



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

Germany introduces new SCCs for clinical trial agreements

On 19 September 2025, Germany's new *Standard Contractual Clauses for Clinical Trials* came into force, forming part of a national effort to make the country more attractive for medical research. The clauses apply to all commercial pharmaceutical clinical trial agreements (CTAs) signed after 17 December 2025.

Although not mandatory, the clauses are expected to become the default reference point in contract negotiations. Replacing the previously used industry-drafted CTA template, these government-backed model clauses cover 10 key sections, including publication rights, liability limitations, and data protection.

Data protection clause

The dedicated data protection clause sets out requirements for compliance with the:

- General Data Protection Regulation (GDPR)
- Clinical Trial Regulation (CTR)
- German Medicines Act (AMG)

It also addresses data transfers to non-EU/EEA countries, the processing of study staff data, and scenarios where joint controllership between sponsors and trial sites may apply. Notably, the Module 1 EU Standard Contractual Clauses (SCCs) are not included, meaning these will likely need to be appended separately when international data transfers occur.

Next steps

Sponsors and CROs should review the new clauses and assess their impact on existing CTA templates. Whilst the clauses aim to reduce negotiation delays, they introduce new language and assumptions that may require cross-functional alignment between legal, privacy, and clinical teams.

[View the German SCCs](#)

BLOG

Clinical trials part 1: Data protection considerations for Clinical Trial Agreements



A DPO'S PERSPECTIVE

US-UK pact will boost advances in drug discovery, create tens of thousands of jobs and transform lives

The newly announced US–UK Tech Prosperity Deal aims to deepen collaboration in AI research and accelerate breakthroughs in AI and drug discovery. **Amy Saksena, DPO at The DPO Centre**, shares how organisations can ensure data protection keeps pace.

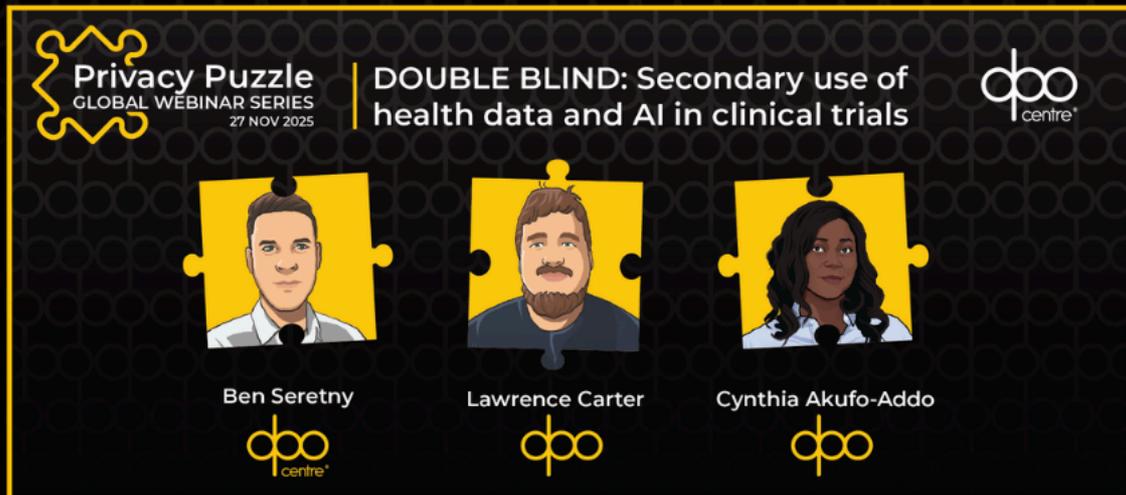
'To support responsible innovation, organisations should embed transparency, risk management, and governance into their AI strategies from the outset. This means:

- **Making transparency a priority**
Individuals should be clearly informed about what their data is used for and why. Providing this information builds trust and embeds transparency into organisational culture.
- **Conducting a Data Protection Impact Assessment (DPIA)**
A robust DPIA demonstrates accountability and helps identify and mitigate risks early, especially when using health-related data or engaging in cross-border research.
- **Ensuring compliant data transfers**
Where personal data is transferred from the UK to the US, appropriate safeguards must be in place. This includes using the UK Addendum to EU SCCs or the International Data Transfer Agreement (IDTA) and carrying out a Transfer Risk Assessment (TRA).

'As AI capabilities expand, organisations must place data protection at the heart of their innovation strategies. Aligning privacy with organisational and leadership priorities will be essential for maintaining public trust and meeting regulatory expectations.'

GLOBAL WEBINAR EVENT

ONLINE WEBINAR



Privacy Puzzle
GLOBAL WEBINAR SERIES
27 NOV 2025

DOUBLE BLIND: Secondary use of health data and AI in clinical trials

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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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