



## 20<sup>TH</sup> eHEALTH NETWORK 8 NOVEMBER 2021, BRUSSELS, BELGIUM

### COVER NOTE

#### 4.2. eHealth Network General guidelines revision

##### 1. Issue at stake

The eHealth Network General guidelines (latest release Nov 2016) <sup>1</sup> purpose and role has always remained unclear as well as its relevance and impact have been limited.

To bring a renewed purpose and actual relevance to such guidelines, the eHealth Network (June 2021) has mandated the Subgroup on Semantics to explore the potential and review the general guidelines.

##### 2. Summary

The eHealth Network subgroup on Semantics proposes the following rationale for the revision eHealth Network General guidelines:

The proposed audience for the new eHealth Network general guidelines should be:

- eHealth Network subgroups working on the preparation of new eHealth Network guidelines;
- Member States and implementing initiatives/projects.

The new general guidelines should focus on 4 pillars (different chapters in the guidelines):

1. General provisions applicable to all eHealth Network type of guidelines
2. Procedure for eHealth Network guidelines
3. Specific template for DATASET guidelines
4. Interoperability Assets Catalogue

##### *1. General provisions applicable to all eHealth Network type of guidelines*

- Objectives of this General guidelines are addressed to the Member States of the European Union and apply to the implementation of interoperable health data exchange. These guidelines aim to support the Member States to achieve a minimum level of interoperability, taking considerations of patient safety and data protection into account. In cross-border context, interoperability is essential to the provision of high quality care. Member States shall therefore engage in taking appropriate measures to make their respective information systems interoperable, both technically and semantically, for those Use Cases agreed by the eHealth Network.
- These eHealth Network General guidelines are non-binding in relation to Member States' national implementation, notwithstanding Member States are considered to use open standards for public health activities, decide freely whether they want to

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<sup>1</sup> [https://ec.europa.eu/health/sites/default/files/ehealth/docs/ev\\_20161121\\_co092\\_en.pdf](https://ec.europa.eu/health/sites/default/files/ehealth/docs/ev_20161121_co092_en.pdf)

adopt such requirements into local legislation and bear in mind these General Guidelines when adapting their legislation.

- These General Guidelines are intended as guidance for eHealth Network sub-groups working on the preparation of new eHealth Network guidelines and for Member States and implementing initiatives/projects, supplemented by project-specific guidelines.

## **2. Procedure for eHealth Network guidelines**

- One way to ensure that eHealth Network guidelines have the desired quality is by establish a procedure to be followed by the ones drafting the guidelines. While on its own a procedure is not sufficient to ensure quality of the outcome, it can contribute significantly to attain the expected quality independently from the ones preparing the guidelines or the matter at stake. The procedure should contemplate, at least, the following steps:
  1. *Diagnoses (problem statement)*, to identify and characterise the issue at hands and to determine its causes and describe negative impacts (if possible: healthcare, ethical, legal, social and environmental aspects, as well as economic and fundamental rights)
  2. *Design (use case and guidelines, key performance indicators)*, to describe the use case, propose key performance indicators, identify and describe candidate interoperability solutions including the Legal, Organisational, Semantic and Technical frameworks.
  3. *Consultation (including impact assessment)*, collect feedback from stakeholders on the candidate interoperability options and assess its potential impact. This phase implies the consolidation of the guidelines and prepare them for submission for eHealth Network adoption.
  4. *Adoption (at eHealth Network)*, discussion and adoption process by the eHealth Network, according to the applicable rules of procedure.
  5. *Implementation (roadmap)*, eHealth Network guidelines should have an annex on implementation roadmap indicating major milestones including timelines for evaluation and revision.
  6. *Impact evaluation (key performance indicators)*, following the timeline in roadmap an evaluation should be conducted to assess the key performance indicators. The evaluation should lead to a decision on review or revoke the guidelines.
  7. *Review or Retire*, according to the decision stemming from the impact evaluation phase, the guidelines can be reviewed (redo the guidelines procedure). In case guidelines are to be retired, it should be issued an eHealth Network statement explaining the reason why and, when available, pointing to alternative interoperability provisions.

## **3. Specific template for DATASET guidelines**

- The health Network guidelines on Patient Summary and ePrescription are great examples of dataset guidelines. This type of guidelines provides a specific context, use case, common principles, and a description of a dataset (collection of data structured according to an agreed and standards way) to fulfil a use case.
- eHealth Network should ensure consistency and interplay between the existing and coming guidelines. One way to ensure that data blocks (e.g. patient identification,

health professional, vaccine records) reused across several guidelines follow the same specification (e.g. vocabularies, field names, field description and examples)

- The structure from an eHealth Network DATASET guideline should follow a pre-defined structure to ensure consistency between different guidelines.
- The new general guidelines should provide the common elements and the pre-defined structure for eHealth Network dataset guidelines

#### ***4. Interoperability Assets Catalogue***

Information on interoperability is scattered and often hard to find. Also, once you find something, the amount of information provided is often daunting and not very actionable. A central place is needed that reflects the accumulated knowledge on interoperability and standardisation in healthcare IT in the EU. The catalogue can be started up with selected assets from the vast work that has already been done within EU projects, combined with generic information and references. The catalogue can incrementally grow into a valuable tool and a central reference point for any interoperability initiative within the EU and beyond. The information can be presented in the form of lists, webinars, courses, information packages, references, overviews, images, videos, presentations, development tools and collaboration environments such as ART-DECOR, github or Confluence.

It can also serve as a sustainable source for version and change management with relation to the further development of the European EHRxF, harbouring the results from project such as epSOS, X-eHealth and others.

Some suggested categories for information and educational material for the first stage of the IAC (longlist) are:

- Models - interoperability, maturity, data (PS, eP, lab, images, discharge, rare diseases) , architectural, ...
- Templates - use case and realisation scenarios; reports, surveys, ...
- Value sets - health professions, country codes, organisations, ...
- Building blocks - patient, consultation, healthcare provider, report, ...
- Legal - rights and obligations regarding data protection, identification, authentication and consent, transparency, information exchange, ...
- Standards - Standards and profiles, SDOs, implementation experiences
- Innovation - innovative initiatives, programs with an outlook to international collaboration, ...
- Mapping, transcoding and translation - translation tables (and services)
- Community, FAQ - sharing ideas and experiences, frequently asked questions, collaboration tools
- Glossary - terms and definitions
- Links - to further information
- Project support - methodologies, tips and tricks, funding possibilities

### **3. Format of procedure in the meeting**

For discussion.

The chair of the Subgroup on Semantics presents the results of the revision so far and ask for eHealth Network endorsement of the rationale proposed for the revision.