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Published in:
Journal of AI Law and Regulation

DOI:
10.21552/aire/2024/2/12

Publication date:
2024

Document Version
Publisher's PDF, also known as Version of record

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I. Introduction

The emergence of digital technologies (DTs) in medical practice is a revolutionizing field, marked by increasing adoption of digital devices and artificial intelligence (AI)-based software solutions by both physicians and patients. In this paper, the authors assess the potential of AI-based DT for better personalised medicine from the perspectives of physicians, data scientists, patients, and lawyers. In doing so, the authors explain the added value of the use of digital technology for medical practice (II), the possibilities from a data science perspective (III), the way patients perceive such use to advance medical research and care (IV), as well as the legal challenges in the European Union (EU) for using AI in clinical research, development, and routine (V). The report ultimately outlines points of attention for decision makers willing to regulate the use of AI for medical research and practice in the EU (VI).

DOI: 10.21552/aire/2024/2/12

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II. Physicians' Perspective: The Added Value of the Use of Digital Technology for Medical Practice

A major challenge in medical practice is accurate diagnosis, especially in the early stages of the disease when symptoms are often minimal or unspecific. Diagnoses are often based on self-reported symptoms or physician-based examinations, which are subjective. DTs offer an objective, less time-consuming and cost-effective alternative. In this line, the EU-wide project DIGIPD[1] demonstrated that DTs can positively contribute to a more precise and accurate diagnosis.

Chronic diseases require continuous symptom monitoring to effectively select and adapt treatments. Current practices of regular doctor visits at fixed intervals are not only inefficient, but also place a significant financial burden on the healthcare system, especially with an aging population. DTs are bridging this gap. Tools such as body-worn sensors for gait

analysis in Parkinson's disease (PD) or tablet-based cognitive tests for dementia enable continuous home monitoring and timely treatment adjustments, leading to better patient outcomes and more efficient healthcare delivery reaching high clinical utility.

In terms of prognosis, digital biomarkers such as gait measurements have shown promise in predicting disease progression in conditions such as PD. This predictive capability is critical for early intervention in at-risk patients, potentially preventing complications and aiding in life planning, including occupational adjustments and home modifications.

Beyond clinical decision support, DTs are also emerging as potential non-pharmaceutical interventions, such as customised cognitive training programs that adapt to patients' specific deficits and cognitive levels.

Furthermore, DTs are making significant advancements in clinical research. They offer more cost-efficient methods to conduct clinical trials by replacing subjective markers of disease progression with objective digital markers or endpoints. This advancement is particularly beneficial in reducing the number of patients required for clinical studies, facilitating the development of new drugs, and resulting in substantial cost savings.

In summary, the integration of DTs in medical practice is a cornerstone in the evolution towards a new paradigm of personalised medicine. It brings forth innovative diagnostic methods, individualised treatments, and home monitoring of disease progression, thereby enhancing the quality of life for patients while optimisng resource utilisation in healthcare. This transformation promises substantial benefits for patients and the broader medical community, marking a significant leap forward in healthcare delivery and management.

III. Data Scientists' Perspective: The Possibilities Regarding the Use of Digital Technology for Better Personalised Medicine

The DIGIPD project aimed to provide a systematic and objective data-driven evaluation of DTs, in particular, in the field of PD. DIGIPD focused on gait assessments via a digital gait device[2], joint audio and face movement video recordings via a computer at the hospital, and telephonic voice recordings from subjects' homes. Each of these DTs produces large volumes of patient specific data, processed via dedicated algorithms, including AI and specifically machine learning. AI algorithms can process complex datasets to identify patterns that may be imperceptible to humans. Overall, the DIGIPD consortium brought together data from more than 1,000 patients across three different cohort studies from Germany, France and Luxembourg. The analysis of these datasets demonstrated:

– DT derived data from voice and video recordings allow for a highly sensible discrimination between PD and healthy subjects and could thus support an earlier diagnosis.
– Data derived from a digital gait sensor correlate well with traditional questionnaire-based symp-

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Acknowledgments: a preprint version of this report was made available on ResearchGate. DOI: 10.13140/RG.2.2.11638.82241. We thank Pier Giorgio Chiara for the valuable comments he made on that first version.
Funding statement: this work was funded by DIGIPD (01KU2110), a project supported by the Fund for Scientific Research (F.R.S.–FNRS), the Agence Nationale de la Recherche (ANR), the Federal Ministry of Education and Research (BMBF), the Federal Ministry of Health (BMG), and the National Research Fund (FNR, INTER/ERAPerMed 20/14599012, INTER/22/17104370/RECAST), under the frame of ERA PerMed.
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1 Validating DIGItal biomarkers for better personalised treatment of Parkinson's Disease <https://www.digipd.eu/> accessed 31 May 2024.

2 Portabiles HealthCare Technologies <https://www.portabiles-hct.de/> accessed 31 May 2024.

tom assessments and can thus be used for objective monitoring of motor symptom progression.
– Data derived from a digital gait sensor can be used to construct an endpoint for a clinical trial. As a digital device can easily collect data at a far higher frequency than hospital visits, disease symptoms can be monitored at a higher temporal resolution. A physician can thus directly observe the trend in symptom progression between one hospital visit to the next. Our analysis has shown that such high frequency digital gait monitoring can increase the statistical power of clinical trials. Hence, DTs can support bringing urgently needed novel medications to the market.

In summary, our analysis of a large volume of patient data coming from different DTs highlights the potential of modern AI-based technology for better disease management and clinical research.

IV. Patients' Perspective: The Way Patients Perceive the Use of Digital Technology to Advance Medical Research and Care

DT has emerged as a transformative force in the realm of medical research and care, reshaping the patient experience and engagement. Within the DIGIPD project, we conducted a survey of more than 300 PD patients across Germany, France and Spain. Our study revealed that PD patients are eager to embrace the digital transformation of healthcare. It provides valuable insights into the patient perspective regarding the integration of DT into their healthcare journey bringing forth a mix of optimism, empowerment, and expectations.

Although we found small differences across different sociodemographic groups, participants across France, Germany, and Spain expressed overall willingness to share their health data, share information, and actively engage in digital health initiatives, provided privacy and security measures are ensured. This inclination persisted even among those who had not previously used digital health monitoring devices, signifying a widespread readiness to adapt to the evolving healthcare landscape.

Notably, the majority of patients exhibited confidence in and acceptance of the use of sensitive data for a better personalised treatment of PD. Their approval was contingent on the perceived medical benefits, with inquiries during interviews focusing on the reliability and accuracy of AI solutions. Patients expressed a keen interest in understanding how their data contributes to advancements and innovations in PD research and treatment.

However, despite the patients' willingness to adopt DT, our real-world testing has also revealed practical challenges. For instance, we observed that numerous patients encounter difficulties related to device setup or usage. This discrepancy between the expressed willingness and the real-world challenges underscores the importance of addressing not only initial perceptions but also practical barriers to achieve successful implementation and sustained engagement in the use of DT in healthcare.

This may also be one of the reasons why patients emphasised the importance of device co-design, advocating for familiarity, simplicity, and intuitiveness. The call for a 'Design for All' approach echoed the need for inclusivity, catering to a diverse range of users, including those with varying levels of age, experience, cognitive functioning and disease stage. Additionally, participants sought devices that minimised physical effort for efficient and comfortable use.

To foster sustained patient engagement, our study underscores the importance of providing clear information about participation in data research studies as well as regular feedback on the outcomes of their contributions. This approach empowers patients, allowing them to make informed decisions and fostering a sense of responsibility for their health.

V. Legal Situation: The Legal Challenges in the European Union for Using Artificial Intelligence in Clinical Research, Development and Routine

The General Data Protection Regulation[3] (GDPR) imposes a multiple set of obligations on data processing parties willing to process patient data for medical research and practice. From a practical point of

3 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

view, fulfilment of these requirements imposes a non-trivial challenge, specifically with respect to sharing of historical patient-level data, which is required to develop AI models. Typically, a joint controller agreement or a data processing agreement might be put in place between collaborating organisations, and the finalisation of such a contract can take up to 2 years before any data driven research and development can start depending on the number of parties/partners. A reason is that stakeholders (decision makers, legal departments, data protection officers) within the different organisations fear a possible violation of the GDPR. Hence, they seek to take steps to minimise this risk (eg by implementing comprehensive definitions of approved data processing within the project), and because different partner organisations have different interests and legal perceptions, a lot of different aspects need to be negotiated. This delays the further processing of the personal data for the research and given the typical funding period of 3 years for research projects, it imposes a major challenge and risk for the success of such projects.

Besides that, the solutions chosen often do not adequately increase the level of data protection compliance within the project. Therefore, the legal necessity and justification for vast agreements should ideally be scrutinised critically in the early phases of a project. The collaborating organisations should orientate themselves towards pan-European, autonomous standards of EU law to the largest extent possible. Capacities and efforts of scientists and professionals can then be directed towards measures which in fact increase legal and ethical compliance to the benefit of the data subjects as well as the risk carrying parties.

In the future, the European Health Data Space[4] is meant to facilitate data sharing not only for medical practice (primary use of data) but also for research (secondary use of data). However, the following GDPR principles and obligations also challenge the processing operations at stake:

- A data protection impact assessment must be carried out, including to assess the necessity and proportionality of the processing operations in relation to the purposes (medical research or medical practice purposes). This is important to ensure that the risks to the personal rights and freedoms of the data subjects are always adequately mitigated and to comply with the purpose limitation principle, which requires that the purposes are legitimate.
- While features describing characteristics within an individual patient are not 'human understandable', accuracy of personal data must be maintained. This is crucial to comply with the accuracy principle.
- Understanding the outcomes of the processing operations is crucial as well, as digital biomarkers and the advanced analytical methods will not be usable in medical practice if a human cannot take decisions based on the outcomes. This human involvement in the diagnostic and treatment decisions is required because solely automated individual decision-making is prohibited.
- This human involvement jibes with the necessity that the controller remains able to provide meaningful information about the logic involved in the processing operations leading to a decision, in order to comply with the transparency principle, and more specifically with the obligation to provide a set of information to the data subject.
- The controller must be able to explain the personal data it processes in a concise, transparent, intelligible and easily accessible form, using clear and plain language. This is important to 'provide a copy' of the personal data where the data subject exercises the right of access.

Furthermore, the Artificial Intelligence Act[5] (AI Act) has been formally adopted by the Parliament in its March 2024 plenary session and the Council endorsed the final text in May 2024. The AI Act will soon enter into force, ie 20 days after its publication in the EU's Official Journal, and it will apply 2 years after its entry into force, with some exceptions for specific provisions. While it does not apply to AI systems specifically developed and used for the sole purpose of scientific research, the AI Act adds a set of further obligations to providers and deployers of high-risk AI-based medical devices. These concern,

4 Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space, 3 May 2022, COM(2022) 197 final – updated according to the provisional political agreement reached at the fifth trilogue on 14 March 2024.

5 Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828.

i.a. active devices intended to allow direct diagnosis or monitoring of vital physiological processes, and software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes. For the related AI systems, a set of requirements are added to the ones stemming from the Medical Devices Regulation[6]. Interestingly, pursuant to the new Regulation, the systems concerned must be designed and developed in such a way that the natural persons to whom human oversight is assigned are enabled to correctly interpret the system's output and use it appropriately. This seems to suitably complement the transparency requirements stemming from the GDPR, mentioned above.

While most provisions of the AI Act, including the quality criteria for training, validation, and testing datasets, seem necessary to ensure appropriate development of high-risk AI-based medical devices, it remains to be seen what the practical impact of additional requirements for companies and physicians active in the field will be.

VI. Conclusion

Physicians and data scientists agree on the strong potential of digital device technologies and data driven decision support for medical diagnosis, prognosis and symptom monitoring. Patients have in general a positive attitude towards these new technologies. At the same time, the current European legislation imposes a multitude of obligations for researchers, tech companies and physicians which are derived from the GDPR and from the Medical Devices Regulation, soon to be combined with the AI Act. It is important that European decision makers carefully identify the necessary legal constraints on data sharing and AI developments in the health sector, bearing in mind their strong potential for science, patients and economy as well as the potential negative consequences of overly complex regulations while enabling innovation and protecting European values in healthcare.

6 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.