

Bird & Bird

Data-Driven Innovation and the EHDS

The Relationship Between Secondary Use of Data and
the European Biotech Act

Attorneys-at-law

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Agenda

1. Secondary use in the EU Biotech Act
2. The EDPB & EDPS opinion on the EU Biotech Act
3. The EU Biotech Act v. the EHDS
4. Questions and answers

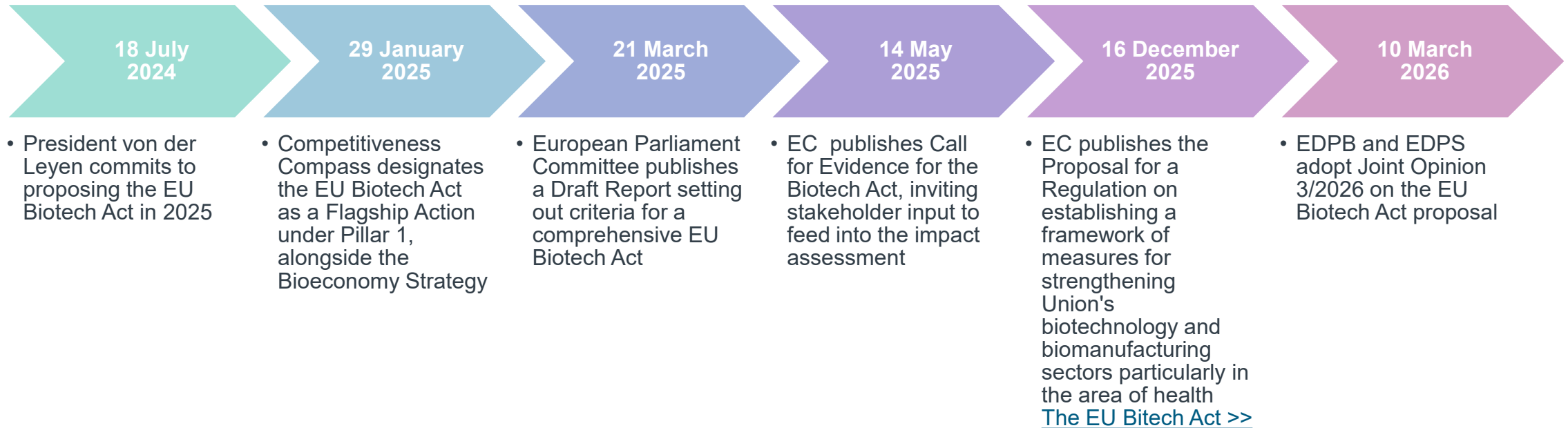


1

Secondary use in the EU Biotech Act

The EU Biotech Act

Timeline



Clinical Trial Regulation (EU) No 536/2014 (CTR)

Secondary use – current state of play

Art. 28 (2) of the CTR

2. Without prejudice to Directive 95/46/EC, the sponsor may ask the subject or, where the subject is not able to give informed consent, his or her legally designated representative at the time when the subject or the legally designated representative gives his or her informed consent to participate in the clinical trial to consent to the use of his or her data outside the protocol of the clinical trial exclusively for scientific purposes. That consent may be withdrawn at any time by the subject or his or her legally designated representative.

The scientific research making use of the data outside the protocol of the clinical trial shall be conducted in accordance with the applicable law on data protection.

Art. 93 of the CTR Data protection

- 1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.*
- 2. Regulation (EC) No 45/2001 shall apply to the processing of personal data carried out by the Commission and the Agency pursuant to this Regulation.*



CTR: secondary use & processing personal data

The EDPB study on the secondary use of personal data in the context of scientific research (10.2020)

- *The reuse of personal data for scientific research remains legally uncertain, as selecting the correct legal basis under Articles 6 and 9 GDPR – especially for transnational research involving health data – is a challenging task.*
- *Member States continue to apply divergent interpretations, with some still requiring consent despite the EDPB and the European Commission's position on clinical trials – in Opinion 3/19 (23.01.2019) - that consent will not be the appropriate legal basis in most cases in clinical trials, and that other legal bases such as public interest or legitimate interest must be relied upon instead.*

EDPB Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (23.01.2019)

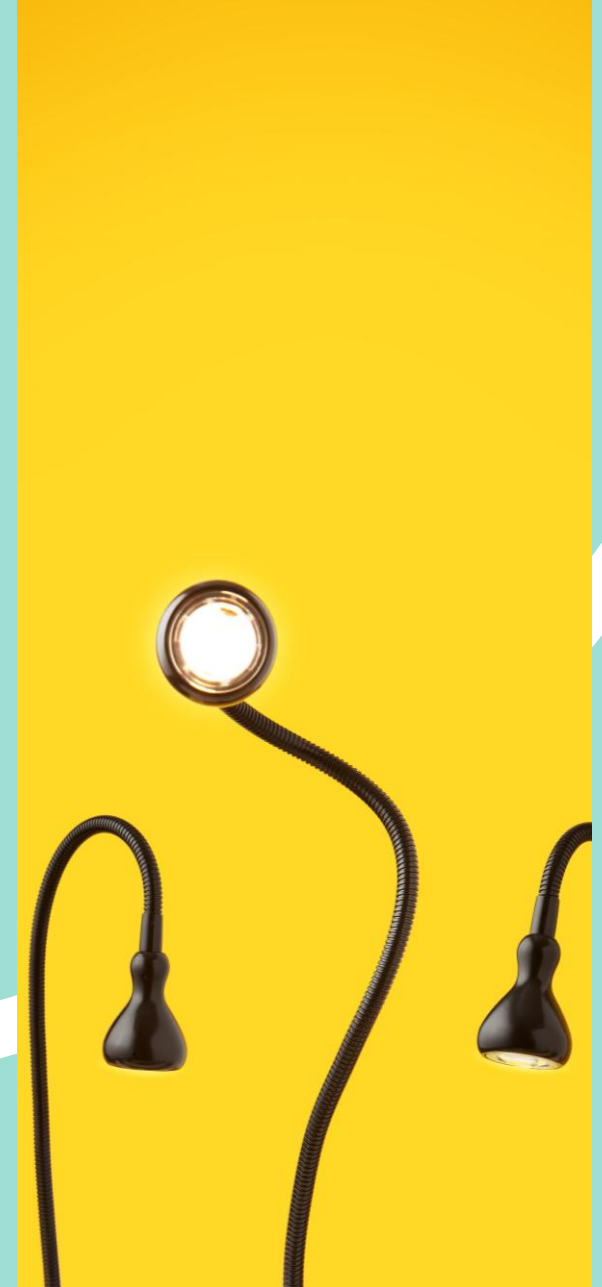


The EU Biotech Act

Recital 122 of the EU Biotech Act

*Amending Regulation (EU) No 536/2014 of the European Parliament and of the Council to bring simplification and shorten the time for biotechnology innovations to reach the Union market is crucial to streamline and accelerate clinical trials processes in the Union **and to make the legislative framework competitive globally so as to attract more clinical research to the Union.***

*Without an efficient, accelerated and streamlined legislative framework for clinical trials authorisation in the Union, the other measures in this Regulation, and in particular the framework for the recognition and support of health biotechnology strategic projects and high impact health biotechnology strategic projects would be deprived of their effectiveness, **as all health biotechnology medicinal products require state of the art clinical research and a globally competitive regulatory framework for clinical trials authorisation.***



The EU Biotech Act amends the CTR

Art. 58 of the EU Biotech Act amending CTR

New Art. 93 (6) of the CTR

Personal data collected and processed in accordance with this Regulation may be further processed by the same controller for the purposes of other clinical trials conducted under this Regulation, or for scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research.

Recital 153 of the CTR

Personal data which is collected and processed under each authorised protocol in accordance with Regulation (EU) No 536/2014 as amended by this Regulation may be further processed by the same controller for the purposes of other clinical trials, conducted in accordance with Regulation (EU) No 536/2014. Such data may include names, contact details, health and genetic data of subjects. It should also be possible to further process such personal data by the same controller for scientific research purposes.

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EDPB & EDPS opinion on the EU Biotech Act

EDPB & EDPS Joint Opinion on the EU Biotech Act

Recommendations on Art. 93(6) CTR

Legal basis

- Recitals should clarify a legal basis for further processing that is Art. 6(1)(e) GDPR (or Art. 6(1)(c) GDPR where Art. 93(1)/(2) applies).
- The legal basis should comply with Art. 6(3) GDPR.
- Art. 9(2)(i) or (j) GDPR could apply if specific safeguards are provided.

Proportionality

- "Where such processing is necessary" should be added to ensure proportionality.

Precision

- The purpose of "(...) fostering the innovation capacity of European medical research" is overly broad and should be more precise and restrictive.

Safeguards



Appropriate safeguards in line with Art. 89 GDPR, e.g.:

- Enhanced transparency towards data subjects, beyond the GDPR requirements,
- Right to object (Art. 21(6) GDPR) and right to erasure (Art. 17(3)(d) GDPR),
- Pseudonymisation where direct identification is not necessary,
- Governance structures for oversight of personal data processing,
- Confidentiality obligations for researchers and staff with access to personal data.

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Secondary Use: EU Biotech Act v. the EHDS

The EU Biotech Act / CTR v. the EHDS (1/3)

Secondary use

	EU Biotech Act/ CTR	EHDS
What type of data does it concern?	Personal data collected and processed under each authorised protocol in accordance with the CTR, including health data and genetic data of trial subjects (clinical trial data)	Electronic health data – including EHR data, genomic data, clinical trial data , registry data, wellness application data, and biobank data
Who is obliged to provide data?	Sponsors and investigators	Health data holders
Who is entitled to obtain data?	The same controller that originally collected the data	Health data users: natural or legal person, including EU institutions, which has been granted lawful access pursuant to a data permit, a health data request approval or an access approval by an authorised participant in HealthData@EU
What is the purpose of use?	Other clinical trials under the CTR, or scientific research for public health, improve standard of care, and fostering the innovation capacity of European medical research	Public/occupational health, policymaking, statistics - access only for public sector and EU bodies Education, scientific research related to health or care sectors that contributes to public health or health technology assessments (including development and innovation activities, and training, testing AI systems), and improving care delivery

The EU Biotech Act / CTR v. the EHDS (2/3)

Secondary use

	EU Biotech Act/ CTR	EHDS
Is consent required?	No	No
Is there a right to object?	Yes, but not expressly provided – opt out is available where Art. 6(1)(e) GDPR is a legal basis EDPB & EDPS recommend it should be expressly added	Yes, a right to opt out at any time, without reason, reversible (Art. 71 EHDS) With limited exception that can be introduced by Member States
Is there a legal basis for processing?	Not explicitly provided EDPB & EPDS suggest that the recital should clarify it is Art. 6(1)(e) GDPR; Art. 6(1)(c) GDPR; Art. 9(2)(i) GDPR for special category data	GDPR Art. 6(1)(c) for health data holders GDPR Art. 6(1)(e) for health data access bodies GDPR Art. 6(1)(e) or f) for health data users GDPR Art. 9(2)(g) – (j) for special categories (Recital 52 EHDS)

The EU Biotech Act / CTR v. the EHDS (3/3)

Secondary use

	EU Biotech Act/ CTR	EHDS
What additional information obligations apply?	N/A EDPB&EDPS recommends introducing it	Public transparency obligations on health data access bodies; publication of results by health data users; notification of significant health findings
Is there a need for approval of the authority?	No	Yes – health data access bodies grant access via a data permit, health data request approval, or HealthData@EU access approval
Should data be pseudonymised or anonymised?	Not clear EDPB & EDPS recommend to clarify it	Anonymised as a rule; pseudonymised only where the purpose cannot be achieved with anonymised data
What additional safeguards are in place?	Not clear EDPB & EDPS recommend introducing them	Secure processing environment; data minimisation/pseudonymisation; prohibited uses; re-identification ban; data localisation within the EU; administrative fines



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Questions & Answers





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