dpo centre Life Sciences

Welcome to our Life Sciences newsletter!
A quick monthly read with useful information, articles, and views from our team of experienced DPOs on the latest data protection news specific to the Life Sciences.

LIFE SCIENCES IN THE NEWS

Proposed US health IT certification changes: What organisations should review now

In December 2025, the Assistant Secretary for Technology Policy and the US Office of the National Coordinator for Health Information Technology (ASTP/ONC) proposed changes to the country's health IT certification programme. The proposal would reduce certification requirements from 60 to 34, aiming to simplify regulatory obligations for health IT developers.

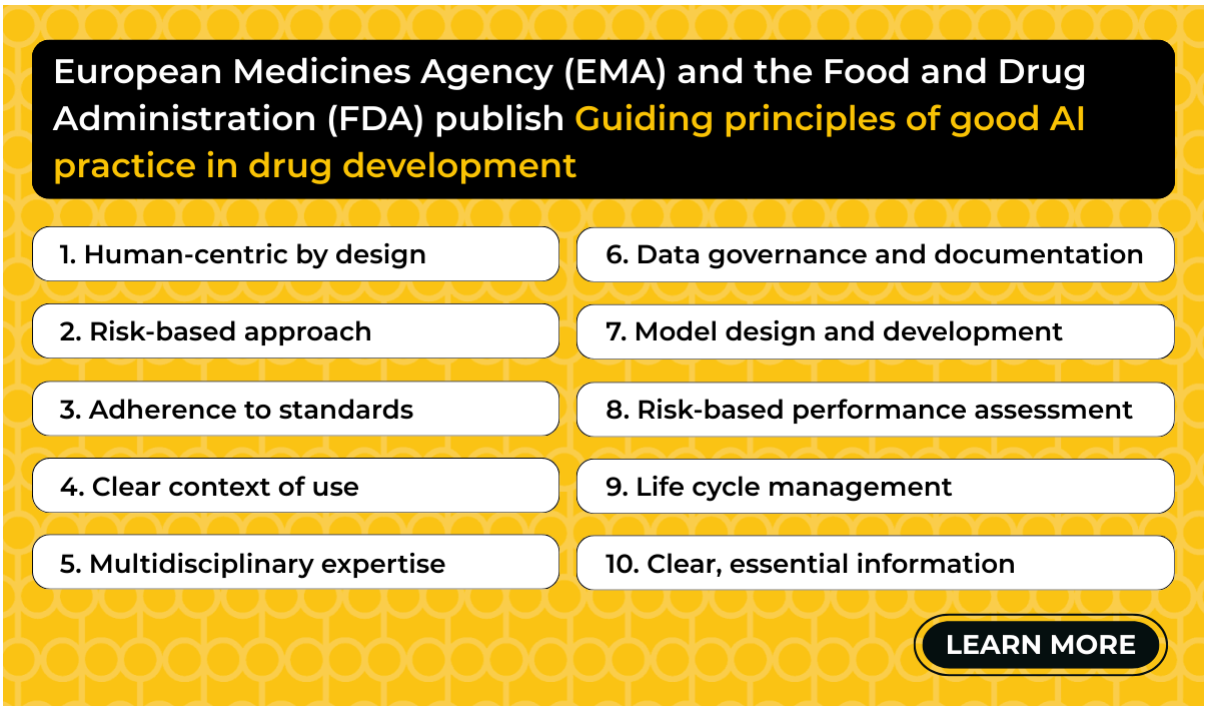
The changes could also affect how privacy and security safeguards are demonstrated within certified health technologies. Requirements linked to controls, such as authentication, access management, and audit logging may be removed or adjusted as part of the proposed updates.

What to review now:

- Check how much you rely on certified health IT systems and identify which privacy and security safeguards are built into your vendors' platforms
- Reassess your vendor due diligence and procurement processes to ensure essential controls, such as authentication, access management, and audit logging, remain in place
- Monitor regulatory developments so you can anticipate how changes could affect your data governance and cybersecurity responsibilities

Learn more about the proposals

INFORMATION, BLOGS & ARTICLES



A DPO'S PERSPECTIVE

UK medical device trials hit record high as MHRA accelerates innovation in neurotech and AI

Chris Bentley, DPO at The DPO Centre, explores the growing role of AI in medical device development and the governance steps organisations should take to manage emerging risks.

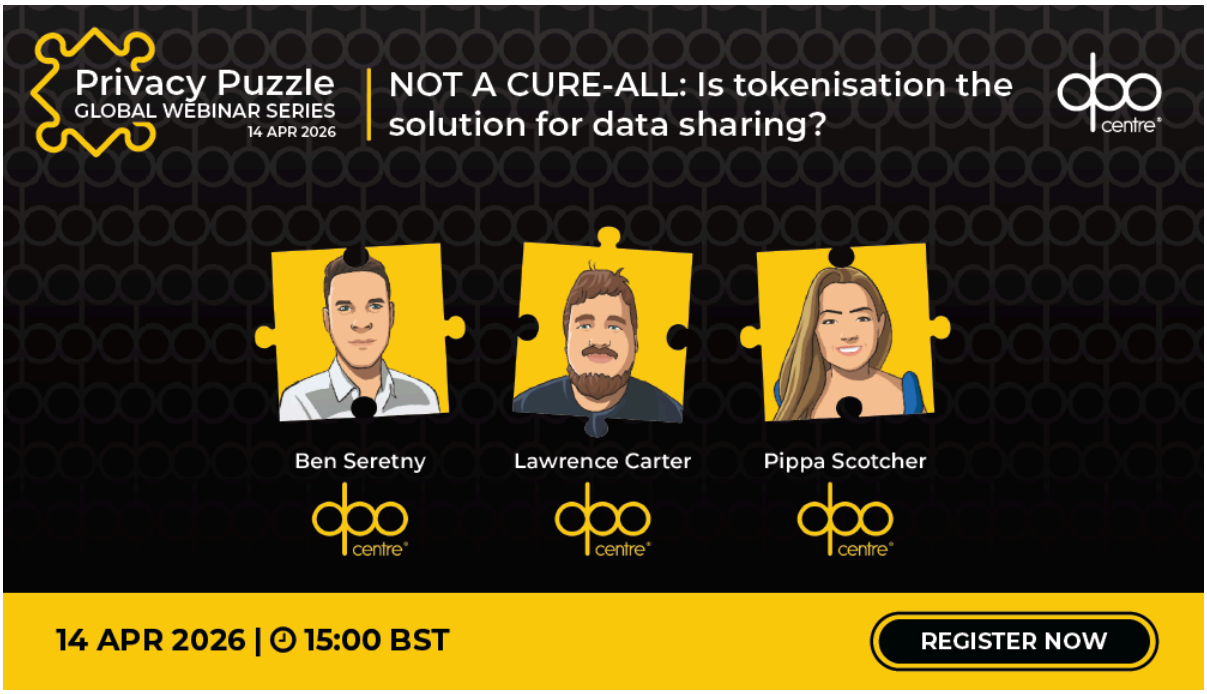
'Innovations in neurotechnology and AI-driven diagnostics present significant opportunities, but also introduce complex regulatory and governance risks.

'Key concerns include data privacy, cybersecurity vulnerabilities, algorithmic bias, hallucination risks in generative systems, and over-reliance on automated decision-making.

'To address these risks, organisations should:

- ***Ensure correct regulatory classification** under the Medical Devices Regulations applicable in the EU and the UK and align development activities with GDPR*
- ***Engage privacy and data protection professionals early** in the development lifecycle to support governance and embed Privacy by Design*
- ***Assess algorithmic risks**, including bias, transparency, explainability, and broader lifecycle risk management*
- ***Implement strong oversight and controls**, including robust human oversight, data integrity safeguards, and clear accountability for automated decision-making*
- ***Maintain continuous monitoring**, ensuring AI systems are subject to post-market surveillance as they evolve over time'*

GLOBAL WEBINAR EVENT



For any data protection queries you may have, or for further information about how The DPO Centre can support your organisation, please contact us.

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