



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

### EU Data Act: New rules for medical devices now in force

On 12 September 2025, the EU Data Act's new rules for connected products and related services, including medical devices, came into effect, introducing fresh data access and sharing requirements.

For certain Life Sciences organisations and their technology partners, the Act expands data governance obligations beyond the General Data Protection Regulation (GDPR), requiring greater transparency, user access, and built-in technical capabilities.

Unlike the GDPR, which focuses solely on personal data, the Act applies to:

- Raw and pre-processed data generated during device use
- Metadata associated with device functionality
- Both personal and non-personal data, such as sensitive patient information and anonymised technical logs

#### New requirements for organisations

Organisations placing new connected medical devices (and their associated software platforms or remote dashboards) on the market must now comply with the following obligations:

- **Inform users before purchase or lease** about what data will be generated, its format, frequency, storage, and any third-party access
- **Provide continuous, real-time access and portability** so users can obtain their data and transfer it to third parties of their choice
- **Justify refusals to share data in writing**, for example where trade secrets or confidentiality need to be protected
- **Disclose data to public authorities during emergencies**, such as pandemics, when required
- **Use non-personal data only with explicit user agreement**, set out contractually
- **Appoint an EU representative if based outside the EU**, and ensure non-personal data is not transferred to foreign authorities without judicial safeguards
- **Apply EU Data Act Model Contractual Terms** where necessary

From 12 September 2026, devices and related services will also need to be designed so that users can obtain their data directly, securely, and free of charge in a machine-readable format.

[Learn more about the EU Data Act](#)

[Download the Model Contractual Terms](#)

## BLOG

# [Life Sciences playbook: European clinical trials and the GDPR](#)



## A DPO'S PERSPECTIVE

### [The Court of Justice clarifies the scope of the concept of personal data in the context of a transfer of pseudonymised data to third parties](#)

Lawrence Carter, **DPO and Life Sciences Sector Lead at The DPO Centre**, reacts to the recent CJEU ruling on the SRB vs EDPS case:

*'The recent EDPS v SRB ruling confirms that pseudonymised data is not always treated as personal data under EU law — it depends on whether the recipient can reasonably re-identify individuals.'*

*'This could have a significant impact on the Life Sciences sector, as coded clinical trial data has until now been assumed to be pseudonymous (rather than anonymous) and therefore within scope of the EU General Data Protection Regulation (GDPR). The finding also appears to conflict with the current draft [European Data Protection Board \(EDPB\) guidance](#) on pseudonymisation, adding further complexity to interpretations.'*

*'The case and subsequent appeals did not address whether processors receiving pseudonymised data from controllers might also fall outside GDPR, so further clarification*

from the EDPB and national regulators will be needed before organisations can safely apply this ruling to wider scenarios.

'For organisations running clinical trials, three considerations are worth noting:

1. **Identifiability:** Detailed attributes (e.g. age, ethnicity, medical history, genetic data), when taken together, may still enable re-identification. Applying concepts like k-anonymity can help mitigate this risk.
2. **Exceptional circumstances:** In rare cases such as serious adverse events, sponsors may need to act in a participant's clinical interests. Even without direct identifiers, this may constitute 'singling out' under GDPR Recital 26, bringing the data within the scope of EU GDPR.
3. **EU vs UK divergence:** The ruling applies under EU GDPR, but UK GDPR and [ICO guidance](#) currently take a stricter view that processors inherit the controller's position on pseudonymised data, potentially leading to different outcomes.
4. **Secondary use of data:** For non-live trials or third-party datasets, the judgement may support arguments that some pseudonymised data falls outside the GDPR, aligning with the EU's broader direction of travel encouraging secondary use of research data under the forthcoming European Health Data Space (EHDS).'

## SPEAKER EVENTS

### WE'RE SPEAKING EUROPEAN HEALTH DATA PROTECTION CONGRESS



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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