

EDPS Formal comments on the draft Commission Implementing Regulation laying down the necessary measures for the establishment and operation of the European Health Data Space Board

THE EUROPEAN DATA PROTECTION SUPERVISOR,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals 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 ('EUDPR')¹, and in particular Article 42(1) thereof,

HAS ADOPTED THE FOLLOWING FORMAL COMMENTS:

1. Introduction and background

1. On 22 December 2025, the European Commission consulted the EDPS on the draft Commission Implementing Regulation laying down the necessary measures for the establishment and operation of the European Health Data Space Board ('the draft Implementing Regulation').
2. The objective of the draft Implementing Regulation is to detail the types of actions that the Board established under Article 92 of Regulation (EU) 2025/327² ('EHDS Regulation') may take when performing its general tasks to ensure consistent application of the EHDS Regulation.³ This includes issuing written contributions in the form of non-binding guidelines and in relation to technical specifications, among others.⁴ The EHDS Board would also foster exchanges of best practices among national authorities, the Commission and other relevant bodies, authorities and

¹ OJ L 295, 21.11.2018, p. 39.

² Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847 (OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>).

³ Recital 3 of the draft Implementing Regulation.

⁴ Recitals 3 and 4 of the draft Implementing Regulation.

agencies, as well as cooperate with other fora such as the Artificial intelligence Board established under Regulation (EU) 2024/1689⁵.

3. The draft Implementing Regulation also aims to define the rules for the designation of the co-chairs of the EHDS Board, for the reimbursement of expenses and confidentiality, and access to documents and transparency.⁷
4. The draft Implementing Regulation would be adopted pursuant to Article 92(11) of the EHDS Regulation.
5. The EDPS previously issued, together with the European Data Protection Board ('EDPB'), a Joint Opinion on the Proposal that led to the adoption of the EHDS Regulation, which contained relevant recommendations concerning the setting up and functioning of the EHDS Board.⁸
6. The present formal comments of the EDPS are issued in response to a consultation by the European Commission pursuant to Article 42(1) of EUDPR. The EDPS welcomes the reference to this consultation in Recital 12 of the draft Implementing Regulation.
7. These formal comments do not preclude any additional comments by the EDPS in the future, in particular if further issues are identified or new information becomes available, for example as a result of the adoption of other related Implementing or Delegated acts⁹.
8. Furthermore, these formal comments are without prejudice to any future action that may be taken by the EDPS in the exercise of his powers pursuant to Article 58 of the EUDPR and are limited to the provisions of the draft Implementing Regulation that are relevant from a data protection perspective.

2. Comments

9. The EDPS welcomes the objectives of the draft Implementing Regulation. Given the important tasks assigned to the EHDS Board under Article 94 EHDS, it is paramount to ensure its functioning is structured and foreseeable.

⁵ 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>).

⁶ Recitals 4 and 5 of the draft Implementing Regulation.

⁷ Recitals 7-11 of the draft Implementing Regulation.

⁸ EDPS, 'Towards a Digital Clearinghouse 2.0' Concept Note, adopted on 12 July 2022, paragraphs 117-120.

⁹ In case of other Implementing or Delegated acts with an impact on the protection of individuals' rights and freedoms with regard to the processing of personal data, the EDPS would like to remind that he needs to be consulted on those acts as well. The same applies in case of future amendments that would introduce new or modify existing provisions that directly or indirectly concern the processing of personal data.

10. The EDPS notes that the final version of the EHDS Regulation establishes that the EDPB and the EDPS shall be invited to attend the meetings of the EHDS Board, where relevant according to the EHDS Board.¹⁰ Given the interplay between the EHDS Regulation, the EUDPR and Regulation (EU) 2016/679¹¹ ('GDPR')¹², the EDPS considers that such invitations would be particularly useful in cases where discussions on matters concerning personal data protection are to take place, to foster consistency in the interpretation and application of the EHDS Regulation, the EUDPR and the GDPR. The EDPS recommends clarifying this in a recital to the draft Implementing Regulation.
11. Digital health authorities, health data access bodies, the EDPS, EDPB members and other competent authorities that participate in the EHDS Board should be able to effectively cooperate as foreseen in the EHDS Regulation¹³. The EDPS therefore welcomes that the thematic exchanges envisaged by Article 2(1)(c) of the draft Implementing Regulation would also include relevant bodies, agencies and authorities invited to attend EHDS Board meetings, including data protection authorities.

Brussels, 23 January 2026

(e-signed)

Wojciech Rafał WIEWIÓROWSKI

¹⁰ Article 92(3) EHDS Regulation.

¹¹ 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, pp. 1–88.

¹² See, as an example, Article 58 EHDS Regulation.

¹³ Recitals 30, 78, 98 and 99 and Articles 19(2)(k), (l) and (m), 22, 30(1)(m) and 5, 44(6) and (9), 55(1), 57(2), and 65 EHDS Regulation.