KPMG

AI in Healthcare

Life Science and Biotech Regulatory Solutions

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The new frontier in healthcare innovation

The Next Generation of Healthcare Delivery

Developments in artificial intelligence (AI) over the last 10 years have revolutionised the way we interact with businesses, social media and advertising. Tech companies optimize deep learning (DL) and other machine learning (ML) techniques within their internal processes to both improve feed suggestions and target advertising more effectively.

Translating these innovations to a healthcare setting to improve patient outcomes is the new frontier of healthcare innovation with wide-ranging implications for patients, regulators, payers and life science businesses. ML algorithms capable of providing insight and predictions can assist healthcare practitioners (HCPs), delivering risk factors, diagnoses and treatments for patients earlier on in their care pathway and disease progression. Furthermore, using ML to provide individualised diagnostic and treatment decisions for patients is also of great interest to pharmaceutical companies and reimbursement agencies looking for greater impact on patient outcomes.

AI strategy

Pharmaceutical, Medical Device and Diagnostic companies should act now to adopt an AI strategy for bringing these technologies into the hands of HCPs and patients.

In September 2021, the UK government announced its National AI strategy[(1)] highlighting key multi-sector initiatives including developing a national and international semiconductor supply chain review, launching a new National AI Research and Innovation programme and ensuring increased diversity in AI to develop the UK's industry over the next 10 years. The responsibility for regulating these developing technologies overlaps several UK regulating agencies as well as global regulators.

The life sciences sector must be agile and forward thinking to navigate the regulatory landscape for AI use in healthcare applications. KPMG's Life Science & Biotech Regulatory Solutions team helps businesses to work proactively, enabling them to pre-empt regulator demands around their software and continuously improve their processes in the areas of data integrity, data privacy, patient safety and quality management processes.

Potential use cases

Radiology & Hospital Bed Optimisation

AI has shown great promise in the field of healthcare. Radiology is an area of consistent staff shortages in the UK[2] and using AI to address this shortage is an obvious use case given the superlative nature of deep learning neural networks in analysing and classifying images. Nationally the NHS has taken great strides to scale up efforts to implement AI across the service, particularly during the pandemic, where NHSX successfully gathered COVID-related chest Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) scans of over 60,000 images to create a national database for training ML models[3] in conjunction with the drafting of the NHS Data Saves Lives strategy[4].

The NHS has targeted the freeing up of 2000 to 3000 hospital beds as the first point in its 10 Point Efficiency Plan. Patient bed allocation is another potential use for AI in the healthcare service, where it could be used to predict the flows of patients being admitted from A&E. The NHS has demonstrated using a Monte Carlo tree search and reinforcement learning to better predict capacity and improve patient experience[5]. Using AI can help understand the nuances of the reality of hospital bed space, which is well understood by hospital staff but difficult for traditional computer systems to schedule.

Drug Discovery

Recently winning Science Magazine's breakthrough of the year, a highlight for AI in 2021 has been Deepmind's AlphaFold system producing accurate AI predictions of protein folding[6]. The implications of which is strongly felt in the drug discovery community, where accuracy of protein folding can greatly increase the effectiveness of new drug discovery. Furthermore, AI has potential to be used for in silico virtual trials in the pre-market drug discovery phase, simulating outcomes that would not be possible in a clinical trial potentially cutting down the need for animal models and reducing R&D spend.

AI in Healthcare Start-Up Spotlight: Qureight

Extensive imaging datasets are required to train and develop machine learning models. The initial step of data curation is perhaps the most crucial element of this process as it requires a dedicated infrastructure and human expertise. The Cambridge based data company **Qureight** analyses and curates clinical information to better understand disease progression and drug response in patients with complex diseases.

CEO Dr Muhunthan Thillai said "our platform technology utilises complex imaging and structured datasets to identify combined biomarkers of progression in diseases such in Idiopathic Pulmonary Fibrosis (IPF). We recently showed that the platform could utilise models of CT scans and complex data to track this condition over a short period of time[7]. We believe that these tools will be very useful in the development of new drugs for IPF".

CSO Dr Alessandro Ruggiero said: "data curation, labelling and segmentation is a very lengthy process and requires highly skilled radiologists to help build the machine learning algorithms. AI-assisted annotation tools available on the Qureight platform can speed up this process and deliver models faster and more accurately."

How will regulators respond?

AI as a medical device

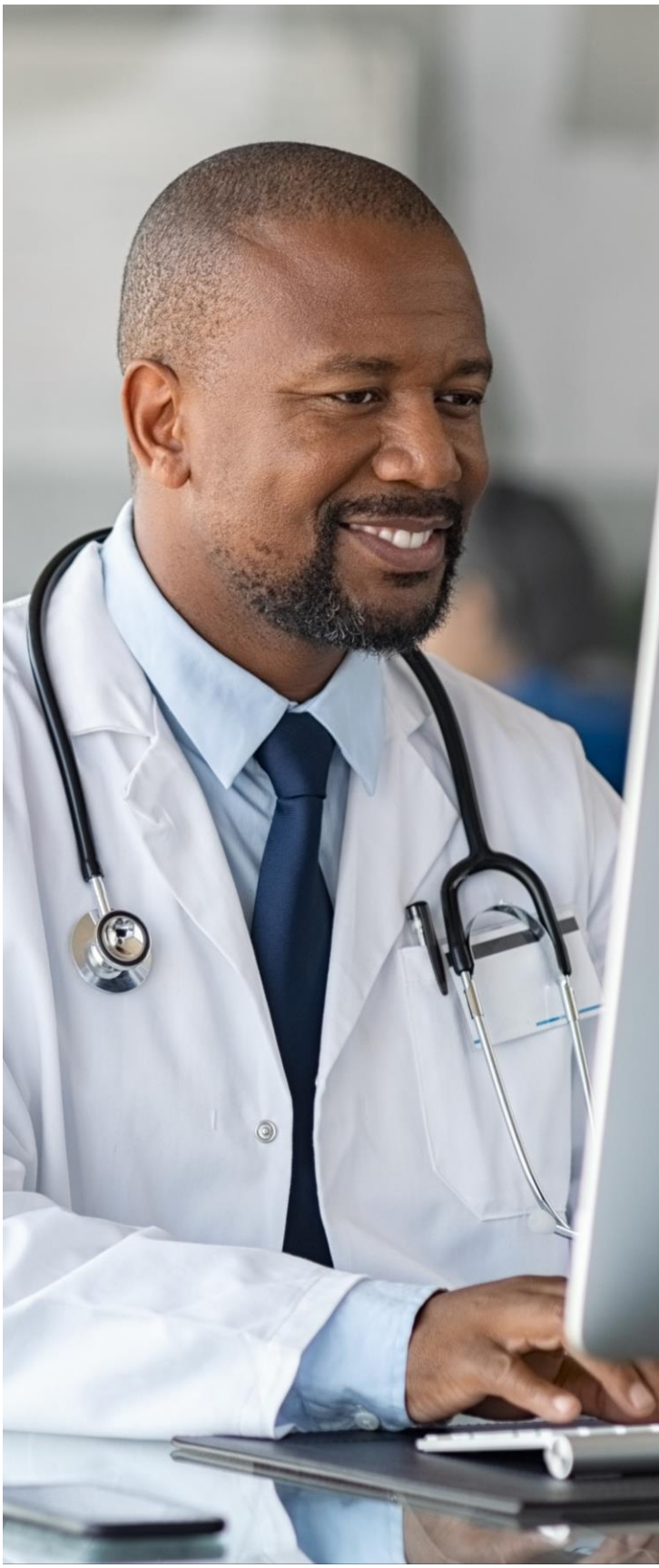
The question facing all life science companies wishing to use AI in their products and services to improve patient care is how regulators around the world will respond to developments in the AI space. Albeit imperative to utilise, healthcare data is highly sensitive, so it is expected that individuals, healthcare providers and regulators will want to know who has access to these data and how it is protected. In the EU, AI used in medical applications falls under the Medical Device Regulation (MDR) 2017/745. Under this regulation, AI applications would be classed as Software as a Medical Device (SaMD) which have specific requirements for businesses to meet in demonstrating safety, validation and clinical evidence.

Regulator oversight

For life sciences businesses wishing to develop SaMD, the regulatory oversight for their AI technologies will be subject to the MHRA, FDA, European Competent Authorities, Health Canada and other global regulators.

The FDA, MHRA and Health Canada have released a guide to Good Machine Learning Practice (GMLP)[8] which covers 10 areas manufacturers can address to support the safe and effective development of AI for Healthcare. A focus on representative patient validation data sets, good software engineering principles and re-training risk management is key to comply with these principles.

An important consideration for regulators in this space is the balance between fostering of innovation and the primary directive of ensuring patient safety. When considering the checks needed on AI SaMD products the regulators need to develop their understanding of the potential upsides and pitfalls of AI with a clear and transparent system that places patient safety at the heart.



Future Considerations

Cyber security for AI companies

Despite the attractive prospects of AI use cases, a challenge for the sector are the real-world impacts to patient safety and privacy if AI used in Connected Medical Devices or the manufacturing process of a Connected Medical Device is compromised by a cyber-attack.

Most governments and regulators have become more proactive in minimising security flaws by guiding connected medical device companies through development of specific design recommendations. These include the protection of networks, enhancing product cybersecurity resilience, remediating vulnerabilities, and mitigating potential cybersecurity risks associated with products from design and development, to manufacture and testing, and throughout the product lifecycle.

Currently, there is a lack of requirements for connected medical device cyber security that companies responsible for the design, manufacture, packaging and labelling of a medical device, such as biopharmaceutical, medical technology, and manufacturers need to comply with. There are typically many characteristics of a connected medical devices, making a 'one size fits all' set of requirements to cyber security compliance difficult to achieve.

KPMG Life Science & Biotech Regulatory Solutions for AI companies

Businesses that incorporate AI as a part of a healthcare process will need to be alert to the current regulations in the medical device space, developing quality management processes to cover their internal product development. Moreover, it is essential that these businesses are forward thinking when it comes to regulatory compliance.

KPMG's Life Science Regulatory Solutions team can help companies to evaluate the forthcoming regulatory challenges and prepare for all eventualities enabling you to bring your product to market in a streamlined and patient focused way. Regulators will want to see a high level of data integrity and privacy as well as significant risk management processes to enable these devices to reach the hands of healthcare practitioners and ultimately benefit patient outcomes

KPMG will be hosting an AI in Healthcare Regulatory roundtable in March 2022 to discuss the important topics in this article. Please contact: ewan.kerredwards@kpmg.co.uk for more information and details of this exciting event.

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