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Digital Health 2022

Third Edition

Contributing Editor:
Roger Kuan
Norton Rose Fulbright

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59 Tanner Street
London SE1 3PL
United Kingdom
+44 207 367 0720
info@glgroup.co.uk
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Production Editor
Jane Simmons

Publisher
James Strode

Senior Editor
Sam Friend

Head of Production
Suzie Levy

Chief Media Officer
Fraser Allan

CEO
Jason Byles

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Introductory Chapters

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Introduction


Roger Kuan


David Wallace

Norton Rose Fulbright
Johnson & Johnson

What is Digital Health?

The rapid convergence of digital technologies with healthcare over the past five years (even prior to the COVID-19 pandemic) has transformed how healthcare is delivered to the masses. The promise of digital technologies continues to transform the healthcare delivery model from a traditional model based on a "one size fits all" practice of medicine that was characterised by a provider-centric approach with information silos, to a new model that is focused on patient-centric treatment personalisation with high data accessibility and utilisation. The result is a highly personalised healthcare system that is focused on data-driven healthcare solutions and individualised delivery of therapeutics and treatments to patients using information technologies (IT) that enable seamless integration and communication between patients, providers, payors, researchers and health information depositories. A November 2020 report by Precedence Research published on *GlobeNewsWire* indicates that the global digital health market is poised to grow at a compound annual growth rate (CAGR) of around 27.9% over the next seven years to reach approximately $833.44 billion by 2027.[1]

Traditional Healthcare Paradigm

"One size fits all" approach

Disease diagnosis and treatment have traditionally been based on efficacy validation models that neatly packaged patient populations into distinct buckets (often focused just on the disease state in question) that rarely allowed for differentiation between the individual constituents. This "one size fits all" approach did not enable true personalisation of patient diagnosis and treatment based on their innate individual characteristics (e.g., genome, epigenome, proteome, microbiome, metabolome, morphology, etc.) and exposome (e.g., lifestyle, environmental exposure, socio-economic status, etc.).

One main reason why the healthcare industry adhered to the "one size fits all" paradigm for so long was the lack of capable and affordable tools and methodologies that could accurately monitor and determine all aspects of an individual's innate characteristics and then utilise that data to precisely tailor treatments or infer clinical outcomes for an individual. Due to recent digital health advances and availability of large volumes of relevant data, many of those technical hurdles have been overcome. The cost of generating and processing data that is indicative of an individuals' uniqueness (e.g., whole genome sequencing, proteomic analysis, high resolution imaging, etc.) has recently come down to such an extent that it is readily accessible to the masses and recent advances in artificial intelligence (AI) (more specifically, machine learning (ML)) techniques have powered the analysis of large and complex datasets generated by these tools to make clinically relevant insights that can help guide the diagnosis and treatment of patients based on their individual uniqueness.

Provider-centric model

Until recently, healthcare services were delivered to patients primarily through a provider-centric model, whereby patients seeking medical attention were required to go to a medical practitioner, clinic or hospital to be diagnosed and/or treated for their condition. This approach was largely driven by the healthcare industry's slow adoption of new IT (e.g., Internet of Things (IoT), wireless video communication, text messaging, electronic medical record systems, etc.) and the lack of digital health tools (e.g., wireless diagnostic medical devices, wearables, mobile apps, etc.) that allow for remote patient diagnosis and monitoring.

In the last few years, the healthcare industry's adoption of new IT technologies and other digital health tools has accelerated significantly, ushering in a new patient-centric paradigm (e.g., telemedicine, virtual healthcare, etc.) whereby healthcare services are delivered remotely to patients (almost on-demand), regardless of where they are. When the COVID-19 pandemic took hold of the world, a measure of urgency was also added as the provider-centric approach to healthcare now included a component of danger that patients would be exposed COVID-19 if they visited their providers in person.

Siloing of health information and data

Data access and analytics is the fuel that drives digital health. Patient health information has traditionally been either stored as physical files at a provider site (e.g., doctor office, clinic, hospital, etc.) or in electronic health record management systems that are incompatible with one another. This resulted in health data being siloed where they were stored, which hindered the seamless communication and sharing of health data. This also prevented the use and aggregation of such data to power analytics tools (many of which are driven by AI/ML) that are used in a variety of different applications, including drug discovery, diagnostics, digital therapeutics, pre-surgical planning, and clinical decision support.

New Digital Technologies

A host of different digital technologies are helping to provide the infrastructure and know-how to drive the digital health revolution in healthcare.

Wireless connectivity and IoMT

Wireless/mobile devices (e.g., mobile phones, wearables, medical devices, mobile applications, etc.) allow patients to access their healthcare providers and resources from anywhere around the world with wireless or WiFi data connectivity. In turn, this also allows their healthcare providers to monitor their current health status and condition. This amalgamation of devices can all be connected to enterprise healthcare information systems using networking technologies to form an Internet of Medical Things (IoMT) that allow for uniform transfer of medical data over a secure network.

Big data analytics/storage

The voluminous quantity of medical data captured and transmitted through an IoMT is then stored and analysed using Big Data storage and analytics systems that manage, curate and process the data to generate predictive insights and/or visualise the data to aid analysts in quickly interpreting the data. A 2017 white paper from Stanford University School of Medicine estimates that 153 exabytes of healthcare data was generated in 2013, and that was projected to grow to 2,314 exabytes by the year 2020.[2] Analytics can be performed on the data using traditional statistical data analysis tools or more advanced AI/ML methodologies.

Enabling New Digital Health Solutions

The adoption of digital technologies in healthcare has given rise to a number of different categories of transformative digital health solutions.

Remote patient monitoring and delivery of care

Perhaps the most visible and impactful of the categories of digital health solutions are telemedicine/telehealth and virtual care. 2020 was a banner year for telehealth as the COVID-19 pandemic led to an exponential leap in the number of patient consults using telehealth platforms due to social distancing measures and to minimise exposure.

A 2020 report by Amwell found that before COVID-19, fewer than 1% of all physician visits in the U.S. were conducted via telehealth; in just over a month after the start of the pandemic, analysis of health claims data found that this number had increased to over 50%. Of those patients who used telehealth platforms, over 90% said that they planned to continue using those platforms post-COVID-19.[3] The digital technologies that enable telehealth are wireless/mobile devices and the applications that run on them.

Moving beyond virtual doctor's visits through telehealth platforms is the concept of virtual care, whereby healthcare providers remotely deliver the full range of health services to patients by remotely monitoring patient condition and vitals (remote patient monitoring) using IoMT connected wearables and wireless medical devices; and communicate with patients to provide treatment advice and answer their questions using wireless/mobile devices that enable live and secure video, audio and instant messaging communication. This next step in the evolution of telehealth will truly change the traditional provider-centric model of healthcare delivery to patients to a patient-centric model where the wide range of healthcare services can be delivered virtually on demand and remotely wherever the patient is located.

Big data analytics and AI/ML-powered healthcare solutions

- **Personalised/precision medicine**
  Personalised/precision medicine is another digital health solution that has recently gained traction. These are healthcare models that are powered by Big Data analytics and/or AI/ML to ensure that a patient's individual uniqueness (e.g., genome, microbiome, exposome, lifestyle, etc.) factors into prevention and the treatment (e.g., therapeutics, surgical procedures, etc.) of a disease condition that the patient is suffering from. An example of this would be companion diagnostic tests that are used to predict a patient's response to therapeutics based on whether they exhibit one or more biomarkers. Large quantities of patient records including measured data of one or more patient biomarkers, the therapeutic(s) the patient is taking and the patient's clinical outcome can be analysed using Big Data statistical software tools to determine the biomarker(s) associated with a particular clinical outcome when the patient is treated with a particular therapeutic; or be used to train AI/ML algorithms that can identify biomarker(s) of relevance and infer patient clinical outcomes when treated with a particular therapeutic.
- **AI/ML enabled Diagnostics**
  The application of advanced AI/ML algorithms and techniques to process healthcare data enables critical clinical insights that link previously unrelated data inputs (e.g., imaging features, genomic/proteomic/metabolomic/microbiome biomarkers, phenotypes, disease states, etc.) to disease conditions and progression. This has resulted in diagnostic tests that have a high degree of predictive accuracy for some previously difficult to diagnose health conditions such as dementia, depression, Alzheimer's, and also enabled more non-invasive methods to diagnose and monitor disease conditions (i.e., cancer) that previously required surgical biopsies or other more invasive techniques.
- **Intelligent drug design and discovery**
  The same data that is used to train AI/ML algorithms for personalised/precision medicine purposes can also be repurposed to train algorithms that can be used for intelligent drug design and clinical cohort selection applications that aid in the discovery and the clinical study of new or novel therapeutics and re-purposing of existing therapeutics.
  For example, an AI/ML algorithm trained to predict biological target response and toxicity can be used to design novel (i.e., non-naturally occurring) chemical structures that have strong binding characteristics to a biological target with correspondingly low chemical and/or systemic toxicity. This ability to design a therapeutic compound "backwards" from looking at desired attributes (e.g., binding strength, toxicity, etc.) and then custom designing a therapeutic compound with those attributes, instead of traditional drug discovery methods that screen millions of compounds for the desired attributes, is potentially game-changing. Not only does it hold the promise to shorten the initial drug target discovery process as it moves away from looking for the proverbial "needle in a haystack" to a "lock and key" approach, but it will likely lead to drugs that have greater efficacy and less side effects for larger groups of patients.
  Those novel chemical compounds can then be administered to clinical cohorts selected using AI/ML algorithms trained to choose the most suitable patients to enroll for clinical trials used to study the efficacy and toxicity of the compounds. Currently, it takes an average 10–15 years and

$1.5–2.0 billion to bring a new drug to market with approximately half of the time and investment consumed during the clinical trial phases of the drug development cycle. One of the main stumbling blocks in the drug development pipeline is the high failure rate of clinical trials. Less than one third of all Phase II compounds advance to Phase III. More than one third of all Phase III compounds fail to advance to approval. One of the primary factors causing a clinical trial to fail is clinical cohort selection that fails to enroll the most suitable patients to a clinical trial.[4] Minimising errors in clinical cohort selection can potentially shorten the clinical trial phase and reduce the risk of clinical trial failures that are not attributable to the drug being studied.

Digital hospital

Traditional hospital workflows can be highly inefficient because of disorganisation in patient treatment workflows and difficulties that clinicians have in readily accessing or utilising patient medical information. Through the use of digital medical information management tools, much of this inefficiency can be eliminated by ensuring less workflow downtime and gaps in the way that a patient is diagnosed and treated once he/she is admitted to a hospital and allowing patient medical information to be accessed anywhere within the hospital through a multitude of different means (e.g., workstation terminals, mobile devices, etc.) and from information stored externally from the hospital.

Digital Health Legal Issues

There are many important legal issues that apply to digital health. These issues can be broadly divided into two categories: intellectual property rights (IPRs); and regulatory compliance.

Intellectual Property Rights

With respect to IPRs, there are registrable IPRs (e.g., patents, copyrights, etc.) and unregistered IPRs (e.g., data rights, trade secrets, know-how, etc.).

Patents and copyrights

With respect to digital health and patents, the most burning issue is subject matter patentability (or what qualifies as patentable). A series of US Supreme Court cases in the past 10 years have cast a shadow over the patentability of software (See *Alice Corporation Pty. Ltd. v. CLS Bank International*)[5] and diagnostic methods (See *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[6] and *Association for Molecular Pathology v. Myriad Genetics, Inc.*).[7] Successfully navigating these patentability hurdles is often a critical part of protecting the substantial investments that companies make in bringing their digital health solutions into the marketplace. Some recent US Supreme Court and Federal Circuit cases have begun to chip away at the patentability hurdles for diagnostics innovation (See *Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.*[8] and *CardioNet, LLC v. InfoBionic, Inc.*)[9] and the current expectation is that future cases will continue to swing toward protection of this important area of innovation. And in other jurisdictions around the world, computational software driven innovations face similar hurdles toward patentability.

Copyrights can be used to protect software, including code for learning platforms like various machine and deep learning models. Copyrights can also be used to protect databases and some types of data content that which is itself original (e.g., structured compilations of genomic sequencing data, structured compilations of images, audiovisual recordings, detailed diagrams, etc.), but cannot protect factual data (e.g., raw genomic sequencing data, metabolite data, proteomics data, etc.). However, there may be other legal mechanisms that can be used to protect factual data, such as contract law and trade secret protection.

Trade secrets

Because of the current limitations of patent law, trade secret protection plays an outsized role in protecting digital health innovation relative to other industries. But trade secret law has inherent limitations that make it less protective of innovation than patents. For example, trade secret law does not protect against third parties independently developing identical solutions (i.e., digital health innovations) and it requires that the trade secret owner mark their trade secrets and demonstrate that they are taking active measures to ensure that their trade secrets are not misappropriated.

Data rights

Digital health solutions tend to both generate and utilise large quantities of health data, therefore, data rights are a vital component of digital health IPRs that needs to be protected. This is particularly true for digital health solutions that are powered by AI/ML algorithms as the accuracy of their predictions are largely determined by their training using large quantities of quality training data.

As discussed above, raw factual data is generally not protectable under copyright law, so the primary means used to guard data rights is currently with contract and trade secret laws. As the value of health data rights increases, the expectation is that the body of law dealing with data rights protection will also evolve to more adequately safeguard the rights of data owners.

Regulatory legal issues

Moving beyond IPRs, compliance with state and federal regulations is also essential for digital health companies seeking to successfully develop, market or implement digital health solutions in the US.

Data privacy

Continued access to medical data relies on patient trust and the laws and regulations that underpin that trust. As data gathering and access are critical components of most digital health solutions, it is vital that digital health companies adopt data privacy policies and infrastructure that are compliant with the data privacy laws and regulations of the jurisdiction(s) in which they operate.

In the United States, the most pertinent data privacy laws are the Health Insurance Portability and Accountability Act (HIPAA) and the California Consumer Privacy Act (CCPA). The jurisdictional boundaries of HIPAA and CCPA are carved out based on both the entity gathering the data (HIPAA Covered Entities and their Business Associates) and the legal residence of the individual whose data is being gathered. That is, HIPAA only applies to a statutorily defined group of Covered Entities such as health plans (e.g., health insurance companies, Medicare, Medicaid, etc.), healthcare clearinghouses (e.g., billing service, community health information

systems, etc.), and healthcare providers (e.g., physician, clinic, hospitals, pharmacies, etc.) that are considered traditional healthcare data custodians. Importantly, this leaves a coverage gap for non-traditional healthcare data custodians such as the technology companies (e.g., Amazon, Apple, Facebook, Google, etc.) that have recently entered the healthcare marketplace through their IoT and mobile app product offerings that can diagnose and treat healthcare-related issues. The first state to attempt to fill the HIPAA coverage gap was California when it enacted the CCPA in 2018. The CCPA provides privacy rights and consumer protection for data obtained from residents of California irrespective of the type of business.

Generally, both HIPAA and CCPA regulate how businesses collect, handle and protect an individual's personal information (PI) to ensure their privacy and give them control over the sharing (informed consent) of their PI with third parties.

FDA regulatory

Another set of regulations that digital health companies need to consider are those that regulate the safety and efficacy of digital health solutions. The Federal Food, Drug and Cosmetic Act (FFDCA) and related laws are federal statutes that regulate food, drugs, and medical devices. The FFDCA is enforced by the US Food and Drug Administration (FDA) which is a federal agency under the US Department of Health and Human Services (DHHS).

Depending on whether the digital health solution is a device, system or software, the FDA may enforce a number of different regulations and programs, including: 510(k) certification; Premarket Approval (PMA); Software as a Medical Device (SaMD); Digital Health Software Pre-certification Program (Pre-Cert Program); and Laboratory Developed Test (LDT) regulated under the Clinical Laboratory Improvement Amendments (CLIA) program. One technology area of focus for the FDA recently is AI/ML-powered digital health software, which is dynamic by design and thus poses particular challenges for the FDA as the current regulatory regime is based on software being static by design. The FDA recently launched a Digital Health Center of Excellence to further the advancement of digital health solutions and address the unique regulatory issues they pose.[10]

State-specific practice of medicine laws (telehealth and virtual health)

For telehealth and virtual health companies that provide physician consultations across state lines, the Interstate Medical Licensure Compact Commission (IMLCC) regulates the licensure of physicians to practice telemedicine in member states.

The Interstate Medical Licensure Compact (IMLC) speeds up the licensure process for physicians practising telemedicine as it eliminates the need for them to individually apply for licences in each state they intend to practice in by allowing them to obtain an IMLC licence that is valid in all states that have joined the compact. The following states have joined the IMLC: Alabama; Arizona; Colorado; Idaho; Illinois; Iowa; Kansas; Maine; Maryland; Michigan; Minnesota; Mississippi; Montana; Nebraska; Nevada; New Hampshire; Pennsylvania; South Dakota; Tennessee; Utah; Vermont; Washington; West Virginia; Wisconsin; Wyoming; and the District of Columbia and Guam.[11]

The Stark Law and Anti-Kickback Statutes

Telehealth and virtual health providers who enter into business arrangements with third parties that incentivise care coordination and patient engagement are also subject to federal Stark Law and Anti-Kickback Statutes (AKSs).

The Stark Law (or physician self-referral law) prohibits referrals by a physician to another provider if the physician or his immediate family has a financial relationship with the provider. The AKS, meanwhile, bars the exchange of remuneration (monetary or in kind) for referrals that are payable by a federal healthcare program like Medicare.

These laws provide another necessary consideration for telehealth companies as they can hinder opportunities for large health systems and companies to work together and to help smaller systems and hospitals develop their own platforms or take part in a larger telemedicine network.[12]

State and federal medical reimbursement laws and regulations

2020 has been a banner year for telehealth. Even before the COVID-19 pandemic, the remote care delivery model had been gaining traction among patients, particularly those who have grown up with technology.

Currently, all 50 states and the District of Columbia now provide some level of reimbursement coverage for telehealth services for their Medicaid members. At the federal level, the Mental Health Telemedicine Expansion Act was passed as part of the Omnibus Appropriations and Coronavirus Relief Package and the CONNECT for Health Act of 2019 and has been introduced but not passed.

Conclusions

The digital health sector experienced explosive growth even before the COVID-19 pandemic accelerated its adoption by mainstream payors, providers and patients. With the continued rapid pace of change in digital health, the expectation is that the delivery of healthcare will continue to transform. Within this transformation there will be some common themes.

The ability to gather data, generate clinical insights and transform those insights into actionable clinical solution(s) will form the foundation of value creation within digital health. In this paradigm, data access becomes the new "oil rush" as data will fuel the analytics engines behind many future digital health solutions. As a result, traditional technology players such as Amazon, Apple, Facebook and Google, may create substantial competition for traditional healthcare providers. It remains to be seen whether those advantages will translate to success in the digital health marketplace.

Clinical adoption of digital health solutions will continue to be a challenge as there are significant clinician concerns about how to safely integrate these solutions into their day-to-day practice. Moreover, digital health companies must navigate the myriad of state and federal regulations/laws relating to data privacy, FDA regulatory, practice of medicine, and medical reimbursement in order for their solutions to be even accessible by clinicians in the first place.

Lastly, there are brewing geopolitical factors that may impact how well digital health companies succeed in the marketplace. Regional regulations on health data access and usage (e.g., General Data Protection Regulation (GDPR), HIPAA, CCPA, etc.), reimbursement and product approval are additional requirements to contend with for companies that are foreign to the jurisdiction to contend with. Also, many countries have begun to aggressively invest in the gathering of healthcare data (especially whole genome data) on a national level, which can potentially be leveraged to

give domestic companies an edge over foreign ones. Examples of this are the UK Biobank Whole Genome Sequencing Project and Beijing Genome Institute (BGI) Million Chinese Genome Project. It is conceivable (and likely) that the UK and China will implement data access policies that specifically benefit domestic digital health companies to give them a home-grown advantage.

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Roger Kuan is a Partner at Norton Rose Fulbright and US head of the Precision Medicine and Digital Health Practice Group, where he counsels companies that are uniquely positioned in the convergence of the life/medical sciences and technology industries on how to successfully navigate the complexities of the intellectual property (IP), data rights and regulatory challenges they encounter.
Roger has extensive experience in IP strategy and portfolio management (utility/design patents, trademarks, copyrights, and trade dress), data rights strategy, licensing and technology transactions, freedom-to-operate clearances, enforcement, monetisation, IP due diligence, and dispute resolution. His practice is focused in the life sciences sector (e.g., research tools, analytical instrumentation/software, digital therapeutics, medical devices, diagnostics, biomanufacturing equipment, etc.) with an emphasis in emerging technologies such as precision medicine (e.g., genomic sequencing platforms, AI/ML, computational genomics/bioinformatics, molecular diagnostics, companion diagnostics, etc.), digital health (e.g., mobile apps, clinical decision support, software, AI/ML imaging diagnostics, wearables, etc.) and 3D printing/bioprinting.

Norton Rose Fulbright
555 California Street
Suite 3300
San Francisco, 94104
California
USA

Tel: +1 628 231 6800
Email: roger.kuan@nortonrosefulbright.com
URL: www.nortonrosefulbright.com

David Wallace is a member of the Johnson & Johnson Law Department, and Group Leader of the Health Technology Team. In his role as Group Leader, David is primarily responsible for day-to-day activities regarding the patent aspects of the health technology initiatives across the Johnson & Johnson Family of Companies.

Johnson & Johnson
510 Cottonwood Drive
Milpitas, California 95035
USA

Tel: +1 408 273 5101
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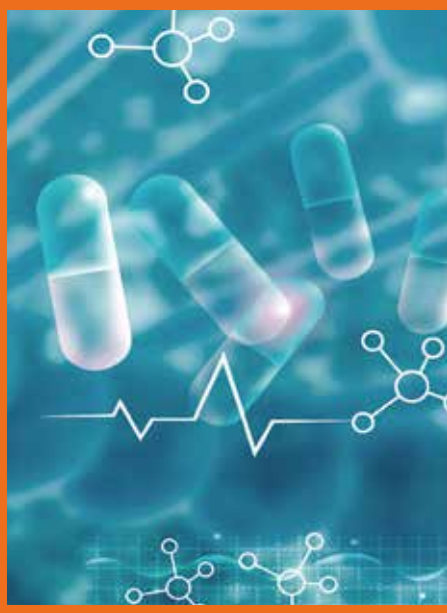

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