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Editorial

The Emerging Field of Medical Regulatory Technology and Data Science

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Regulations contain rules setup by (governmental) authorities to control specific aspects of certain industries, which often influences the way companies operate. These rules affect how industries are managed, and the importance of regulations is such that many companies create specific divisions focused solely on the regulatory strategy. Regulatory frameworks encourage consumers to adopt innovations by ensuring that their safety and effectiveness has been evaluated. However, they also create barriers that can hold up the innovative process. For innovative firms, regulations are one of the most significant barriers of perceived environmental uncertainty [1], which is especially problematic for start-ups with constrained resources [2]. Entrepreneurs need more information to better identify the relevant regulation and understand the requirements for conformity based on these regulations [3], which are the initial steps in the regulatory navigation pathway. The exact impact of regulation on innovation varies between both industries and countries [2]. Certain sectors, such as finance, energy and medical products, are rigorously regulated. It has been suggested that the successful disruption of an industry from pioneering innovation is always followed by regulation. A strategy must be in place to react to the legislations introduced as a result of new innovation. An example of this is data protection laws, which resulted from an increased level of personal information being stored by organizations due to advances in medical care, telecommunications, transportation systems and financial transfers [4]. When used effectively, regulation drives the direction of innovation and can stimulate it within industries [5]. Environmental policies forced car manufacturers to improve gas mileage, resulting in improvements in engine technology. A better understanding of legislation can help to alleviate the barrier to innovation that regulation presents.

Technology and data science has become an integrated part of how many industries operate, and it often affects their regulatory strategy. The rapid expansion of digital technology has also started to impact regulations themselves. Not only is legal information now available in a digital form, but some of the data held by regulators have become freely available online. The particular intersection between regulations and technology is known as Regtech. The main focus of Regtech is to support the different processes that are related to regulations. RegTech was initially suggested for addressing regulatory challenges in the financial system, through the use of innovative technologies [6]. However, the term has evolved to capture any area of regulation, including medical regulation. Buckley et al. have stated that RegTech can help create more effective and efficient ways to comply with the regulations [6]. RegTech can be applied to obtain better regulatory compliance or give the same level of compliance at a lower-cost. It is easy to see that both these outcomes are valuable for those working in the medical technology sector.

As mentioned, regulations are a key part of the medical innovation roadmap. It provides a framework to ensure patient safety and aims to guarantee a beneficial clinical performance of novel solutions. Any medical device that wants to be brought onto a (regulated) market needs to adhere to the regulations that have been set out by governments. All major markets in the world are regulated, and thus manufactures need to think carefully about their regulatory strategy. At the moment, there is relatively little research on RegTech

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Citation: Bergmann, J.H.M. The Emerging Field of Medical Regulatory Technology and Data Science. *Prosthesis* **2022**, *4*, 169–171. https://doi.org/10.3390/prosthesis4020017

Received: 2 April 2022
Accepted: 6 April 2022
Published: 9 April 2022

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within the medical field. Nonetheless, this is very likely to change in the future, due to the potential benefits it can offer to the different stakeholders (such as manufacturers, regulators and healthcare professionals). The digitisation, data availability and need for more concise understanding of regulations are all driving this change. We have already seen a similar thing happening within the financial sector, where the label Fintech was coined for financial RegTech. However, FinTech encapsulates more than just regulatory technology, as it also covers the technology which replaced traditional financial services. The term FinTech is thus not limited to just regulations, and this has muddied the waters somewhat. Despite this limitation, value can still be derived from a common term that can capture relevant regulatory developments in a specific field.

Such a label is currently missing for medical regulations, whilst it could be captured by the introduction of a new term, such as "MedRegTech". Unfortunately, the term MedTech is not appropriate in this case, as it represents medical technology more generally. This issue mirrors the problem described with the label FinTech. Introducing a more specific term of MedRegTech should allow for an easier classification of (scientific) articles that apply or describe RegTech in the medical area. This will help the (research) community to find relevant studies quicker, whilst making it easier to identify new research trends.

One of the benefits of MedRegTech research is that it could inform policymakers in an objective and critical manner. For example, the exploration of complexity within the regulations can provide new insights into how regulations can be made more user-friendly. We have showed that complexity can vary between the different medical device regulations [7]. Creating less-complex regulations, without losing the legal context of the regulation, can increase overall adherence and understanding. Moreover, this research also found that there is a need for better metrics in terms of regulatory complexity in general. How we best define complexity within regulations is still an open question. These kinds of studies can therefore provide starting points in the debate of determining an appropriate level of regulatory complexity.

Understanding regulations is essential for medical innovators, as they will need to be able to navigate them. Developing new ways to help people navigate the regulations forms another interesting avenue of exploration. Decision trees that are rule-based can potentially help with this. They offer an approach to the digitisation of the regulation that is logic-based [8,9]. These techniques are not perfect, and a good understanding of the context is still needed in order to apply them correctly. Yet, at the same time, they can also bring to the surface potential issues regarding some of the logic behind these regulations. Mapping the rules using data science techniques can help to consider them more holistically.

The unfamiliarity with the regulations often makes it hard for innovators to engage with them during the early research and development (R&D) stages. Health service providers are particularly well placed to comment on the R&D routes that medical devices take when they enter the clinical setting. It seems that a lot of new medical technology reaches the UK health service provider through non-commercial studies [10]. This is a thought-provoking finding, as a commercial company normally brings these medical technologies into the market. Delays in translation might occur if these non-commercial studies are not or less aware of the regulations. It should also be noted that only a very small number of these clinical studies seem to relate to software as a medical device (defined as a device that is entirely composed of software without any additional hardware). This poses a fascinating question in terms of how fast the field of software as a medical device is really growing. Looking at the number of devices that are registered in Australia, as software as a medical device, we found that there is indeed an upward trend [11]. However, these data from a publicly accessible database also made clear that software as a medical device only made up 1.6% of the total number of registered devices. It indicates that the majority of medical devices that are entering the market in this region are not software-based. These outcomes shed a more quantitative light on how fast stand-alone software with a medical purpose is moving into the market. Much of the research on medical Artificial Intelligence (AI) or Machine Learning (ML) might not yet have translated into a real market entry. This

is likely because these methods are still relatively new from a regulatory standpoint, as well as the fact that software poses a different set of safety and performance problems compared to hardware. Nonetheless, it is important to look ahead and see how medical regulations might influence these new developments.

Another obvious topic that is gaining momentum is the environmental impact of healthcare innovation. The environmental impact of regulations on the product life cycle should be researched more thoroughly. Single-use devices and equipment are often selected to prevent pathogen transmission, but this tactic does come at an environmental cost [12]. More recently, the rising dependence on digital health records and information technology is starting to be mentioned in relationship to the environmental impact. Digital solutions might reduce landfill waste, but the energy requirements might create new challenges. These aspects will need to be considered along the more obvious waste management approaches of hardware.

In general, there is a strong need to take a more multi-disciplinary, holistic and data-driven approach in order to tackle the interconnected problems that emerge at the interface of regulations and medical technology. MedRegTech research allows for a critical appraisal of our current situation and could assist in the planning for the future. It can disrupt the regulatory landscape and help push the boundaries of our understanding forward to create better regulations for all.

Conflicts of Interest: The author declares no conflict of interest.

References

1. Ettlie, J.E.; Bridges, W.P. Environmental uncertainty and organizational technology policy. *IEEE Trans. Eng. Manag.* **1982**, *EM-29*, 2–10. [CrossRef]
2. Utterback, J.M.; Allen, T.J.; Hollomon, J.H.; Sirbu, M.A. The process of innovation in five industries in Europe and Japan. *IEEE Trans. Eng. Manag.* **1976**, *EM-23*, 3–9. [CrossRef]
3. Çanakoğlu, E.; Erzurumlu, S.S.; Erzurumlu, Y.O. How Data-Driven Entrepreneur Analyzes Imperfect Information for Business Opportunity Evaluation. *IEEE Trans. Eng. Manag.* **2018**, *65*, 604–617. [CrossRef]
4. Banisar, D.; Davies, S. Global Trends in Privacy Protection: An International Survey of Privacy, Data Protection, and Surveillance Laws and Developments. *John Marshall J. Comput. Inf. Law* **1999**, *18*, 1–112.
5. Gerstenfeld, A. Government regulation effects on the direction of innovation: A focus on performance standards. *IEEE Trans. Eng. Manag.* **1977**, *EM-24*, 82–86. [CrossRef]
6. Buckley, R.P.; Arner, D.W.; Zetzsche, D.A.; Weber, R.H. The road to RegTech: The (astonishing) example of the European Union. *J. Bank. Regul.* **2020**, *21*, 26–36. [CrossRef]
7. Arnould, A.; Hendricusdottir, R.; Bergmann, J. The Complexity of Medical Device Regulations Has Increased, as Assessed through Data-Driven Techniques. *Prosthesis* **2021**, *3*, 314–330. [CrossRef]
8. Mingay, H.R.F.; Hendricusdottir, R.; Ceross, A.; Bergmann, J.H.M. Using Rule-Based Decision Trees to Digitize Legislation. *Prosthesis* **2022**, *4*, 113–124. [CrossRef]
9. Bergmann, J.; Hendricusdottir, R.; Lee, R. Regulatory navigation: A digital tool to understand medical device classification pathways. *Compr. Biotechnol.* **2019**, *5*, 167–172.
10. Kwong, M.T.; Stell, D.; Akinluyi, E. Medical Device Regulation from a Health Service Provider's Perspective. *Prosthesis* **2021**, *3*, 261–266. [CrossRef]
11. Ceross, A.; Bergmann, J. Evaluating the Presence of Software-as-a-Medical-Device in the Australian Therapeutic Goods Register. *Prosthesis* **2021**, *3*, 221–228. [CrossRef]
12. Arun Kumar, P. Regulating Environmental Impact of Medical Devices in the United Kingdom—A Scoping Review. *Prosthesis* **2021**, *3*, 370–387. [CrossRef]