

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

Health Canada proposes modernised clinical trial framework

On 20 December 2025, Health Canada launched a consultation on its proposed [Clinical Trials Regulations](#). The stand-alone framework is designed to improve access to innovative therapies and reduce regulatory complexity, whilst maintaining strong safety protections for participants.

The new regulations would apply to clinical trials involving drugs for human use, including pharmaceuticals, biologics, radiopharmaceuticals, and cannabis-based therapies.

Key features include:

- A single, consolidated regulatory framework replacing multiple existing clinical trial provisions
- Clear rules governing the application, authorisation, amendment, suspension, and revocation of trials
- Updated requirements for good clinical practice and safety reporting
- New and revised guidance for sponsors, including expectations around sex- and gender-based analysis in trial design

For Life Sciences organisations, the proposals signal a shift toward a more streamlined and predictable regulatory environment in Canada. Sponsors and CROs running North American or global trials should monitor the reforms closely, as the new framework could affect trial design, authorisation timelines, and compliance obligations.

[Respond to the consultation](#), open until 20 March 2026.

A DPO'S PERSPECTIVE

[EDPB reconsiders anonymisation and pseudonymisation after SRB: What Life Sciences organisations need to know](#)

Katarzyna Wieckowska, DPO at The DPO Centre, unpacks the European Data Protection Board's evolving stance on anonymisation and pseudonymisation, and what it means for clinical trial sponsors and their processors.

‘The EDPB’s recent reflections on anonymisation and pseudonymisation raise renewed legal uncertainty for organisations conducting clinical trials in the EU. Two interpretative models are being discussed: recipient-centric and controller-centric.

‘At first glance, a recipient-centric view may suggest that sponsors fall outside the scope of the GDPR if they cannot re-identify individuals. But in practice, sponsors can often ‘single out’ participants (for example in adverse event reporting and safety management). Sponsors also routinely instruct processors to handle identifiable data for participant administration and reimbursement purposes. For these reasons, a recipient-centric lens alone may be too narrow to determine whether the GDPR applies.

‘The controller-centric model considers whether downstream processors automatically inherit the sponsor’s GDPR obligations. Some processors will clearly remain in scope, particularly those handling directly identifiable data (such as participant reimbursement information or eCOA application data). Processors involved in pharmacovigilance are also likely to have GDPR requirements, as the possibility of occasional re-identification in safety reporting may be considered ‘reasonably likely’. However, the position is less clear for processors carrying out more limited, targeted analysis on restricted datasets, and it remains uncertain whether they too will be required to inherit the controller’s GDPR obligations.

‘Importantly, sponsors submitting clinical trial applications in the EU are currently required to explicitly confirm GDPR compliance. Until the EDPB’s position develops into a clearer picture, sponsors and their processors should proceed on the basis that GDPR requirements continue to apply to clinical trials conducted in the EU. ‘

BLOG

[Pseudonymisation under the GDPR: What the latest EU ruling means for organisations](#)



**PSEUDONYMISATION
UNDER THE GDPR:
WHAT THE LATEST EU RULING
MEANS FOR ORGANISATIONS**

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**FULLY ASSURED: Getting privacy
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Lawrence Carter



Pippa Scotcher



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24 FEBRUARY 2026 | ⌚ 14:00 GMT

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