Artificial Intelligence Considerations for FemTech and Beyond

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Incorporating artificial intelligence (AI), machine learning (ML), and software, FemTech is an emerging industry that is already changing medical practice. AI can have a profound effect on women's health outcomes in diagnosis, monitoring, management, and treatment of conditions. Some applications of AI in FemTech include the use of genetic testing to assess and offer personalized data-based health advice to women and the identification of patterns and indicators for potential underlying conditions.

Developers of digital health solutions generally should be aware of the current and emerging legal framework in order to maximize the use of AI for their purposes. In addition, FemTech developers also face some unique challenges, i.e., in relation to data availability and elimination of bias, that this article briefly examines.

Ensuring safe, effective, and performant devices

Software that falls within the definition of a medical device in the EU should be certified in accordance with the Medical Devices Regulation (EU) 2017/745 (MDR). However, current legal frameworks in Europe and globally are not yet equipped to cover AI/ML models and applications as these types of software are continuously evolving based on the "self-learning" elements. Regulators are grappling with how to ensure that AI-enabled medical devices, apps, and other digital tools used in healthcare are safe, effective, and performant. A key challenge in this regard is to design and establish proportionate regulation, which enables a safe, yet risk-based, approach to oversee AI-powered systems.

Challenges for developers of AI products, including FemTech, include **generalizability**, i.e., avoiding failure when a technology is deployed in a population or setting with different characteristics from its training environment, and **continuous assurance** of safety and efficacy of a system that is subject to frequent updating or continuous learning. The challenge of generalizability is particularly prevalent for FemTech products as many diagnostic and treatment products have traditionally been developed with male study participants; they aim to reflect diverse user or patient data sets in order to eliminate bias.

To address some of the above-mentioned gaps in the EU regulatory framework, the European Commission (Commission) published a proposal for a EU Artificial Intelligence Regulation (draft AI Act) in April 2021. The draft AI Act proposes to lay down harmonized rules for the "placing on the market," the "putting into service," and the use of AI systems in the EU.

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In addition to its importance for operations in the EU, the draft AI Act will also have global significance. The AI Act as proposed (a) has an extraterritorial scope, because it applies to AI systems where the product output is used in the EU (irrespective of the location of the providers and users of the system who might be located in a third country), and (b) may function as a reference legislation to shape global standards, as has been the case with the EU's General Data Protection Regulation 2016/679 (***GDPR***).

Access to data, interoperability, and building trust

Key questions for regulators revolve around "data access," in particular (a) how the industry will receive and grant access to data especially for AI- and ML-systems that are developed by training on large amounts of data, (b) how to ensure trust in terms of granting access to data, and (c) how to enable the cross-border exchange of medical data.

The Commission has recently launched an attempt to tackle this issue with the proposal for a regulation on European data governance (Data Governance Act) and with a proposal for a regulation on harmonized rules on fair access to and use of data (Data Act), published on February 23, 2022, setting out new rules on who can use and access data generated in the EU. In addition, on May 3, 2022, the Commission published a proposal for a Regulation on the European Health Data Space, which aims to create a common space to promote better exchange and access to different types of health data, including electronic health records, patient registries, and genomic data. The basic premise will be a safe data system, built on a transparent foundation to ensure a strong system of data governance and common infrastructure and interoperability for the exchange of high-quality data, including for the use in AI systems.

Challenges and opportunities for FemTech developers

The new legislative proposals create a promising, yet complex, ecosystem. The draft AI Act will create a complementary, rather than integrated, regulatory system that will be additional to existing regulations such as the one for medical devices. It is to be hoped that an overlap of these horizontal and sectoral regulations will not lead to a duplication of obligations, such as two parallel conformity assessments for medical device products incorporating AI- or ML-solutions. The draft AI Act provides for the creation of a new advisory body at the EU level, namely the European AI Board, which will be supplemented by new regulators at national level for enforcement. In this respect, Spain has already announced that it will create a national supervisory agency for AI. This will add an extra layer of oversight (and potential risk for divergence).

Reimbursement of digital technologies represents one of the key questions with regard to market access and the provision of innovative solutions to patients. Although frameworks are

evolving, as for example with the Health Technology Assessment Regulation (EU) 2021/2282 or the German reimbursement fast track procedure for digital health applications (DiGA) and national health technology assessment agencies or competent bodies, conducting consultations on reimbursement frameworks (such as the recent consultation on the evidence standards framework for digital health technologies by UK National Institute for Health and Care Excellence), the European landscape remains — without set procedures in the digital health space — fragmented.

The intentions behind the emerging regulatory frameworks are encouraging toward innovation and aim to assist public trust, interoperability, and the scaling up of technologies, including FemTech solutions. One can hope that the draft AI Act will open the door to approvals of technologies, enabling developers to have a better understanding of the regulatory environment and encourage patients to input and use these technologies.

To view the second interview in our series of 'FemTech in the Spotlight', please click here. Eva von Mühlenen and Josefine Sommer talk to oncologist Wolfgang Hackl — the founder of a FemTech start-up that guides doctors in the treatment of breast cancer — about regulation, research and development (R&D), and the vast potential of artificial intelligence in the field of health technology for women.