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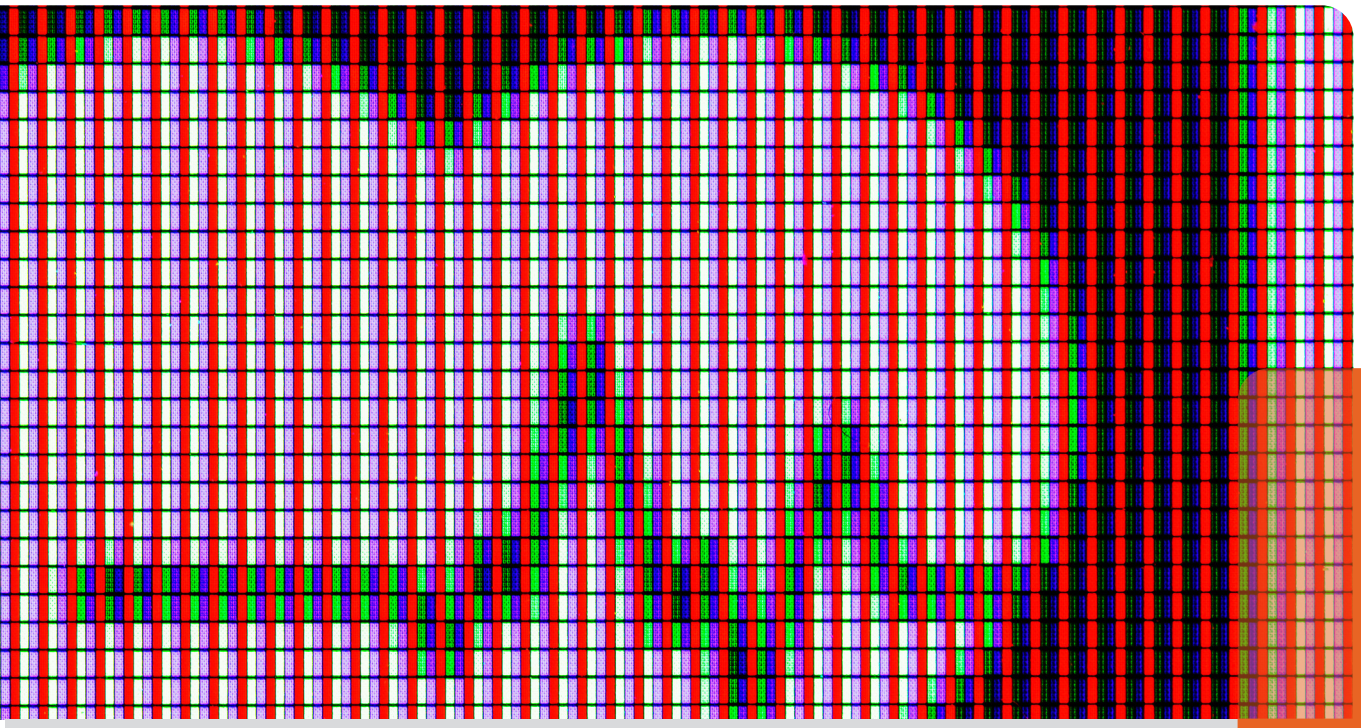

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Introductory Chapter

Expert Analysis Chapters

Q&A Chapters

Recent Updates on Emerging Trends in the Global Regulation of Digital Health: Fragmented Frameworks Continue Striving to Catch Up With Technological Advancement

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Introduction/Overview

Continued advances in healthcare technology create an enormous opportunity to enhance healthcare delivery and accessibility, reduce healthcare costs, and advance public health as a whole. Digital health technologies are becoming increasingly prevalent and are being utilised in innovative ways that benefit both patients and providers. For example, these technologies are changing the dynamics of care delivery through platforms like telehealth, transforming when, where, and how patients receive care. They also facilitate broader patient involvement in clinical research through "decentralisation" of clinical trials, allowing for remote patient monitoring ("RPM") to collect health-related data at home. Advancements in digital health have also established new ways or mechanisms to document and transfer electronic health records and facilitate correspondence between providers. These technologies have advanced the capability to detect early, sub-clinical signs of disease, aiding providers in offering preventive care or treatment sooner. Digital health technologies have also been used to promote general health and wellness, such as through mobile applications and wearables intended for everyday use. Therefore, the scope for digital health applications is vast and holds great potential, paving the way for innovative solutions in patient care, disease management, and health system efficiency that could revolutionise the medical field.

The proliferation and implementation of digital health tools, however, have been moderated by laws and regulations that predate these novel approaches to healthcare using digital technologies. Consequently, government and regulatory bodies are faced with the challenge of reconciling the rigid enforcement of their established legal structures with the evolving landscape of digital health, all while fostering ongoing progress in the sector. In this chapter, we discuss certain key legal constructs that digital health companies and investors must consider, and the emerging legal trends impacting applications of digital health in the United States ("US"), European Union ("EU"), and United Kingdom ("UK").

Key Legal Constructs for Digital Health Companies

Medical device considerations

One of the key legal constructs that companies and investors in the digital health industry must consider is the framework applicable to medical devices across jurisdictions.

US

In the US, the Food and Drug Administration ("FDA") has the legal authority to regulate medical devices. The law defines a device to mean "an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or similar or related article, including any component, part, or accessory, which is" among other things, either "intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body" and "does not achieve its primary intended purposes through chemical action" and is "not dependent on being metabolized for the achievement of [those] purposes".[1] Certain software functions that might otherwise fall within the scope of this broad definition fall within an exemption under the law and will not be deemed a device. For example, in general, a software function intended for "maintaining or encouraging a healthy lifestyle and [that] is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition" will not be regulated as a device.[2]

With the exception of those software functions deemed to be shielded from the FDA's medical device oversight by statute, the law paints a broad brush; it sweeps many digital health technologies, including certain software – which may not traditionally be viewed as a "device" or "product" – within the FDA's reach. Because the medical device framework was established prior to the relatively recent explosion in the development and use of digital health technologies, it is not tailored to the unique features of digital health and is often a poor fit. Indeed, the FDA and industry alike have recognised that the existing regulatory framework for medical devices can present a barrier to innovation and stifle or slow the utility and hamper the promise digital health may present for improving the public health.

With this construct in mind, the FDA has issued a variety of guidance documents designed to apply flexibility to this new class of technologies that might otherwise fall within its regulatory crosshairs. For example, the FDA has issued guidance on its approach to regulating device software functions and mobile medical applications,[3] general wellness products,[4] and clinical decision support software[5] in an effort to establish a clearer line between certain digital health technologies that are subject to FDA oversight and those that are not. In some cases, the FDA has applied a policy of enforcement discretion, noting that although the technology may technically constitute a medical device subject to FDA oversight, the FDA has declined to assert its medical device authority and apply medical device requirements over such technologies. Consistent with its increased attention to digital health, in September 2020 the FDA

announced the launch of its Digital Health Center of Excellence to establish a "comprehensive approach to digital health technology" to "set[] the stage for advancing and realizing the potential of digital health".[6] In January 2024, the FDA elevated the Digital Health Center of Excellence to a full office within the Office of Strategic Partnerships and Technology Innovation as an ongoing expansion in digital health.[7] Continuing with this trend, in October 2023, the FDA announced that it is establishing a Digital Health Advisory Committee, which will include core voting members with expertise in several key areas in digital health,[8] as well as non-voting representatives of industry interests.[9] The committee's members will be called on to advise FDA on issues relating to digital health technologies and the approach the FDA should take to regulating them.

The FDA has also engaged in a number of actions in recent years to address certain novel digital health technologies, including artificial intelligence and machine learning ("AI/ML") in medical applications.[10] Specifically, the FDA has proposed the establishment of a new regulatory framework to enable a more flexible approach to regulating these technologies, which may be designed to iterate and improve after commercialisation. The FDA has continued to expand on this framework by publishing in 2023 a guidance document focused on enabling applicants to submit a marketing application that seeks authorisation for certain anticipated changes to the product after marketing, even prior to initial marketing authorisation (a "predetermined change control plan"),[11] and the agency announced that it plans to publish several new AI/ML-related guidance documents in 2024.[12] Finally, in December 2023 the FDA issued a final guidance governing the use of digital health technologies for remote data acquisition in clinical investigations, the use of which has the potential to allow for further decentralisation of clinical trials.[13] The FDA issued draft guidance in May 2023 to assist the industry in mapping the existing regulatory landscape governing clinical trials – with the assumption that clinical trials take place at a physical clinical trial "site" – to the new world of decentralised studies, where some or all of the trial-related activities take place at locations other than clinical trial sites.[14] While these efforts are commendable, regulatory uncertainty remains and opportunities abound for the industry to play a role in shaping the resulting framework.

EU

Similarly, in the EU, regulatory authorities may consider digital health technologies to be regulated as devices, pursuant to Regulation (EU) 2017/745 on medical devices ("MDR") or Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices ("IVDR"). The MDR and IVDR clarify that software that is intended by the manufacturer to be used for one of the medical purposes listed in these regulations will be classified as a medical device or *in vitro* diagnostic medical device, respectively. These regulations could therefore capture many digital health solutions, including software incorporating AI when intended for use for medical purposes. As such, to be placed on the EU market, these solutions must be compliant with general safety and performance requirements as a prerequisite for European conformity, or "CE" marking, without which medical devices, including *in vitro* diagnostic medical devices, cannot be marketed or sold in the EU. To guide manufacturers, the Medical Device Coordination Group has issued guidance on the qualification and classification of software under the MDR and IVDR,[15] and on Medical Device Software intended to work in combination with hardware or hardware components,[16] and the Manual on borderline and classification in the EU regulatory framework for medical devices contains many examples related to qualification of software and mobile applications.[17]

Today, more than 25% of medicines assessed by the European Medicines Agency ("EMA") incorporate a medical device component, which increasingly include digital technologies (such as "digital pills"). In its 2021 guideline, the EMA addressed the challenges related to the development of these combination products that use emerging technologies by recommending that developers engage with the relevant medicines authorities and notified bodies in a timely manner, e.g., by requesting formal scientific advice, or through an Innovation Office.[18]

As related to AI, on December 8, 2023, the European Parliament and Council reached political consensus on the world's first regulatory framework on AI ("AI Act") after protracted negotiations following the AI Act's initial publication of the initial proposal for the AI Act in April 2021. The AI Act is expected to enter into force in 2024, and the majority of the substantive requirements will apply two years later. The AI Act will apply to AI in all sectors, including the health sector. Under the AI Act, it is expected that most AI systems that are part of medical devices and *in vitro* diagnostic medical devices, or are themselves such products, will be classified as high risk and require a conformity assessment by a notified body (e.g., a device, such as a pacemaker, that uses an AI system to identify the user's normal cardiological parameters and thus monitor the proper functioning of the patient's heart). As most software-based medical devices and *in vitro* diagnostic medical devices are already subject to conformity assessment by MDR- or IVDR-notified bodies, there is a possibility they would have to undergo a second conformity assessment procedure under the proposed AI Act, which could lead to increased cost, resources, documentation and regulatory scrutiny. In addition, such a requirement could create additional constraints for those notified bodies designated under the MDR and IVDR, which are already experiencing enormous backlogs. While the agreed text has not yet been published or formally approved, given the overlap between the medical device and AI frameworks, it remains to be seen whether the AI Act will advance innovation in the digital health space, or ultimately stifle it. The EMA has recently published a draft reflection paper outlining the current thinking on the use of AI to support the safe and effective development, regulation and use of medicines, the consultation process on which ended on December 31, 2023.[19] The reflection paper primarily focuses on providing regulatory strategy guidance for pharmaceutical companies on the use of AI/ML in the lifecycle of medicinal products (including R&D, authorisation, and post-authorisation) but also covers the interplay between medical devices and medicines. Acknowledging the rapid development in this field, the reflection paper discusses the scientific principles relevant for regulatory evaluation when these emerging technologies are applied to support safe and effective development and use of medicine. It emphasises that further reflections are needed regarding advice on risk management as the impact of system malfunction or degradation of model performance can range from minimal to critical or even life-threatening.

UK

As a result of Brexit, the MDR and IVDR do not apply in Great Britain, though they are applicable in Northern Ireland pursuant to the Northern Ireland Protocol. On June 26, 2022, the UK Medicines and Healthcare products Regulatory Agency ("MHRA") published its response to a 10-week consultation[20] on the future regulation of medical devices in the UK. The aims of the consultation included exploring amendments to the current Medical Devices Regulations 2002 with a view to creating an innovative framework for regulating software and AI as medical devices. The new regime was originally scheduled to come into force in July 2023, but has recently been postponed

to July 2025. For the most part, the proposed changes in many of these areas align with the new EU regime under the MDR and IVDR.

With respect to AI, in contrast with the approach taken by the EU, on March 29, 2023, the UK government published a white paper entitled "A pro-innovation approach to AI regulation", which sets out the UK's proposal to not introduce new legislation, but instead to leverage existing regulatory frameworks and empower regulators to apply a principles-based approach to supervising AI applications within their remit (rather than introducing new legislation or a new AI regulatory body). The government is expected to publish its full response to the white paper consultation in early 2024, further detailing its proposed approach to AI regulation.

On October 17, 2022, the MHRA published guidance on "Software and AI as a Medical Device Change Programme – Roadmap",[21] a programme aiming to reform the regulation of these technologies and ensure that the regulatory requirements for software and AI are clear, and that patients are protected. The programme consists of proposals to make key reforms across the lifecycle of these products, including qualification, classification, pre- and post-market requirements, and cybersecurity.

As regulators in the US, EU and UK continue to refine their approaches to digital health technologies, including when and how such technologies should be regulated as medical devices, the legal and regulatory frameworks are likely to shift. This changing landscape can present difficulties for companies in the digital health industry when assessing the regulatory burdens that may apply across the lifecycle of their products and services. Furthermore, despite regulators' attempts to adapt to technological innovation in a flexible manner, future advancements in digital health may continue to outpace the legal frameworks, with regulators seemingly playing a constant game of catch-up.

Telehealth considerations

Digital health technologies that pertain to the delivery and use of telehealth to deliver care require a thorough evaluation of another set of healthcare regulatory laws outside of the FDA and comparable medical device regulations globally.

US

No uniform federal law governs the delivery of telehealth services. Instead, telehealth is regulated at state level, and digital health companies must evaluate a patchwork of state laws to understand the restrictions that impact how healthcare providers and healthcare entities use technology, and how each step in the care delivery model can be structured to comply with varying state laws. Because state standards were developed when care was predominantly provided through in-person encounters, state laws lag behind innovation and do not fully contemplate the range of available technology that is changing the healthcare delivery model.

Each state has developed its own licensing requirements and standards governing: (i) the general practice of telehealth and the ability for remote delegation, supervision, and prescription; (ii) whether the delivery of care can be synchronous or asynchronous; and (iii) the scope of clinical care, coordination and management that can be delivered digitally. Specialty societies are stepping in to shape the standards of practice and spur policy discussion relating to digital health and use of AI. For example, the American Medical Association ("AMA") has developed a Digital Health Implementation Playbook[22] and has defined the concept of "augmented intelligence", focusing on AI's assistive functions.[23] The AMA has also issued principles for augmented intelligence development, deployment and use, with the goal of advancing high-quality, clinically validated augmented intelligence in patient care.[24] A presidential executive order was issued in October 2023 designed to establish guidelines on the safe, secure and trustworthy development and use of AI in the healthcare sector, and recently a number of healthcare providers and payors organisations made voluntary commitments to advance AI technology safely and equitably.[25]

In addition, state licensing laws limit the geographic reach of licensed healthcare professionals ("HCPs") by requiring them to be licensed where the patient resides, unless the care was provided, for example, directly to another HCP (rather than to the patient) or in an emergency situation. The onset of the COVID-19 pandemic prompted states to temporarily loosen licensure restrictions on the practice of telehealth and apply waivers from these requirements, accelerating the use and acceptance of telehealth services and allowing HCPs to provide services to patients across state lines. However, many of the state waivers that were implemented during the pandemic expired and have not been extended, resulting in a setback in the advancements in telehealth that were gained over the past few years. Efforts to reduce these licensure barriers continue, including allowing for out-of-state licensure exemptions, providing for telehealth licensure pathways under certain circumstances, and continued expansion of state licensure compacts, such as the Interstate Medical Licensure[26] and Psychology Interjurisdictional Compact,[27] which are designed to streamline the licensing process for HCPs who wish to be licensed in multiple jurisdictions.

Lastly, leveraging technology to deliver remote care or augment an HCP's ability to diagnose and treat patients through AI implicates another set of laws, called state corporate practice laws. These laws generally prohibit lay, unlicensed entities from delivering healthcare or exercising undue influence or control over the delivery of healthcare services. These laws may require companies to implement certain corporate structures, operational models or other safeguards to ensure that HCPs maintain unfettered control over clinical decision-making.

EU

The European Commission defines telehealth as "the provision of healthcare services, through the use of [information and communications technology], in situations where the health professional and the patient (or two health professionals) are not in the same location" and involves "secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients".[28] As in the US, the regulation of telehealth services in the EU remains fragmented, as such services are essentially regulated at a national level. The most relevant effort to regulate health services across the EU is Directive 2011/24/EU on patients' rights in cross-border healthcare (the "Cross Border Healthcare Directive"), which ensures continuity of care for European citizens across borders (e.g., e-prescribing) and dates back many years.

A 2018 European Commission market study on telemedicine concluded that "most telemedicine solutions are deployed at the national or regional level" and that "this is due to the significant differences in national regulations and social security schemes".[29] The study recommended that "EU countries… harmonize their legal frameworks in order to make solutions compatible and to enable cross-border telemedicine practices".[30] The recent European Commission proposal for a Regulation on the European Health Data Space included provisions seeking to harmonise and encourage cross-border telemedicine,[31] but

these provisions were removed by the European Council during the ongoing legislative process. Trilogue negotiations on the European Health Data Space commenced in December 2023, so it remains to be seen what position is ultimately reached on the proposals regarding telehealth. While recent developments at the EU level in this space remain limited, it is worth noting that in November 2022, the World Health Organization ("WHO") issued a consolidated telemedicine implementation guide, which provides an overview of the key considerations for implementing telemedicine globally.[32]

UK

No specific laws govern telehealth in the UK. However, the provision of health or social care (including by remote means) in England is primarily governed by the Health and Social Care Act 2008 and the Health and Care Act 2022. Similar legislation covers Northern Ireland, Scotland, and Wales. The Electronic Commerce (EC Directive) Regulations 2002 (the "eCommerce Regulations"), which impose certain requirements for the provision of online services, may also apply to the provision of telemedicine services.

The provision of health and social care is regulated on a regional basis by different agencies. For example, in England, the Care Quality Commission ("CQC") regulates telehealth providers under the regulated activity of "transport services, triage and medical advice provided remotely". Telemedicine service providers (including individuals or corporate entities) are required to register with CQC or the equivalent body in Northern Ireland, Scotland, and Wales.

While these regulators have authority over healthcare service providers (i.e., the individual or the entity), individual providers are also subject to licensing and enforcement by their professional bodies. In particular, the General Medical Council has licensing and enforcement authority in respect of doctors, and the General Pharmaceutical Council has such authority in respect of pharmacists. The obligation to be appropriately qualified and registered with a professional governing body applies regardless of whether the service is provided remotely or in person. As a result of Brexit, the "country-of-origin" principle under the eCommerce Regulations – which allow European Economic Area ("EEA") online service providers to operate in any EEA country, while only following relevant rules in the country in which they are established – and the rules on cross-border care from the Cross Border Healthcare Directive no longer apply. This means that professionals providing telemedicine services from the UK to patients in the EEA may also need to be licensed in the country where the patient is located.

Coverage and reimbursement considerations

Beyond the legal considerations applicable to compliance of digital health technologies with the medical devices framework and telehealth restrictions and requirements, companies must consider the laws and regulations applicable to coverage and reimbursement for their digital health technologies, or coverage and reimbursement of healthcare services provided using digital health technologies.

US

Coverage and reimbursement for health services that use digital health technologies (like telehealth) are often determined on a payor-by-payor basis, which can make it difficult for companies to navigate the payor landscape and achieve certainty with respect to payor adoption of their technologies. While the US does not have a single payor system that establishes uniform reimbursement and coverage for healthcare services that use digital health technologies, policies established by the Centers for Medicare & Medicaid Services ("CMS") – which administers Medicare, the nation's single-largest public insurance programme – are particularly important because they often influence coverage and payment policies adopted by other payors.

In recent years, CMS has expanded coding and payment policies for remote monitoring services and payment for certain software-based diagnostic tools. However, as a recent fraud alert issued by the Office of Inspector General signals,[33] RPM is under increased scrutiny by federal regulators and payors as utilisation of these services have grown. RPM and digital health companies should monitor these enforcement developments and coverage and utilisation restrictions that may be issued by payors this year, as well as monitor their operations and billing practices for compliance with Medicare, Medicaid and other payor requirements.

In addition, Congress and various federal and state agencies have continued to provide expanded flexibilities to enable coverage and reimbursement for telehealth services, including policies allowing certain telehealth services to be reimbursed at the same rate as equivalent in-person services. While some of these flexibilities have been extended through the end of 2024, pay and coverage parity for telehealth services is under review. The explosion of telehealth and digital health offerings in the US healthcare system because of these policies has been paralleled by an increasing number of enforcement actions, scrutiny by federal regulators, and the issuance of a special fraud alert around the use of telehealth services.[34] It is important that digital health companies stay abreast of this increased regulatory scrutiny, and the evolving regulatory scheme, as they structure their operations.

EU

The reimbursement landscape for digital health tools is fragmented across the EU, given that reimbursement decisions are made at a national or even regional level, and not by EU authorities. This poses particular challenges to both the manufacturers that are developing digital health technologies and the health authorities that are evaluating them. In particular, these authorities' traditional methods to evaluate products for coverage and reimbursement do not focus on aspects that are relevant to digital health technologies (e.g., interoperability, privacy, data security, and ethical considerations). Moreover, because these technologies are often updated more quickly than traditional devices (especially when incorporating AI/ML), they require similarly speedy evaluation decisions. As a consequence, national reimbursement schemes for digital health technologies are inconsistent across the EU, including with respect to the type of evidence that is accepted as sufficient, and little guidance is available to assist manufacturers in navigating the requirements. Certain countries have implemented specific frameworks for reimbursement decisions with respect to digital health technologies. Germany, for instance, is the first EU country to have recently implemented a "fast track" reimbursement for certain digital medical products, such as wearable devices or mobile applications.

The EU Health Technology Assessment ("HTA") Regulation (2021/2282) ("HTAR"), which for the first time introduces a permanent legal framework for joint HTA work (i.e., joint clinical assessments and scientific consultations) by EU Member States, is an important step toward a more uniform assessment of innovative high-risk medical devices, including digital health technologies. In preparing for the regulation's phased implementation from 2025 onwards, several national HTA bodies in Europe have recently joined forces with EU-level

organisations, such as the European Network for HTA, to develop recommendations on harmonised evaluation guidelines for digital medical devices. For instance, in October 2022, a European taskforce was launched by nine EU Member States with the objective to reach a mutual understanding between national HTA agencies for digital medical devices in order to harmonise assessment criteria and clinical evidence requirements and improve access to digital health technologies in the EU.[35]

UK

The National Health Service ("NHS") funds the majority of digital health products and services provided to patients in the UK. In addition, there exists a smaller, but growing, private healthcare sector, which is funded through private insurance or directly by patients. There are a number of routes for products to be made available for reimbursement by the NHS, including selling directly to NHS trusts or primary care organisations, or procurement through the NHS supply chain or public tenders. In addition, digital health products can undergo a technology appraisal from the National Institute for Health and Care Excellence ("NICE"), and the NHS is obligated to fund and resource treatments recommended by NICE.

The NHS has published a "guide to good practice for digital and data-driven health technologies",[36] which is designed to help innovators understand the NHS requirements when the NHS buys digital and data-driven technology. NICE has published the "Evidence standards framework for digital health technologies",[37] which describes the standards for digital health technologies to demonstrate their value in the UK healthcare system.

Data privacy and data use

Data and digital health go hand-in-hand, whether they involve the analysis of large and complex datasets by an AI/ML tool or the collection of an individual's health and lifestyle data through a wearable device. As such, navigating the complex and continually evolving web of privacy and cybersecurity laws is critical to the deployment of any digital health solution.

US

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder (collectively, "HIPAA") imposes privacy, security, and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as "covered entities", as well as their "business associates" that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information referred to as "protected health information" ("PHI") for or on behalf of such covered entities, and their covered subcontractors. HIPAA requires covered entities and business associates to develop and maintain policies with respect to the protection of, use and disclosure of PHI, including the adoption of administrative, physical, and technical safeguards to protect such information, and certain notification requirements in the event of a breach of unsecured PHI.

The data protection landscape is rapidly growing and evolving on a state level. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act, and regulations promulgated thereunder (collectively, "CCPA"), requires companies that process information on California residents to make certain disclosures to consumers about their data collection, use, and sharing practices. CCPA also allows consumers to opt out of certain data sharing with third parties and exercise certain individual rights regarding their personal information, providing a private right of action for data breaches and penalties for noncompliance. Similar laws have been passed in other states and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the US.

The Federal Trade Commission ("FTC") and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination, and security practices that appear to be unfair or deceptive. Recent FTC guidance on AI/ML has focused on the potential risks to fair and transparent consumer transactions represented by opaqueness in automated decision-making and predictive analytics. The FTC is also concerned about misleading representations to consumers regarding a company's data collection and handling practices that underwrite the datasets on which algorithms are trained. The FTC has highlighted the particular risks to healthcare consumers in unfair or deceptive data practices leveraging AI as an area of developing regulatory concern. Of particular relevance to the digital health sector are potential harms to patients introduced as a result of improper oversight when AI tools are used for automated decision-making, leading to discriminatory clinical or treatment outcomes.

Further, on December 13, 2023, the U.S. Department of Health and Human Services through the Office of the National Coordinator for Health Information Technology issued its final Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing rule ("HTI-1 Rule") that establishes transparency requirements for the use of AI/ML in certified health IT. The HTI-1 Rule is focused on mitigating bias and inaccuracy in healthcare AI/ML tools and will require healthcare AI developers of certified health IT to provide more information about their AI/ML products to users, including information about funding sources, data used to train the model, intended use cases, external validation processes and description of approaches to manage, reduce, or eliminate bias.

EU

In the EU, the processing of personal data is primarily governed by Regulation (EU) 2016/679 ("GDPR"). The GDPR imposes comprehensive data-privacy compliance obligations in relation to the use or "processing" of information relating to an identifiable living individual or "personal data". The GDPR applies not only to entities established in the EU, but also to entities established outside the EU if they offer goods or services to EU individuals or monitor their behaviour. Organisations deploying digital health solutions to individuals across the EU and the UK may therefore need to comply with both the GDPR and the UK data protection regime. While the GDPR was intended to harmonise data protection laws across the EU, national implementing laws diverge in certain areas, such as the processing of personal data for public health or scientific research purposes. Therefore, companies must navigate not only the GDPR, but also national implementing and supplementary legislation, as well as legal, ethical and professional rules designed to protect patient confidentiality.

Although the GDPR was enacted to be technology-neutral, the advent of the digital health industry has led to challenges in the interpretation and application of the GDPR. For example, some digital health applications, such as wearables, have led to questions on the distinction between health data (which is considered "special-category data" under the GDPR and subject to enhanced protections) and other non-health "lifestyle"

data. This distinction, in turn, leads to potential compliance challenges, such as identifying appropriate legal bases for processing such health data and other personal data under the GDPR and ensuring that individuals are adequately informed of the processing of their data.

Other applications of digital health, such as AI/ML algorithms, have raised difficult questions regarding transparency and how data subjects can be informed in easy-to-understand terms of how the algorithm processes their data. Where personal data has been used to train an algorithm, withdrawal of a subject's consent (where consent has been used as the legal basis for such processing) to limit further use of their data may not be practical or possible and could affect the integrity of the algorithm. In such cases, the developer will need to consider whether it can continue to legitimately use that data, such as whether it has been effectively anonymised or aggregated. Ensuring data accuracy and the absence of bias are also key considerations for these types of tools.

Another increasingly tricky area for digital health operators is in relation to international data transfers. Where personal data are transferred from the EU to a country that is not considered to provide an "adequate" level of protection for the data, such transfer is prohibited unless a relevant derogation applies or certain safeguards are implemented. As a result of EU caselaw, complexity and uncertainty remain regarding such transfers, particularly in relation to transfers to the US.[38] The shifting sands of data transfers can be difficult to navigate and companies must pay close attention to the complex data flows that are often involved in digital health solutions in light of the legal developments governing such transfers.

Many digital health solutions, such as wearables and apps, may use cookies or other tracking technologies. While cookies that are strictly necessary for the device, site, or app to function correctly can be used without opt-in consent, others such as analytics or advertising trackers will require specific opt-in consent under EU Directive 2002/58/EC and national implementing laws, which may not be straightforward depending on the nature of the device. User data collected from devices is also subject to the GDPR. The use of cookies, tracking technologies, and user profiling is subject to increasing regulatory scrutiny and enforcement, particularly around the use of individuals' data for marketing and advertising.

Beyond the general requirements to ensure the security of personal data in the GDPR, there is a trend toward increasing regulation of cybersecurity through sector-specific or device-specific rules. For example, the MDR requires the manufacturing of certain devices to take into account information security principles. In addition, on November 28, 2022, the EU adopted Directive (EU) 2022/2555 on measures for a high common level of cybersecurity across the EU ("NIS-2 Directive"). The NIS-2 Directive establishes cybersecurity risk-management measures and reporting requirements for critical sectors, including manufacturers of medical devices. The draft EU Cyber Resilience Act, for which the European Parliament and Council reached provisional agreement on November 30, 2023, also proposes a framework of consistent security standards for digital products, applicable through the whole product lifecycle.

In parallel with the trend toward increased regulation and scrutiny, there is a trend toward enabling greater sharing and reuse of data, particularly for research and innovation. For example, on May 3, 2022, the European Commission launched its proposal for a Regulation for the European Health Data Space to "unleash the full potential of health data", facilitating the systematic digitisation of health records and secondary use of clinical data for research purposes. In addition, the EU Data Act, which was adopted by the European Parliament and Council in November 2023, regulates the sharing and use of data generated by connected devices, includes new rights for users of connected services, introduces data portability obligations, imposes restrictions on the use of user data, and regulates data sharing contracting.

Across the EU, there is a trend toward increasing enforcement of data protection laws and ever-larger fines. There is also increasing scrutiny and enforcement from a broader range of regulators – including data protection regulators, consumer protection authorities, and competition regulators – and increasing coordination efforts around data and digital platforms. At the same time, there is increasing momentum for policies and proposals designed to unlock data for research purposes, including for the development of AI and other digital health tools with the potential to advance healthcare.

UK

Following Brexit, the GDPR has been mirrored in UK law as the "UK GDPR", which together with the Data Protection Act 2018 form the UK's data protection regime. The UK Information Commissioner's Office has introduced specific data-transfer mechanisms to safeguard transfers of data out of the UK, namely the International Data Transfer Agreement and the International Data Transfer Addendum to the EU's standard contractual clauses.

The UK government has proposed wide-ranging reforms to UK data protection laws, set out in the UK Data Protection and Digital Information Bill (which was introduced to the House of Commons in March 2023 and at the time of writing is being reviewed by the House of Lords). The bill largely maintains the GDPR framework in UK law, albeit with modifications reflecting the government's intention to move away from prescriptive requirements and toward a more risk-based approach. While the UK has signalled a more business-friendly and flexible approach, which would be welcomed by operators in the digital health sector, it remains uncertain where the post-Brexit UK privacy landscape will land.

On June 29, 2022, the UK government published a policy paper titled "A plan for digital health and social care",[39] which sets out its far-reaching plans for the digital transformation of health and social care in England. The plan includes proposals for the systematic digitisation of health and social care records, and the creation of a life-long health and social care record. The proposal also aims to equip the NHS with the capacity to develop image-sharing and other technical capabilities based on AI, to enable "digitally supported diagnoses" and to establish a network of trusted research environments to support research and development.

Conclusion

Digital health companies must stay attuned to the emerging trends in the global regulation of these technologies, with the recognition that the frameworks are continuing to evolve. As demonstrated in the US, EU, and UK, a myriad of legal requirements create a spider's web for companies and investors to carefully navigate in order to avoid compliance issues and maintain momentum in a competitive marketplace. By remaining aware of the key legal constructs and staying abreast of proposed changes in these frameworks, stakeholders can play a part in shaping the legal regimes applicable to their digital health solutions. Moreover, they can reduce the risk of a compliance misstep, which may be more likely in an industry in which technological advancements outpace the legal frameworks and innovators, in many cases, operate in uncharted territory under the law.

Endnotes

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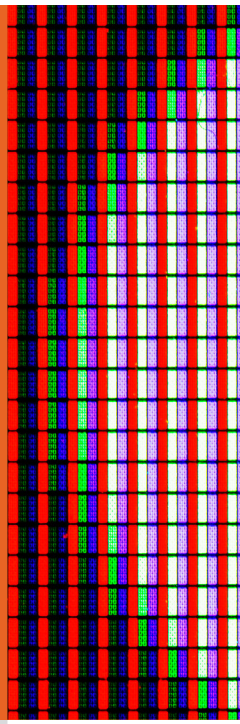

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