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HEALTH TECH TRENDS 2023

— THOUGHT LEADERSHIP

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What is on the horizon for the use of data and technology in the healthcare and life sciences sectors? Where do opportunities lie, and what should participants be thinking about before making the next big move? We provide an outlook on Health Tech trends to watch in 2023.

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Artificial intelligence and machine learning will continue to enhance the healthcare and life sciences sectors

Artificial intelligence (AI) and machine learning technologies are becoming ever more embedded within the healthcare and life sciences sectors. In diagnostics, as the technology continues to develop to provide greater accuracy and reliability, we are beginning to see cases where AI is proving better at recognising and diagnosing health irregularities than humans. AI is also now playing a greater role in drug discovery and development, leading to more time-efficient and cost-effective processes than traditional methods. This technology is also paving the way for effective personalised medicine at scale by allowing targeted treatment and therapies for individuals based on deeper analysis of genomic, biochemical and other patient data to help analyse patterns in huge data sets.

What's next?

- As biotech and pharmaceutical companies continue to evolve the healthcare and life sciences sectors through development and commercialisation of AI technology, and as AI becomes more sophisticated and "creative", key legal issues in focus in 2023 will include concepts of "inventorship" and "patentability" of products created by, or using, AI as well as provenance and ownership of data.

- Although AI technology is developing faster than the legal frameworks that seek to regulate it, in 2023 we can expect significant evolutions in the regulatory frameworks governing AI. The EU's AI Regulation is set to be adopted, and the proposed AI Liability Directive is expected to follow. The UK plans to create an AI framework for sector-specific requirements. In the US, we can expect to see progress of the AI Bill of Rights. These laws and regulatory guidance will overlay existing privacy, product safety and other laws, as well as emerging ethical frameworks, in regulating and shaping AI development, use and governance.

- In parallel to the development of legislative frameworks for AI, we will see litigation and regulatory enforcement testing key issues, in particular around liability, transparency of use, and intellectual property (IP) rights.

We are seeing divergence across jurisdictions in approach to concepts of "authorship" and "inventorship" in connection with AI. Development of the law in this area will fundamentally impact how intellectual property rights are secured and licensed, and ultimately the successful commercialisation of products generated with AI involvement.

—**CLAUDIA MILBRADT**
Partner

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Apps and wearables will become more integrated into mainstream healthcare

Health-related apps and wearables have become commonplace. As their capabilities and accuracy improve, the role they play in healthcare is evolving. In particular, devices for monitoring and management of certain medical conditions are becoming more mainstream, such as diabetes monitors being incorporated into patient treatment plans. This multi-billion dollar industry is forecasted to increase significantly over the next few years.

What's next?

- In 2023, companies providing health-related apps and wearables will need to navigate an evolving range of legal frameworks as these services are increasingly provided across geographic borders, with different regulatory environments multiplying the risk that wearables and apps deployed internationally are classified as regulated devices and services.

With increasing cross-border provision of products and services, identifying and navigating the relevant regulatory regimes – such as those relating to healthcare provision, medical devices, intellectual property and data use – will be critical to the success of pioneers in this area and a potential weapon in competition.

—**STEPHEN REESE**
Partner

- Increased reliance on cloud technology to support apps and wearables is becoming increasingly regulated, with the EU's proposed Data Act making its way through the legislative process in 2023, a number of cloud market studies and consultations underway in various jurisdictions, and localisation requirements under privacy laws impacting server locations.

- As we see increased integration between providers of apps and wearables and third-party platforms to enable holistic patient care, we will see innovative collaborations backed by complex contracting arrangements to address issues such as IP and data ownership, data privacy and allocation of liability.

Medical robotics, devices and augmented or virtual reality technology will become more established in providing remote treatment and healthcare training across borders

The use of virtual and augmented reality technology to support the training of surgeons is no longer science fiction, and new applications of these technologies in a live healthcare setting are being explored. Pilot projects testing the use of medical robotics will continue to break-down barriers in the provision of remote healthcare treatment. Treatment performed on a patient by a medical specialist in another country will move from concept to reality.

What's next?

- In addition to having to navigate the complexities of cross-border provision of services, technologies that seek to overcome challenges of spatial separation between doctor and patient will face novel questions in relation to allocation of roles and responsibilities under medical device laws, product liability regimes, data protection regulations, and cyber security requirements, as well as facing new and unique applications of medical professional licensing and liability rules, medical services reimbursement laws, telecommunications regulations and employment laws.

- The use of medical robotics, devices and augmented or virtual reality requires seamless integration of hardware and software. Where their development has involved collaborations or use of third-party technology, proper licensing of the underlying IP rights to ensure the correct scope of permitted and prohibited uses, as well as appropriate IP ownership allocation between various parties, will be crucial to protect their respective commercial interests and financial contributions.

Harnessing health data will drive healthcare innovation

The range and volume of data processed in the healthcare sector is large and growing. The rules governing its use globally are fragmented, nuanced and often uncertain. New legal frameworks are developing, new consent and opt-out models are being put forward, and anonymisation and pseudonymisation techniques are being refined. Big technology companies are leveraging their ability to provide valuable insights from large datasets to unlock health-related insights from individuals' data, and thus make a real difference in the way healthcare is provided. Thoughtful data use and governance strategies are increasingly key to success.

What's next?

- Extracting value out of personal data, such as genomic data, will unleash the potential of drug discovery and new, personalised medical treatments. For the benefits of this data to be realised, however, the public needs to be reassured that the data is protected and used appropriately. We can expect a growing number of rules governing

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The commercialisation of medical robotics and technologies enabling remote medical care will give rise to novel applications of existing legal frameworks and expose areas where laws have not kept pace with the potential uses of increasingly sophisticated technology in a digitally connected world. Clear contractual arrangements as to rights, responsibilities and legal recourse will also be crucial.

—**GUNNAR SACHS**
Partner

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Laws affecting how health data may be shared are increasing in number and some come with extraterritorial effect as well as severe and active enforcement regimes. In 2023 many healthcare and life sciences businesses will be reviewing their data infrastructure, processes and risk positions to tackle data transfer frictions and data governance requirements in a holistic manner, as well as exploring options for anonymisation, pseudonymisation and encryption.

—**CLARICE YUE**
Consultant

As antitrust and competition enforcers put a premium on protection of competitive healthcare markets, we anticipate them continuing to analyse the role of healthcare data as an asset with the potential to impact competition.

—**LEIGH OLIVER**
Partner

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As integrated online healthcare platforms grow internationally, they need to manage compliance with multiple legal regimes, including local rules on healthcare services, privacy and cross-border transfers. In regions that do not have harmonised rules, it is up to the platform operators to create systems that enable the seamless provision of services and circulation of data, while achieving compliance across their geographic footprints.

—**BRIAN HARLEY**
Consultant

access, sharing and legal requirements for hosting health data. Leading in such efforts will be the EU's proposed Health Data Space regulation, which will seek to empower individuals to control and utilise their electronic health data in their home country or in other Member States, fostering a genuine single market for digital health services.

- We are seeing significant volumes of data flows and data transfers in the healthcare sector, with sector innovation being driven by partnerships and collaboration. In 2023 businesses will face increased complexity in navigating laws relating to the transfer and governance of health data, particularly due to the proliferation of data protection laws and enforcement, with health data being subject to additional rules in relation to its storage, collection and hosting, in many cases.
- Access to, and appropriate use of, healthcare data will continue to be an input for the development of innovative products and services. Competition enforcers have focused on data as an asset that is important to competition in digital markets. As the role of data continues to increase in importance for healthcare innovation and delivery, competition authorities are likely to give greater attention to its role in the competitive dynamics of healthcare markets.

Telemedicine and integrated healthcare services platforms to become the 'new normal' in healthcare

COVID-19 accelerated the digital transformation of the healthcare sector, with virtual healthcare services becoming culturally accepted and often the preferred patient mode of access. Despite the exceptional groundwork of the last few years, the market has experienced a levelling out in investment and use. That is expected to change as rising costs of in-person healthcare provision combine with advances in technology and remote options such as "virtual wards" are explored. Market players that thrive in 2023 (and beyond) will be those who can reimagine medical care and deliver new customer journeys that unlock speed, better quality and a wider range of medical care options.

What's next?

- We are seeing an increase in clients developing fully integrated platforms and rolling out cross-border telemedicine offerings. Service providers are connecting physicians, pharmacists, hospitals and health insurers in a virtual environment, and bringing together an ever-wider range of market participants, including private retail clinics, large technology firms and digital health start-ups.
- Cloud services, device connectivity and interoperability will be in the spotlight in 2023 and beyond. Health data must be able to flow to and from the hands of the various participants who store, aggregate and process that data – patients, service providers, platform operators, insurers, research institutions and others. Robust contractual

foundations will be key to guarantee effective service allocation, IP and data ownership, and compliance with technical security measures regarding the handling and storage of health data in line with applicable laws.

Healthcare critical infrastructure will remain an attractive target of cyber crime

As the healthcare sector continues to digitalise its infrastructure, and given the particularly high sensitivity of the personal data it processes, cyber criminals will continue to target healthcare businesses, seeking to exploit any vulnerabilities.

What's next?

- In 2023, life-critical services will remain an attractive target of cybercrime. We can expect attacks to be more sophisticated – from social engineering using deepfakes to targeted ransomware attacks adapted to a particular hospital's information systems.
- Governments and regulators have been working on updates to their cybersecurity policy frameworks, including new legislative initiatives in the EU such as NIS2, the Cyber Resilience Act, and the European Health Data Space, which will help ensure the cyber security of digital products and critical networks. A greater number of healthcare businesses are becoming subject to legal requirements to have incident response plans in place. Even where not legally required, business are increasingly relying on such plans to navigate the various incident management and reporting requirements under a patchwork of laws.

Supply chain resilience and transparency will be a key focus

Medical sector supply chains are subject to a number of regulatory requirements aimed at ensuring quality standards and stock availability. Tragic incidents where contaminants in medicines have resulted in deaths have shaken trust in these standards in certain markets, and 2023 will see a spotlight on accountability and traceability throughout the supply chain.

What's next?

- Geopolitical tensions, State-protectionism and the continued limitations in the flow of goods and people across the globe are significantly impacting the supply chain for packaging, raw materials or key components and chemicals. The supply chain for health tech products is also suffering from the semiconductor chip shortage.
- Additionally, medical supply chains are also expected to be in scope of the incoming ESG requirements in Europe, including supply chain due diligence obligations regarding environmental and social impact, and the need to substantiate green claims.
- In 2023, we will see businesses exploring strategic M&A transactions, commercial partnerships, investments in blockchain and other technologies to monitor and manage supply chain traceability in order to procure components – whether chips, packaging or active ingredients – with greater efficiency, reliability, transparency and safety assurance, as well as to help ensure compliance with regulatory requirements.

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We are seeing businesses becoming more resilient and cyber-aware, and expect key projects for healthcare businesses in 2023 to include investment in the resilience of systems and supply chains, and preparations to respond effectively to high-risk cyberattack, including navigation of the various regulatory and customer reporting requirements involved.

—**DARYL FAIRBAIRN**
Counsel

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Like the tech sector, the scarcity of chips arising from bottlenecks and disruptions in the semiconductor supply chain is reducing the number of med tech devices available in the market and limiting research and development activities for new products. To manage this and other challenges, rethinking the health tech supply chain will become a key focus for many healthcare and life sciences businesses in 2023.

—**ANDREA ANDOLINA**
Senior Associate

CONTACTS

Gunnar Sachs
Partner
Düsseldorf
T: +49 211 4355 5460
E: gunnar.sachs@cliffordchance.com

Stephen Reese
Partner
London
T: +44 207006 2810
E: stephen.reese@cliffordchance.com

Daryl Fairbairn
Counsel
New York
T: +1 212 878 4960
E: daryl.fairbairn@cliffordchance.com

Claudia Milbradt
Partner
Düsseldorf
T: +49 211 4355 5962
E: claudia.milbradt@cliffordchance.com

Rita Flakoll
Global Head of Tech Group Knowledge
London
T: +44 207006 1826
E: rita.flakoll@cliffordchance.com

Ling Ho
Partner
Hong Kong
T: +852 2826 3479
E: ling.ho@cliffordchance.com

Josep Montefusco
Partner
Barcelona
T: +34 93 344 2225
E: josep.montefusco@cliffordchance.com

Leigh Oliver
Partner
Washington, DC
T: +1 202 912 5933
E: leigh.oliver@cliffordchance.com

Brian Harley
Consultant
Hong Kong
T: +852 2826 2412
E: brian.harley@cliffordchance.com

Dessislava Savova
Partner
Paris
T: +33 1 4405 5483
E: dessislava.savova@cliffordchance.com

Devika Kornbacher
Partner
New York
T: +1 212 878 3424
E: devika.kornbacher@cliffordchance.com

Jonathan Kewley
Partner
London
T: +44 207006 3629
E: jonathan.kewley@cliffordchance.com

Clarice Yue
Consultant
Hong Kong
T: +852 2825 8956
E: clarice.yue@cliffordchance.com

Carolin Kemmner
Counsel
Düsseldorf
T: +49 211 4355 5488
E: carolin.kemmner@cliffordchance.com

Andrea Tuninetti Ferrari
Counsel
Milan
T: +39 02 8063 4435
E: andrea.tuninettiferrari@cliffordchance.com

Andrea Andolina
Senior Associate
Milan
T: +39 02 8063 4240
E: andrea.andolina@cliffordchance.com

Yannick Frost
Senior Associate
Düsseldorf
T: +49 211 4355 5617
E: yannick.frost@cliffordchance.com

Molly Margiotta
Associate
London
T: +44 207006 2888
E: molly.margiotta@cliffordchance.com

Jennifer Saionz
Associate
New York
T: +1 212 878 8346
E: jennifer.saionz@cliffordchance.com

Laura de Arroyo Garcia
Trainee Solicitor
Paris
T: +33 1 4405 5259
E: laura.dearroyo@cliffordchance.com

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CHANCE

www.cliffordchance.com

Clifford Chance, 10 Upper Bank Street, London, E14 5JJ

2302-004612