of adverse events.

Clinical readiness level targets the requirement within health care to conduct careful risk analysis utilizing an interdisciplinary approach involving representation from intended users and technical expertise. Importantly, the risk analysis can under many circumstances form the foundation of the product specification and should therefore be done early in the development phase. It is of key importance that any development and prototyping must harmonize with contemporary regulation (in the European case currently Medical Device Regulation, MDR, and In Vitro Diagnostic Medical Devices Regulation, IVDR, and for the United States

U.S. Food and Drug Administration, FDA). This is because the output from the risk analysis will lay the foundation for products that can be realistically implemented in clinical practice. At this stage of the progression of the innovation, the clinical readiness level also requires extensive user tests and experiments with a prototype of the technology in question. In the early phase of an innovation this approach might appear too comprehensive, but we argue that it instead will function as a structured and efficient way to get all professions expertise into the product in a critical early phase and thereby avoid development in directions that ultimately will prove clinically infeasible.

Furthermore, modern health care is governed by clinical feasibility, empirical evidence, and economical value. Therefore, some crucial steps will be mandatory for a clinical innovation to prove its place in the clinic. We have identified the need for two kinds of studies. One: for evaluation and validation of the performance of the device with respect to stability of the system, e.g., precision and accuracy of a diagnostic instrument. Two: prove the performance of the device in a clinical trial according to regulatory requirements. This step involves ethical permission, study execution, monitoring, eventual interim analyses, and endpoint analysis. The results of the clinical trial should contribute with information to a health-economic analysis of the

innovation, and the results should also be published in a journal relevant to the field.

Feedback through the development process have continuously improved both the guide and the web application. While some of the feedback referred to the guide being too general and lacking some of the complexity in the innovation process, the background research pointed towards a need of a more general guide that could both encourage to innovation and guide innovators, entrepreneurs, and researchers through the process. Anyone using an innovation model will most certainly have their own specific needs. Hence, this guide is developed to balance specific and general needs within medtech research, to provide a useful model for most users. A more specific target group would probably make a model with higher reliability but become less useful for the more general target audience. The model is based upon a regionally identified, and during several years consolidated, recognition of a need within medtech research. Subsequently, the model has been evaluated on a national level and we believe that the model in its current state will most certainly be of value to anyone that are working with research or development within medical technology. However, the full value of the model will be shown in future studies. In line with results from previous research, e.g., [13], the results from validation show that the smaller companies, entrepreneurs, and researchers are the ones that benefit the most from using a model. Larger organizations usually have their own routines for innovation and development.

### 4.3 Web based application for increased usability

The innovation guide is implemented as a web application that visualizes and integrates the guide's checklists and can be used as a light-weight project management tool. After registering an account, the user can create a new project and start using the integrated innovation guide, which is interactive with various features that emerged from the MoSCoW prioritization—must have (M), should have (S), could have (C), and won't have (W) [54] (Activity 14, see Fig. 3). The user can mark activities as initiated and finished, set deadlines, and document the start and finished date of an activity. It is also possible to add comments and link to more information relevant to an activity. The activity status is visualized with progress bars associated to each Theme and Phase, which together gives an immediate overview of how far along the project is in different parts of the innovation process. Both Themes and activities can be expanded and collapsed to more easily be able to focus on specific parts of the guide. To further ease navigation, there is a search function which lets the users find activities associated with specific terms.

To allow for a more flexible guide, a feature of excluding activities that are not applicable was added, as well as the possibility of creating new activities. Custom-made activities are specific to the project they were added to, thereby not affecting the original innovation guide. Furthermore, it is possible to collaborate around the innovation guide and

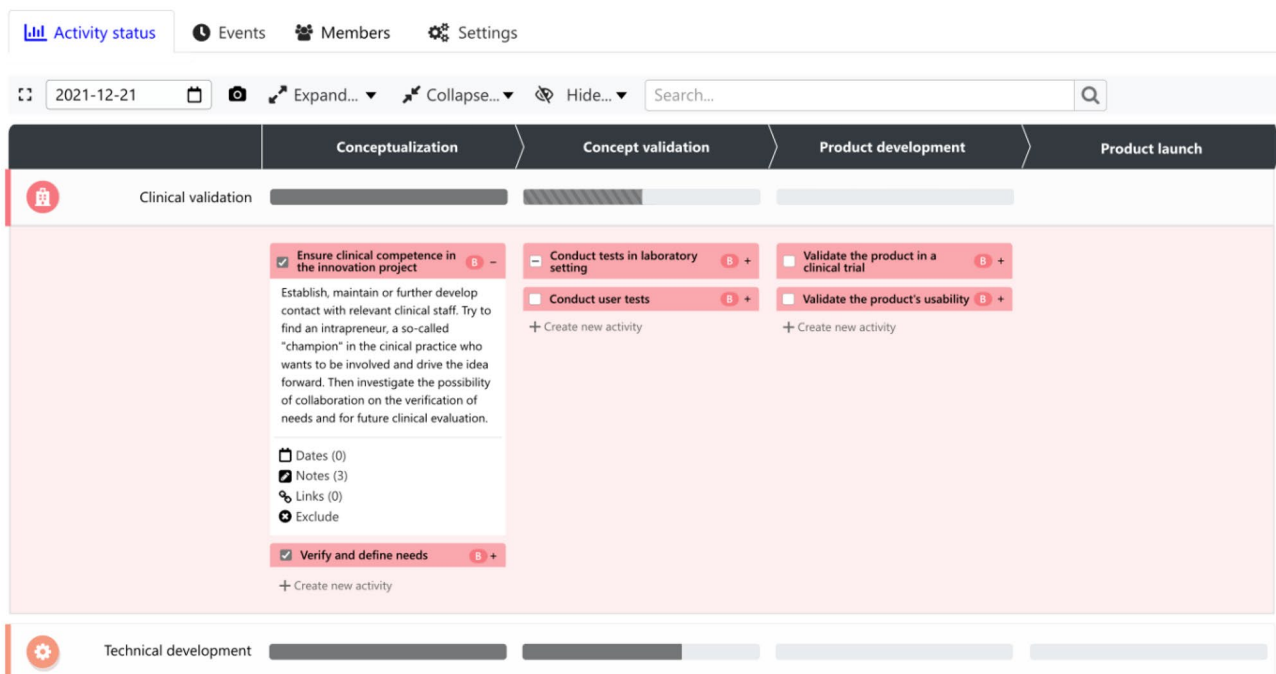


Fig. 3 The web application of the Medtech Innovation Guide

share the project with different stakeholders. The user that registers a new project becomes the project owner and is able to make configurations and invite new team members, either as read-only or full collaborators. A status report that illustrates an overview of the project status can also be generated, which could be used to provide investors or business coaches with regular reports from the team.

The web application meets all requirements set in the General Data Protection Regulation (GDPR) [55] and all user information is encrypted in the attached database.

#### 4.4 Centre for Biomedical Engineering and Physics (CMTF)

Lastly, we want to present the context and the environment where this model was developed. Since 2001, the Centre for Biomedical Engineering and Physics (CMTF), northern Sweden, has been working with triple-helix cooperation between scientific research, biomedical industry, and health care. CMTF, being an academic organization founded by Umeå University and consists also of Luleå University of Technology, established an intense co-operation with health care and the health care industry to catalyze a creative environment for growing innovations and startups for the benefit of the health care industry and the patients [30]. During the last 20 years, 14 new health care companies were started based on scientific results from the centre and 11 new patents were granted. At the most around 200 scientists and technicians and health care professionals were engaged in the work. Furthermore, more than 400 scientific publications were produced, and 15 mature biomedical engineering companies were included in the CMTF industrial network. The work presented within the present study represents an attempt to summarize important lessons learned through successes, but also through failures, in the commercialization process. This work has identified a need for a model supporting the innovation on the path to commercialization in the medtech sector.

## 5 Concluding remarks

This paper presents an innovation guide and a corresponding web application to support researchers, entrepreneurs, and innovators to navigate the most crucial steps in the process of medtech innovation. The guide is based upon well-established methods and tools and has been developed using a design-based process in a real-world context involving several innovation projects connected to regional companies as well as national experts and innovators. The process for securing safe products makes innovation more complex compared to research and development within other industries. Consequently, our innovation guide has a high relevance and potential to provide an effective support

for innovators within the medtech industry. The aim is to increase awareness and shorten the time between idea and product on the market. The proposed guide constitutes of the most common, and important parts of the innovation process. Its four phases – *Conceptualization*, *Concept validation*, *Product development*, and *Product launch*, which in turn have activities separated into ten different themes make it possible for a more holistic view of the innovation process. Furthermore, the Clinical Readiness level (CRL) is proposed with a clear focus on the importance of the clinical part of medtech innovations. The scale can be used to determine the readiness of a product for evaluation purposes and custom design the clinical implementation.

To increase the usability of the guide, a supporting web application has been developed as a simple planning and documentation tool during the lengthy innovation process. The design of the web application further stresses the differences that occur in the innovation process between different products and areas within medtech. Using the web application, it is possible to customize the activities in the innovation process by allowing both to create own activities in the guide and exclude pre-defined activities.

The innovation guide has been tested and evaluated by involving potential users of the model in the development and evaluation process. Even though testing the guide on an increased number of innovation projects would have created a higher validity of the model, the iterative development process, involving both expert groups and users, have been structured and methodical. This process has created a structured and integrated model that has been evaluated and constitutes support for researchers, innovators, and entrepreneurs within medtech research.

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**Code availability** N/A.

## Declarations

**Conflicts of interest** The authors declare no conflict of interest regarding this research.

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