



EDPS Formal comments on the draft Commission Implementing Regulation laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medical devices and in vitro diagnostic medical devices at Union level, as well as templates for those joint clinical assessments

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 16 June 2025, the European Commission consulted the EDPS on the draft Commission Implementing Regulation laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment², procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medical devices and in vitro diagnostic medical devices at Union level, as well as templates for those joint clinical assessments ('the draft Implementing Regulation').
2. The objective of the draft Implementing Regulation is to lay down detailed procedural rules for joint clinical assessments of medical devices and in vitro diagnostic medical devices ('medical devices') at Union level, as regards³:
 - a. Cooperation of the Member State Coordination Group on Health Technology Assessment established under Article 3 of Regulation (EU) 2021/2282 ('the Coordination Group') and the Commission acting as secretariat of the Coordination Group ('the HTA secretariat') with the notified bodies designated in accordance with Regulation (EU) 2017/745 or Regulation (EU) 2017/746 ('the notified bodies') and with the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 ('the expert

¹ OJ L 295, 21.11.2018, p. 39.

² Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU, OJ L 458, 22.12.2021, p. 1–32.

³ Article 1 of the draft Implementing Regulation.

- panels’) in the form of exchange of information as regards the preparation and update of joint clinical assessments;
- b. interaction, including the timing thereof, with and between the Coordination Group, its subgroups and health technology developers, patients, clinical experts and other relevant experts (‘individual experts’) during joint clinical assessments and their updates;
 - c. general procedural rules on the selection and consultation of stakeholder organisations and individual experts in joint clinical assessments;
 - d. the format and templates for dossiers with information, data, analyses and other evidence to be provided by health technology developers for joint clinical assessments;
 - e. the format and templates for joint clinical assessment reports and summary reports.
3. The draft Implementing Regulation is adopted pursuant to Article 15(1)(b)-(c), Article 25(1)(b), and Article 26(1) of Regulation (EU) 2021/2282.
 4. The present formal comments of the EDPS are issued in response to a consultation by the European Commission pursuant to Article 42(1) of the EUDPR. The EDPS welcomes the reference to this consultation in Recital 31 of the draft Implementing Regulation.
 5. 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 acts⁴.
 6. 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

2.1. Selection of individual experts for joint clinical assessments of medical devices

7. The draft Implementing Regulation provides for rules on the identification and selection of individual experts to be consulted during the joint clinical assessments on medical devices⁵. It provides, with the necessary modifications, for similar rules as:

⁴ 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.

⁵ Article 8 of the draft Implementing Regulation.

- Article 6 of Commission Implementing Regulation (EU) 2024/1381⁶, which provides for the selection of individual experts for joint clinical assessments of medicinal products for human use;
 - Article 5 of the Commission Implementing Regulation (EU) 2024/3169⁷, which provides for the selection of individual experts for joint scientific consultations on medicinal products for human use; and
 - Article 6 of Commission Implementing Regulation (EU) 2025/117⁸, which provides for the selection of individual experts for joint scientific consultations on medical devices and in vitro diagnostic medical devices.
8. In this regard, the EDPS recalls its formal comments on the Commission Implementing Regulation (EU) 2024/1381 and welcomes that Article 8 of the draft Implementing Regulation takes into account his previous recommendation⁹.

2.2. Processing of personal data

9. Any documentation referred to in Regulation (EU) 2021/2282 and the draft Implementing Regulation should be sent in a digital format and should be exchanged with and between the Coordination Group, the JCA Subgroup, the HTA secretariat, the health technology developer and individual experts during joint clinical assessments and updates of joint clinical assessment through the HTA IT platform¹⁰. This platform is referred to in Article 30 of Regulation (EU) 2021/2282 ('the HTA IT platform').
10. The EDPS welcomes that recital 28 of the draft Implementing Regulation recalls that any processing of personal data by the members of the Coordination Group and the JCA Subgroup and their representatives outside of the HTA IT platform is to take place in accordance with Regulation (EU) 2016/679 (the 'GDPR')¹¹.

⁶ Commission Implementing Regulation (EU) 2024/1381 of 23 May 2024 laying down, pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medicinal products for human use at Union level, as well as templates for those joint clinical assessments, OJ L, 2024/1381, 24.5.2024.

⁷ Commission Implementing Regulation (EU) 2024/3169 of 18 December 2024 laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council with regard to the procedures for joint scientific consultations on medicinal products for human use at Union level, OJ L, 2024/3169, 19.12.2024.

⁸ Commission Implementing Regulation (EU) 2025/117 of 24 January 2025 laying down rules for the application of Regulation (EU) 2021/2282 with regard to the procedures for joint scientific consultations on medical devices and in vitro diagnostic medical devices, OJ L, 2025/117, 27.1.2025.

⁹ See [EDPS Formal comments on the draft Commission Implementing Regulation laying down, pursuant to Regulation \(EU\) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments of medicinal products for human use at Union level, as well as templates for those joint clinical assessments](#), issued on 4 April 2024, paragraphs 18-21. Article 8 of the draft Implementing Regulation provides that to compile a list of individual experts, the consultation of other sources than those specifically listed should only take place in case the consultation of the specifically listed sources does not yield a sufficient number of relevant individual experts.

¹⁰ Article 20 and recital 25 of the draft Implementing 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, p. 1–88.

11. The EDPS also welcomes that the draft Implementing Regulation lays down the rules for processing of personal data for the purpose of conducting joint clinical assessments of medical devices and their updates under the draft Implementing Regulation¹². The EDPS notes that similar provisions are included in other Implementing Regulations under Regulation (EU) 2021/2282¹³. In particular, the EDPS welcomes that the draft Implementing Regulation:

- details the role of the Commission as controller¹⁴;
- lists the categories of personal data processed per category of data subjects¹⁵;
- requires access controls to ensure that representatives appointed to the Coordination Group and the JCA Subgroup would only have access to the parts of the secure system of the HTA IT platform which are relevant for the performance of their tasks¹⁶;
- provides that the personal data of patients involved in joint clinical assessments and their updates shall not be published¹⁷; and
- defines the storage period for processing of personal data, that ensures that data is kept no longer than necessary for the purpose of conducting joint clinical assessments of medical devices and their updates, and in any event no longer than 15 years after the date on which the data subject no longer participates in the joint clinical assessment¹⁸. The EDPS positively notes the requirement of a review every 2 years to ensure that personal data is not stored longer than necessary in practice. The EDPS also positively notes that the draft Implementing Regulation provides for a shorter maximum storage period for personal data of individual experts not selected to be consulted in a joint clinical assessment¹⁹.

12. The EDPS welcomes that the draft Implementing Regulation further provides as an additional safeguard that only individual experts who have signed a confidentiality agreement should be involved in joint clinical assessment of medical devices²⁰. Insofar these individuals have access to personal data in the context of a joint clinical assessment, those confidentiality agreements can serve, among others, as an important safeguard for the protection of personal data.

¹² Article 22 and recital 27 of the draft Implementing Regulation.

¹³ Article 21 of Commission Implementing Regulation (EU) 2024/1381; Article 15 of Commission Implementing Regulation (EU) 2024/3169; and Article 16 of Commission Implementing Regulation (EU) 2025/117.

¹⁴ Article 22(1) and recital 28 of the draft Implementing Regulation.

¹⁵ Article 22(2) of the draft Implementing Regulation.

¹⁶ Article 22(3) of the draft Implementing Regulation.

¹⁷ Article 22(4) of the draft Implementing Regulation. See also recital 28 which explains that the identity of the patient may reveal the patient's health status in relation to the subject matter of the joint clinical assessment and should therefore be considered a special category of personal data under Article 10 of Regulation (EU) 2018/1725, which should only be processed where the criteria set out in Article 10(2)(i) EUDPR are met.

¹⁸ Article 22(5) of the draft Implementing Regulation. Recital 30 of the draft Implementing Regulation justifies the storage period to ensure the possibility to verify whether the joint clinical assessments were conducted in the procedurally compliant manner, notably in the event of complaints or litigation.

¹⁹ Article 22(5) of the draft Implementing Regulation.

²⁰ Article 9 and recital 29 of the draft Implementing Regulation.

13. In light of the safeguards already included in the draft Implementing Regulation, the EDPS does not have any further recommendations.

Brussels, 15 July 2025

(e-signed)

Wojciech Rafał WIEWIÓROWSKI