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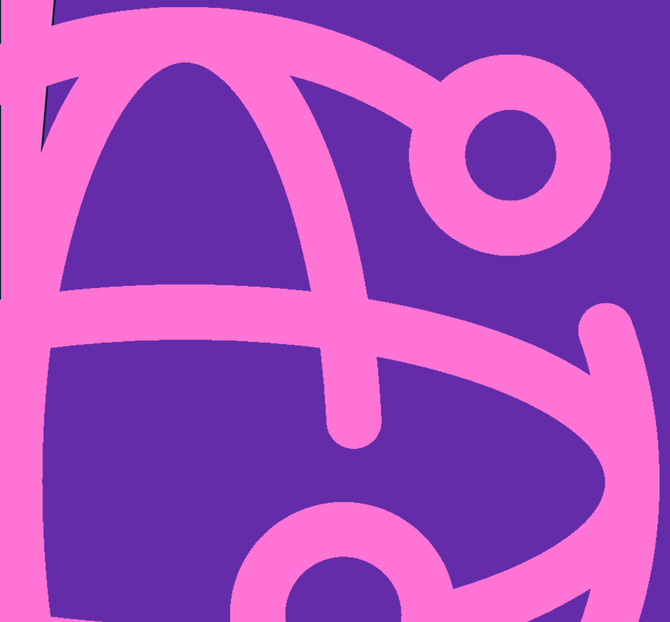
The Market Access People

If you're unsure about AI digital clinical safety risks...



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AI Digital Clinical Safety Risk

The advent of artificial intelligence (AI) in healthcare promises to revolutionise patient care pathways, offering unprecedented advances in digital clinical support and decision-making systems. AI-driven systems have the potential to significantly improve condition severity assessments, treatment pathways, and diagnosis accuracy. However, their integration into healthcare settings introduces a new class of clinical risks that necessitate careful consideration and a new approach to safety standards.

The Limitations of Current Standards

DCB 0129 and DCB 0160 have been the cornerstone of clinical risk management in the UK for more than two decades, guiding the development and deployment of Digital Health systems. However, they were drafted at a time when AI's role in patient care was not anticipated, and the dynamic, data-driven nature of AI, coupled with its evolving learning capabilities, introduces potential hazards that necessitates a re-evaluation of clinical risk management. The existing frameworks may be sufficient to guide clinical safety activity, but what we need to think about AI related risks and hazards is radically different.

The Need for a New Approach

The integration of AI into clinical decision-making processes necessitates a re-evaluation of risk management.

AI Digital Clinical Safety Risk

The unique attributes of AI-driven systems including traceability, explainability, drift, bias, fairness, and transparency require explicit attention. These terms demand a simple plain English definition if we are going to truly understand the risks associated with them:

Traceability refers to the ability to track the decision-making process of an AI system, including the data inputs and algorithmic paths taken to arrive at a conclusion.
Explainability entails the capacity of an AI system to present its processes and decisions in understandable terms to users, ensuring clinicians can interpret AI recommendations accurately.
Drift denotes the change in an AI system's performance over time, as it learns from new data, which can lead to deviations from its original accuracy.
Bias refers to systematic errors in AI decision-making that can arise from unrepresentative training data or flawed algorithms, potentially leading to unfair outcomes for certain patient groups.
Fairness is the principle that AI systems should make decisions without discrimination or prejudice, ensuring equitable treatment for all patients.
Transparency is the degree to which AI's functioning and decision-making processes are open and understandable to users.

The deployment of AI-driven systems introduces new patient safety hazards and changes the focus of existing ones. Those with oversight and governance roles need to be mindful of:

Data-Driven Hazards: The risk of poor data quality leading to erroneous AI outputs and poor decision making.
Algorithmic Complexity Hazards: The complexity and lack of transparency of AI algorithms can obscure errors or biases and inhibit explainability and usability.

AI Digital Clinical Safety Risk

Adaptive Learning Hazards: Unintended changes in system behaviour due to machine learning including drift in a model and lack of predictability and consistency.

Interoperability Hazards: Compatibility and data exchange issues with other healthcare IT systems.

Security and Privacy Hazards: Risks of unauthorised access and breaches of patient privacy through 'leaky' AI systems.

Ethical and Governance Hazards: Concerns over consent, transparency, fairness and accountability as well as how collected data might be used for continuous improvement training and learning.

Regulatory and Compliance Hazards: The challenge of staying compliant with evolving regulations.

Clinical validity: The effectiveness of human in the loop oversight and impact of AI on human effectiveness.

Usability Hazards: Trustworthiness, usability and transparency risks that inhibit confidence and adoption of AI and impede the potential benefits.

Mitigation Strategies for AI Risks in Clinical Settings

Where does this leave decision makers when they want to introduce AI driven systems into the care pathway to benefit both patients and clinical staff, but aren't sure how to assess the safety and efficacy of those systems?

There is a proliferation of AI governance framework to consider, but the short answer is to look for system providers that can demonstrate they have mitigated the AI system specific risks within their design, development, training and testing processes to the extent possible at those stages of the AI System lifecycle and conduct additional testing as part of the implementation. Possible mitigation strategies for AI related risks are listed overleaf.

ISO 42001:2023, the international standard for AI Governance offers a framework for managing the ethical and safe use of AI in healthcare. Aligning with ISO 42001:2023, manufacturers and healthcare providers can evaluate the AI systems and demonstrate that the systems are not only effective but also ethically responsible and safe for patient care.

Regulatory & Compliance Strategy

Risk Type	Mitigation Strategies
Transparency	Purchase AI systems with open algorithms where possible. Request detailed documentation and user training to explain how AI systems make decisions. Look for systems compliant with standards and frameworks promoting transparency in AI development and deployment.
Explainability	Look for providers who incorporate user feedback to improve their interface and explanations provided by AI systems. Prioritise the purchasing of systems that incorporate principles of Explainable Artificial Intelligence models users can understand, trust, and effectively manage AI outputs.
Fairness	Undertake a fairness analysis to identify and correct disparities in the systems you use with data sets representative of your population. Look for providers who can demonstrate that they design and train AI models with equity considerations. Request evidence from providers that they regularly review and adjust AI to ensure equitable outcomes after you have purchased the system.

Regulatory & Compliance Strategy

Risk Type	Mitigation Strategies
Drift (Model or Data Drift)	Establish continuous monitoring systems for AI performance. Look for providers who can demonstrate that they regularly update models with new data to reflect current clinical scenarios. Look for providers who can demonstrate that they implement adaptive learning systems that can adjust to new data patterns while maintaining oversight.
Bias in Training Data	Ensure diverse and representative datasets have been used for training. Look for providers who can demonstrate they use transparent and explainable AI models for easier identification and correction of biases. Engage with diverse stakeholders in system procurement activities.
Security and Privacy Risks	Look for providers who can demonstrate they implement robust data encryption and secure access protocols. Look for providers who can demonstrate they regularly conduct security audits and updates to AI systems. Ensure you and your system providers adhere to strict data governance and privacy regulations.
Regulatory and Compliance Risks	Ensure the AI systems you purchase are designed and updated in accordance with current regulations. Engage with regulatory bodies to anticipate changes in legislation. Implement compliance monitoring and reporting mechanisms.

About us

At Deviceology we on a mission to make medical device compliance easy. We provide self-service compliance guidance and regulatory support for medical device manufacturers, and health organisations.

We aim to solve your AI governance, certification, compliance, digital clinical safety and market access challenges, so you can focus on delivering innovation, bringing and safely maintaining products in your chosen markets.

We're passionate about doing things the right way and delivering pragmatic, value-adding insight and assurance. Our services include regulatory strategies, market access, reimbursement models, product registration and post market surveillance for major markets including Europe, UK, U.S, Brazil, Japan, Australia and Canada,

www.deviceology.net
info@deviceology.net
www.linkedin.com/company/deviceology/