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Digital Health 2022

Third Edition

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Roger Kuan
Norton Rose Fulbright

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Global Landscape of Digital Health: Impact on Healthcare Delivery and Corresponding Regulatory and Legal Considerations


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Global Context

The World Health Organization (WHO) considers digital health – a broad umbrella term encompassing e-health, as well as developing areas such as the use of advanced computer sciences in the fields of "big data", genomics and artificial intelligence (AI) – to play an important role in strengthening health systems and public health, increasing equity in access to health services, and in working towards universal health coverage.

The emerging digital health industry therefore encompasses digital products or platforms that can monitor, analyse, educate or improve health. The industry can be segmented into telehealth, mobile health (mHealth), Artificial Intelligence (AI), digitalised health systems and electronic health records (eHRs), big data initiatives, analytics and more. The integration of digital health into national health systems and daily lives has become more ingrained. The COVID-19 pandemic has accelerated this integration, with increased funding and deployment of new technologies and care models to address challenges posed by the pandemic. Healthcare professionals provided remote video consultations, prescriptions were ordered via apps, and patients relied on digital screening questionnaires and other tools to inform their healthcare decisions. The pandemic, and the demonstration of the benefits of remote healthcare, gave fresh impetus for digital developments that, for a long time, had been discounted by many.

Unsurprisingly, the digital health market has grown significantly in recent years. The size of the digital health market exceeded US $141.8 billion in 2020 and is estimated to grow at approximately 18% between 2021 and 2027. Digital health technology will unquestionably have a significantly transformational impact on healthcare delivery and patient outcomes concerning such matters as early disease prevention and diagnosis, management and monitoring of chronic conditions, tailoring of medicines and treatment, lowering of healthcare costs and increased accessibility to healthcare.

Along with mHealth, eHealth has been defined by the World Health Organization as "the cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health care services, health surveillance, health literature, and health education, knowledge and research". eHealth has enabled more efficient and responsive healthcare systems around the world and continues to improve and allow for cost and time savings.

Greater emphasis is increasingly placed on adjusting lifestyle to maintain wellness and prevent disease. Wearable trackers have historically focused on measures of fitness and wellness. Originating with counting steps, certain wearables can now monitor metrics such as sleep, reproductive health, calories burned, heart rate and even take electrocardiograms.

AI software with the capacity to perform operations analogous to learning and decision-making in humans has been increasingly applied in the pharmaceutical, medical technology and healthcare sectors to assist various stages of research and development, as well as treatment of patients. In order to meet the societal and patient needs of the 21st century, current research, development, and patient treatment will need to dramatically improve in efficiency. AI has the ability to streamline the process of translating a molecule from the initial inception to a market-ready product, to identify eligible patients for clinical trials, and to provide assistance, such as clinical decision support for providers, in the care setting. Big data-enabling companies to process and analyse large amounts of data generated post-market can mean better insight into how a new product works in the real world and so improve knowledge and accuracy of treatment choices.

The technological evolution based on convergence of biological, physical and mathematical sciences brings about significant legal and regulatory policy challenges. In general, national regulatory frameworks do not adequately address the distinct features and rapid pace of innovation of digital health technologies. To harness the full potential of these technologies, it is imperative that regulatory frameworks across the world evolve and harmonise to encourage innovation and allow for regulatory flexibility, while ensuring the core principles of quality, performance characteristics, safety and effectiveness. We discuss below some of those issues surrounding such technological advances.

Regulation and Enforcement

The emerging and constantly developing innovation of digital health poses regulatory challenges that are being met in varying ways across jurisdictions. In most jurisdictions, digital health is not regulated by a single bespoke legislation but by a number of different legal regimes. However, the national or regional regulatory and enforcement rules share the common theme that they are designed to achieve a high level of protection of human health and consumer interests.

Not all software used in the healthcare setting is considered to be a medical device. Countries or regions with a well-established regulatory regime for healthcare products have considered certain software to be regulated as a software medical device. The borderline classification takes account of the intended purpose or use of the software. The intended purpose is largely determined by the manufacturer and can be inferred from the label, the instruction for use and the promotional material related to a given software, among other sources depending on the jurisdiction.

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The International Medical Device Regulators Forum ("IMDRF"), a consortium of medical device regulators from around the world, has defined software as a medical device ("SaMD") as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device". In the United States, the Food and Drug Administration ("FDA") has adopted this definition of SaMD in its regulatory framework for digital health, which has been evolving over the last decade. The FDA has been working to establish a new regulatory framework for digital health technologies that adopts a risk-based approach based on the intended use and functionalities of the product. The FDA's risk-based approach generally classifies digital health technologies into one of three categories: (1) a non-device, not subject to regulation (lowest risk); (2) a device for which the FDA will not enforce certain regulatory requirements, such as premarket authorisation (medium risk); or (3) a device subject to full regulatory oversight (highest risk), including premarket authorisation requirements as applicable.

In China, the National Medical Products Administration ("NMPA") formed its regulatory framework for SaMD in 2015. SaMD is typically classified as a Class 2 or a Class 3 medical device in China and is subject to the premarket authorisation requirements. In 2020, the NMPA published the draft amendment of the SaMD technical review guidelines. The draft guidelines emphasised the marketing authorisation holder's responsibility to establish oversight during the SaMD's total product life cycle. The higher risks the SaMD carries, the more stringent controls the marketing authorisation holder must adopt in the quality management system.

The EU regulatory framework similarly classifies medical devices according to their performance characteristics and intended use. Software must have a medical purpose for it to be so classified. European jurisprudence considers that a medical purpose covers an object intended by its manufacturer to be capable of appreciably restoring, correcting or modifying physiological functions in human beings. Such an assessment takes account of the composition of the product, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks its use may entail. Classification of software is fraught with practical challenges because, unlike classification of general medical devices, it is not immediately apparent how these parameters apply to software, given that software does not ordinarily act on the human body to restore, correct or modify bodily functions. The Court of Justice of the EU ("CJEU") had ruled in Case C-329/16 SNITEM and Philips that software, of which at least one of the functions makes it possible to use patient-specific data for the purposes, *inter alia*, of detecting contraindications, drug interactions and excessive doses, is, in respect of that function, a medical device, even if that software does not act directly in or on the human body.

The new Regulation (EU) 2017/745 ("MDR") replacing Directive 93/42/EEC on medical devices reflects and expands the European jurisprudence on a medical purpose and defines a medical device very broadly to include, among others, any instrument, apparatus, appliance, or software intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specified medical purposes such as diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

Similarly, Regulation (EU) 2017/746 ("IVDR") on *in vitro* diagnostic medical devices ("IVDs") and repealing Directive 98/79/EC also defines an *in vitro* diagnostic medical device very broadly to mean any medical device which is, among others, a calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, solely or principally for the purpose of providing information concerning such matters as a physiological or pathological process or state, the predisposition to a medical condition, prediction of treatment response or reactions.

Since MDR and IVDR were not directly applicable EU law instruments in the UK before its departure from the European Union, these regulations were not implemented in the UK domestic law. However, in September 2021, the UK Medicines and Healthcare products Regulatory Agency ("MHRA") launched a comprehensive public consultation on the future of medical device regulation in Great Britain. Similar to the MDR and IVDR, the overarching themes seek to create a robust, transparent and sustainable regulatory framework that addresses: (a) improved patient and public safety; (b) greater transparency of regulatory decision-making and medical device information; (c) close alignment with international best practice; and (d) more flexible, responsive and proportionate regulation of medical devices. The future framework for the UK for medical devices and IVDs is forward-looking to regulate such software technology by balancing between enhancing safety measures while incentivising innovation through earlier market access of an innovative medical device.

Adaptive AI technologies pose a challenge to existing regulatory frameworks because they are constantly evolving and learning. Read-out can be flawed due to quality of the source data used to develop the algorithm, resulting in algorithmic bias and a lack of contextual specificity, and thereby compromising patient safety. AI programmes use complex algorithms and black box deep learning for any person, including the initial programmer, to navigate. The recently proposed regulation for AI in the EU broadly defines it to include: machine-learning approaches; logic and knowledge-based approaches, including inference and deductive engines, reasoning and expert systems; statistical approaches; and search and optimisation methods. The proposed regulation classifies AI systems into three risk categories, namely:

- unacceptable-risk AI systems that present a clear threat to the safety, livelihoods and rights of people (e.g., subliminal, manipulative or exploitive techniques that could cause harm) will be banned;
- high-risk AI systems in various defined settings (e.g., systems utilising biometric identification in non-public spaces; systems that would put the fundamental individual rights and health of citizens at risk due to system failure) will be subject to strict requirements; and
- limited (where users can make an informed decision to continue or step back) and minimal risk (which represent only minimal or no risk for citizens's rights or safety) AI systems (e.g., AI chatbots) will be subject to minimal regulation.

The proposal has an extraterritorial reach and applies to providers placing on the market or putting into service AI systems in the EU, irrespective of whether those providers are established within the EU; users of AI systems located in the EU; and providers and users of AI systems that are located outside the EU (i.e. a third country) where the output produced by the system is used in the EU. Companies that use banned AI practices in breach of EU rules, or provide incorrect or misleading information to authorities, could face significant fines.

In China, the NMPA defines artificial intelligence/machine learning ("AI/ML") SaMD as software that leverages AI to process, measure, model and analyse medical device data for medical purposes. If the software processes non-medical device data (e.g., patient claims or lab reports), or processes, measures, models or analyses medical device data for non-medical purposes, or its core functionality does not include processing,

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measuring, modelling or analysing medical device data, such software will not be regulated as AI/ML SaMD. The classification of AI/ML SaMD will depend on the maturity of the AI/ML algorithm being applied in medical practice and the intended use. If the AI/ML has not been widely applied in medical practice or if the intended use is to assist with medical decisions, the AI/ML SaMD will very likely be regulated as a Class 3 medical device.

In the United States, the FDA has also focused on the regulation of AI/ML technologies in recent years and released an Action Plan in January 2021 that outlines key actions for advancing the effort toward practical oversight of AI/ML software. These actions include: issuing guidance on the FDA's expectations for submissions related to software modifications; encouraging harmonisation of Good Machine Learning Practices; promoting user transparency and a patient-centred approach to regulation; supporting efforts for evaluating and improving algorithms to address issues such as bias; and working with stakeholders piloting real-world performance initiatives to better understand how AI/ML products are being used and to respond proactively to safety and usability concerns.

The FDA has taken some regulatory actions related to digital health technologies in recent years, though enforcement in this area remains low. For example, the FDA recently issued a warning letter to a company for marketing a smart monitor without seeking pre-market regulatory clearance. Additionally, to promote the uptake of digital health products during the COVID-19 pandemic, the FDA announced temporary policies to suspend enforcement of certain legal requirements for certain lower-risk digital health technologies, such as those treating psychiatric disorders. The FDA enforcement will likely increase in the future with the increased adoption of digital health technologies.

In the EU, Member States are responsible for enforcing the requirements set out in EU legislation governing medical devices and IVDs. The penalties to be applied must be effective, proportionate, and dissuasive. In the UK, the MHRA enforces regulatory compliance under the domestic law governing protection of consumer interests and public health. The MHRA's policy is to achieve compliance without resorting to enforcement activity wherever possible; it is only in the most serious or persistent cases that they take enforcement action.

Impact on Healthcare Delivery

The WHO has considered that digital health could revolutionise healthcare delivery, and should therefore be an integral part of each country's health priorities. Such health-related tools should be developed according to the principles of transparency, accessibility, scalability, replicability, interoperability, privacy, security and confidentiality.

The European Commission has identified robotics and AI as cornerstone technologies to improve health and care within the internal single market. The recent report on the State of Health in the EU concluded that only by fundamentally rethinking the EU health and care systems can one ensure that they remain fit-for-purpose. Accordingly, innovative solutions should be considered in response to changes in the demographics and multiple morbidities and the rising burden of preventable non-communicable diseases caused by risk factors such as tobacco, alcohol, and obesity, and other diseases including neuro-degenerative and rare diseases. Digital health would meet the objective of promoting research, disease prevention and personalised patient-centred health and care. Such digital solutions can increase the well-being and radically change the way health and care services are delivered to patients, if designed purposefully and implemented in a cost-effective way. One specific area is to standardise the specification for eHRs to facilitate cross-border care. As such, the European Commission has considered the need to review Directive 2011/24/EU on the application of patients' rights in cross-border healthcare and the relevant implementing decisions to advance the interoperability of eHealth solutions and to clarify the role of the e-Health Network in the governance of the e-Health digital service infrastructure and its operational requirements.

Outside the scope of this chapter, the reimbursement pathway for digital health technologies is currently unclear. That said, in recognition that digital health technologies are developed at an increasing pace, in the UK, the National Institute for Health and Care Excellence, NHS England, Public Health England, MedCity and Digital Health London have developed an evidence standards framework for digital health technologies to assist innovators and commissioners in understanding what good levels of evidence for digital health technologies would look like to ensure new technologies are clinically effective and offer economic value. In the United States, reimbursement for healthcare services provided remotely through telehealth and other digital health technologies have historically been limited; however, government and commercial payors are increasingly reimbursing such services, in part due to the realities of the COVID-19 pandemic.

Data Generation for Real-World Evidence

Observational studies are a fundamental part of epidemiological research to complement knowledge from randomised controlled trials and fill certain gaps, particularly where clinical trials cannot be conducted to characterise the clinical safety and efficacy profile as well as the therapeutic position of an innovative product in a real-world setting. Such a methodological approach has become more important in providing evidence on safety and effectiveness of vaccines and treatments for COVID-19 as it is critical to understand how exposure to certain medicines can affect the risk or the severity of infection with the circulating virus in the community.

eHRs and databases (including registries) containing other health-related data (claims, pharmacy) can support high quality observational research and pragmatic clinical trials, both of which can be important sources of real-world evidence. Integrating data from different sources creates a richer, more robust dataset than any one single source can yield. However, combining data from different sources can be a labour-intensive process due to challenges with data standardisation and interoperability.

In order to gain acceptance of such data sources by regulatory authorities as supportive evidence, data quality management should be prospectively defined and implemented with a focus on a core set of data elements and data systems to ensure integrity, completeness and security of the data sources.

Use of real-world evidence in product development has traditionally been limited by a lack of clear guidance from regulators or comfort with the reliability of the real-world data set. During the COVID-19 pandemic, regulators and industry have heavily relied on real-world data by necessity to understand the epidemiology and to assess potential treatment options. For example, in the United States, the FDA collaborated with a health IT vendor to launch a real-world evidence research project focused on the use of diagnostics and medications during the COVID-19 pandemic. The FDA has continued to gain comfort with real-world evidence, and has begun crafting a framework regarding how sponsors can utilise real-world evidence. Specific guidance from global regulators and increased comfort on the part of sponsors, regulators and other stakeholders will likely promote greater use of real-world evidence in the future.

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Product Liability

In the EU, product liability rules under the Product Liability Directive 85/374/EEC aim at maintaining a fair balance between the interests of consumers and producers. Recent reviews of the Product Liability Directive have raised certain legally challenging issues arising from the fact that the distinction between products and services have been blurred in the context of digitalisation and AI. Some have commented whether the Product Liability Directive and civil liability regimes in the Member States are capable of addressing issues that may arise from such digitalised platform technologies.

In June 2021, the European Commission published an inception impact assessment roadmap on adapting civil liability rules to the digital age, AI and the circular economy. This initiative was prompted by the earlier assessment of the Product Liability Directive and addresses challenges that arise when liability rules are applied to such new technologies. The assessment emphasises that the liability framework should seek: (a) to provide legal certainty to companies about the risk they take in the course of their business; (b) to encourage the prevention of damage; and (c) to ensure injured parties are compensated. Accordingly, the liability rules should strike a fine balance between these competing objectives and promoting innovation.

The Commission also identified a number of ways in which software and AI might impact product liability and, hence, the shortcomings of the Directive in coping with the digital technologies. They include: (a) intangibility of digital products where digital content, software and data play a crucial role in ensuring the safety and functional characteristics of such technologies; (b) connectivity and cybersecurity, recognising that new technologies bring with them new risks such as openness to data inputs that may affect safety, cybersecurity risks, risks of damage to digital assets or privacy infringements; and (c) complexity of digital technologies, for example, within Internet of Things ("IoT") systems, makes it challenging for injured parties to identify the responsible producer.

The European Commission points out that importers are treated as producers for the purposes of the Product Liability Directive but that the digital age has brought changes to value chains. The Internet has enabled consumers to access services and buy products from outside the EU without there being an importer, and hence the risk that no one could be held liable under the Directive. Moreover, the specific characteristics of AI make it especially difficult to get compensation for damages under the Product Liability Directive and national civil liability laws.

The most recent ruling of the CJEU in Case C-65/20 *VI v KRONE-Verlag Gesellschaft mbH & Co KG* could be instructive in that it clarifies whether a physical copy of a daily newspaper (an information-sharing medium) can be regarded as a product for the purpose of the Directive in circumstances where the alleged defect was in relation to a health recommendation, which when followed could cause physical harm. CJEU has considered that the liability of service providers and the liability of manufacturers of finished products constitute two distinct liability regimes as the activity of service providers cannot be equated with those of producers, importers and suppliers that are covered by the Product Liability Directive. The ruling considers that a copy of a printed newspaper containing inaccurate health advice relating to the use of a plant, which, when followed, has proven to cause personal injury to the reader of the newspaper does not constitute a defective product within the meaning of the Product Liability Directive.

In the United States, a unified, consistent approach to product liability for digital health technologies has not emerged, in large part because these technologies are novel and product liability law is still evolving to catch up. Product liability is generally codified in state law, meaning that each state has different liability standards. Courts differ on the key question of whether software is even considered a product at all, or rather a service, which would then nullify any product liability claims. The learned intermediary doctrine, which is settled law in a majority of states, limits a device manufacturer's duty to warn of risks to treating physicians, who serve as "learned intermediaries" and assume the duty to convey those warnings to patients. As many digital health technologies empower consumers to make their own healthcare decisions without a physician, it remains to be seen what impact this has on product liability going forward. Digital health products also typically have multiple components, which complicates the determination of which party to target in a product liability suit. U.S. federal law does expressly preempt all state law claims, including product liability claims, directed at Class 3 medical devices (highest risk) that have successfully completed the premarket approval process unless those claims parallel federal requirements. As such, manufacturers of Class 3 medical devices have protection against state laws more rigorous than federal ones, though in practice manufacturers seeking to assert preemption often face challenges.

Conclusion

The digital health industry is dynamic, fast-growing and holds great promise for revolutionising healthcare across the world. There is significant regulatory uncertainty and global inconsistency around how digital health technologies should be regulated, as well as unclear reimbursement rules and policies.

Given that such technologies are increasingly embedded into healthcare delivery, the potential attendant risks that may arise from the design and implementation of such technologies could potentially be far-reaching in terms of exposure to liability claims. However, such a risk assessment will likely be complex as it should take account of the infrastructure of the healthcare system in which the technology is being applied, which may vary considerably country to country.

Acknowledgment

The authors would like to thank Jessica Band for her invaluable assistance in the writing of this chapter. Jessica is an associate in Ropes & Gray's FDA regulatory practice group and routinely advises life sciences companies on a wide range of FDA regulatory matters including product research and development, promotional compliance, post-market risk mitigation, and digital health. Jessica also routinely provides regulatory counsel for complex transactions, including mergers, acquisitions, and strategic collaborations, as well as public offerings of FDA-regulated companies, including drug, device, dietary supplement, and cosmetic manufacturers, and clinical research organisations. Prior to joining the firm, Jessica worked for Kaiser Permanente and the Advisory Board Company where she counselled hospitals and health systems on technology adoption and quality monitoring.

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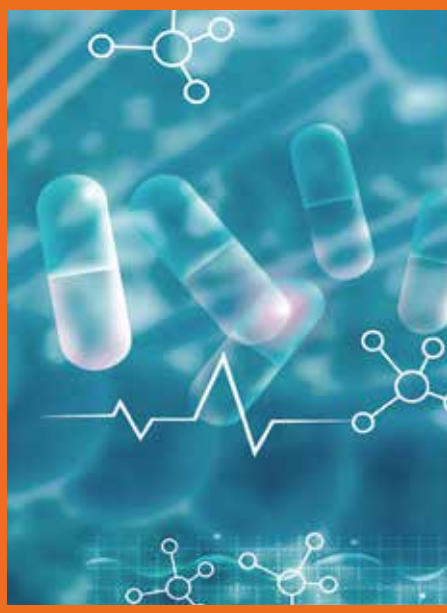

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