Enhancing Sustainability and Risk Management by Digital Twin of Medical Devices

Roberto A. Riascos Castaneda[1,2], Egon Ostrosi[2], Jean-Claude Sagot[2], Josip Stjepandić[3]
[1]Roche Diabetes Care GmbH, Mannheim, Germany
[2]ERCOS/ELLIADD EA4661, Université Bourgogne Franche-Comté, UTBM, Belfort, France
[3]PROSTEP AG, Darmstadt, Germany
roberto.riascos@roche.com

Abstract - Over the last few years, the concept called Digital Twin has being ever more present in the strategic decision of manufacturers. The concept implies the possibility of having a digital surrogate of a physical product. Having this certain processes can be accelerated as taking decisions in the digital world can be considerable cheaper and efficient than taking the same decisions based on an expensive physical version of the product. For this concept to work a bi-directionality between the digital and physical product is necessary. Technologies such as Internet-of-Things technology has drastically lowered the costs of Digital Twin computing and computing real-time data from the fields. This is the foundation for connected products and services. Over the last decades, too, sustainability has been a goal for manufacturing companies. Depending on the industry meeting sustainability targets has being difficult and costly. In this paper, we aim to explain how a Digital Twin approach can help companies achieve the two goals interconnected but not competing: a transparent decision-making based on risk management and proving that sustainability goals can be met in a simpler, cost-efficient way. Using the RACER evaluation methodology we will assesses four fields in which the Digital Twin can add value to a medical devices company. Finally, we show a real life use case of the Digital Twin.

Keywords: Sustainability, Risk Management, Digital Twin, Product Lifecycle Management, Medical Devices.

I. INTRODUCTION

The concept of sustainable development—fulfilling and enhancing human well-being while sustaining the life-support system of the earth—was initiated globally by the report of the World Commission on Environment and Development, Our Common Future, in 1987 [1]. The United Nations Conference on Environment and Development ("The Summit of Rio") in 1992 endorsed this initiative and sharpened by agreement on the commitment of academia to engage actively in addressing development and environmental problems. Based on these and subsequent international conventions, the sustainable innovation becomes the dominant principle of development in today's world, not reduced exclusively to the energy and transportation sector [2].

Since the initial development of the lean innovation principles, which had the goal of creating value without waste, the framework conditions for companies in the manufacturing industry have changed significantly. Above all, the change towards a competitive environment characterized by increased volatility, uncertainty, complexity and ambiguity (VUCA), posing major challenges for modern enterprises [3].

Sustainability requirements are omnipresent for companies with direct end customer business and for suppliers in the value chain. Although many approaches for sustainability metrics are published in the literature [4][5], the target values hidden behind the requirement "sustainability" are not precisely defined. Terms such as "sustainability" and "climate neutrality" are strategically operationalized within the companies. However, their definition is constantly in flux and sustainability indicators are defined case by case. Given that, sustainability requirements can have several sources, within the company, local, country, trade agreements, etc. it has become increasingly clear is that flexibility in these definitions is crucial for the success of the individual company and thus the successful adoption and meeting the targets as a whole.

In general, risk is defined as a known but potentially undesirable outcome, the probability of which can be estimated [6]. This probability is tied to an uncertainty of its occurrence, tying the risk to level of uncertainty. This describes situations where a decision has more than one possible outcome and in which the probability of adverse outcomes is unknown, due to lack of information or unstable variable structure in the given environment [7].

Risk is a natural concomitant of all activities of a company, at all levels, and can result in visible deterioration in the quality of products and services, and, therefore, a lowering of competitiveness [8]. Therefore, risk is often subject of internal and external regulation and audits (e.g., by a regulatory body) [9]. When a risk should be raised, its description and

evaluation vary widely depending on the business area of application, the domain and the industry.

Digital Twins (DT) are virtual surrogates of products, processes or services which encompass the high-fidelity description of the physical twin. Digital twin aims to combine the best of all worlds, namely, twinning, simulation, real-time monitoring, analytics and optimization. Digital twin has been recognized as the next breakthrough in digitization, and as the next wave in simulation. It can save cost, time and resources for prototyping, as one does not need to develop the physical prototype(s), but can instead effectively and accurately perform the same tests on a virtual prototype, without affecting the real operation [10].

While the actual context urges for innovation, the digital twin can be understood as both expression and means of innovation. Effects such as stakeholders, environment, disruptive technologies, pandemic, digitalization of services and operations and its respective business models adaptations, customer behavior interaction with brands gained more attention of strategy and decisions in the last years, posing fields for possible implementation of digital twins [11]. From the digital transformation perspective, new technology such as digital twin is commonly used to achieve more efficiency and consequently lower costs and more profit, and alternatives to improve sustainability have been implemented with the support of the 4.0 technologies [2].

The questions addressed here emerge at one of the global medical device manufacturers that operates in a strictly regulated environment and where any malfunction of their products may impair the patient's health. This environment prerequisites a tight relationship with regulators.

In this paper, we will figure out how digital twin can enhance the sustainability and risk management of medical devices. In section II, the literature review is presented. The benefits of digital twin, in particular for medical devices, are explored in section III. In section IV, we discover how digital twin works in practical, collaboration context, followed by discussion in section V and conclusions in section VI.

II. Literature Review

A. *Sustainable innovation*

In line with the general model of innovation, several authors have recognized that the effectiveness of sustainable innovation can be ascribed to internal factors, often related to the management of the development, commercialization, and dissemination phases of new products and services. Conversely, other studies have underlined the pivotal role of external factors, especially highlighting the relational aspects involving sustainable supply chains [12].

A study showed that Industry 4.0 enables sustainable innovation through 11 intertwined functions of advanced manufacturing competency, green absorptive capacity development, green process innovation capacity, green product innovation capacity, inter-functional collaboration and learning, new product development competency, product life-cycle management capability, sustainable innovation orientation development, sustainable partnership and collaboration, sustainable talent management, and value chain integration. This led to the development of the specific model of Industry 4.0-enabled sustainable innovation, and the roadmap to sustainable innovation capability development [13].

There is considerable potential regarding studying resilience, innovation and sustainability together, as there is a great overlap among these concepts. Innovation is important for obtaining both resilience and sustainability, while resilience is involved in processes towards achieving and maintaining sustainability. Multi-scale and multi-stakeholder approaches should be adopted when studying resilience, sustainability and innovation simultaneously [14].

B. *Risk management*

While the list of possible risks is very long, an appropriate approach is necessary to classify, prioritize and assign them to a certain process in order to understand which ones need attention and to allocate resources. This yields the risk assessment, which determines the likelihood and consequences of each risk for a subsequent scoring [15].

Although intuitive approaches for estimating the likelihood and consequences are common practices for experienced engineers, systematic approaches for assessing the likelihood and consequences of risks related to product are necessary in order to define a repeatable process which can be implemented in PLM [16].

In area of management risk, significant contributions were made to systemic risk, coordination, communication, labor relations, outsourcing, and offshoring [17]. Further contribution belongs to issues related to distributed environment (geographical distribution, stakeholder relation, cultural distribution) [18]. A generic process for risk management which includes a.o. budget, objectives, requirements, supplier, legal and regulatory is given in source [19]. Collaboration is always identified as a possible source of risk [20].

C. *Digital twin*

The reason why digital twins gain more and more attention for industry is primarily sparked by their two inherent capabilities: the ability to integrate large volumes of static, real-time, structured and unstructured data and to intertwine these data with enhanced data processing methods such as artificial intelligence or high-performance computing to put simulation, control and self-improvement [21].

Understood as a virtual replica of a real product, digital twins pose their own specificity within each lifecycle phase of the product: design, manufacturing, and service. As a result, each application of digital twin varies depending on a different perspective and needs accordingly. An advanced and up-to-date picture of the state-of-the-art considering the main features and challenges of existing scientific research on digital twins is provided, focusing on the different application domains and their related technologies [22].

D. Approach to evaluation

For the existing approaches, in particular the evaluation of indicators, criteria must be carefully selected regarding the discrepancy in objectives: the procedure must take into account the trade-off between the limitations indicated during the design stage and, the quality and range of the resulting measures and indicators [5]. The approach must be sensitive enough to cover the full range of an indicator.

The frequently used approach "RACER criteria", used among others for evaluation of electronic systems, was selected for setting up evaluation criteria. It was adapted to meet the challenges and objectives in the generation of the digital twin of medical devices. The criteria are highlighted in Table I [5]:

TABLE I.

Criterion	***Meaning***
Robust	Reproducible data Comparable and applicable to further products or new generations of products
Accepted	Accepted by stakeholder (in particular: designers) by means of applicability on product level Applicability to medical devices.
Credible	Easy to evaluate, interpret and justify
Easy	Minimum input data required Data availability at design stage Low calculation time
Relevant	Quantitative data Based on chemical and physical characteristics Linked to environmental impacts

The existing indicators can be categorized within several dimensions. In the evaluation process, indicators were identified according to the set up RACER criteria and collected within an Excel spreadsheet. To structure the indicators and reduce the complexity, the indicators were categorized into a matrix with two dimensions.

The first dimension is based on a lifecycle assessment (LCA) approach, using several use cases in the lifecycle stages of a medical device for structuring. Exemplary, we have selected four use cases of high relevance in the daily business. To find the trade-off between important stages and data availability, the interviews with stakeholders were conducted.

The second dimension considers the objectives which will be addressed by generation of a digital twin. For sake of this presentation, we have selected two objectives which are specific for medical devices: sustainability and risk management. Due to the mutual dependence of both objectives in some cases, the evaluation was conducted using three characteristics, as highlighted in Table II.

III. Benefits of Digital Twin

The benefits of a digital twin are three-fold. First, virtual models driven by real-time data are capable to provide a representation with a high level of fidelity of the real environment and infrastructure and, as such, can be structured to support diverse (e.g., immersive) interactions between machines or humans and machines. Secondly, digital twin can integrate, merge and analyze real and simulated data, enabling the user to get a comprehensive description of the whole environment and a deeper understanding of the physical entities. Finally, digital models provide concise, intuitive and easy-to-use platforms such as front-end software and mobile apps that could be adopted by users in different fields.

In order to classify these benefits, we have derived the corresponding characteristics for each combination of four exemplary use cases and two objectives in three tiers, as highlighted in Table II. These characteristics are, of course, not exhaustive and could be evaluated for further use cases.

1) Supplier selection

While the vertical integration continuously declines, suppliers get increased attention [23]. One of the most important means for the supplier selection is a timely evaluation of performance related to the components they deliver. Decision framework already are available to assess sustainable innovative suppliers [24].

Regarding supplier selection, the digital twin helps to improve the sustainability in the critical point of the performance evaluation of a supplied components, reducing the number and the extent of tests. With these results, the number

of suppliers can be reduced, the lot size increased and, thus, a lower purchase price achieved.

The digital twin supports the risk management in the early prediction of risks in the collaboration with the suppliers. Subsequently, the digital twin facilitates the identification of critical steps. With this information, the risk share between the vendor and its suppliers can be optimized.

TABLE II.

	Sustainability	***Risk management***
Supplier Selection	Early, shared performance evaluation	Supplier and manufacturer risk share
	Reliable component quality	Controlled uncertainty of component risk
	Reduced scrap material due to quality issues	Dependability on supplier output for risk management
Lifespan prediction	Higher product reliability	Reduced risk of malfunction
	Reduction of recalled material on warranty	Better control of service information
	Update products faster to adapt to real-life use	High understanding of how the product is used and handleded.
Auditability	Quicker, reliable auditing information available	Easier certification
	Digital presentation of changing product	Better quantification of risks as a consequence of changes.
	Foster confidence	Transparency in risk evaluation
Ecological footprint	Exact prediction of metrics	Metric achievement drive further risk assessements
	Prediction of operational cases	Better customer service and updated risks based on sergice
	Increased customer satisfaction, less improper disposed devices	Risk assessment of product risk disposal

2) *Functional assessment: lifespan prediction*

Hence, the reality of an exhaustive high-fidelity DT, which replicates every aspect of the physical system and maximizes services while minimizing expense and technical difficulty of implementation, is ambiguous [25].

With such a digital twin, the lifespan can be precisely predicted and thus reliability increased. The accurate behavior prediction yields decrease of warranty expenditure. In total, a precise prediction increases the customer satisfaction and contributes to the overall sustainability.

The digital twin facilitates the risk management in the early prediction of malfunctions which may impair the function of the devise and subsequently the patient's health. With this outcome, customer service can be better controlled. Finally, the risk management has to deal with fewer unpredictable events.

3) *Auditability*

The digital twin as such poses the digital replica of the medical device and is inherently suited auditing purposes. It provides reliable proof about the product performance and detailed records of the performed changes, why they were made and a quick reflection of the state before and after the change reside in the Digital Twin [26].

Therefore, the sustainability aspect of the auditability is enhanced with higher transparency and lower effort of information production. This causes lower expenses. Finally, it fosters the confidence of the auditor.

The digital twin supports the risk management by prediction of issues which are relevant for auditors. Subsequently, risks evaluations and quantification can better explained during the audit. Altogether, an instant reaction to the audit requirements is enabled by the digital twin.

4) *Ecological footprint*

In addition to the classic evaluation dimensions of cost, time and quality, the ecological footprint is increasingly gaining a significant role in companies in the context of product performance. Apart of regulatory requirements, the customers are increasingly demanding environmentally friendly products [27].

Regarding ecological footprint, the digital twin provides the accurate prediction of metrics in order to improve the sustainability. Sustainability can be enhanced further by precise calculation of operational cases. With these figures, an exact forecast of waste can be conducted.

The digital twin supports the risk management by provision of information which is needed for a seamless certification. In that way, the digital twin contributes to the improvement of the customer service. Finally, the risk management benefits from the better waste disposal supported by the digital twin.

IV. Digital Twin in Practice

In order to highlight the obvious advantages of the digital twin in practice, an illustrative example was selected where the application of the digital twin is demonstrated with regard to sustainability and risk management in engineering collaboration with suppliers [28]. A critical part of a medical device was identified which has high impact on the proper function of device and is delivered by suppliers. With this representative example, the feasibility of digital twin for four afore-mentioned use cases (supplier selection, lifespan prediction, auditability, ecological footprint) should be proven.

A portable medical device composed of several critical modules, developed in tandem between several manufacturing

sites and integrating suppliers, in this constellation it is critical to ensure the expected product quality is delivered as any challenges in quality may lead to health harm on the patients and users. In this specific case, the critical components comprise the power module. The central role is delivered by an interchangeable battery that must need specific power supply requirements such as delivering power for 3 weeks of normal use. The battery output is modelled with several parameters that such as:

- Type and frequency of usage,
- Environmental constraints, variables such as humidity and temperature affect the battery output.
- System triggered in the usage, during the usage some functionalities might be triggered more or less often and these consume different amounts of battery in order to function.

To make sure the device is usable during the required time the R&D department invests heavily in battery tests, in order to collect data. With this data design decisions are taken to meet standard, expected user profiles. Standard profiles are in line with edge cases of the requirements and specifications. Given that the manufacturer buys batteries in the market, the tests are based on market available batteries. Although these batteries have similar public specifications, their performance varies greatly.

It is important to note that the project developing this product is operating in an Agile environment. For this reason the scope and breadth of the test needs to adapt to the current sprints. Performing all extensive testing was deemed as impractical due to the fact that new battery load cases may show up during the development. To support the short-cycled simulations needed for Agile releases the R&D department decided to create a DT that reflect the real-life design information of the medical device (marked with an arrow in Figure 1).

To make sure the tests are broad enough to have reliable and unbiased data the R&D department partners with a supplier that has extensive experience in the matter of battery simulations especially in other industries such as transportation (Figure 2). Taking as a baseline the requirements and specifications which are transparently controlled in an Application Lifecycle System (ALM) by the R&D department. These requirements are used to define several usage profiles; availability and costing requirements define batteries in the market to be considered to create the DT.

The supplier then scouts the market to find the batteries that at a high-level meet the expected requirements creating a short-list. The short listed batteries re then bought in the market and analyzed in a laboratory tests. The result is a characterization of the batteries. In a further step the characterization is validated against physical tests performed on the several medical devices under several environmental and usage conditions. AT this point too the risks associated to the selected batteries and resulting of the test will be raised and logged. The validated results are the mathematical basis of the battery DT. During the development process and any change in the design, an impact analysis will determine if the battery is impacted, taking into account the risks that need to be updated or mitigated. An update of the design with result in an update of the DT simulation/update only of the change is supported by simulation data. A change in the design might mean a change in the standard usage profiles and thus on the battery consumption.

The results of the DT simulation may confirm the model or demand updates from it. It is possible that an updated standard profile is better met with a specific battery brand, for this reason the DT simulates the short-listed brands. All of the resulting from the simulations is stored in a specific data base for this digital twin. The information is referenced in PLM system to materials, batches, version, studies etc. for later traceability. This includes the performance of the devices in reference to the risks associated to them. The documentation is referenced to the updated version of the battery item in the PLM system and only when previously defined release criteria is met can a formal release happen of the item and thus the related information. The released item will determine which battery in which version will be part of the released product. Released items are then allowed to be procured and built into the next version of the physical device. The consolidation of all this information is made available through a dashboard for easy and transparent decision making. Any update on the design of requirements will trigger the process mentioned.

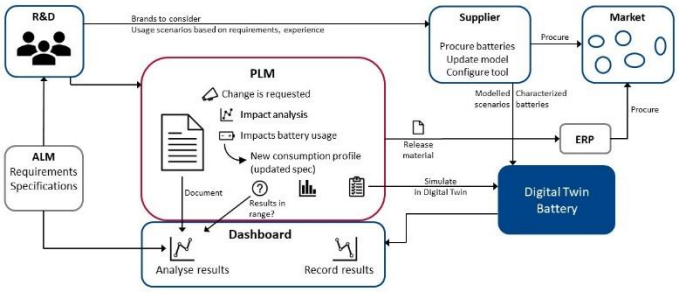

Figure 1. Use case Battery Digital Twin

This model has the focus to support the development process. An extension of the model to gather real time data from the devices using internet of things is proposed.

V. Discussion

For developing a digital twin, the intended application and use need to be considered as well as the estimated benefits of the digital twin on the processes and people in the organization [29]. Doing so, a digital twin of a medical device as whole as well as of each aggregate and component has a noteworthy downstream repercussion that must be taken into account [30]: It may impact both the design and the production process as well as collaboration with the suppliers. By its simulation and training functions, it can an increase the confidence from the users/patients using the device and facilitate the work of the healthcare staff [31]. Moreover, the digital twin can be used as carrier of the knowledge needed for treatment, medication and analysis of the patients' course of disease [32].

While the risk of unintentionally sharing of patients' data raises, appropriate measures for protection of patient's privacy must be provided [33]. As demonstrated in this study, the application of digital twin can be either use case-oriented or focused to fulfill a specific objective. This facilitates crucial tasks such as supplier selection. Not only that digital twin influences and facilitates the work of numerous stakeholders. but also demands the involvement of further stakeholders. In particular, medical ethics and law might also play an important role e.g. the define state of urgency [28].

Doing so, it is realistic to expect that digital twin will become the prerequisite for certification of each medical device.

VI. Conclusion and Perspectives

Digital technologies offer the opportunity to make products and processes more efficient and resource-saving. In addition, digital platforms can be used to link sectors and leverage cross-industry and cross-sectoral synergy effects [34]. Digital solutions also offer the opportunity to network existing supply and recycling chains into circular value chains.

In this way, product development should be enabled to use digital technologies to design products that are sustainable. The tools used should provide a comprehensible basis for improved and accelerated decisions. This should enable the ecological transformation - via sustainable products for circular value creation.

Digital Twin is an appropriate mean to provide an architectural basis for further development of a medical device in terms of device's efficiency, safety, risks and sustainability. As a rule, however, sustainability is not specified in such concrete terms and, above all, it is extremely volatile, and, therefore, needs adequate models and approaches. Companies therefore first of all need urgent support to demonstrate sustainability in their product.

With the mission to ensure the patient's health and well-being by provision of an adequate therapy and care on a high level of quality and sustainability, gain the sustainability and risk management to the primary objectives [35]. By using methods of system science and systems engineering, which are used in other industries [36], the implementation of engineering and IT solutions to enhance or replace singular human functions paves a rapidly emerging way for further development.

An integrated application which includes the surgery promises more outsized potential for further advances. The personalized medicine supported by artificial intelligence [37] looks like a logical consequence of the application of digital twin. A transdisciplinary approach, to consider all the involved aspects, from technical knowledge, to personnel management to economics and innovation would foster the multitude of social requirements and provide the basis for a continuous adaption.

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