NEW PRODUCT DEVELOPMENT PROCESS FOR MEDTECH COMBINATION PRODUCTS

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ABSTRACT

The MedTech product development is experiencing a growing complexity of the design process. The design challenge is to keep the medical device simple and user-friendly while maintaining its interconnectivity with the other systems and products. The additional layer of complexity comes from the need to satisfy both - direct customers (pharma companies), and indirect ones (patients, health care practitioners, and pharmacists). Solving those design challenges must not compromise the safety of the end-user and must follow the regulatory requirements.

This research proposes the systematic design process for MedTech combination product development with the emphasis on product strategy and concept development operationalized by design thinking participative toolkit. The proposed approach serves the purpose of increasing the traceability between the early made business decisions on a product strategy level of MedTech company, and the engineering decisions made on product concept level. The ultimate goal of the research is to support the decision-makers with methods and tools which would allow them to make informed decisions on investment in a new MedTech combination product by Pharma and MedTech companies.

Keywords: MedTech, Systems Engineering (SE), Design Thinking, New product development, Design process

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1 INTRODUCTION

Medical technology (MedTech) products grow in their complexity due to a higher level of interconnectivity with other systems. Future MedTech systems, such as autoinjectors, may not only perform their core function of self-administered drug injection, but also provide patient and emergency services with a full spectrum of the person's health condition data to prevent life-threatening consequences. However, the patient still prefers having a user-friendly and intuitively comprehensible medical device with a clear and limited number of steps required to perform a personalised self-injection. The lenses through which the product is viewed should be calibrated between the product complexity from the engineering standpoint and usage simplicity from the user perspective. Such zoom-in/zoom-out-zoom-right/zoom-left lenses are also needed within the MedTech companies where a variety of expertise are combined to develop a MedTech product – from product strategy to marketing to engineering – and ultimately to meet the regulatory approval. Even though the primary customer for MedTech products is a patient, for many MedTech industry players working in B2B the intermediate customer is pharma companies. Thus, complexity is also associated with the necessity to satisfy the direct requirements imposed by pharma and indirect ones – imposed by end-users (such as patients, health care practitioners, pharmacists, and caregivers). Therefore, there is a need to keep a product simplicity for the end-user, while ensuring an increasing complexity of the product itself, and the design process associated with it.

This is where two approaches meet – design thinking (DT) with its emphasis on human-centered design (HCD), and systems engineering (SE) with its focus on systemic approach to the product development. This research argues that when DT and SE are properly integrated, they can beneficially complement each other to unleash the new product development (NPD) strategy for MedTech combination products. Therefore, the first objective of the paper is to define the advantages of DT and SE approaches applied to MedTech industry. The second goal of work is to propose a framework for a new product concept development for MedTech industry. Such a framework would support the product strategy within the MedTech companies.

In the next section, the definition of a combination product in its application to MedTech advanced drug delivery systems is provided. The research method is provided in section 3. Section 4 discusses the topics of HCD and its application to MedTech industry, as well as how DT and SE – when combined – could bring an increased value for keeping human aspects and creativity in an SE approach. The product concept framework for MedTech combination products is developed using SysML and demonstrated in section 5. The conclusion summarises this work in section 6.

2 BACKGROUND: MEDTECH COMBINATION PRODUCT DEVELOPMENT

In this paper, among MedTech, we concentrate on advanced drug delivery systems, especially medical autoinjectors, which are drug/device combination products. According to the FDA, "*a combination product is a product composed of any combination of a drug and a device; a biological product and a device; a drug and a biological product; or a drug, device, and a biological product*". According to the 21 CFR Part 3 Subpart A § 3.2, a combination product can be single-entity, co-packaged, cross-labelled or packaged separately.

The development of new MedTech combination products is original as it requires the articulation of two new product development (NPD) processes – the drug NPD process and the device NPD process – in a B2B business strategy where both business – the pharmaceutical company and the MedTech device manufacturer – work in parallel without communication as long as the pharmaceutical company has developed a new drug that requires a drug delivery system to be injected. This situation makes the device manufacturer's NPD process challenging as they not only have to make strong assumptions to start designing a device that will potentially meet the direct pharmaceutical company market needs, but also meet the indirect end-users (patients, health-care practitioners, pharmacists, and caregivers) needs.

Each manufacturer of any class II or class III medical device shall establish and maintain procedures to control the design of the device to ensure that specified design requirements are met. Design controls provide for a standardized, systematic, prospective, iterative model for device design and development to ensure that the device is safe and effective. As discussed in the design control guidance (FDA, 1997), the process of design controls (user needs, design input, design process, design output, medical device, verification, validation and review) does not represent the iterative nature of product development to

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make the influence of the design controls on the design process more distinct. According to 21 CFR Part 820 Subpart C § 820.30, design controls shall include the following elements: design and development planning, design input, design output, design review, design verification, design validation, design transfer, design changes, and design history file (DHF).

3 RESEARCH METHOD

As the first step of the research method the literature review is performed. Its emphasis is made on the topics of HCD and its application to MedTech industry, DT implementation in IDEO design approach, and the additional value which SE could bring when combined with the DT toolkit. The purpose of this step is to identify the relevant methods and tools which can support in unleashing the creativity, on the one hand, but being able to guide the innovative process with a systemic methods and tools, on the other hand. Keeping both paradigms is especially important for such innovative products as medical autoinjectors, because they should be simple in use and user-friendly for the patients, but complex in design enabling the effective integration of hardware and software from the product/system design perspective. From the perspective of the MedTech device manufacturer, the additional complexity arises from the need to satisfy the needs of the Pharma companies (B2B), and the needs of the end-users – patients, health care practitioners, pharmacists, and caregivers.
At the second step, the SysML-based activity diagram has been constructed with the purpose of building the product concept development framework for MedTech combination products. The framework can be considered through different lenses: 1) core decisions made along the concept development process with a traceability of at which exactly step these decisions were made; 2) core design steps and activities associated with them; 3) key DT and SE tools that should be used to achieve the goals of specific design activities; 4) core design/business reviews where the key stakeholders are making the final decision on the investment in a specific MedTech solution.

4 LITERATURE REVIEW: DESIGN THINKING & SYSTEMS ENGINEERING

The literature review spans across the topics of DT and SE positioning them as complementary design approaches, rather than competing ones.
HCD is "*an approach to interactive systems that aims to make systems usable and useful by focusing on the users, their needs and requirements, and by applying human factors/ergonomics, and usability knowledge and techniques*" (ISO 9241-210:2010). HCD has been grown as a method for a wide variety of design approaches and applications. Of a particular interest of this work is the application of HCD to the MedTech. Bazzano et al. identified 21 documents from database and grey literature, which discussed HCD in its connection to healthcare (Bazzano et al., 2017). After the analysis of this literature, they noted the shortage of the description of the socio-institutional dynamics of the HCD, such as the analysis of the design team's relationship to users. To increase the likelihood of MedTech innovations reaching the market, gathering of stakeholder insights on early stage of design process is needed (Fisher and Johansen, 2020). Such data should be related to both – the product development and the regulatory approval information (Glazkova et al., 2022).
Among the alternatives to execute HCD, DT is a prominent candidate. Before being a design approach and a toolset, DT is a human-centric, collaborative, optimistic and experimental mindset whose motto could be "*try and fail, fail fast and learn from failures*". The DT mindset aims to find solutions to problems by establishing empathy with end-users. Indeed, design thinkers concentrate on the understanding of end-users needs by adopting an anthropological approach. While DT is a way of thinking driven by cycles of convergence and divergence, it is often operationalised by a participatory and iterative design process: IDEO 3 I (Inspiration, Ideation, Implementation), IDEO HCD (Hearing, Creating, Delivering), d-school of the Hasso-Plattner-Institute at University of Potsdam (Understand, Observe, Define point-of-view, Ideate, Prototype, Test), d-school of the Hasso-Plattner-Institute at Stanford University (Empathy, Define, Ideate, Prototype). Although DT is often supported by practical tools (e.g. techniques such as literature review, user surveys, questionnaires, focus groups, interviews, ethnography, benchmarking competitive products, and role-playing support the inspiration activity), the lack of a unique process and toolkit makes the application of DT difficult. The DT toolbox (Lewrick et al., 2019) proposes a finer-grained process supported by methods and tools to put DT into action.
The lack of design in SE in general and in the INCOSE Systems Engineering Handbook in particular has been discussed in the literature (Shafaat and Kenley, 2015). The authors underline the importance

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of the active participation of the designers in the evolution of the problem description and the establishment of a consensus among designers with different interests in the design. However, looking at the big picture of design methods, DT and SE stare stonily at each other. The historical context and values underlying each approach explain why DT and SE evolved independently (Greene et al., 2017). Comparisons of both design methods showed that the former is a qualitative and HCD approach that relies on a diverge-converge process and is often preferred for small-scale projects, whereas the latter is a quantitative and function-centred design approach that relies on a decomposition-integration process and is often preferred for large-scale projects (Lee et al., 2020; Wade et al., 2017). There exists a common belief that DT and SE are two mutually exclusive design attitudes (Greene et al., 2017; Lee et al., 2020; Zhao, 2015). The former is perceived as a creative and emphatic "solution-centric" approach whereas the latter is a systematic and analytic "problem-centric" approach. In their psychometric research, (Greene et al., 2019) show that engineering and design attitudes are complementary.

The willingness to mix DT and SE is not new. Indeed, 15 years ago, in 2008, the NATO architecture framework was reworked to integrate a new architectural view "*to define the role of the human in the system and to capture the human operator activities, tasks, communications and collaborations required to accomplish mission operations and support operational requirements*" (Handley and Smillie, 2008). One of the first unification attempts consisted in integrating design tools into the V-model process in an active project-based education curriculum (Haruyama et al., 2013). Studies show that mixing the unstructured DT techniques with the structured SE thinking can be jointly applied in innovative system development. This is especially relevant for the specification and development of concept solutions (Batista et al., 2020), since their synergy effect appears useful for acquiring a broader understanding as well as refining and reframing a problem (Sjøkvist and Kjørstad, 2019; Watanabe et al., 2017), need-finding (Sjøkvist and Kjørstad, 2019; Zhao, 2015), discovering requirements and functions (Zhao, 2015), especially those related to human values and usability and to create solutions that satisfy the emotional need of the stakeholders (Sjøkvist and Kjørstad, 2019), solve ill-defined problems (Tomita et al., 2017). One major benefit of using DT as methodological guidelines to perform early SE activities is to propose participative workshops that boost customer engagement. (Guntveit et al., 2020) found that the active participation of key stakeholders in collaborative exercises such as co-creation sessions supported by visual tools contributes to anchor, align and validate stakeholders needs. (Lee et al., 2021, 2020) integrate some principles borrowed from DT and SE in a cross-disciplinary and human-centered system design inspiration toolkit that can help designers balance the functional requirements of a system with the emotional need of the key stakeholders.

DT brings with it a human-centered approach supporting problem formulation, stakeholders definition, user context and needs with agile cycles that help to refine the design problem and elucidate implicit needs through testing with a minimally functional product. The DT toolbox (Lewrick et al., 2019) is easy to learn and follow and provides very practical guidelines to perform design activities, whereas SE concentrates on the process level with the definition of activities to be performed without detailing how they should be performed. DT also supports the definition of the design problem as well as the development of concepts in an interdisciplinary team, whereas core SE and model-based SE (MBSE) activities are usually conducted by a systems engineer or architect in a more isolated way. Moreover, the abstract diagramming syntax of MBSE notations, which meaning is purely conventional and must be learned, makes their adoption difficult, especially by notational nonexperts whose voice is crucial during the system concept development phase, whereas DT provides visual and intuitive techniques with predefined templates (https://en.dt-toolbook.com/tools). However, the instructions coming out of the workshop are not formalized. This makes it harder to establish a traceability between the decisions made on early phases of product development and later stages of product lifecycle. This is where SE can overcome this limit, as it provides a formalized approach, integrating product strategy, innovation, and implementation.

5 MEDTECH COMBINATION PRODUCT DEVELOPMENT PROCESS

In this section, a new product concept development framework for MedTech combination products is proposed (Figure 1) based on a parsimonious integration of various methodological design principles borrowed from SE, DT and agile design. Firstly, the proposed framework is detailed, especially the activities and the core decisions made along the MedTech product development processes. Secondly,

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participative techniques of the DT toolbox (Lewrick et al., 2019) are mapped – i.e. the HOW – with the activities of the process – i.e. the WHAT.

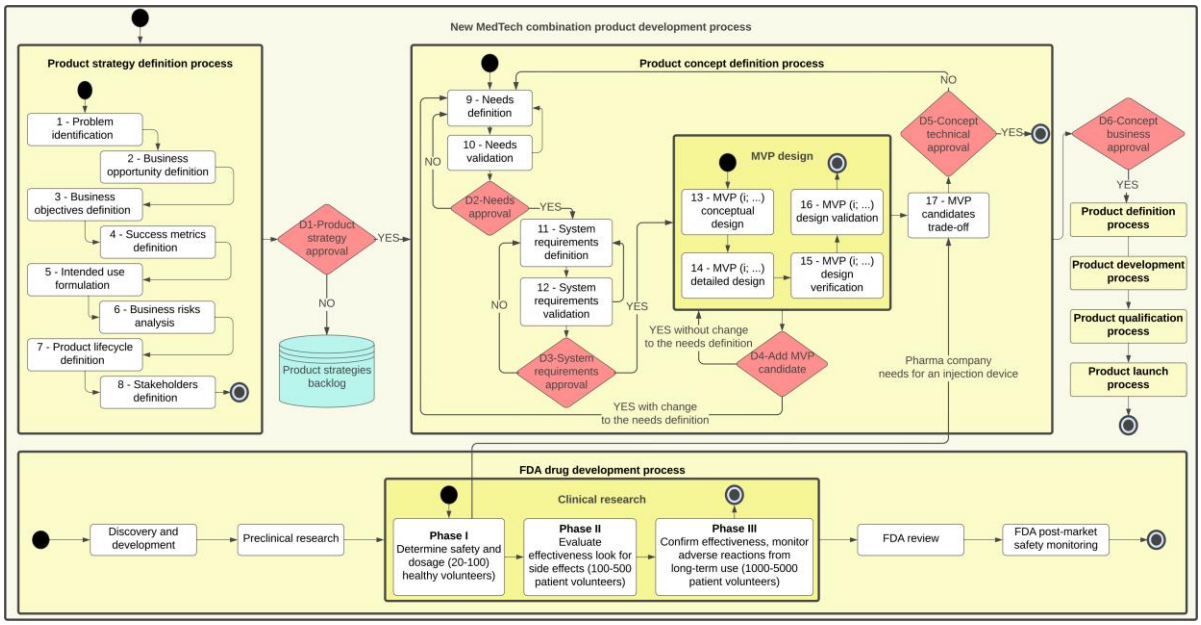

Figure 1. New MedTech combination product development process

5.1 Concurrent and integrated development of a MedTech combination product

The design of a new MedTech combination product implies a concurrent development of the device (including package and instructions for use) and drug. Both processes - device development and drug development - are followed by the regulators, such as the United States Food and Drug Administration (FDA) or the European Medicines Agency (EMA). According to the FDA, the drug development process can be broadly divided into five steps: discovery and development, preclinical research, clinical research, FDA review, and FDA post-market safety monitoring (FDA, 2018). When initiating a specific drug development, the pharma company does not necessarily know the drug properties (e.g., viscosity and volume) required to specify a drug delivery device. A pharma company spends most of its resources on basic research to design or discover a new drug. During preclinical testing on animals, the pharma company does not need a drug delivery device as well. It is when it enters the Phase I of clinical research on patients (see the description of the phases in Figure 1) that a device – at least a minimum viable product (MVP) – will be necessary. However, if the device manufacturer waits for the pharma's request, a competitor may have a conceptual solution to offer that would facilitate the establishment of an NPD partnership. Therefore, for the MedTech device company, there is a critical need to have concepts explored until a certain stage of maturity in an uncertain environment - when not all data is available from the direct customer, a pharma company. The partnership is essential for numerous reasons, especially to reduce the number of questions from the regulator and, more broadly, to design and perform the studies needed to demonstrate required compliance from development through and post-commercialisation. The co-development of a combination product requires the device manufacturer to identify and understand the features that may impact drug delivery. Similarly, the pharmaceutical company needs to understand device manufacturing as the design choices such as material selection could impact drug delivery performance. The development of combination products should not only be concurrent but also integrated. Nevertheless, the co-development process can only start when the pharma company and the device manufacturer make a business deal if the latter is able to provide product concept that is aligned with the new drug to inject. This asynchronous B2B NPD process requires a proactive design strategy to engage agility in the development of modular product concepts without any customers inputs to be able to draw the attention of one or more pharmaceutical companies and quickly tailor the product concept to their needs. The first two sub-processes of the proposed framework (see Figure 1) are: the product strategy definition process and the product concept definition process. The decisions made along these sub-processes by the involved decision-makers and design teams are core decisions, as based on them the MedTech device manufacturer and pharma company would establish a partnership, or not. Therefore, systematically tracking and storing these decisions and the rationale for

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them is a core competence required at the initial phase of MedTech product concept development. The framework presented in Figure 1 represents such a systematic approach tailored to the SE paradigm and exploiting the MBSE capabilities.

5.2 Product strategy definition process

The product strategy definition process involves high-level decision-makers such as funding sponsors corporate executives, marketing managers and product visionaries from the MedTech device manufacturer. The design challenge requires capturing the product-related problem (activity 1), which must be broad enough to allow creative freedom and narrow enough to be able to solve it with the existing resources (e.g. team size, time, budget). Then comes the definition of the business opportunity (activity 2) that exists and the market in which the product will be competing. Benchmarking of rival products and the articulation of the envisioned solutions with market trends or corporate strategic directions are good practices for defining business opportunities. The evaluation of whether the problem is solved or the opportunity exploited requires the definition of quantitative business objectives (activity 3) and success metrics (activity 4) that will help to make sure the project is on track to meet its business objectives and finally evaluate the success of the project when it is complete. It is then necessary to formulate the intended use (activity 5) to be later explored by the regulatory body. As a concise vision statement, the intended use formulation summarizes the intent of the product that will satisfy the needs of diverse stakeholders. After establishing a common ground regarding the business objectives and intended use, the product strategy definition team should analyze the major business risks (activity 6) associated with developing - or not - the product. This includes the identification of potential losses, probability of occurrence, and mitigation actions. The product life cycle definition (activity 7) outlines potential external entities directly or indirectly involved in the product life cycle. Stakeholders definition (activity 8) is defined on a product strategy level to position a product in a business environment. It should be noted that in practice the above-mentioned activities can have the iterative nature. A context diagram visually depicts the established boundary and external interfaces between the product and everything else in the external environment. All this data should be translated from the product strategy level to the product concept level, with an appropriate transition of the business-oriented high-level goals to the engineering-oriented product information. The system architect is needed in both processes to facilitate such a transition. Therefore, this role should be added to the product strategy team which is traditionally comprised of the president, the regional general manager, the vice president of each function (R&D, strategic marketing, quality assurance, operations, medical affairs), a finance officer, The product strategy definition process is critical, as it defines the later stages of product/system development and approves the further development at the decision point 1 (see Figure 1). Yet this step is not always stored systemically in a digital environment, as the decisions at the product strategy level are made by corporate high-level members and the marketing analysis providers. Another potential outcome of this decision point is to store the product strategy data in a design backlog (see Figure 1) allowing MedTech company to store the data for future innovative products and market opportunities. Therefore, the data is preserved, but not lost even at this very early stage of the decision-making process. The output of the product strategy definition process shall enable everybody on the team to share a common understanding of specific core information, such as the patient population (e.g., medical disorder, demographics), the injection site (area on the body where the drug product is injected) and tissue, the depth of injection (e.g., subcutaneous, intramuscular, intradermal), the type-of-use (e.g., individual patient use as a single, disposable, reusable, or refillable injector), the purpose of product use (e.g., for general use or for use with a product class, family, product line, or a specifically named drug or biological product), and the intended user (e.g., patient, caregiver, health care provider). It is important to note that, unlike traditional B2B or B2C businesses, at this stage of development, the device manufacturer does not yet have a customer to discuss with.

5.3 Product concept definition process

The product concept definition process starts with the needs definition (activity 9), which are formulated based on the outcome of the product strategy process. Often there is a distinct set of stakeholders associated with each lifecycle stage (activities 7 and 8 within the product strategy), each having unique needs and requirements (activities 9 and 11). Not addressing a lifecycle stage could result in missing needs and requirements. Then, the environment of the system is defined for each

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stage of the product lifecycle. The environment of a system-of-interest (SOI) is the super-system (assumed with no external interface) that contains all external entities (i.e. belonging to the environment) that have an influence or interaction on the SOI. An external entity is a human, software, hardware, environmental property, facility, standards, etc. that directly interacts with or indirectly influences the SOI. An external entity can either receive a service (i.e., intended effect by its stakeholder) resulting from the interaction of the system with its environment under determined conditions of use or impose a constraint to the system. Since not all stakeholders are equal, a cartography of extreme users/lead users and stakeholders maps based on their position and role can help to capture their "power" and influence. Thus, higher-ranked stakeholder's needs and stakeholder-owned requirements will have more importance (higher priority) than lower-ranked stakeholders. The rank of stakeholders is used to resolve any needs or requirements that are conflicting or cannot be met by the proposed solution within the defined constraints. When the analysis results in a bewildering array of stakeholders, it may not be practical to collaborate with all of them to elicit their needs. In this case, their categorisation and the definition of personas can be implemented to designate a representative of the group. This is a job of system architect to identify the product context by defining the external interfaces (ports and flows) between the external entities and the SOI. During the identification of external entities for each lifecycle stage, a particular attention should be paid to any interactions of the SOI with external entities as these interactions could represent interfaces. The product context is the first source of needs since the outputs of the SOI correspond to effects by stakeholders and inputs are conditions or constraints. Alternative techniques to elucidate needs include customer journey, storytelling, peers observing peers, interviews, use cases, operational scenarios, according to the DT techniques (mapping of alignment of the SE activities with the DT toolbox is provided in Figure 2). A need is either a service provided by the product/system to a stakeholder (e.g., to assemble the injector at the point of clinical use; to load the drug; to prime the injector; to pre-set the dose; to inspect the drug; to prepare and position for an injection, to adjust the dose; to reset after use, to change and dispose the needle, to read, understand and follow instructions; to adequately set up the injector; to perform the injection or self-injection; and to dispose of sharps and other disposable materials) or a constraint imposed by an external entity to the product/system. When recording needs, it is important to record their priority and rationale concerning "why". When there is a difference in opinion as to priority, the ranking of the stakeholder must be considered. The validation of needs consists in making sure that the integrated set of needs is sufficiently complete and correct. Evaluation of completeness and correctness relies on questions (Katz et al., 2022; Wheatcraft et al., 2022) such as: Have all relevant stakeholders been involved in the elicitation activities? Have all lifecycle stages been addressed? Have all interactions with external systems identified during elicitation been recorded? Have all needs been justified by a rationale? Have the needs been communicated at the right level of abstraction? Does a rationale have been captured for each need? Does each need clearly communicate the intent? Have the real needs been uncovered from implementation statements by focusing on what would be observable externally? The validated set of needs (activity 10), if approved at the decision point 2, feeds the system requirements definition (activity 11) which transforms the baselined integrated set of needs into a set of requirements expressed as "shall" statements. A requirement is a statement of an agreed-to obligation for an object to possess some property within specified constraints under some conditions. This may be expressed as "When condition C is met, the values of property P of object O shall be in the subset D" (Micouin, 2014). Similarly to the validation of needs, system requirements validation (activity 12) and the decision point 3 ensures that the system requirements are sufficiently correct and complete and that the assumptions made about the environment of the system are also sufficiently correct and complete. Since the MedTech device manufacturer does not have received any request yet, the set of needs and requirements is probably partially validated, that is, only a subset of needs has been derived into a complete and correct subset of system requirements. Based on one or more main functional system requirements validated, the product concept definition team responsible for the innovation process can start designing an MVP (activities 13 and 14). The verification of the MVP concept design (activity 15) facing the subset of system requirements is the confirmation, through the provision of objective evidence, that a virtual or real MVP concept design conforms to the subset of system requirements for a specific intended use. As a final activity of the MVP design process, the validation of the MVP (activity 16) aims at making sure the MVP design fulfils the external stakeholders' needs. The device manufacturer will design several MVP concepts that will require a trade-off session attended by members of the product

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strategy development team mixed with members of the product concept development team (activity 17). The selected MVPs will be finally presented to target pharmaceutical companies during a technical review (decision point 5). If any MVP is not aligned with the needs of the pharmaceutical companies, then the device manufacturer has to update the definition of needs and develop at least one new MVP accordingly. However, if one or more MVPs partially or fully satisfy the customers' needs, then a business review (decision point 6) serves to negotiate the conditions of the deal, especially the financial participation of the pharma company and its initial order which will serve as GO/NO-GO decision for starting a new product planning process that consists in developing an accurate project plan before going to the subsequent development, qualification and launch processes which are beyond the scope of this paper. All product concept development activities are performed by the members of a product concept development team, which includes a project manager, a system architect (Core Team Leader), and a representative (Core Team Member) for each function (R&D, strategic marketing, quality assurance, operations, medical affairs).

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Problem statement	X																
Interview for empathy	X				X				X								
Explorative interview	X				X				X								
Ask 5x why	X								X								
5 WH questions	X								X								
Jobs to be done	X								X								
Extreme/lead users								X			X						
Stakeholder map								X									
Emotional response cards									X								
Empathy map	X								X								
Customer journey					X		X	X	X								
Persona/user profile	X							X	X								
AEIOU	X				X		X	X									
Analysis question builder	X	X	X			X			X								
Peers observing peers	X				X			X	X								
Trend analysis		X							X								
"How might we" question		X											X				
Context mapping	X	X				X	X	X									
Define success				X													
Vision cone		X	X		X	X											
Critical items diagram													X				
Brainstorming		X											X				
2x2 matrix											X						X
Dot voting											X						X
6-3-5 method		X											X				
Special brainstorming		X											X				
Analogies/Benchmarking		X											X				
NABC		X								X			X				
Blue ocean tool		X											X				
Exploration map									X				X			X	
Prototype to test															X	X	
Service blueprint									X							X	
MVP									X	X						X	
Testing sheet									X							X	
Feedback capture grid									X							X	
Powerful questions									X							X	
Solution interview									X							X	
Structured usability test									X							X	
A/B testing									X							X	X
I like, I wish, I wonder									X							X	
Retrospective sailboat									X								
Lean canvas	X	X	X	X													

Figure 2. Alignment of SE activities with the DT toolbox

6 CONCLUSION

This research discusses that although the level of complexity of MedTech products is growing, the product itself should remain simple in use and user-friendly. The additional complexity for MedTech companies appears because the product should meet the needs of direct customers - pharma

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companies; whereas the end-users are patients, pharmacists, and health care practitioners. These challenges require new approaches to the design process - such a new method is considered through the integration of DT and SE approaches.

The elucidated framework for the new MedTech combination product development process is built in an activity diagram revealing few important results. The traditionally exploited stage-gate approach should not only be improved through a more iterative, agile-based method, but also the innovation phase itself should span towards the product strategy level. The framework's diagram demonstrates a clear need for the system architect from the product concept team (mainly responsible for the innovation phase) to participate in the high-level meetings of the product strategy team, where a product/system mission is defined. This traceability has specific importance, as the decisions made at the phase of product/system mission definition influence subsequent phases. The SE-based framework with incorporated elements of DT allows unleashing creativity during the early phases of MedTech product development, but also keeps a systemic approach enabling data preservation, knowledge reuse and management. The product concept framework tracks which decisions were made, by whom they were made, and how they impacted further processes – in one diagram, as opposed to creative methods, which have unstructured nature, and require multiple frameworks or post-its to be gathered together.

Further work is needed to improve the current version of the product concept development framework. First, it is necessary to extend it with additional processes (e.g., the safety process), especially the detailed design stage, and integrate it with domain design activities. It is also necessary to articulate the system development process with the drug development process so as to conduct co-development activities and design reviews with representatives of pharmaceutical companies. The active participation of pharmaceutical companies in the development of new drug delivery systems is also crucial to demonstrate compliance of the combined product and potential generalizability of the approach. The implementation of this framework with an MBSE approach (based on SysML and CatiaMagic, for example) will require the definition of a modelling method to structure the outcomes of SE activities supported by DT workshops. Finally, before applying the framework with the preferred MBSE toolset on existing and future industrial advanced drug delivery systems, we will define metrics to evaluate the impact of the framework compared to current practices.

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