

Xt-EHR Targeted Stakeholder Consultation

Guidelines on how to provide comments

D6.1

The goal of the targeted stakeholder consultation procedure is to collect feedback from relevant stakeholders on Xt-EHR deliverables that are related to specifications detailed in the **European Health Data Space (EHDS) regulation**.

The consultation aims to compile comments on each draft deliverable that reflect a broad and balanced view of all relevant stakeholders on the content, including important details. The comments provided in the consultation will be key to shape and **further improve the content of the deliverable**. This consultation should also make sure, that the status quo and individual realms of healthcare systems in the participating European countries are adequately reflected.

Please note that the targeted stakeholder consultation procedure is **not held as a public consultation** but that a public consultation on Xt-EHR results that are critical for implementation of European Health Data Space (EHDS) regulation will follow later on.

If you wish to forward the draft deliverable for further feedback within your organisation or to relevant experts within your network, you are welcome to do so.

Please enter your feedback in the provided **excel file** "03_D6.1_Xt-EHR_commenting form_v3", which serves as a common template for the consultation on all Xt-EHR deliverables in the targeted stakeholder consultation procedure.

When providing comments, please **follow the guidelines listed below**. Please note that there will be only one round of comments at this stage, the work package (WP) that prepared the draft deliverable will provide an observation/ response to each comment.

The **resolution of comments** is anticipated by the end of December 2025.

- Please provide your feedback by the end of the consultation phase, sending the commenting form to the national representative (WP2/EC contact) who shared documents on the stakeholder consultation. The **deadline to provide comments on D6.1 is 15.09.2025**.
- Please provide your **comments in English**, as comments are collected and compiled from all participating European countries and will be forwarded to the Xt-EHR WP that prepared the deliverable.
- Please **fill in all the green columns** in the form to provide comments (column 1-11).
- Please qualify the **category of your comment as major or minor** (column 8):
Major: This comment is decisive for the implementation in your country. If it is not addressed by the WP, this would prevent/ hinder the implementation of the EHDS regulation.
Minor: This comment is for improvement of the deliverable, but will not hinder the implementation in your country.

- Please indicate the **type of comment** as editorial, general or technical (column 9):
Editorial comments are considered to improve the format or wording, i.e. improve readability and comprehension of the text.
Technical comments are considered to address topics which will need to be addressed by technical experts within the WP.
General comments are considered to address overarching topics, for example a change of policy, a new aspect, which has not yet considered, or topics where the WP will have to elaborate a balanced view across all participating European countries.
- Please make sure that your comments have a **clear indication in the column “proposal”** (column 11) on what is expected to be changed in the document and how the document should be improved, i.e. which information should be added, changed or removed.
- **Per organisation** only one commenting document is accepted. If applicable: Please align **and compile your feedback within your organisation**.

Contacts for questions

For questions related to the organisation of the consultation, please ask the representative from your country (WP2/EC contact) who shared the information and documents on the stakeholder consultation.

For questions related to the content of D6.1, please reach out to the following Xt-EHR work package 6 representatives of T6.1:

Lead: Marcello Melgara at marcello.melgara@melgara.onmicrosoft.com

Co-lead: Anna Adelöf Kragh at anna.adelof-kragh@socialstyrelsen.se