



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

European Commission unveils proposal for Biotech Act

On 16 December 2025, the European Commission published its proposal for the EU Biotech Act – the first legislative step in a wider initiative to regulate biotechnology and position the EU as a global industry leader.

For Life Sciences organisations, a key development is the proposed amendment to the Clinical Trials Regulation (CTR), which would make Legal Obligation the default lawful basis for processing personal data. Diverging interpretations across Member States often delay multi-country trials and complicate compliance. By standardising these rules, the Act seeks to reduce administrative burdens, accelerate approvals, and enable more flexible, digitally integrated trial designs. This would pave the way for faster, more efficient cross-border studies.

Lawrence Carter, Life Sciences Sector Lead and DPO at The DPO Centre, shares his view on this proposal:

'The CTR was overdue an update on data protection, as its current form references the now-repealed 1995 Directive. In particular, the move to standardise the lawful basis for processing is most welcome and will substantially reduce data protection-related national divergences in multi-country trials.'

'However, it's surprising the Commission has selected Legal Obligation as the appropriate lawful basis. To date, only Spain and Portugal have adopted a similar approach, while the 2019 European Data Protection Board (EDPB) guidance generally recommends Legitimate Interests. It will be interesting to see how the EDPB responds to this proposal, along with jurisdictions like Germany where Consent is codified in national law.'

The Act also introduces a range of measures to accelerate innovation and attract investment, including:

- **Strategic project designation** for high-impact biotech initiatives, offering accelerated procedures and priority access to EU funding
- **Creation of an EU Health Biotechnology Investment Pot** to bridge the funding gap for scale-up and late-stage biotech firms
- **A 12-month Supplementary Protection Certificate extension** for eligible products (e.g., advanced therapy medicinal products (ATMPs))
- **Integration of AI and advanced technologies** into biotech development pipelines

- **Regulatory sandboxes** to test innovative biotech products in controlled environments

The proposed Act marks a significant shift toward a more coordinated and innovation-friendly regulatory landscape. Life Sciences organisations should monitor the proposal closely as it progresses through the legislative process in 2026.

[Read the proposed EU Biotech Act](#)

BLOG

[Data protection considerations for vendor Data Processing Agreements](#)



A DPO'S PERSPECTIVE

[Pennsylvania: Bill on genetic data disclosures passes House](#)

As Pennsylvania moves closer to passing its Genetic Information Privacy Act, covered entities should begin preparing now to align with the Bill's new requirements. **Pippa Scotcher, DPO at The DPO Centre**, shares her key recommendations:

'Start by mapping how genetic data is handled across your organisation. Understanding where this data is collected, processed, stored, and for what purposes will form the foundation of your compliance efforts.'

'Review your Privacy Notice to ensure it clearly explains how genetic data is collected, used, disclosed, transferred, secured, retained, and deleted. Internal policies should reflect these practices.'

'Assess your consent mechanisms to confirm they are robust, well-documented, and meet the Bill's requirements for valid, informed consent.'

‘Establish clear procedures to support ongoing compliance, including:

- *Responding to disclosure requests, particularly from government entities or other third parties, where the consumer has not consented to such disclosure*
- *Handling consumers' rights requests, such as access and deletion of their genetic data*
- *Maintaining appropriate security controls to safeguard genetic information*

‘Taking these steps will help organisations stay ahead of the curve and demonstrate a responsible approach to genetic data protection.’

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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