



Extended EHR@EU Data Space for Primary Use - Xt-EHR Joint Action

Call: EU4H-2022-JA-IBA/Joint Actions 2022, Topic: EU4H-2022-JA-09

Type of Action: EU4H-PJG/EU4H Project Grants, Proposal number: 101128085

D6.1 - Patient summary: EEHRxF, requirements, and specifications for EHR systems

Stakeholder Consultation

Supporting Document

2025, 14 July

(Co-)Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

Table of Contents

1	Stakeholder Consultation Target Groups -----	1
2	Overview of Work Package 6 -----	1
3	Overview of Deliverable 6.1 – Patient Summary: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems -----	2
4	Stakeholder feedback requested for D6.1 -----	2
5	Contacts for questions -----	6

1 Stakeholder Consultation Target Groups

As part of Xt-EHR strategy, selected deliverables will undergo stakeholder consultation. This document intends to engage stakeholders with knowledge on the following topics:

- National and local implementation of patient summaries
- Support of national or local patient summaries
- MyHealth@EU services, including cross-border patient summary service
- Vendors of Development or specification of Electronic Health Record (EHR), including vendor and health professional perspectives
- Users of EHR systems providing data to patient summaries in healthcare settings
- Health professionals perspectives involved in on specification and/or procurement of EHR-systems?

This work is closely related to MyHealth@EU¹ services within the scope of the European Health Data Space (EHDS) regulation². Consequently, specific terminologies associated with these services are referred to throughout this work.

2 Overview of Work Package 6

The work in WP6 – *Electronic* prescriptions and patient summary towards EHDS – builds on previous work done by the eHealth Network, including the MyHealth@EU services. WP6 provides proposals for harmonized datasets, coding systems and values, and technical interoperability specifications for the European Electronic

¹ MyHealth@EU - Flyer addressed to patients and health professionals [available [here](#)]

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. [available [here](#)]

Health Record Exchange Format (EEHRxF) according to Article 15 of the EHDS Regulation ². The proposals aim to support both national and cross-border exchange of health data.

To achieve this, two reports are developed:

- D6.1 – *Patient Summary: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems*
- D6.2 – *Electronic prescription and electronic dispensation: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems*

This document focusses on the stakeholder consultation for D6.1.

3 Overview of Deliverable 6.1 – Patient Summary: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems

D6.1 – *Patient Summary: Implementation guides on EEHRxF, functional and technical requirements and specifications for EHR systems* provides specifications that will be commonly used, machine-readable and allow transmission of personal electronic health data between different software applications, devices and healthcare providers. It aims to support transmission of structured and unstructured health data.

The deliverable includes elements in accordance with Article 15) of the EHDS regulation, namely harmonized datasets containing electronic health data and defining structures, coding systems and values to be used as well as technical interoperability specifications for the exchange of electronic health data. This will be achieved by focusing on the requirements for interoperable and safe exchange of patient summaries including a thorough review of EEHRxF, as well as of different specific functional and technical requirements, and specifications developed under eHN and EU-funded projects, deployed under the MyHealth@EU. In addition, the International Patient Summary has been taken into consideration to meet extended requirements on EHR systems according to EHDS.

The two major use cases the deliverable aims to support is that of national and cross-border exchange of patient summary, meaning the support of both national health data sharing and cross-border exchange of data between a country A (country of origin) and country B (country of treatment).

The deliverable includes and references to the Xt-EHR logical models and to HL7 FHIR implementation guides (IG) developed in collaboration with HL7 Europe and IHE.

4 Stakeholder feedback requested for D6.1

Here we present a set of questions deemed relevant for the consultation of this deliverable. The questions are meant to trigger comments, not all questions need to be answered, and comments not related to these specific questions are of course welcome.

To ensure that the description of the EEHRxF, the functional and technical requirements and specifications are understandable to stakeholders, including healthcare providers and EHR system vendors, WP6 seeks specific feedback from consultation participants in the following areas:

01 General definitions

The document presents different definitions that were summarised for the use of this document. The main sources used for the definitions were the proposed EHDS regulation and MyHealth@EU. Other sources were used when available to complement missing definitions.

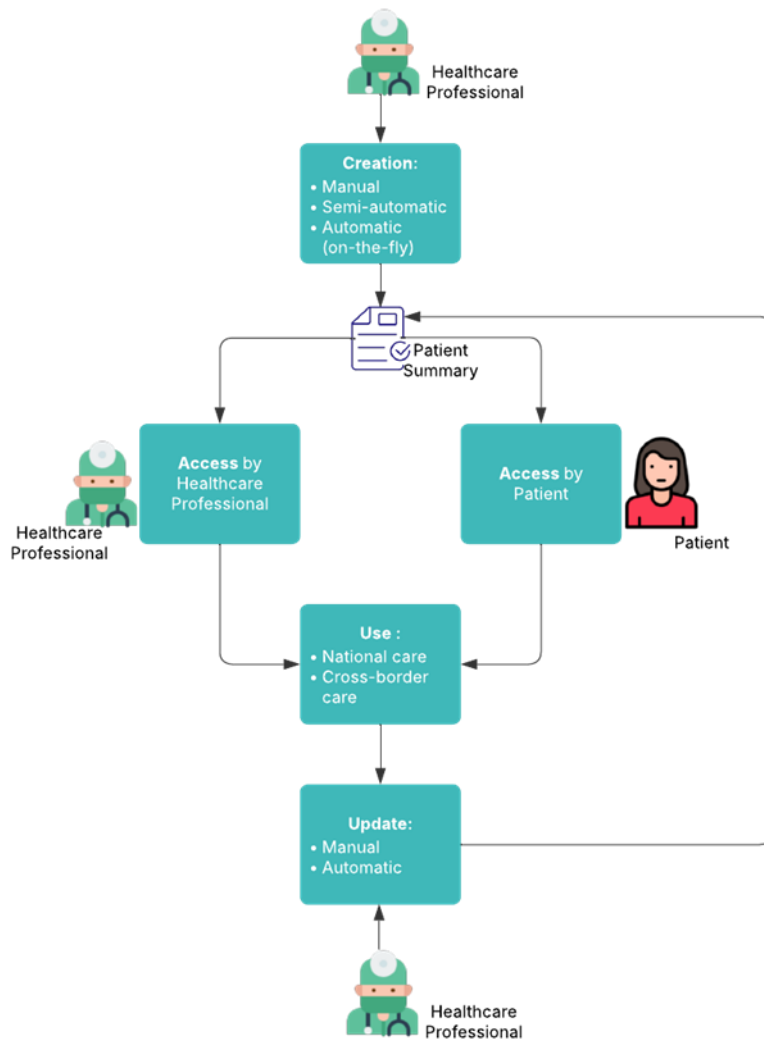
1 Feedback Requested

- Are the definitions clearly and appropriately described for the context of the deliverable document?
- What improvements would you like to propose?

02 Use Case description

In section *Use case description* - the focus is to keep the current logic of the eHealth Network guidelines as well as adding the national perspective. It contains a brief explanation of the purpose, relevance, situation, context, main participants, and functional process steps. As mentioned, two main uses cases were proposed, national and cross border, which can be divided into multiple perspectives:

- Manual creation of Patient Summary by Health Professional (HP).
- Automatic (on-the-fly) creation of Patient Summary.
- Patient Summary sharing on a national scale.
- Patient Summary sharing on a cross-border scale.
- Request for the Patient Summary by the Patient or patient's representative.
- Update the Patient Summary after provision of healthcare service.
- Automatic update of the Patient Summary after provision of healthcare service.
- Patient's request to rectify the PS and/or inclusion of patient's provided information.



2 Feedback Requested

- Are the use cases clearly described and relevant in their entirety?
- Are there additional use cases that should be included?
- Are the actors described relevant? Are there actors missing?
- Are there any comments on the Adjacent topics section?

03 Data set

A number of tables describe the data sets of the deliverable. Dataset overviews are also provided as UML diagrams and mindmap-style diagrams to aid readers.

The columns of the detailed descriptions table include:

1. Cardinality – the minimum and maximum occurrence of a value of a data element
2. Data element – the name of the data element and its path in the logical model

3. Description
4. Data type – the data type of the value of the data element
5. Obligation (conformity requirements)
6. Preferred code system (in case the datatype allows coded data).
7. Associated Value Sets (if existing and meaningful).

The tables also include numbers (No.) to present the hierarchical structure of the data elements and allow referencing to the individual data elements. The tables presented in the deliverable are views of the logical models developed by Xt-EHR. These logical models are presented in full elsewhere. The web link to the full logical models will be provided when the draft deliverable is made available for consultation. Following the tables with datasets are search parameters and obligations. The obligation framework is a way to express which data elements are required given a certain EHR system function.

3 Feedback Requested

- Does the respective dataset include all relevant data elements?
 - Can you identify any missing data elements?
 - Are there any elements that should be excluded?
- Are the datasets and data elements described to a sufficient level of detail?
 - Is there any ambiguous or unclear content in the descriptions for the data sets elements, please elaborate?
- Are the preferred code systems in the datasets adequate? Are there code systems missing? Which elements require a preferred code system?
- Are there any risks regarding structuring data in the proposed way?
- Are there any foreseen administrative burdens for health professionals?
- Are the dataset obligations (conformity requirements) for the dataset correct and sufficient?
- Any data elements that should be considered to be removed?
- Considering the Associated Value Sets:
 - Which type of ValueSets?
 - Required, i.e. fixed sets of values, to facilitate translations?
 - Extensible, i.e. fixed sets of values, with the possibility of adding other concepts, elements to have a common set, plus National extensions
 - Preferred, i.e. as non binding indication of values to be used, to minimize the constraints?

04 Implementation guide

The technical interoperability specifications were developed in collaboration between Xt-EHR and HL7 Europe based on requirements from Xt-EHR supporting EHDS implementation. These specifications are not presented in whole in the deliverable but published elsewhere at a later point. As decided by the Xt-EHR participants,

the technical specifications are represented using the HL7 FHIR standard. The web link to the implementation guide will be provided when the draft deliverable is made available for consultation.

The HL7 Europe FHIR IGs will also be balloted by HL7 Europe and the results of the Xt-EHR consultation will be shared with HL7 Europe to support the balloting of the IGs.

4 Feedback Requested

- For which data elements would you like to see more restricted terminology bindings (what would they be)?
- Are the defined extensions adequate?
- Are the examples adequate and helpful? Are there specific scenarios that are not covered by examples?
- What kind of additional narrative guidance would you expect to see in the implementation guide?
- Is the mapping from logical models to FHIR profiles helpful?

5 Contacts for questions

- **For questions related to the organisation of the consultation:** please ask the representative from your country who shared the information and documents on the stakeholder consultation.
- **For questions related to D6.1 content:** please reach out to the following Xt-EHR WP6 representatives:
 - WP6 T6.1:
Lead: Marcello Melgara at marcello.melgara@melgara.onmicrosoft.com>
Co-lead: Anna Adelöf Kragh at anna.adelof-kragh@socialstyrelsen.se