Current regulatory issues of AI in the field of medical technology

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Abstract. This paper describes current issues regarding regulatory requirements in medical devices with a focus on data-driven / AI based approaches. It shows that the EU Medical Device Regulation (MDR) sets high requirements to assess product performance based on systematically collected data, whereas the collection of data is difficult in the EU. Contrary, it demonstrates that the FDA is currently very active in supporting the development of software based systems in the US with dedicated regulatory programs. In particular, it pursues more dynamic approaches for releasing software devices. The overall situation favors developments in the US. Thus, the paper surveys a program to support local entities on adapting AI technologies.

Keywords: regulatory requirements, Medical Device Regulation (MDR), FDA, data-driven approaches, artificial intelligence

1 Introduction

Artificial intelligence (AI) is considered to have a huge potential in the field of medicine and medical devices. This includes areas like automated diagnosis of pathologies or personalized therapies using individual patient data from different sources. Additionally, optimization of processes in the development, production, and marketing of devices based on systematically acquired business data may substantially benefit from AI technologies.

But, medical devices also have wide-ranging regulatory requirements, e.g. regarding performance, reliability and traceability throughout the entire life-cycle of the device. On the one hand, these requirements set limitations on a rapid availability of AI based products. On the other hand, regulations may/should be a key to ensure better control and sustainability of the development. Already highly regulated domains like medical devices may be important to establish appropriate rules for this.

The main objective of this paper is to clarify the applicable regulations and to describe challenges and opportunities for AI based devices. In a first step, the requirements and current trends in regulatory processes will be analyzed which apply to AI technologies. In a second step, a way to enforce discussions about and develop best practices is outlined, which aims to improve competencies at local entities.

2 Current evolution of the regulatory environment

The following section delineates the current regulatory landscape and development trends w.r.t. software and AI based medical devices. It focuses on a comparison between the European Union (EU) and the United States (US).

2.1 Current regulatory activities in the EU

In the EU, the Medical Device Regulation (MDR) [1] is the main reference regarding regulatory requirements for medical devices. It became effective in May 2017 and will get compulsory in May 2020. The MDR includes software in terms of stand-alone systems as well as software components. Thus, it also is the main reference for using AI in the field of medical devices or medicine in general.

However, the development of the MDR was mainly driven by major issues caused by medical implants (e.g. breast and hip implants). There was less focus on devices, which are based on software. Specific rules or recommendations for such devices were only addressed in a limited way. Additional regulations or guidances are not yet available to the best of the author's knowledge. In particular, this applies to AI based methods which do not have to be considered as fixed devices, but as adaptive systems that dynamically change according to additionally provided data.

In the development of the MDR, an evidence based approach to perform clinical validation as well as a comprehensive post-market surveillance were two of the pivotal points. According to the MDR, clinical validation has to be based on a systematic analysis of clinical data which prove the success of the devices. These data are considered to be provided through high-level clinical studies. Post-market surveillance includes an assessment about the entire chain of the development, production, and application of the device in the field. This requires comprehensive collection and analysis of data in a dedicated evaluation process. The usage of AI technologies seems to be a natural fit to address these requirements. A high-level approach w.r.t. data analysis may be considered as a crucial point in the implementation of the MDR.

In contrast, the EU General Data Protection Regulation (GDPR) [2] sets high restrictions on collecting data, which are necessary to pursue an evidence based approach for assessing the performance of medical treatments. Besides the right for protection of personal data, there is a certain need for the availability of clinical data to achieve this. In some aspects, medical applications require special rules, which have to be carefully balanced between personal rights and public demands.

In general, the GDPR sets substantial impediments for developing innovative applications using AI in the EU. The EU considers AI as a field, where the development should be more deliberatively controlled to achieve sustainability. See also the recently published EU guideline for trustworthy AI [3], which tries to establish best practices to include ethical aspects into AI development. In [3], medical applications are mentioned but the considerations were not aligned with the MDR, e.g. regarding high-level standards on clinical validation.

In summary, there is a substantial discrepancy between the high requirements on the one hand and the hurdles and uncertainties regarding the practical implementation on the other hand. Further clarification is important to develop appropriate ways for the evolution of requirements and best practices.

2.2 Current regulatory activities in the US

While the relevant players in the EU are still struggling with a clear interpretation and implementation of the MDR rules, the situation in the US is much different. There is considerable effort to develop an appropriate regulatory environment, which fosters software and AI technologies.

In general in the US, there is a substantially higher willingness to provide data for the development of AI based technologies as well as a better established knowledge how

to implement and market AI systems. This includes an agile mind set which considers product development as a dynamic learning based approach, that incrementally improves product performance. On the one hand, this attitude and environment matches very well with the basic goals of the MDR in terms of a continuously applied evaluation process. On the other hand, less restrictions are placed w.r.t. development and implementation of data-driven applications including AI methods.

The US Food & Drug Administration (FDA) as the regulatory authority for medical devices in the US is currently proactively supporting the development of software and AI technologies. It recently published a series of of guidances and programs which are dedicated to this. This includes guidances about "Clinical and patient decision support software" [4], which clarifies the status of software tools preparing information for clinical decision making, as well as "The use or real-world evidence to support regulatory decision-making for medical devices" [5]. The latter provides opportunities to derive clinical validation data from real world scenarios and release medical devices based on this without the necessity of setting up dedicated clinical studies. Real world data are considered to be any data related to patient health status that could e.g. be collected from electronic health records, product and disease registries, or patient-generated data collected from in-home-use settings.

Basic FDA strategies to foster the development of software devices are described in the "Digital health innovation action plan" [6] as well as the "Digital health software precertification (Pre-Cert) program" [7]. In the latter, the FDA tries to establish a regulatory process, which can be considered as a dynamic systems adapting its rules according to the assessment of its own performance. Thus, it realizes a learning-based approach, which is capable to dynamically react on changes in the development landscape. In particular, this addresses the quicker development cycles which usually occur in software devices. This is in major contrast to the development of the MDR which took approximately ten years to define a rather strict and extensive set of rules for governing the regulatory pathways.

2.3 AI based technologies as a dynamic process

These endeavors show that the FDA considers data-driven approaches and dynamic development processes as an important way to improve not only patient health but also opportunities for software-based devices. In general, AI systems have to be considered as dynamic systems. They are designed to get improved when providing additional data. Thus, AI based devices are not intended to have a fixed status, but are continuously changing in nature.

In contrast, medical device regulations require a fixed status for the release. This status has to be comprehensively validated before release. This would require a re-release of the device each time new data come in. This inhibits continuous changes of the data base during application. A validation and release of the entire process (incl. on-site data collection, training, and validation) would be necessary (see fig. 1). This is not yet covered in the regulations.

In principle, such a process-oriented validation not only applies to products but also to other software based tools within the quality system of an organization. Thus, it is also applicable for the continuous evaluation of medical devices, as required by the MDR, when they are addressed based on AI tools.

The FDA currently takes basic steps towards such a strategy in its pre-cert program [7]. It allows companies to quickly release medical devices once the validity of basic

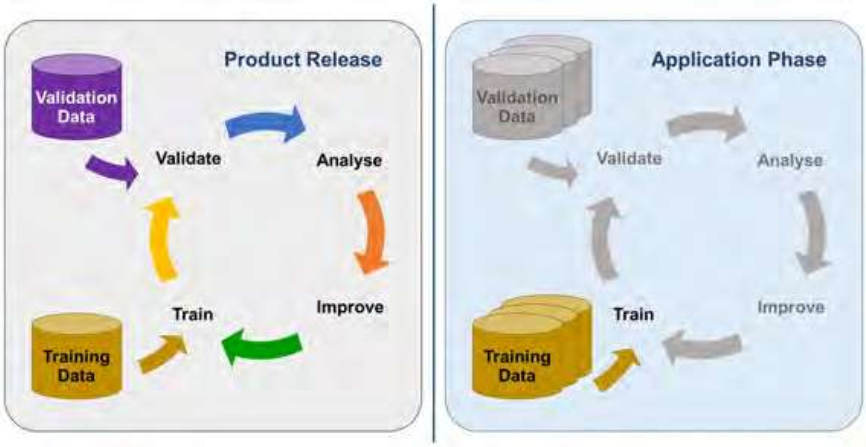

Fig. 1. Development cycles of AI based devices. On the left, a standard development cycle is shown which leads to the release of the device. On the right, a dynamic increment of the data basis is sketched, which would require re-releases of the device or a process-based validation of the overall system.

development steps have been proven. The final step, to allow continuous validation during the application phase of hr product is not covered.

3 Conclusion

In summary, there are unclarified issues in the regulatory landscape for AI based medical technologies, including product as well as process development steps. Additionally, there are major differences between EU and US, which can have a substantial impact on the progress in each area. This is intensified by the MDR, which requires a substantially data-driven approach to assess the performance of the devices.

This discrepancy may compromise the currently still strong position of EU companies in this field in comparison to US counterparts. A similar situation was observed in the second half of the 20th century in the pharma industry when the standards for developing drugs were substantially raised by requiring comprehensive validation in terms of clinical studies before releasing a product. This resulted in a substantial shift of major players towards the US.

Thus, strategies should be developed to overcome these issues. On the one hand, practical hurdles should be eliminated and requirements should be clarified. On the other hand, a high quality approach should be pursued which keeps a major focus on reliability and sustainability of the development.

4 Outlook

At the Hochschule Furtwangen University (HFU), this is intended to be addressed in a combination of educational and research activities. It is considered that such a development needs a close cooperation between the academic and the industry side. This will start with general informative talks which address a broad audience before it is continued in smaller workshops and expert tables. Detailed discussions about common issues and opportunities are pursued in these smaller groups to develop best practices for addressing integration of AI methods in compliance with regulatory requirements. The final objective is to transfer particular activities into dedicated research projects.

Currently, this program is not directly part of a funded research program. It is considered as part of the transfer strategy. The Innovation and Research Centre (IFC) Tuttlingen is the central institution where such cooperation oriented programs are implemented at the HFU. The IFC's mission is to provide impulses for a transformation of the local industry towards innovative technologies.

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