C L I F F O R D



HEALTHTECH TRENDS 2024



- THOUGHT LEADERSHIP







From medical microrobots to patient digital twins to generative Al for the creation of synthetic health data, we take a look at the next wave of tech innovations creating opportunities and challenges for healthcare and life sciences in 2024 and beyond.

Advances in AI/ML and machine perception are supporting the rise of next generation medical robotics

In <u>Healthtech Trends 2023</u>, we explored how advances in medical robotics are moving remote healthcare treatment from concept to reality. For years, robotic assistance has been transforming healthcare provision in other areas too: surgical-assistance robots are becoming capable of more complex and precise procedures, rehabilitation robots are supporting therapy, and other robots are monitoring and transporting patients, dispensing medicine and disinfecting equipment. Now, medical robotics is advancing even further as AI/ML and machine perception are progressing and innovations to overcome technical challenges are being engineered.

What's next?

- With the increasing integration of AI/ML, IoT technologies, data analytics and machine
 perception robotics across a range of healthcare use cases is expected to reach
 higher levels of precision, accuracy, and autonomy and to have the capacity to react
 and adjust performance in real-time. In some cases—such as medical microrobots in
 the body—microscopic technologies have the potential to yield massive results.
- These technologies will continue to face regulatory and other legal hurdles in addition
 to traditional requirements for the provision of medical care. These include navigating
 obligations under medical device regulations, product liability regimes, new Al-related
 rules, and data and cyber laws.
- The integration of hardware and software to enable medical robotics will continue to raise legal and commercial issues. Contracting for the use of third-party technology will become more strategic and complex, with a focus on extended supply chain due diligence and security assurances, incentivisation of reliable service levels, and appropriate allocation of rights, responsibilities and liabilities.
- Availability of reliable connectivity and digital infrastructure will also be crucial, adding another layer of complexity to contract negotiations and deployment considerations, particularly in contingency plans and the allocation of risk for system outages and connectivity failures.

Technology is continuing to help democratise healthcare

The pandemic supercharged the proliferation of telehealth, telemedicine, and other remote health-monitoring solutions in many jurisdictions and, with this, discussions on broadening access to health data. However, despite services being increasingly digitalised and patients being empowered to actively manage their health, healthcare systems remain strained with providers continuing to confront the challenges of aging or expanding populations, staff shortages and burnout, inefficient processes, and access limitations.

What's next?

 New requirements and guidance from regulatory authorities relating to access to healthcare services and clinical trials are providing an opportunity to tackle these issues and perhaps to also combat health inequities.



- Digital solutions are expected to continue supporting greater efficiencies in the provision of care in hospitals. Al-enabled digital assistants will provide greater efficiencies by helping to manage administrative tasks and by optimising waiting lists and resources. Digital wards will alleviate some impacts of staff shortages by facilitating automated point-of care observation capture, real-time tracking of patient results and staff alerts for scheduled tasks.
- With a continuing shift to decentralised healthcare, including higher quality care at home, some providers are turning to healthcare-as-a-service (HaaS) and monitoringas-a-service (MaaS) models to bring together connected devices and IoT infrastructure for more integrated data and clinical workflows. The EU Data Act includes rights and obligations designed to increase the accessibility of data generated by connected products, creating both challenges and opportunities for providers of IoT-connected medical devices and health wearables and for other participants who could use that data to provide services to the users of such connected products.
- Expectations about the capabilities of online symptom checkers and other Al-powered technology will increase as they become more accurate and tailored. This will bring into focus issues around when laws relating to medical devices and provision of healthcare services begin to engage.
- In the life sciences, real-time tracking through wearable technology is expected to increase the adoption of decentralised clinical trials, further widening access and recruitment by reducing location-based limitations on participation.
- Increased reliance on technology will require effective integration of patient-facing and provider-facing platforms and devices and could trigger the attention of regulatory authorities who may want to scrutinise the role of the various stakeholders involved. The delivery of personalised, location-agnostic healthcare services will increase potential vulnerabilities given the greater number of points of supplier failure, cyber incidents, and privacy issues and could broaden their impact across the healthcare ecosystem. Legal requirements for cyber and operational resilience in critical infrastructure are multiplying, expanding in scope, and becoming more stringent.

Patient digital twins are advancing personalised medicine

Precision medicine is continuing to make use of multiomic data to improve predictive accuracy and ultimately to improve diagnoses and targeted treatment. Efforts are also continuing to integrate multimodal patient and population data with updates in real time on both the patient and the environment. Advancements in processing, integrating, and applying data are bringing us closer to the ultimate form of personalised care: digital twins (virtual representations) of patients. Patient digital twins can provide powerful predictive capabilities for both emergency response and preventive care through real-time monitoring.

What's next?

- Digital twin technology for personalised medicine is expected to develop in the form of digital biological systems that model and monitor conditions in a more targeted way. Even without a "full" patient digital twin, genomic data and large volumes of digitised personal health data combined with AI, provide the tools for increasingly personalised treatments. Projects and partnerships that unlock health data and genomic data pooling will be an area of focus and investment. In collaborations involving data pooling, parties will focus on precisely defining the permitted uses of data and the ownership and licensing of IP to protect their respective commercial interests.
- Digital twins are also expected to significantly assist with clinical trials—for example, by increasing control and test group size by forecasting clinical outcomes of a subset of clinical trial participants.



- Parties will need to navigate privacy considerations, particularly in connection with secondary uses of health data. This issue will feature prominently when parties rely on third parties to collect any patient consents or to deliver transparency information.
- We can expect to see a growing number of big data and technology companies
 entering the healthcare market, retailers making further inroads into retail healthcare,
 and insurers focusing on products and services aimed at effective management of
 health conditions. These parties bring with them a different approach to deploying new
 products and services, disrupting traditional healthcare.



Breaking down data silos will be key for value-based care and omnichannel care

Health data access and use is being pursued by businesses and promoted by governments in various parts of the world to help generate new products and services and to stimulate competitive markets. In some jurisdictions, omnichannel patient interactions – where multiple service providers across a patient's journey operate together via the exchange of information across platforms – are growing in popularity as a means of improving the patient experience. In other jurisdictions, there is a continuing shift toward value-based healthcare with a data-fuelled, holistic view of patient populations to pay doctors based on the level of positive impact achieved for patients.

What's next?

- Healthcare providers, life sciences companies and medical organisations are
 accustomed to being required to maintain tight controls on sharing health data.
 However, navigating these rules will become more complicated. Privacy laws
 continue to proliferate and diverge globally including, in some cases, requirements
 specific to health data and we expect more data privacy and security laws to sit
 alongside laws that seek to facilitate, or even mandate, certain types of health data
 sharing and access.
- In the EU, the Data Governance Act and Data Act made groundbreaking changes in this direction, and attention is now focused on the provisional agreement by the Council of the EU and the European Parliament for a European Health Data Space, which sets out rules, common standards and practices as well as infrastructure and governance frameworks to empower individuals through increased digital access to, and control of, their electronic personal health data. It aims to support the free movement of health data, as well as secondary use for research, innovation, policy-making and regulatory activities.
- Data sharing across different stakeholders in the healthcare ecosystem will be key to
 unlock data-driven decision-making. We expect greater focus on data sharing
 between different parties. This will require parties to enter into potentially more robust
 data-sharing agreements in an environment where market norms for such agreements
 are evolving.
- Organisations sharing sensitive data or involved in significant acquisitions of data will
 also need to remain alert to potential antitrust risk. Competition authorities have
 continued to scrutinise transactions that could result in significant acquisitions of data
 and to intervene in pharma IP disputes. Healthcare companies could come under
 scrutiny when implementing IP and data strategies, especially in the event of
 escalations from complainants.

Diversifying AI use is supporting innovation and efficiency

For many years, Al/ML have been making drug discovery, development, trial and assessment more efficient and accurate. We are now seeing an emerging role for generative AI (GenAI) in accelerating de novo drug design to identify drug candidates. The creation of synthetic datasets with GenAl is also unlocking medical research that might have otherwise stalled due to privacy restrictions or other limitations on data availability. GenAl has also been assisting with medical diagnostics in healthcare settings, in some cases achieving accuracies that are on a par with, or even better than, medical professionals.

What's next?

- Al-specific laws will continue to emerge, following notable developments such as the EU Al Act and the US framework for Al with President Biden's Executive Order calling for Al regulation in "critical" fields such as healthcare. The interplay between Al-specific laws, Al-relevant laws and other, related frameworks that already exist – such as privacy requirements and medical device regulations - will require careful consideration for the significant number of medical devices, apps and platforms that will leverage Al-based systems.
- While greater certainty around regulatory positions and acceptable safeguards for Al will help improve acceptance of AI tools in healthcare and the life sciences over time, legacy agreements with service providers that rely heavily on the use of Al will need to be reviewed. Many large business-process-as-a-service (BpaaS) outsourcing arrangements will not have envisaged the use of generative AI and new market conditions and will need to be revisited to address gaps and attendant risks. (See our briefing: Al in US Healthcare Outsourcing – It's Time to Check Your Contracts.)
- We expect to see regulatory enforcement and litigation testing key issues around liability, transparency of use, and IP rights. How the AI works, how it was trained, what data was used, and what steps have been taken to mitigate unfair bias will be among the questions raised when AI, particularly GenAI, is used in clinical trials and drug discovery. Further developments of the law in this area will significantly impact the successful commercialisation of products and services that rely on Al.
- Al companies are collaborating with, and providing services to, pharmaceutical and other healthcare organisations. Al capabilities will continue to be a focus for mergers, acquisitions, investments and strategic collaborations and other alliances. Organisations will need to monitor tightening or otherwise changing rules relating to foreign investments. New proposed EU legislation will increase the number of FDI filings required for large deals across EU member states. Upcoming US restrictions on outbound investment aimed at the development of critical technologies in "countries of concern" for military, intelligence, surveillance or cyber-enabled capabilities will also block, or bring additional complexity to, Al transactions.



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