EDPB-EDPS JOINT OPINION 3/2026

On the Proposal for a Regulation on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health (European Biotech Act)

Adopted on 10 March 2026

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Executive summary

On 16 December 2025, the European Commission issued a Proposal for a European Biotech Act [1] establishing a framework of measures for strengthening the European Union's biotechnology and biomanufacturing sectors and amending a large parts of the European Union (EU) legislation in the area of health ('Proposal').

The EDPB and the EDPS support the Proposal's general objective to foster the EU's competitiveness in the biotechnology and biomanufacturing sectors and to address certain challenges related to the consistent application of the Clinical Trials Regulation ((EU) 536/2014 ('CTR')), with a view to the effective application of the relevant rules. These goals are aligned with the EDPB's Helsinki Statement, where the EDPB committed to take up initiatives facilitating compliance with GDPR[2] and strengthening consistency[3]. The EDPB and the EDPS underline the importance that the proposed simplifications clarify obligations and bring legal certainty while maintaining the high standard of protection provided by the GDPR and EUDPR for the processing of personal data relating to health.

Changes relating to the Clinical Trials Regulation

The EDPB and the EDPS support the Proposal's objective to harmonise how sponsors and investigators should process personal data in the context of clinical trials across the EEA. In this regard, the EDPB and the EDPS welcome that the Proposal aims to establish a single legal basis for the processing of personal data by sponsors and investigators in the context of clinical trials. This will help to adress the existing fragmentation of the regulatory framework and improve legal clarity. In this Joint Opinion, the EDPB and EDPS provide specific recommendations on how to further enhance the clarity and foreseeability of the legal obligation to process personal data under the proposed Article 93(1) and (2) CTR.

The EDPB and the EDPS also welcome the introduction of additional safeguards to protect the individuals whose personal data data will be processed. In this regard, the EDPB and EDPS provide a number of recommendations to provide greater legal certainty and further safeguards for the rights and freedoms of data subjects:

- **Qualification of sponsors and investigators as controllers**. The EDPB and the EDPS welcome that the Proposal clearly identifies the entities acting as controllers. However, they recommend clarifying the respective roles of the sponsors and investigators as sole or joint controllers, taking into account the processing purposes referred to in the proposed Article 93(1) and (2) CTR.
- **Retention period of personal data**. The EDPB and the EDPS recommend clarifying that the 25-year minimum retention period applies only to personal data contained in the clinical trial master file.

[1] Proposal for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act), COM(2025) 1022 final.

[2] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) OJ L 119, 4.5.2016, pages 1–88.

[3] EDPB's Helsinki Statement on enhanced clarity, support and engagement, A fundamental rights approach to innovation and competitiveness, adopted on 2 July 2025.

- **Further processing for other clinical trials or for scientific research.** The EDPB and the EDPS understand that the objective of the proposed Article 93(6) CTR would be to provide a legal basis under Union law for the further processing of personal data by the same controller and recommend stating this objective more clearly in the Proposal. The EDPB and the EDPS recommend clarifying that the proposed Article 93(6) CTR would provide a legal basis for further processing pursuant to Article 6(1)(e) GDPR (except where clinical trial data are further processed under the proposed Article 93(1) or (2) CTR, in which case Article 6(1)(c) GDPR would apply). In addition, the EDPB and the EDPS recommend specifying more clearly the purposes of the further processing, as well as the relevant safeguards.
- **Appropriate technical and organisational measures**. The EDPB and the EDPS recommend that the proposed Article 93(8) CTR requires the use of pseudonymisation whenever it is not necessary to process directly identifiable personal data. They also recommend that Annex I, Part I, point D CTR refers to all the technical and organisational measures listed in the last sentence of Recital 151 Proposal.

As regards the potential access to personal data by competent authorities and the Commission under the proposed Article 93(3) CTR, the EDPB and the EDPS recommend expressly limiting access to the personal data of clinical trial's participants by competent authorities or the Commission to the extent necessary for the exercise of their tasks and in a pseudonymised format whenever the access to directly identifiable personal data is not necessary. They also recommend including examples of cases where competent authorities or the Commission may need access to personal data to exercise their tasks in a recital.

Furthermore, the EDPB and the EDPS make several recommendations in relation to other proposed amendments to the Clinical Trials Regulation:

- **Requirements related to review of the compliance with the GDPR as referred to in the proposed Article 7(1)(d) CTR**. In order to further harmonise the procedure for assessing compliance of clinical trials with the GDPR across the Member States, the EDPB and the EDPS invite the co-legislators to consider the possibility of expressly mandating the EDPB to adopt guidance on how such assessments should be performed.
- **Informed consent and possibility to provide it using electronic means in compliance with Regulation (EU) No 910/2014 or the equivalent standards**. The EDPB and the EDPS recommend clarifying that the use of the European Digital Identity wallet is voluntary and the provision of informed consent shall remain possible by other existing identification and authentication means.
- **Possibility to establish regulatory sandboxes at EU level for clinical trials**. In addition to recalling that the GDPR and EUDPR will remain fully applicable, the EDPB and the EDPS recommend that the implementing act of the Commission identifies the relevant legal basis as well as the derogation under Article 9(2) GDPR that would apply to the processing carried out in the context of this sandbox. In addition, the advisory role of the EDPB and the EDPS for ensuring consistency on data protection aspects and the oversight of these regulatory sandboxes should also be recalled.
- **Introduction of obligations on sponsors when they intend to use AI models or AI systems in the context of a clinical trial.** The EDPB and the EDPS recommend clarifying that these obligations will apply in addition to the obligations already applicable under the AI Act. In addition, they recommend providing for the obligation of the European Medicines Agency ('EMA') to cooperate with the EDPB for development of relevant guidance insofar as the protection of personal data is concerned.

Changes relating to artificial intelligence and data as biotechnology enablers

The EDPB and the EDPS welcome the possibility for the EMA to consult other relevant authorities at national and European level to develop and update non-binding guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development. The EMA may in this context consult the EDPB to ensure consistency of such guidance with data protection legislation.

In a similar vein, the Commission or the designated authority at national level should, where appropriate, consult supervisory authorities under the GDPR when assessing whether high impact health biotechnology strategic projects comply with relevant legislation, if they involve the processing of personal data.

Moreover, with respect to high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators, the EDPB and the EDPS welcome that the modalities of the processing of personal data would be specified in implementing acts of the Commission, but the Joint Opinion includes several recommendations to ensure legal certainty and the lawfulness of such processing.

Changes relating to regulatory tools for novel health biotechnology products, the Food law Regulation and the Regulation (EU) 2024/1938

The EDPB and the EDPS understand that the Proposal does not expressly envisage the processing of personal data and therefore does not aim to provide a legal basis for it in the context of **(i)** regulatory sandboxes for the testing and development of a health biotechnology product not falling under other regulatory sandboxes in the Union legislation in the health sector, **(ii)** regulatory sandboxes for specific food-related innovations and **(iii)** regulatory sandboxes for the development and testing of innovative products, services, processes or substances in the field of substances of human origin ('SoHO'). Any processing of personal data that would take place in these contexts would require a valid legal basis under the GDPR.

Changes relating to the biodefence and preventing biotechnology misuse

With respect to the verification of the legitimate need for biotechnology products of concern, the EDPB and the EDPS recommend determining the data required for the proof of identity of the prospective customer and clarifying the notion of "relevant factors" under the definition of suspicious transactions, which the economic operators must report to national contact points.

The European Data Protection Board and the European Data Protection Supervisor

Having regard to Article 42(2) of Regulation 2018/1725 of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC[4],

Have adopted the following joint opinion

1. BACKGROUND

1. On 16 December 2025, the European Commission ('Commission') issued a Proposal for a Regulation on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 ('European Biotech Act' or 'Proposal'). On 18 December 2025, the Commission formally consulted the EDPB and the EDPS in accordance with Article 42(2) of Regulation (EU) 2018/1725 ('EUDPR').
2. The objective of this Proposal is (i) to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector, (ii) to create the conditions for the development and timely placing on the European Union ('EU') market, of biotechnology innovations, products and services, (iii) while safeguarding high safety standards. For these purposes, the Proposal establishes measures to strengthen the EU biotechnology sector by creating EU strategic projects, improving access to EU investment, promoting artificial intelligence ('AI') use in biotechnology and health technology manufacturing, preventing biotechnology misuse and enhancing biodefence, and updating EU legislation in areas such as clinical trials, veterinary medicines, and food and feed safety[5].
3. The aim of this Joint Opinion is not to provide an assessment of all the proposed amendments, but instead, to address the most relevant aspects of the Proposal which are of particular importance for the protection of individuals' rights and freedoms with regard to the processing of personal data.

[4] OJ L 295, 21.11.2018, pages 39–98.
[5] See COM(2025) 1022 final/2, pages 10-11 in the Explanatory Memorandum accompanying the Proposal.

2. GENERAL REMARKS

4. The EDPB and the EDPS welcome the Proposal's objectives of making the EU biotechnology and biomanufacturing sectors more competitive, in particular concerning health biotechnology, by reducing the fragmentation and complexity of the applicable EU regulatory framework and promoting the responsible use of artificial intelligence and data in the health sector[6]. These goals are aligned with the EDPB's commitments in its Helsinki Statement to take up initiatives to facilitate GDPR compliance and strengthen consistency[7], in order to empower responsible innovation and reinforce competitiveness in Europe.

5. In particular, the EDPB and the EDPS support the Proposal's objective to harmonise how sponsors and investigators should process personal data in the context of clinical trials across the EEA in the context of Regulation (EU) No 536/2014[8] ('Clinical Trials Regulation' or 'CTR'), in compliance with the General Data Protection Regulation ('GDPR')[9]. The Proposal aims to address the regulatory fragmentation of clinical trials across different EU Member States.

6. The EDPB and the EDPS acknowledge that a conducive regulatory environment for clinical trials is important to speed-up market access for novel medicines. At the same time, they stress that the simplification objectives of the Proposal should not lower the level of protection of the fundamental right to the protection of personal data of clinical trial participants, taking into account the particularly sensitive nature of the personal data that is normally processed during clinical trials[10].

7. The EDPB and the EDPS note that the Proposal refers in several provisions to the need to ensure a consistent application of the Proposal with Regulation (EU) 2024/1689[11] ('AI Act')[12]. Although the Proposal states that it would apply without prejudice to the AI Act[13], the EDPB and the EDPS recommend to further explain in the Proposal to which extent the provisions of the Proposal related to research activities would interact with the AI Act, considering that the latter does not apply to research, testing or development activity regarding AI systems or AI models prior to their being placed on the market or put into service[14].

[6] See COM(2025) 1022 final/2, pages 1, 3 and 10 in the Explanatory Memorandum accompanying the Proposal.
[7] EDPB's Helsinki Statement on enhanced clarity, support and engagement, A fundamental rights approach to innovation and competitiveness, adopted on 2 July 2025.
[8] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158, 27.5.2014, pp. 1–76.
[9] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, pages 1–88. Concerning the processing of personal data under the current Clinical Trials Regulation, see 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) (art. 70.1.b)), adopted on 23 January 2019.
[10] This includes data concerning health and genetic data, which are considered special categories of data under Article 9(1) GDPR and thus subject to heightened protection.
[11] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj.
[12] See, for example, Articles 31(1), 32(1)(a) and Article 58(24) (Article 27d(2) CTR) Proposal.
[13] See Article 1(6) and Recital 9 Proposal.
[14] Article 2(8) AI Act.

3. AMENDMENTS TO REGULATION (EU) NO 536/2014 ('CLINICAL TRIALS REGULATION' OR 'CTR') (ARTICLE 58 PROPOSAL)

3.1 Amendments to Article 93 CTR ('Data protection')

3.1.1 Legal basis under Articles 6 GDPR and application of Article 9(2)(i) and (j) GDPR (proposed Article 93(1) and (2) CTR)

8. The EDPB and the EDPS support the proposed paragraphs 1 and 2 of Article 93 CTR, which aim to establish a legal obligation within the meaning of Article 6(1)(c) GDPR for the processing of personal data carried out by sponsors and investigators for the purposes listed in those provisions. These paragraphs would enhance harmonisation and legal certainty, as investigators and sponsors would be able to rely on a single legal basis - Article 6(1)(c) GDPR - for the processing of personal data for those purposes[15].

9. The EDPB and the EDPS note that, in accordance with Article 6(3) GDPR, the purpose of the processing is determined in the enacting provisions of the CTR. In addition, Recital 151 Proposal specifies the objective of public interest of the obligations imposed in the proposed Article 93(1) and (2) CTR, in particular "to ensure the safety and efficacy of medicinal products". The EDPB and the EDPS further recall that, prior to authorisation, the clinical trial protocol under Annex I, Part I and point D CTR is subject to an assessment, including a review of its compliance with the GDPR[16]. Following this authorisation, the sponsor and the investigator would be explicitly required under the proposed Article 93(1)(b) and 93(2)(a) CTR to ensure that the clinical trial is conducted in accordance with the protocol as authorised by the national competent authorities in accordance with Annex I, Part I, point D CTR. Finally, the EDPB and the EDPS welcome the introduction of additional safeguards in the proposed Article 93(8) CTR[17] which aim to ensure that natural persons whose personal data are affected benefit from sufficient guarantees that their data will be effectively protected against the risk of abuse.

10. However, the EDPB and the EDPS consider that several improvements should be made to enhance the clarity and foreseeability of the legal obligation to process personal data under proposed Article 93(1) and (2) CTR[18].

[15] See, concerning the legal bases for processing personal data under the current Clinical Trials Regulation, 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) (art. 70.1.b)), adopted on 23 January 2019.
[16] Article 7(1)(d) CTR.
[17] This includes the retention period under the proposed Article 93(5) CTR and technical and organisational measures under the proposed Article 93(8) CTR. See the recommendations of the EDPB and the EDPS with regard to these provisions in Sections 3.1.4 and 3.1.6 below.
[18] In accordance with Recital 41 GDPR, the legal basis laying down a lawful ground for processing under Article 6(1)(c) and (e) GDPR should be clear and precise, and its application should be foreseeable to the persons subject to it. This requirement also derives from Article 52(1) of the Charter of Fundamental Rights of the European Union according to which any legislation involving interference with the fundamental rights guaranteed by Articles 7 and 8 of the Charter must lay down clear and precise rules governing the scope and application of the measure in question and imposing minimum safeguards, so that the persons whose personal data are affected have sufficient guarantees that their data will be effectively protected against the risk of abuse. See, in this regard, Judgment of the Court of Justice of 1 August 2022, *OT v Vyriausioji tarnybinės etikos komisija*, C-184/20, ECLI:EU:C:2022:601, paragraph 69.

11. First, the EDPB and the EDPS recommend amending the proposed Article 93(1) and (2) CTR to specify that investigators and sponsors are required to process personal data, "where such processing is necessary" for the purposes listed in those paragraphs. In addition, the EDPB and the EDPS recommend adding to the list under the proposed Article 93(1) and (2) CTR the processing carried out by sponsors and whenever necessary by investigators for the purpose of the monitoring of the clinical trial under Article 48 CTR.

12. As regards, more specifically, the purpose referred to in the proposed Article 93(1)(b) and (2)(a) CTR, the EDPB and the EDPS recommend replacing the words "perform research activities" with "conducting scientific research", to align with the terminology used in the GDPR.

13. In addition, the proposed Article 93(1)(b) and (2)(a) CTR refers to the "protocol as authorised by the national competent authorities in accordance with point D, Part I of Annex I". In this regard, the EDPB and the EDPS note that point (ak) of this Annex, Part I, point D CTR refers to the "description of the arrangements to comply with the applicable rues on the protection of personal data". The EDPB and the EDPS consider that such description should include elements defining the scope of the processing operations to be carried out by sponsors and investigators when conducting scientific research in accordance with the protocol under Annex I, Part I, point D CTR. This includes, inter alia, the processing operations, the categories of personal data[19] and the necessity for their processing, the categories of data subjects concerned, the entities to, and the purposes for which the personal data may be disclosed, as well as the retention period for these personal data.

14. Furthermore, considering that the processing of personal data under the proposed Article 93(1) and (2) CTR would rely on Article 6(1)(c) GDPR, the EDPB and the EDPS invite the co-legislators to reflect on the impact of this legal basis on the data subjects' rights. In particular, the EDPB and the EDPS note that the Proposal would remove the last sentence of the current Article 28(3) CTR according to which "the withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal". The EDPB and the EDPS recommend providing - in Article 28 CTR - the conditions according to which the personal data obtained before the withdrawal of informed consent may continue to be used and would not affect the results of scientific research already carried out. In addition, if personal data are to be kept by controllers despite such withdrawal, the EDPB and the EDPS recommend providing for additional safeguards for the protection of participants' rights and freedoms[20]. The same clarification and additional safeguards would be relevant in the situations where participants did not themselves provide their informed consent, such as participants who are not able to give informed consent (Article 29 CTR), incapacitated subjects (Article 31 CTR), minors (Article 32 CTR) or subjects included in emergency situations (Article 35 CTR).

15. Finally, the EDPB and the EDPS recall that, where EU or Member State law envisages the processing of special categories of personal data, it must ensure that the conditions laid down in Article 9 GDPR are fulfilled. In this regard, the EDPB and the EDPS welcome Recital 151 Proposal which refers to the application of Article 9(2)(i) and (j) GDPR for the processing of special categories of personal data in the context of clinical trials. The EDPB and the EDPS also understand from this Recital that the proposed Article 93(8) CTR aims at providing safeguards in order to rely on Article 9(2)(i) and (j) GDPR, and therefore refer to the recommendations made in relation to that provision in Section 3.1.6 below.

[19] In accordance with Recital 151 Proposal, "The categories of personal data to be collected and processed in the context of a specific clinical trial should be specified in the authorised protocol". However, this requirement is not reflected in the elements to be included in the protocol pursuant to Annex I, Part I, point D CTR.

[20] For example, by obliging controllers to explain the reasons why their personal data is kept despite the withdrawal of their informed consent from the clinical trial.

3.1.2 Sharing of personal data with competent authorities and the Commission (proposed Article 93(3) CTR)

16. The proposed Article 93(3) CTR concerns situations where sponsors and investigators are required to make personal data, including genetic data or data concerning health, available to competent authorities of Member States for oversight purposes (including inspections) under Article 78 CTR and to the Commission for control purposes under 79 CTR. In addition, the EDPB and the EDPS note that amendments are also made to Articles 78 and 79 CTR to further delineate the tasks of the competent authorities of Member States and of the Commission when performing such inspections and controls.

17. In light of the data minimisation principle, the EDPB and the EDPS note that the supervision of compliance with the CTR may not always entail the need to process personal data. Therefore, the EDPB and EDPS recommend clarifying that access to the personal data of clinical trial participants by competent authorities of Member States or the Commission should only take place to the extent necessary for the exercise of their tasks, and that personal data should be shared in a pseudonymised format whenever the access to directly identifiable personal data is not necessary[21]. The EDPB and EDPS also recommend including in a recital examples of cases where competent authorities of Member States or the Commission may need access to personal data to exercise their tasks.

3.1.3 Qualification of sponsors and investigators as controller under Article 4(7) GDPR (proposed Article 93(4) CTR)

18. According to the proposed Article 93(4) CTR, sponsors and investigators would be controllers within the meaning of Article 4(7) GDPR "for the processing assessment leading to the authorisation of clinical trial applications and operations referred to in [Article 93 CTR]".

19. The EDPB and the EDPS recall that Article 4(7) GDPR provides that, where the purposes and means of the processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided by that law.

20. According to the case law of the Court of Justice of the European Union ('CJEU'), where a law designates an entity as controller, the determination of the purposes and means of the processing by that law may be implicit, provided that that determination is derived with sufficient certainty from the role, task and powers conferred on that entity. That condition is met if those purposes and means arise, in essence, from the provisions of the law governing the activity of that entity[22].

21. In this regard, the EDPB and the EDPS welcome the fact that the identification of the entities acting as controllers is set out directly in the enacting terms of the Proposal.

22. The EDPB and the EDPS understand that the proposed Article 93(4) CTR is intended to designate sponsors and investigators as controllers in respect of all processing operations referred to in the proposed Article 93 CTR. The EDPB and the EDPS also note that there is a significant overlap between the purposes for which sponsors and investigators are required to process personal data under the proposed Article 93(1) and (2) CTR. The proposed Article 93(4) CTR does not specify, however, whether sponsors and investigators are to be regarded as independent controllers or as joint controllers in relation to these processing operations.

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[21] See, in this regard, EDPB Guidelines 01/2025 on Pseudonymisation, Adopted on 16 January 2025 (version for public consultation), paragraph 36.

[22] See Judgment of the Court of Justice of 27 February 2025, *Amt der Tiroler Landesregierung v Datenschutzbehörde*, C-638/23, ECLI:EU:C:2025:127, paragraphs 28 and 37; Judgment of the Court of Justice of 11 January 2024, *État belge v Autorité de protection des données*, C-231/22, ECLI:EU:C:2024:7, paragraph 30.

23. Against this background, the EDPB and the EDPS recommend clarifying the respective roles of the sponsors and investigators as sole or joint controllers, in order to clarify their respective responsibilities for compliance with their obligations under the GDPR in relation to processing purposes referred to in the proposed Article 93(1) and (2) CTR. Insofar as the sponsors and investigators jointly determine purposes and means of processing, they should be considered as joint controllers[23]. In the same vein, the EDPB and the EDPS recommend clarifying in the proposed Article 93(4) CTR that co-sponsors under Article 72 CTR should be regarded as joint controllers. The determination of these responsibilities in the law would ensure greater legal certainty for (co-)sponsors and investigators, as well as for data subjects in the exercise of their rights.

24. In addition, the EDPB and the EDPS note that sponsors and investigators are to be designated as controllers "for the processing assessment leading to the authorisation of clinical trial applications". However, it remains unclear which processing operations are covered by the first sentence of the proposed Article 93(4) CTR. The EDPB and the EDPS therefore recommend further specifying what is the "processing assessment" under the proposed Article 93(4) CTR to better identify the processing operations for which sponsors and investigators would be controllers.

25. Finally, the EDPB and the EDPS note that the term "investigator" is defined in Article 2(15) CTR as "the individual responsible for the conduct of a clinical trial at a clinical trial site"[24]. In practice, investigators are generally physicians or other members of the medical staff acting under the authority of a clinical trial site. Their qualification as controller would make them directly liable for compliance with the GDPR. The EDPB and the EDPS therefore invite the co-legislators to reflect on the possibility to attribute such roles and responsibilities to the organisation (i.e., the clinical trial site) within which the principal investigator, or, where applicable, the investigator, conducts the clinical trial[25].

3.1.4 Retention period of personal data, including genetic data or data concerning health (proposed Article 93(5) CTR)

26. The proposed Article 93(5) CTR provides that personal data, including genetic data or data concerning health, shall be retained as long as required pursuant to Article 58 CTR and in accordance with the conditions laid down therein[26]. In order to ensure clarity and legal certainty, the EDPB and the EDPS recommend explicitly clarifying that this provision (and thus, the 25-year minimum retention period under Article 58 CTR) applies only to personal data contained in the Clinical Trial Master File, and not to all personal data processed in the context of a clinical trial.

[23] In accordance with Articles 4(7) GDPR and 26 GDPR. See also, EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR, Version 2.1, adopted on 7 July 2021, Section 3.
[24] This definition was not amended by the Proposal.
[25] EDPB Guidelines 07/2020 on the concepts of controller and processor in the GDPR, Version 2.1, adopted on 7 July 2021, section 2.1.1. Should controllership be allocated to the clinical trial site, the EDPB and the EDPS invite the co-legislators to reflect this change in the proposed Article 93 CTR.
[26] Article 58 CTR ('Archiving of the clinical trial master file') is not modified under the Proposal and reads as follows: "Unless other Union law requires archiving for a longer period, the sponsor and the investigator shall archive the content of the clinical trial master file for at least 25 years after the end of the clinical trial. However, the medical files of subjects shall be archived in accordance with national law. [...]".

27. In addition, the EDPB and the EDPS note that Article 58 CTR provides for a minimum period of archiving of “at least 25 years” for the content of the Clinical Master File. In this regard, the EDPB and the EDPS recall that controllers should provide information on the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period and that, after this period of 25 years, personal data should be kept for no longer than is necessary for the purposes for which they are processed[27].

3.1.5 Further processing for other clinical trials or for scientific research (proposed Article 93(6) CTR)

28. The proposed Article 93(6) CTR provides that personal data collected and processed in accordance with the CTR “may be further processed by the same controller for the purposes of other clinical trials conducted under [the CTR], or for scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research”.

29. The EDPB and EDPS understand that this provision intends to provide a specific legal basis under Union law for the further processing of personal data by the same controller, when such further processing is carried out by the same controller for the purposes defined in this provision. In the interest of legal certainty, the EDPB and the EDPS recommend stating more clearly in the recitals of the Proposal this objective of providing a legal basis for the further processing of the data for the purposes mentioned in the proposed Article 93(6) CTR. More specifically, they recommend specifying that the proposed Article 93(6) CTR would provide a legal basis for further processing under Article 6(1)(e) GDPR (except where clinical trial data are further processed under the proposed Article 93(1) or (2) CTR, in which case Article 6(1)(c) GDPR would apply in accordance with Article 93 (1) and (2) CTR).

30. In addition, the EDPB and the EDPS recall that, in order to constitute a legal basis for processing pursuant to Article 6(1)(e) GDPR, such legal basis must comply with the requirements of Article 6(3) GDPR.

31. Similarly to their recommendation on the proposed Article 93(1) CTR[28], the EDPB and the EDPS recommend, to ensure that the processing by the controllers under the proposed Article 93(6) CTR would remain proportionate to the legitimate aims pursued by the provision, the inclusion of the wording "where such processing is necessary” before “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”.

32. In addition, the EDPB and the EDPS note that a clear identification of the purpose is a precondition for enabling the controller to assess which processing operations are necessary to comply with the law or to pursue a task in the public interest[29]. In this regard, the purpose of conducting scientific research “with the aim of (...) fostering the innovation capacity of European medical research” is overly broad and may be subject to diverging interpretation. Therefore, the EDPB and the EDPS recommend defining more precisely and restrictively this purpose.

[27] In accordance with Articles 5(1)(e) and 13(2)(a) GDPR.
[28] See paragraph 12 of this Joint Opinion.
[29] In accordance with the principle of purpose limitation under Article 5(1)(b) GDPR, this purpose should be specified, explicit and legitimate. See also Judgement of the Court of 24 February 2022, *‘SS’ SIA v Valsts ieņēmumu dienests*, Case C-175/20, ECLI:EU:C:2022:124, paragraphs. 72 to 74.

33. Furthermore, the EDPB and the EDPS recommend defining specific safeguards that would apply to the further processing by the same controller under the proposed Article 93(6) CTR, specifically in what concerns further processing for scientific research with the aim of protecting public health, improving standard of care and fostering the innovation capacity of European medical research. This is all the more important given that such further processing would involve special categories of personal data under Article 9 GDPR and that processing under Article 9(2)(i) or (j) GDPR on the basis of Member State or Union law requires that such law provides for suitable and specific measures to safeguard the rights and freedoms of data subjects.

34. Given that further processing under the proposed Article 93(6) CTR could rely on Article 6(1)(e) GDPR, the EDPB and the EDPS invite the co-legislators to reflect on the impact of this legal basis on the data subjects' rights. The EDPB and the EDPS recommend including appropriate safeguards, in line with Article 89 GDPR, such as an obligation to provide enhanced transparency (beyond the requirements of the GDPR) towards data subjects when their personal data are further used, including the rights to object and right to erasure subject to conditions under Articles 21(6) and 17(3)(d) GDPR. They also suggest providing other safeguards, such as pseudonymisation of the data whenever the access to directly identifiable personal data is not necessary, the implementation of governance structures for the oversight of the processing of personal data, and confidentiality obligations for researchers and other staff members with access to personal data.

3.1.6 Appropriate technical and organisational measures (proposed Article 93(8) CTR)

35. The proposed Article 93(8) CTR would require controllers (i.e., sponsors and investigators) to implement appropriate technical and organisational measures to ensure the protection of the rights and freedoms of data subjects in the context of clinical trials. This also includes the further safeguards that are appropriate for a specific clinical trial as requested in point D, Part I of Annex I (ak), (al), (am) CTR and that should be described in the protocol.

36. In this regard, the EDPB and the EDPS recall that Article 89(1) GDPR requires that processing for scientific purposes be subject to appropriate safeguards for the rights and freedoms of data subjects. Those safeguards entail the identification and implementation by the controller of technical and organisational measures to ensure, and in particular, the respect of the principle of data minimisation[30].

37. One of the measures listed in the proposed Article 93(8) CTR requires that the controller obtains the informed consent of the subject in accordance with Article 29 CTR[31]. While informed consent in the context of clinical trials is not primarily a measure for data protection compliance, but rather a measure to ensure the protection of the rights to human dignity and to integrity of individuals[32], informed consent under the CTR could also be considered as a data protection safeguard in the meaning of Article 9(2) GDPR[33]. Therefore, the EDPB and the EDPS welcome its inclusion in the proposed Article 93(8) CTR.

[30] These safeguards apply in addition to other measures that are mandatory under the GDPR including, inter alia, under Articles 5, 24, 25 and 32 GDPR.
[31] Recital 151 Proposal also refers to 'informed consent' as a one of the specific safeguards for the processing of personal data, including genetic data or data concerning health, in compliance with Article 9(2)(i) and (j) GDPR.
[32] 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) (art. 70.1.b)), adopted on 23 January 2019, paragraph 16.
[33] EDPB Guidelines 05/2020 on consent under Regulation 2016/679, Version 1.1, adopted on 4 May 2020, paragraph 154.

38. In addition to the measures already listed in the proposed Article 93(8) CTR, the EDPB and the EDPS recommend that Article 93(8) CTR requires the use of pseudonymisation whenever it is not necessary to process directly identifiable personal data[34].

39. Furthermore, the EDPB and the EDPS recommend referring, in Annex I, Part I, point D CTR to the elements listed in the last sentence of Recital 151 Proposal, according to which the protocol should contain further appropriate safeguards such as specific technical and organisational measures that should be employed, including pseudonymisation, integrity and confidentiality controls, encryption and access restrictions[35].

40. Lastly, to ensure consistency with the terminology of the GDPR, the EDPB and the EDPS also recommend using the wording "measures" instead of "arrangements" in Annex I, Part I, point D, (ak) CTR.

3.1.7 Appropriate transition periods

41. According to Article 67(2) Proposal, the Biotech Act shall apply as of the day of entry into force i.e., on the twentieth day following that of its publication in the Official Journal of the European Union and shall apply on the same day.

42. Regarding the new provisions on data protection in clinical trials in the proposed Article 93 CTR, the EDPB and the EDPS consider that longer transition periods may be necessary for controllers to comply with their new obligations. Alternatively, a clarification that ongoing authorised clinical trials are not covered by the new regulation could be sufficient.

3.2 Other amendments to the Clinical Trials Regulation

3.2.1 Assessment report – Aspects covered by Part II of the application dossier (proposed Article 7 CTR)

43. Under the proposed Article 7(1)(d) CTR, each Member State should assess, for its own territory, the application for authorisation of a clinical trial with respect to compliance with data protection law. The EDPB and the EDPS note that there is no harmonised procedure for assessing compliance with the GDPR across Member States under Article 7(1)(d) CTR[36]. To ensure consistent application of this provision and facilitate its supervision[37], the EDPB and the EDPS invite the co-legislators to consider the possibility to expressly mandate the EDPB to adopt guidance on how such assessments should be performed by the Member States.

[34] In line with Article 5(1)(c) GDPR and the principle of data minimisation, personal data shall be "adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed".
[35] In particular, controllers should be required to take specific measures to restrict access to personal data only to authorised personnel who need to access them for the performance of their task.
[36] According to the information gathered by the EDPB, it appears that in some Member States this assessment is performed either by ethics committees or by national authorities, whereas in others, prior formalities with national supervisory authorities are required.
[37] The proposed Article 79(1) CTR provides the possibility for the Commission to conduct controls in order to verify whether the Member States correctly supervise compliance with the CTR. Under Article 79(1a) CTR, this includes verification as to whether competent authorities and ethics committees have in place adequate and effective mechanisms to ensure compliance with the CTR as regards in particular the requirements related to scientific and ethical review as referred to in Article 7(1) CTR. When performing the controls referred to in the proposed Article 79(1) CTR, the Commission shall consult the relevant best practices (proposed Article 79(3) CTR).

44. The EDPB and the EDPS welcome the replacement of the reference to Directive 95/46/EC[38] with a reference to the GDPR in the proposed new text of Article 7(1)(d) CTR, and recommend updating the references to the relevant data protection legislation also in the other provisions in the CTR, given that some of them[39] still make reference to legislation no longer in force[40].

3.2.2 Collection of "informed consent" via electronic means (proposed Articles 2(21) and 29(1) CTR)

45. Article 58(1)(e) Proposal aims to amend, *inter alia*, the definition of "informed consent" under Article 2(21) CTR and would insert the possibility to provide informed consent remotely through the use of electronic systems, methods and processes, and signed electronically in accordance with Union law or equivalent standards[41]. This is also reflected in amendments to Article 29(1) CTR, according to which the record of the informed consent procedure may have an electronic form and shall be signed relying on electronic identification means complying with Regulation (EU) No 910/2014 ('the eIDAS Regulation') or equivalent standards[42].

46. The EDPB and the EDPS note that informed consent under Article 2(21) CTR constitutes the basis for a subject's participation in the clinical trial and must not be confused with consent as a legal basis for the processing of personal data under Article 6(1)(a) GDPR[43].

47. The EDPB and the EDPS welcome the possibility for research participants to provide informed consent using electronic means in compliance with the eIDAS Regulation or the equivalent standards. However, the EDPB and the EDPS recall that, in line with Article 5a(15) eIDAS Regulation, the use of the European Digital Identity Wallets ('EDIW') shall be voluntary[44]. Consequently, the EDPB and the EDPS recommend modifying proposed Article 29(1) CTR to recall that the use of the EDIW remains voluntary in this context. Furthermore, the provision of informed consent should not in any way be restricted or made disadvantageous to natural persons that do not use or are not able to use electronic identification means and should remain possible by other existing identification and authentication means.

[38] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJ L 281, 23.11.1995, pp. 31–50.
[39] This is the case, for instance, of the current Articles 28(1)(d), 81(4)(a) and 81(10) CTR.
[40] Regulation 45/2001 and Directive 95/46, which were repealed and replaced, respectively, by Regulation 2018/1725 and Regulation 2016/679.
[41] Article 58(1)(e) Proposal.
[42] Article 58(26) Proposal. In addition, Section D, of Annex I - Part I CTR is amended to include the need to provide, in the protocol, a "justification for inclusion of subjects that can only provide an informed consent through electronic means". Section L of Annex I, Part II CTR also includes a new obligation for the sponsor to ensure, in case electronic means are used to obtain informed consent "that the systems used have proportionate security levels, and that safeguards regarding confidentiality are in place".
[43] 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) (art. 70.1.b)), adopted on 23 January 2019, paragraph 15.
[44] Regulation (EU) 2024/1183 of the European Parliament and of the Council of 11 April 2024 amending Regulation (EU) No 910/2014 as regards establishing the European Digital Identity Framework, OJ L, 2024/1183, 30.4.2024, ELI: http://data.europa.eu/eli/reg/2024/1183/oj.

3.2.3 Regulatory sandboxes for clinical trials (proposed Article 27d CTR)

48. The proposed Article 27d CTR introduces the possibility for the Commission to establish and operate regulatory sandboxes at the EU level to enable, under real-world conditions, the testing of innovative approaches in clinical trials, where the full application of certain requirements under the CTR is not possible or appropriate and which therefore may require "regulatory adaptations"[45]. The insights gained from these sandboxes should inform future guidance and, where appropriate, legislative amendments[46].

49. As a general remark, the EDPB and the EDPS note that no "regulatory adaptations" as regards compliance with the GDPR and the EUDPR would be possible without the adoption of specific derogations for those regulations. Therefore, the EDPB and the EDPS recommend clarifying that the GDPR and EUDPR will remain fully applicable for the processing of personal data carried out in the context of these sandboxes.

50. In addition, the EDPB and the EDPS note that, depending on the requirements under the CTR that are temporarily adapted or derogated from in the regulatory sandbox[47], controllers will have to assess whether the legal basis under the proposed Article 93(1) and (2) CTR that would apply to clinical trials in full compliance with the requirements under the CTR can also be relied upon for processing carried out in the sandbox. For the cases in which controllers cannot rely on this legal basis, the EDPB and the EDPS recommend that the implementing act of the Commission provides for the legal basis, as well as the derogation under Article 9(2) GDPR that would apply to the processing of personal data (if any) in these sandboxes. The implementing act should also, in those cases, define the modalities of the processing of personal data (including the categories of personal data that may be processed in the regulatory sandbox) and the appropriate safeguards for the rights and freedoms of data subjects.

51. According to the proposed Article 27d(5) CTR, regulatory sandboxes for clinical trials shall operate under the direct supervision of the competent authorities of the Member State concerned for activities taking place in its territory. However, it is unclear how cooperation between national competent authorities will take place, especially in the context of cross-border processing. The EDPB and the EDPS recommend clarifying that, to the extent that regulatory sandboxes for clinical trials involve the processing of personal data, the national data protection authorities remain responsible for the supervision of aspects related to data protection law. In cases where several data protection authorities and the EDPS would be involved in the supervision of these regulatory sandboxes, the EDPB and the EDPS can play an advisory role to help ensure consistency on data protection aspects. They recommend making reference to this advisory role in the proposed Article 27d CTR.

[45] Under the proposed Article 27d (2) CTR, this may encompass approaches to the authorisation and conduct of the clinical trials. As examples, the proposed Article 27d(3) CTR provides that such adaptation or derogation could relate to source data and documentation requirements, recruitment and informed consent procedures, monitoring and reporting requirements, trial design rules, investigational medicines handling rules, safety reporting rules, site requirements.
[46] Recital 149 Proposal.
[47] According to the proposed Article 27d(3) CTR these adaptations or derogations "may relate to, as necessary, to source data and documentation requirements, recruitment and informed consent procedures, monitoring and reporting requirements, trial design rules, investigational medicines handling rules, safety reporting rules, site requirements".

52. Lastly, the EDPB and EDPS note that, under the proposed Article 27d(2) CTR, regulatory sandboxes for clinical trials may be implemented in coordination and in synergy with regulatory sandboxes established pursuant to the AI Act, with full involvement of competent authorities supervising those AI regulatory sandboxes and in accordance with the relevant procedures and rules for participating in these AI regulatory sandboxes. On this point, the EDPB and the EDPS recall their recommendations in Joint Opinion 1/2026 on the roles of supervisory authorities and of the EDPB in AI sandboxes[48].

3.2.4 Use of AI in Clinical Trials (New Article 27e CTR)

53. Proposed Article 27e CTR introduces obligations on sponsors when they intend to use AI models or AI systems in the context of a clinical trial. It is unclear, however, whether these obligations will apply in addition to the obligations under the AI Act[49]. Therefore, the EDPB and the EDPS recommend clarifying, directly in proposed Article 27e CTR that the obligations laid down in that provision apply in addition to the rules established under the AI Act[50].

54. Under proposed Article 27e(1) CTR, the sponsor shall evaluate the benefits and risks related to patient safety and data robustness arising from the use of AI in the context of the clinical trial. In addition, sponsors shall provide information in the protocol on the specific purpose of using AI models or systems, as well as a description of the process in which they are used in the context of the clinical trial[51].

55. When evaluating the benefits and risks related to patient safety and data robustness of the use of AI in the context of a clinical trial, the sponsor shall consider the non-binding guidelines developed under Article 31 Proposal[52] by the European Medicines Agency ('EMA'), in cooperation with the Clinical Trials Coordination and Advisory Group and, where appropriate, the Medical Device Coordination Group and the AI Board. In this regard, the EDPB and EDPS note that the use of AI models and systems in clinical trials may involve the processing of personal data and have significant consequences for data subjects[53].Therefore, the EDPB and EDPS recommend including an obligation for the EMA to cooperate with the EDPB for the development of the guidelines referred into the proposed Article 27e(4) CTR, insofar as the protection of personal data is concerned.

[48] EDPB-EDPS Joint Opinion 1/2026 On the Proposal for a Regulation as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI), adopted on 20 January 2026, Section 5. In particular, the EDPB and the EDPS recommended to address directly in the AI Act the issue of the competence of supervisory authorities and its interplay with the GDPR cooperation mechanism to avoid legal uncertainty (paragraph 27). In addition, the EDPB and the EDPS recommended to specifically refer to the advisory role of the EDPB for ensuring consistency on data protection aspects, and that the EDPB should be granted the status of observer at the European Artificial Intelligence Board (paragraphs 28-29).
[49] In this regard, Recital 157 only mentions that "it is imperative that [the use of AI tools] in clinical trials adheres to applicable legislation. This includes, when applicable, compliance with Regulation (EU) 2024/1689, [...]".
[50] See, in this regard, paragraph 7 of this Joint Opinion.
[51] Proposed Article 27e(2) CTR. In this regard, Annex I, Part I, point D, (aq) CTR is modified to include, in case an AI tool is used by the sponsor, "a clear explanation of the specific purpose of the use of that tool and a description of the processes in which it is used. If an AI tool is certified according to [AI Act], the sponsor shall provide the information contained in the certificate".
[52] The proposed Article 27e(1) CTR refers to Article 37 of the Proposal. However, the EDPB and EDPS understand that this is an editorial mistake and that this provision should instead refer to Article 31 Proposal.
[53] In particular, Recital 158 Proposal mentions that "untested [AI] systems may introduce gender and other biases and errors, risking unreliable outcomes or failures in interpreting medical data accurately. Such risks could lead to misdiagnosis, incorrect treatment, or inaccurate patient selection, especially hazardous in extensive clinical trials with numerous participants".

4. ARTIFICIAL INTELLIGENCE AND DATA AS BIOTECHNOLOGY ENABLERS (ARTICLES 31 TO 40 PROPOSAL)

4.1 Guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products (Article 31 Proposal)

56. According to Article 31 Proposal, the EMA is obliged to publish non-binding guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products development, including during pre-clinical research, clinical development and trials, manufacturing and post-authorisation monitoring. This guidance shall be developed, updated and published in agreement with the Commission, including with the AI Office. In developing and updating the guidance, the EMA shall consult the relevant authorities, at national and European level, and stakeholders when appropriate[54].

57. The EDPB and EDPS welcome that Article 31(2) Proposal provides for the explicit possibility to consult other relevant authorities at national and European level, which is important to promote a coherent and consistent interpretation of EU law and to provide legal certainty to stakeholders. As the use of AI during the lifecycle of medicinal products development is likely to involve the processing of personal data (e.g. during clinical trials), the EDPB and EDPS consider it of utmost importance to ensure consistency with EU data protection law. Against this background, the EDPB and EDPS recommend providing, by way of a recital, an explicit reference to the possibility to consult the EDPB concerning data protection-related aspects of the guidance to be developed by the EMA, with the aim of ensuring consistency of this guidance with the GDPR.

4.2. Biotechnology testing environments for advanced biotechnology innovations (Article 32 Proposal)

58. Article 32 Proposal would authorise the Commission to recognise projects located in the Union as high impact health biotechnology strategic projects in the form of trusted testing environments for advanced health biotechnology innovations, where such innovations are enabled, enhanced or significantly supported by AI or other advanced computational methods and fulfil specific criteria. The EDPB and EDPS also note that under Article 32(1)(a) Proposal, the Commission would be required to assess whether projects comply with relevant EU and national legislation[55].

59. The EDPB and the EDPS understand that it cannot be excluded that the projects regulated by Article 32 Proposal will involve the processing of personal data. In such cases, the supervisory authorities established under the GDPR and the EDPS would be competent to supervise compliance of the projects with the GDPR and the EUDPR. Against this background, the EDPB and the EDPS recommend adding a reference to the possibility for the designated authority at the national level or the Commission to consult supervisory authorities under the GDPR or the EDPS, in the context of their assessment of the compliance with relevant EU and national legislation, where such projects involve the processing of personal data.

[54] Article 31(2) Proposal.
[55] Article 4(1)(d) Proposal also refers to Article 32(1)(a) Proposal in this respect.

4.3. Biotechnology data quality accelerators (Article 33 Proposal)

60. Article 33 Proposal enables the Commission to recognise projects located in the Union as high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators[56]. Processing of personal data by the entities that lawfully hold the relevant datasets and by the biotechnology data quality accelerator would take place in the public interest[57]. To recognise a strategic project in the form of a biotechnology data quality accelerator, the Commission would adopt a decision by means of an implementing act. The decision would, for each of those projects, also specify the modalities of processing of personal data necessary to achieve the purpose of the project[58]. In particular, the Commission would specify the categories of data to be processed, the roles of the entities participating in the project, the categories of the entities which may use the curated data, and the safeguards.

61. The EDPB and the EDPS welcome that the modalities of the processing of personal data necessary to achieve the purpose of the projects would be specified by the Commission in the implementing acts. They also invite the Commission, when preparing those implementing acts, to consider the principles of Article 5 GDPR and, if the recognised project would entail the processing of special categories of data (which would likely be the case) provide for suitable and specific technical and organisational measures to safeguard the rights and freedoms of data subjects[59].

62. In addition, in line with Article 6(3) GDPR, and for the more legal clarity, the EDPB and the EDPS suggest including the wording "for the purpose of conducting" before "biotechnology data quality accelerator projects" in Article 33(4), to make clear that this Article is only providing a legal basis in the context of the projects. They also suggest adding an explicit mention of Article 6(1)(e) GDPR in Recital 68 Proposal, as a reference to the legal basis under the GDPR to process personal data in the context of Article 33(4) Proposal.

63. In the same vein, the EDPB and the EDPS recommend making it clear that Article 33(4) Proposal is intended to provide a legal basis for processing of personal data by the entities that lawfully hold the relevant datasets enhanced as provided for in Article 33(2)(b) Proposal only for the improvement of data quality, standardising and making other improvements to such data in accordance with Article 33 Proposal, and not for the initial collection of such personal data by the entity that hold already the data. This could be achieved by using the wording of Recital 68 Proposal according to which "the processing of personal data by the entities that lawfully hold the relevant data and by the biotechnology data quality accelerators, in the context of biotechnology data quality accelerators projects, takes place in the public interest".

[56] Such projects may only be recognised where they comply with the criteria laid down in Article 4(1) Proposal, fulfil the conditions laid down in paragraph 2 of this Article and they make a significant contribution to the curation, maintenance and responsible use of high-quality, appropriately annotated and provenance-verified datasets that are essential for the training, validation and testing of AI systems and models used in health biotechnology applications (Article 33(1) Proposal).
[57] Article 33(4) Proposal.
[58] Article 33(7) Proposal.
[59] Article 9(2)(g) and Article 9(2)(i) GDPR.

4.4. Regulatory sandboxes for novel health biotechnology products not falling under other regulatory sandboxes in Union legislation in the area of health (Article 40 Proposal)

64. Article 40 Proposal would authorise the Commission, upon a substantiated request from developers, to set up a regulatory sandbox that provides a controlled regulatory environment for the testing and development of a health biotechnology product that does not fall under other regulatory sandboxes in the Union legislation in the area of health. Developers would be obliged to apply to the Commission to participate in a regulatory sandbox. The testing and development activities within the regulatory sandbox would take place in accordance with a sandbox plan. This plan would have to, among other things, be informed by data provided by, and in consultation with, the developer of the health biotechnology product concerned.

65. The EDPB and the EDPS understand that Article 40 Proposal does not aim to provide for a legal basis for the processing of personal data, as no personal data is expected to be processed in the context of regulatory sandboxes for novel health biotechnology product. However, should the processing of personal data take place, the EDPB and the EDPS recall that such processing must rely on a valid legal basis under the GDPR. Against this background, the EDPB and the EDPS recommend recalling, by way of a recital the need of a legal basis, as well as an exception under Article 9(2) GDPR that would apply to the processing of special categories of data (if any) in the sandboxes.

66. In cases where processing of personal data is foreseen, the EDPB and the EDPS recommend that the sandbox plan to be approved by the Commission under Article 40(5) Proposal also determines the scope and the modalities of the processing, including the categories of personal data that may be processed in the context of the sandbox and appropriate safeguards for the protection of the rights and freedoms of natural persons in line with the GDPR and the EUDPR.

67. The EDPB and the EDPS also recommend explicitly providing the possibility for the Commission to consult with competent authorities (including, if applicable, the supervisory authorities established under the GDPR and the EDPS) before the establishment and in the course of the functioning of regulatory sandboxes under Article 40 Proposal. The purpose of such consultations would be to provide advice to the Commission about compliance of the health biotechnology product under testing with applicable Union or Member State law.

4.5 Verification of legitimate need (Article 44 Proposal)

68. Article 44(2) Proposal sets out the information to be requested by an economic operator from a prospective customer prior to supplying specific biotechnology products of concern. The information to be requested from the prospective customer includes proof of identity of this person[60].

69. Considering that prospective customers can be natural persons, as is specified in Recital 92 Proposal, the EDPB and the EDPS recommend that further guidance is provided regarding which data may be collected to prove the identity of the prospective customer, for example in the guidelines referred to in Article 54(c) Proposal. The data required should be adequate, relevant and limited to what is necessary for proving the identity[61].

[60] Article 44(2)(a) Proposal.
[61] Article 5(1)(c) GDPR.

70. Pursuant to Article 44(5) Proposal, economic operators have an obligation to report any suspicious transaction or attempted suspicious transaction, in accordance with Article 46(5) Proposal, to national contact points referred to in Article 46(3) Proposal. Suspicious transactions are defined in Article 2(2)(d) Proposal as "any transaction concerning biotechnology products of concern for which there are reasonable grounds, taking into account all relevant factors, to doubt the legitimacy of the prospective customer's intentions". The EDPB and the EDPS recommend clarifying the concept of "relevant factors", for example by making a cross-reference to the circumstances listed in Article 46(1) Proposal.

5. AMENDMENTS TO REGULATION (EC) NO 178/2002 ('FOOD LAW REGULATION') (ARTICLE 56 PROPOSAL)

71. Article 56(7) Proposal would insert a new Chapter IIIA in Regulation (EC) No 178/2002[62], thereby allowing Member States to establish regulatory sandboxes for specific food-related innovations. Where a Member State deems it appropriate to establish a regulatory sandbox, it is required to communicate to the Commission, the European Food Safety Authority (EFSA) and other Member States a draft regulatory sandbox plan[63].

72. The EDPB and the EDPS understand that Article 56(7) Proposal does not aim to provide for a legal basis for the processing of personal data, as no personal data is expected to be processed in the context of regulatory sandboxes for novel health biotechnology product. However, should the processing of personal data take place[64], the EDPB and the EDPS recall that such processing must rely on a valid legal basis under the GDPR. Against this background, the EDPB and the EDPS recommend recalling, by way of a recital the need of a legal basis, as well as an exception under Article 9(2) GDPR that would apply to the processing of special categories of data (if any) in the sandboxes.

73. In cases where processing of personal data is foreseen, the EDPB and the EDPS recommend defining, in the draft regulatory sandbox plan to be developed and approved by the Member States, the modalities of processing of personal data, including the categories of personal data that may be processed in the context of the sandbox, as well as appropriate safeguards for the protection of the rights and freedoms of natural persons in line with the GDPR.

6. AMENDMENTS TO REGULATION (EU) 2024/1938 ('SOHO') (ARTICLE 61 PROPOSAL)

74. Article 61 Proposal introduces amendments to Regulation (EU) 2024/1938[65] specifically to establish regulatory sandboxes for the development and testing of innovative products, services, processes or substances in the field of substances of human origin ('SoHO'). The sandbox plan is "informed by data provided by, and established following consultations with, the developers of the concerned innovations" and "identifies the participants in the regulatory sandbox and their respective roles"[66].

[62] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, pp. 1–24.
[63] Article 56(7) Proposal, proposed new Article 49a(1) and 49b(1) of Regulation (EC) No 178/2002.
[64] In particular personal data of consumers. See, in this respect, the proposed new Articles 49a(3)(c) and 49b(1)(g) Regulation (EC) No 178/2002 in Article 56(7) Proposal.
[65] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC, OJEU L 17.7.2024 ELI: http://data.europa.eu/eli/reg/2024/1938/oj.
[66] Article 61(4) Proposal.

75. The EDPB and the EDPS understand that Article 61 Proposal does not aim to provide for a legal basis for the processing of personal data, as no personal data is expected to be processed in the context of SoHO and recommend specifying this in the recital of the Proposal. However, should the processing of personal data take place, the EDPB and the EDPS recall that such processing must rely on a valid legal basis under the GDPR. Against this background, the EDPB and the EDPS recommend recalling, by way of a recital the need of a legal basis, as well as an exception under Article 9(2) GDPR that would apply to the processing of special categories of data (if any) in the context of SoHO sandboxes.

76. In cases where processing of personal data is foreseen, the EDPB and the EDPS recommend defining, in the regulatory sandbox plan, the modalities of processing of personal data, including the categories of personal data that may be processed in the context of the sandbox, as well as appropriate safeguards for the protection of the rights and freedoms of natural persons in line with the GDPR.