eHealth Network

Guideline on

the electronic exchange of health data
under Cross-Border Directive 2011/24/EU

Patient Summary

Release 3.2, Mar 2023

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth.

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TABLE OF CONTENTS

1. USE CASE DESCRIPTION 4
1.1. Patient Summary for Cross Border Care 4
2. GUIDELINES FOR PATIENT SUMMARY 7
Chapter I - General Considerations 7
Chapter II - Legal and Regulatory Considerations 8
Chapter III - Organisational and Policy Considerations 9
Chapter IV - Semantic Considerations 10
Chapter V - Technical Considerations 11
3. SUPPORTING INFORMATION 12
Chapter I - General Considerations 12
Chapter II - Legal and Regulatory Considerations 13
Chapter III - Organisational and Policy Considerations 14
Chapter IV - Semantic Considerations 14
Chapter V - Technical Considerations 16
4. PATIENT SUMMARY DATASET 17
4.1 PATIENT SUMMARY HEADER 17
4.2. PATIENT SUMMARY BODY 20
5. REFERENCES AND EXAMPLES 30
5.1. Common Semantic Strategy 30
5.2. European Electronic Health Record exchange format 30
5.3. MyHealth@EU (a.k.a. eHealth Digital Service Infrastructure - eHDSI) 31
5.4. Code System Assessments 31
5.5. International Patient Summary 32
5.6. Reference to medicines and possible future use of ISO IDMP 33

1. USE CASE DESCRIPTION

1.1. Patient Summary for Cross Border Care

This Use Case represents a high level of consensus on what constitutes European eHealth services, as this Use Case was described by Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare.

Use Case description:

Title	**Patient Summary sharing on a cross-border scale**
Purpose	Sharing information about the medical background and history of a patient from his country of affiliation (*Country A*) with a healthcare professional in the country of treatment (*Country B*). As information sharing is not limited to the cross-border use case, Member States could also use these guidelines for National and regional level interoperability to ensure consistency as well as avoid fragmentation and duplication of efforts.
Relevance	Many people request medical help when travelling, working or living abroad. Information about the medical background and history of a patient (health data) from the country of affiliation should be available to all citizens and health professionals in Europe (in their native language). The treatment of patients without proper information on medical background and history is hazardous. Benefits can be gained from increased quality of care and patient safety and from a decrease in the effort of gathering/exchanging health information and provide health professionals with most up to date information to treat and care for a patient. This Use Case proposes a way towards solving this problem.
Domain	Patient Summary
Situation	Cross-border, (potential inter-regional or national)

Context	Different countries operate different health care systems, support their own culture for healthcare provision, and may use different (or several different) language(s) and possibly different clinical vocabularies and legal basis for the data processing. This raises challenges (e.g. in semantic interoperability) for the support of cross-border exchange of health data and may result in limitations in the use of patients' medical information during patient treatment and care process in different European countries. A Patient Summary provides health information on important aspects such as allergies, current medication, previous illnesses and surgeries, lifestyle indicators, nursing care aspects, etc. These are necessary for the proper treatment and care of a patient, especially when there is a language barrier between the health professional and the patient. Two Use Cases are possible with regard to the Patient Summary (PS). The first is the one in which an occasional visitor needs his/her PS in country B for emergency or planned care. The second is the one in which the person is a regular visitor in country B (i.e. someone who lives in one country but works in another country). The distinguishing characteristic is that the health professional may have some information available from previous encounters in this type of regular visitor. Both, a PS from country A and one from country B, could be consulted. In this Use Case, the Use Case of the occasional visitor is described. eHN PS Guidelines Release 2 covered the Unplanned Care. This was defined by Emergency Health Professionals and GPs as a synthetic document. Data elements were selected to be concise and easily implementable, providing acceptable coverage of the cases to be addressed. In Release 3 of this guideline additions were made to fill in existing gaps (e.g. increased support for the treatment of patients with rare conditions) as well as the extension to the planned care context that requires a wider range of information that can be presented to the health professional in country B. This can e.g. include some elements for the continuity of care to achieve better health outcomes. Planned Care documents call for completeness and higher granularity, to transfer all the relevant information for the specific pathology, which necessitates a wider range of detail for already specified elements from Release 2, like laboratory findings and results. Lessons learned from the experience of the COVID-19 Pandemic show that in case of health care emergencies immediate collection of data on citizens/patients is key to monitor the emergency and to identifying possible solutions. Having a visible and comprehensive Patient Summary definition on European level can serve as the starting point for data collection standardised on European

Title	Patient Summary sharing on a cross-border scale
	level. Moreover, it may foster compliant implementations at national and regional level. Therefore, consensus on the Patient Summary should be promoted and the visibility of the Patient Summary should be enhanced.
Information	Patient Summary
Participants	Citizen/Patient Health professional in patient's country of origin/affiliation (country A) Health professional in country of treatment and care (country B)
Functional process steps	(With the reservation that preconditions are met) The patient consults a health professional in country B The health professional is identified, authenticated and authorised The patient is identified (identity confirmed by country A) Health professional provides information to the patient on how personal health data in the Patient Summary will be collected and processed. The Patient Summary is electronically transferred from the patient's country of affiliation to the health professional in the country that s/he is visiting (the "country of treatment") in a secure way. The health professional retrieves the Patient Summary and uses it to provide health care service. The Patient Summary should be presented to the health professional in an understandable way, namely regarding language, structure and vocabularies.

Table 1: Patient Summary Use Case description

2. GUIDELINES FOR PATIENT SUMMARY

The Member States in the eHealth Network have adopted these supplementary clauses to the general guidelines for the electronic exchange of health data under Cross-Border Directive 2011/24/EU to support the exchange of Patient Summary data for cross border care.

Chapter I - General Considerations

Article 1: Objectives, scope and maintenance

1. These guidelines, as adopted by the eHealth Network, are addressed to the Member States of the European Union and apply to the implementation of a patient dataset for cross-border exchange.
2. These guidelines could serve as a guiding principle for the development and implementation of national implementations for Patient Summary Data Sets.
3. The patient summary facilitates the free movement of patients across borders, as well as national interoperability, avoiding repeated costs, enabling savings for patients and healthcare systems. It also allows for the portability of data, which is one of the rights embedded in several legislative acts, such as GDPR.

Article 2: Definitions

For the purpose of these guidelines, the definitions of Directive 2014/24/EU, of the eHealth Network General Guidelines and the following definitions shall apply:

Term	Definition
Patient Summary	is an identifiable dataset of essential and understandable health information that includes the most important clinical facts required to ensure safe and secure healthcare. This summarised version of the patient's medical data gives health professionals the essential information they need to provide care. Although this dataset is intended to aid health professionals in providing unscheduled care, it can also be used to provide planned medical care (e.g. in the case of citizens movements or cross-organisational care paths). It should be kept in mind that not all information is known or is available at the moment of creation of the Patient Summary document.

Article 3: Concept and intended use

1. The provisions in the "*eHealth Network GUIDELINE on the electronic exchange of health data under Cross-Border Directive 2011/24/EU - General guidelines*" apply.
2. The aim of the Use Case is to help support safe, high-quality cross-border care for emergency, unplanned and planned care events. This does not preclude the Patient Summary being used for other medical purposes.

Chapter II - Legal and Regulatory Considerations

Article 4: Data protection

1. Data contained in patient summaries are special category of personal data within the meaning of Art. 9 of the General Data Protection Regulation and therefore Member States will need to ensure processing and storage are in line with applicable data protection requirements.
2. Regarding patient rights, national law may allow patient to disclose certain elements of Patient Summary records. Patient's sovereignty with regard to the contents is managed by the country of affiliation, and the eventual disclosure of specific information may not be noted. Nevertheless, the sensitive information in the PS must be used confidentially and in the best interests of the patient.

Article 5: Identification authentication and authorisation

Implementation of the Patient Summary implies that each Member State has addressed enabling activities such as:

1. Providing an official ID number for each citizen for healthcare purposes. For cross-border purposes, a unique patient identifier is a necessary requirement for each individual patient to be linked to the patient record in the country of affiliation.
2. Maintaining electronic registers of health professionals.
3. Agree on levels of authentication for citizens and health professionals.
4. Agree on levels of authorisation for certain health professionals roles.

Article 6: Patient safety

Regarding patient safety, there are no specific additional requirements, reference is made to the provisions defined in the general guidelines.

Chapter III - Organisational and Policy Considerations

Article 7: Enablers for implementation

The essential information contained in a Patient Summary makes it highly valuable for unscheduled care where the health professionals have no previous knowledge about the patient. Even so, it can also provide a complementary source of information in planned care by supporting health professionals to connect to the stream of information generated along the patient continuity of care.

1. Taking in consideration the nature of the information contained in the Patient Summary, it is up to each Member State, healthcare provider or initiative to identify the clinical processes that can benefit from its availability and possible updates.
2. The ability to populate the Patient Summary relies on a coordinated and integrated approach to patients' electronic health records. It is up to each Member State, healthcare provider or initiative to establish the necessary policies to ensure that the Patient Summary is available, and it is used in the aimed clinical processes as well as it is updated with new data stemming from patient's healthcare.
3. In view of planned care use case, being the Patient Summary a synthetic collection of clinical information, in some medical situations, it might be important to make reference to external clinical documents, which contain more detailed information.
4. The implementation of a Patient Summary might facilitate the possibility to indicate additional health professionals/healthcare institutions, due to specific patient requirements such as an expert centre for rare diseases and cancers.

Article 8: Quality standards and validation

There being no specific additional requirements, reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 9: Education, training and awareness

1. The added value of the Patient Summary relies on its use under the right conditions. One essential condition is the education and instruction of health professionals to streamline the access to the Patient Summary without adding additional burden when compared to the access of other health information.
2. Taking in consideration the essential nature of the information present in a Patient Summary, it is important to instruct health professionals in the use of key pieces of information available. For instance, the presence of a rare disease code might indicate that specific action should be taken.
3. It is also crucial to raise health professionals' awareness that the Patient Summary contains health data stemming from several healthcare events that took place at different

providers and collected by several health professionals. The diversity of healthcare cultures, recording practices, staff roles in the context of creation of the Patient Summary may introduce variations on how information is collected and recorded. Health professionals should be informed on how to cope with such variations.

4. Along the Citizen/Patient Continuity of Care, several health professionals will interact with the Patient. Each of these health professionals should be trained about the key information that should be included into the Patient Summary.

Chapter IV - Semantic Considerations

Article 10: Data

1. The content of the Patient Summary Dataset is shown in section 4. The Patient Summary Dataset comprises *Patient Summary Header* and *Patient Summary Body*.
2. Clinical information in the Patient Summary will comprise narrative text along with coded data, the latter will allow an unambiguously way of communicating the same information between the country of affiliation and the country of treatment.
3. All clinically relevant information in coded elements must also be included and visible in a narrative part of the Patient Summary.
4. It is the responsibility of the Member State to provide data in compliance with these guidelines. Member States are encouraged to align their future considerations on a national Patient Summary according to the dataset structure given in section 4.
5. For a given patient, some of the elements might be empty as no data would be applicable or available; such situations should be communicated differently. Cardinality (i.e., repetition and optionality) of individual fields or groups of fields are not part of this document and can be defined in detailed implementation guides.
6. The structured and coded content of the Patient Summary is received by the health professional in two languages, Country A language and a translation to Country B language. If Country B language is unavailable for a dataset, English can be used.
7. When the available coded information in one Member State cannot be transcoded into the selected preferred code system currently, the information should, as an interim solution, be transferred encoded, preferably displayed in English, and/or in narrative form.

Article 11: Terminology

1. The Use Cases require the ability to convey both meaning and context in the Patient Summary to enable safe, high-quality care. For that purpose, along with the dataset structure, preferred code systems provide concepts that will be understood by both the provider and the receiver of the Patient Summary.
2. Different code systems are used by Member States. The strategic long-term goal is to gradually reduce fragmentation and converge on the use of international code systems

across Europe also considering, in the future, the expected wider use of new and emerging international standards such as the International Classification for Diseases 11th Revision (ICD-11), SNOMED CT or the International Classification of Health Interventions (ICHI). Likewise, the ISO Identification of Medicinal Products (IDMP) suite of standards should be used for medicinal products identification, as soon as made available by the EMA and National Competent Authorities joint SPOR (Substances, Products, Organisations, Referentials) Project.

3. Member States wishing to engage in cross-border communication are encouraged to use for that communication, the preferred code systems as described in the Patient Summary Dataset in section 4.

Article 12: Controlled Lists (Value set Catalogues)

There being no specific additional requirements, reference is made to the provisions defined in the eHealth Network General Guidelines.

Chapter V - Technical Considerations

Article 13: Technical requirements

Member States are free to choose the technical implementation of their Patient Summary. Nonetheless, for cross-border exchange the format of the document for exchange shall be based on standards and profiles as agreed by the eHealth Network for the particular technical infrastructure. The cross-border specifications are described in section 5.3, which also refers to supporting requirements and other relevant documentation.

Article 14: Security

There being no specific additional requirements, reference is made to the provisions defined in the eHealth Network General Guidelines.

Article 15: Testing and audit

There being no specific additional requirements, reference is made to the provisions defined in the eHealth Network General Guidelines.

3. SUPPORTING INFORMATION

This chapter provides supporting information and explanatory text to aid understanding of the guidelines, and the rationale underlying the recommendations, and follows the same structure as the general guidelines. This chapter can be taken as inspiration for any initiative aiming at implementing interoperable patient summary documents.

The main goal of this chapter is to disseminate common practices for initiatives implementing the exchange of patient summaries and it is highly inspired by the lessons learnt in the MyHealth@EU implementation of these guidelines.

The material in this chapter has built on earlier epSOS experiences, but cites follow-on work in EXPAND, in the relevant Horizon 2020 projects like OpenMedicine, eStandards, VALUeHEALTH, and the joint EU/US Trillium Bridge and Trillium II projects. Additional insights, for future evolutions, are expected from projects as UNICOM and X-eHealth.

Chapter I - General Considerations

Article 1: Objectives and scope

The objective in this Release of the Patient Summary Guidelines is to retain the concept of a controlled Patient Summary but to extend the application to include data elements relevant for planned care. The dataset is non-exhaustive, providing a robust, well-defined core set of data items.

ISO 27269:2021 Health informatics — International Patient Summary (ISO 27269:2021), its implementation guides and eHealth Digital Service Infrastructure (eHDSI) have been taken as reference for the extension of the dataset in eHealth Network Patient Summary Guidelines Release 3.

Article 2: Definitions

There is no specific support information.

Article 3: Concept and intended use

These guidelines are non-binding and Member States are considered to have the right to choose freely their way of implementing national Patient Summary datasets. The Patient Summary guidelines focus on the content issues and the description of possible ways to produce this content for cross-border exchange, taking existing national implementations into consideration.

The selection of data elements comprising the Patient Summary may be extended to hold additional information, such as information about emerging health care conditions or project specific extensions. The use of the Patient Summary to record rare disease information has to be a clinical decision, with leadership and direction from health professional organisations.

These guidelines do not define if certain data elements are mandatory or optional. This is up to each implementation initiative to determine according to the use cases purposes.

Chapter II - Legal and Regulatory Considerations

Article 4: Data protection

Pursuant to GDPR, legal basis for data processing shall comply with Art 6 and 9. Member states may introduce further conditions/limitations with regards to the processing of Patient Summary documents as set forth in Art 9.4 GDPR.

Article 5: Identification, authentication and authorisation

To be able to link patients with their patient records, the existence of a patient identifier is necessary. For cross-border purposes, a unique patient identifier (which is not necessarily specific to healthcare) is also a necessary requirement for each individual patient to be linked to the patient record in the country of origin. Analysis of data shows that most Member States already have a national patient identifier available. In some cases, Member States have a regional patient identifier.

Official documents, such as a passport, ID card or driver's licence, are accepted across MS for identification and authentication**.** In cases where a patient does not have (access to) a national patient ID or an identification document, different kinds of personal information elements, such as the patient's last name, given name and date of birth, are used to create a unique (temporary) form of identification.

Article 6: Patient safety

The Patient Summary is a clinical document to support the Health Professional during healthcare provision. For the patient safety, it is important that the Health Professional is aware of the fact that the Patient Summary can be not exhaustive. The provided data must be reliable, coherent both when it is declared the presence or the noted absence of specific clinical conditions.

Chapter III - Organisational and Policy Considerations

Article 7: Enablers for implementation

Even if the primary goal of the Patient Summary is to support cross-border care, some Member States have implemented, or are in the course of implementing, national or regional Patient Summaries. Some Member States already have more detailed summaries from which this summary data can be extracted. Other Member States may use this guideline for reference for national implementation.

However, the ability to populate the Patient Summary always requires national activity. More advanced and elaborated Patient Summaries exist in some Member States (MS), but the eHealth Network has agreed that the guideline could serve as a common baseline for Patient Summaries at national level. Agreement on the Patient Summary Dataset on European level and widespread implementation of it will assist Member States in the implementation of interoperable solutions for health care emergencies such as a pandemic event. Using the Patient Summary guideline as the guiding principle for all kind of EU-projects and implementations (such as registries and research projects) can foster the use of Patient Summary data within the European Health Data Space.

Article 8: Quality standards and validation

Member States should work together to build a convergent use of code systems. Mappings should be done as shared activities when more Member States are affected. Also licensing activities with Standard Developing Organisations (SDO) partners should be done together. This will reduce the burden of the workload, support capacity building and also foster the EU pathway towards a harmonised way forward. This may be facilitated by the European Commission.

Article 9: Education, training and awareness

There is no specific support information.

Chapter IV - Semantic Considerations

Article 10: Data

The Patient Summary can be created and signed by a health professional or be automatically generated by a system. In both cases, of manually and automatically generated Patient Summaries, information may be derived from multiple sources using different semantic standards and datasets, which complicates the exchange of cross-border Patient Summary information. Therefore, a selection of data elements for Cross border care was compiled to serve

as exchange format throughout the EU and Europe. This dataset can provide countries with a guideline to orient future evolutions of their national patient summary. The content of the dataset is version controlled, subject to change through a change control process.

International standards shall be adopted to convey Patient Summary contents in a structured and coded way, understandable by Health Professional at national and cross-border level. The MyHealth@EUinfrastructure has currently adopted HL7 CDA Level 3 and Level 1 as standard for document exchange. Member States are free to adopt at National level the same HL7 standard or other international or national standard to create and exchange the Patient Summary (e.g. HL7 FHIR or other standards).

In version 3.0 of the guidelines, the notion of allowing links between data elements was introduced. In version 3.2, facilities were added to allow links between health professionals or health care organizations and any other relevant data element in the dataset as well as to allow links between data elements and external knowledge resources. For example, this way individual healthcare providers can be associated as points of contact for specific, potentially rare, diseases. Implementers may choose to use the techniques of their preferred way to implement this functionally (e.g. add references on patient summary, or dedicated entries in each applicable patient summary body section).

The identification of medicinal products, in particular, is posing important challenges for the exchange of information in the Patient Summary. It is expected that the coding schemes currently included within the data set will be complemented by data sets and identifiers developed during the implementation of the ISO IDMP set of standards. The European Medicines Agency is leading the work on this implementation in Europe in coordination with the National Competent Authorities in Member States.

In respect to the results section, it should be used to communicate the observed results for a patient that are relevant for treatment at that moment or in the future. If a specific result observation cannot be comprised into the Patient Summary Dataset, indication on additional information provided with the Patient Summary should be indicated together with a summary of that result.

The Patient provided data section is a section for data reported by a health professional after provision of additional information from the patient, like a travel history relevant for the Patient Summary (e.g. recent travel in a region of high prevalence of a specific infectious disease like Malaria). The section is not intended for data injected directly by the patient. Future revisions of the Patient Summary Guideline might capture the need of such reported data.

Article 11: Terminology

Successful sharing of information requires the effective use of standards to support accurate and complete clinical documentation that is faithful to the patient's situation.

The use of code systems allows the unambiguous exchange of clinical information in the Patient Summary. Both the Member State providing the information and the Member State receiving it need to understand the clinical concepts, therefore it is recommended to use preferred code systems as presented in section 4.

It is up to the eHealth Network to oversee the process by which code systems are kept under review and facilitate licensing arrangements.

Article 12: Controlled Lists (Value set Catalogue)

Since some code systems such as SNOMED CT, LOINC and ICD (to name but three) contain a large number of concepts, it might not always be practical to use them in their entirety within the European context, where some Member States might use internally different code systems that they will have to cross-reference and/or translate. Additionally, some code systems, such as SNOMED CT, are restricted in use. In these cases, available unrestricted subsets should be considered, for example, the content of the SNOMED CT Global Patient Set (GPS). A clear set of criteria should be used to select the most significant concepts and arrive at a reasonable manageable content.

Member States may adopt different international standard code systems, which include not mappable concepts. In those cases, together with the preferred code system, alternate code systems can be used in Patient Summary enabling its exchange in English.

Chapter V - Technical Considerations

Article 13: Technical requirements

There is no specific support information.

Article 14: Security

There is no specific support information.

Article 15: Testing and audit

There is no specific support information.

4. PATIENT SUMMARY DATASET

The datasets indicated in the following tables are considered relevant for patient safety and the provision of adequate level of care both at cross-border and national level.

It is up to each implementation project to decide on the conformance and cardinality (i.e. data elements required or optional and number of repetitions).

The indicated "Preferred Code Systems" are inspired by the eHealth Digital Service Infrastructure implementation and the HL7 IPS implementations.

4.1 PATIENT SUMMARY HEADER

Data Element		**Description**	**Preferred Code Systems** * **
A.1 Patient summary header data elements			
A.1.1 Identification of the patient/subject			
A.1.1.1	National healthcare patient ID	Country ID, unique to the patient in that country. Example: ID for Portuguese patient	
A.1.1.2	Family name/surname	The given name/first name of the patient (also known as forename or first name). This field can contain more than one element.	
A.1.1.3	Given name	The family name/surname/last name of the patient. This field can contain more than one element or multiple fields could be present.	
A.1.1.4	Date of birth	The date of birth of the patient [ISO TS 22220]. As age of the patient might be important for correct interpretation of the test result values, complete date of birth should be provided.	Complete date, without time, following the ISO 8601
A.1.1.5	Gender	This field must contain a recognised valid value for "administrative gender". If different, "physiological gender" should be communicated elsewhere.	HL7 Administrative Gender

A.1.1.6	Country of affiliation	Name of country of affiliation	ISO 3166
A.1.2 Contact information			
A.1.2.1 Patient address			
A.1.2.1.1	Street	Example: Rua dos Campeões	
A.1.2.1.2	House number	Example: 246	
A.1.2.1.3	City	Example: Porto	
A.1.2.1.4	Post code	Example: 4500	
A.1.2.1.5	State or province	Example: Vila Nova de Gaia	
A.1.2.1.6	Country	Example: PT	ISO 3166
A.1.2.1.7	Telephone no.	Example: +351 20 7025 6161	
A.1.2.1.8	Email	Example: jens@bigsmile.eu	
A.1.2.2 Preferred HP to contact - This section can be repeated and linked to any specific information in the Patient Summary, for example a link between a rare disease problem (A.2.3.1) and the rare disease specialist responsible for the care of the individual patient (this section).			
A.1.2.2.1	Name of the HP	Name of the Health Professional that has been treating or taking responsibility for the patient.	
A.1.2.2.2	Role of the HP	Health professional role	
A.1.2.2.3	HP Organisation	Health professional organisation	
A.1.2.2.4	Telephone no.	Example: +45 20 7025 6161	
A.1.2.2.5	Email	Email of the HP/legal organisation	
A.1.2.2.6	Network affiliation	The HP organization is affiliated with a European network, for example an ERN.	
A.1.2.2.7	Related with	Identify the entry or entries of this Patient Summary for which the health professional is the preferred contact.	
A.1.2.3 Contact person/ legal guardian			
A.1.2.3.1	Role of that person	Role of the contact person: legal guardian, next of kin, other person to contact	HL7 RoleClass

A.1.2.3.2	Relationship level	Relationship type with the patient (e.g. father, wife, daughter)	HL7 RoleCode
A.1.2.3.3	Given name	The first name of the contact person/guardian (example: Peter). This field can contain more than one element.	
A.1.2.3.4	Family name/surname	This field can contain more than one element. Example: Español Smith	
A.1.2.3.5	Telephone no.	Example: +45 20 7025 6161	
A.1.2.3.6	Email	Email of the contact person/legal guardian	
A.1.3 Insurance information			
A.1.3.1	Insurance number	Example: QQ 12 34 56 A	
A.1.4 Document data			
A.1.4.1	Date created	Date on which PS was generated	ISO 8601
A.1.4.2	Date of last update	Date on which PS was updated (date of most recent version)	ISO 8601
A.1.4.3	Nature of the PS	Defines the context in which it was generated. Distinguishes between three methodological approaches for generating the PS: direct human intervention by an HP, automatically generated approach and mixed approach	
A.1.5 Author and Organisation			
A.1.5.1	Author organisation	At least one Author and Organisation shall be listed. In the event that there is no Author, at least one Organisation shall be listed This Author should be able to provide further information on the provenance of the data present in the patient summary. Different authors contributing to individual sections and/or entries could be provided at the relevant level.	
A.1.5.2	Legal authenticator	Legal entity (Health Professional or Health Care Provider) who authenticated the Patient Summary	

A.1.6 Additional information / Knowledge resources			
A.1.6.1	External reference	A reference leading to Clinical Practice Guidelines (CPG), emergency and anesthesia guidelines or other clinical relevant guidelines. This should be used only for providing specific guidance which may not be readily available to the health professional caring for the patient.	
A.1.6.2	Related with	Identify the entry or entries of this Patient Summary for which this additional information relates with, for example a link between a rare disease problem (section A.2.3.1) and guidelines for that particular rare disease (this section).	

Table 2: Dataset for Patient Summary Header

4.2. PATIENT SUMMARY BODY

Data Element		**Description**	**Preferred Code Systems** * **
A.2 Patient summary body data elements			
A.2.1 Alerts			
A.2.1.1 Allergy			
A.2.1.1.1	Allergy description	Textual description of the allergy or intolerance	
A.2.1.1.3	Type of propensity	This element describes whether this condition refers to an allergy, non-allergy intolerance, or unknown class of intolerance (not known to be allergy or intolerance)	SNOMED CT GPS
A.2.1.1.3	Allergy manifestation	Description of the clinical manifestation of the allergic reaction. Example: anaphylactic shock, angioedema (the clinical manifestation also gives information about the severity of the observed reaction)	SNOMED CT GPS

A.2.1.1.4	Severity	Severity of the clinical manifestation of the allergic reaction.	SNOMED CT GPS
A.2.1.1.5	Criticality	Potential risk for future life-threatening adverse reactions when exposed to a substance known to cause an adverse reaction.	SNOMED CT GPS
A.2.1.1.6	Onset date	Date of the observation of the reaction	ISO 8601
A.2.1.1.7	End Date	Date of resolution of the allergy (e.g. when the clinician deemed there is no longer any need to track the underlying condition)	ISO 8601
A.2.1.1.8	Status	Current status of the allergy or intolerance, for example, whether it is active, in remission, resolved, etc.	SNOMED CT GPS
A.2.1.1.9	Certainty	Assertion about the certainty associated with a propensity, or potential risk, of a reaction to the identified substance. Diagnostic and/or clinical evidence of condition.	SNOMED CT GPS
A.2.1.1.10	Agent or Allergen	A specific allergen or other agent/substance (drug, food, chemical agent, etc.) to which the patient has an adverse reaction propensity.	SNOMED CT GPS (for non-drug allergy) or ATC* (for drug allergy) (IDMP, when available)
A.2.1.2 Medical alert information (other alerts not included in allergies)			
A.2.1.2.1	Healthcare alert description	Description of medical alerts in textual format: any clinical information that is imperative to know so that the life or health of the patient does not come under threat. - Example 1: intolerance to aspirin due to gastrointestinal bleeding. Example 2: intolerance to captopril because of cough (the patient is not allergic but can't tolerate it because of persistent cough) Example 3: the patient has a rare disease that requires special treatment Example 4: Airway Alert / Difficult Intubation Example 5: Diagnoses such as malignant hyperthermia, porphyria, and bleeding	

		disorders; special treatments like anticoagulants or immunosuppressants; implanted devices. Example 6: transplanted organs illustrate other information that has to be taken into account in a healthcare contact. Example 7: participation in a clinical trial that has to be taken into account in a healthcare contact.	
A.2.2 Medical history			
A.2.2.1 Vaccination/ prophylaxis information			
A.2.2.1.1	Disease or agent targeted	Disease or agent that the vaccination provides protection against	ICD-10* SNOMED CT GPS
A.2.2.1.2	Vaccine/prophylaxis	Generic description of the vaccine/prophylaxis or its component(s)	SNOMED CT GPS ATC* (IDMP, when available)
A.2.2.1.3	Vaccine medicinal product	Medicinal product name	For the time being, this should be the name of the medicinal product as registered in the country. In the future the information on the medicinal product can incorporate the identifiers from the implementation of the ISO IDMP Standards and the medicinal package's unique identifier
A.2.2.1.4	Marketing Autorisation Holder	Marketing Authorisation Holder	EMA's Organisations System data (SPOR)

A.2.2.1.5	Number in a series of vaccinations/doses	Order in the vaccination course	
A.2.2.1.6	Batch/lot number	A distinctive combination of numbers and/or letters which specifically identifies a batch	
A.2.2.1.7	Date of vaccination	The date when the vaccination was administered	ISO 8601
A.2.2.1.8	Administering centre	Name/code of administering centre or a health authority responsible for the vaccination event	
A.2.2.1.9	Health Professional identification	Name or health professional code responsible for administering the vaccine or prophylaxis	
A.2.2.1.10	Country of vaccination	The country in which the individual has been vaccinated	ISO 3166
A.2.2.1.11	Next vaccination date	The date when the vaccination is planned to be given/repeated (e.g. next dose)	ISO 8601
A.2.2.2 Resolved, closed or inactive problems			
A.2.2.2.1	Problem description	Problems or diagnoses that the patient suffered in the past, and which have been resolved, closed or declared as inactive (not included in "current problems or diagnosis") Example: hepatic cyst (the patient has been treated with a hepatic cystectomy that solved the problem and the problem is therefore closed)	ICD-10* SNOMED CT GPS Orphacode if rare disease is diagnosed
A.2.2.2.2	Onset date	Date of problem onset	ISO 8601
A.2.2.2.3	End date	Problem resolution date	ISO 8601
A.2.2.2.4	Resolution circumstances	Describes the reason for which the status of the problem changed from current to inactive (e.g. surgical procedure, medical treatment, etc.). This field includes "free text" if the resolution circumstances are not already included in other fields such as surgical procedure, medical device, etc., e.g.	

		hepatic cystectomy (this will be the resolution circumstances for the problem "hepatic cyst" and will be included in surgical procedures).	
A.2.2.3 Medical history			
A.2.2.3.1	Medical history	This section may provide both synthetic anamnesis (e.g. description of phases of the pathology as a chronological summary of clustered clinical information) and anecdotal evidence that clinicians can collect from the patient, and can read in a narrative form. See Section 2, Chapter III, Art 7, (c).	
A.2.3 Medical problems			
A.2.3.1 Current problems			
A.2.3.1.1	Problem / diagnosis description	Health conditions affecting the health of the patient and are important to be known for a health professional during a health encounter.	ICD-10* SNOMED CT GPS Orphacode if rare disease is diagnosed
A.2.3.1.2	Onset date	Date of problem onset	ISO 8601
A.2.3.1.3	Diagnosis assertion status	Assertion about the certainty associated with a diagnosis. Diagnostic and/or clinical evidence of condition.	HL7
A.2.3.2 Medical devices and implants			
A.2.3.2.1	Device and implant description	Describes the patient's implanted and external medical devices and equipment upon which their health status depends. Includes devices such as cardiac pacemakers, implantable fibrillator, prosthesis, ferromagnetic bone implants, etc. of which the HP needs to be aware.	SNOMED CT GPS* EMDN
A.2.3.2.2	Device ID	Normalised identifier of the device instance such as UDI according to REGULATION (EU) 2017/745	
A.2.3.2.3	Implant date	Date when procedure was performed	ISO 8601

A.2.3.2.4	End date	Date when the device was explanted from the patient or the external device was no longer in use; likewise when the device is planned to be explanted	ISO 8601
A.2.3.3 Procedures			
A.2.3.3.1	Procedure description	Describes the type of procedure	SNOMED CT GPS*
A.2.3.3.2	Body site	Procedure target body site	SNOMED CT GPS*
A.2.3.3.3	Procedure date	Date when procedure was performed	ISO 8601
A.2.3.4 Functional status			
A.2.3.4.1	Description	Need for the patient to be continuously assessed by third parties; functional status may influence decisions about how to plan and administer treatments	
A.2.3.4.2	Onset Date	Onset date of a condition	ISO 8601
A.2.3.4.3	Functional assessment description	Description of the functional assessment	ICF
A.2.3.4.4	Functional assessment date	Date of the functional assessment	ISO 8601
A.2.3.4.5	Functional assessment result	Functional assessment result value	ICF
A.2.4 Medication summary			
A.2.4.1 Current and relevant past medicines (Relevant prescribed medicines whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not, or medicines that influence current health status or are relevant to a clinical decision)			
A.2.4.1.1	Medication reason	The reason why the medication is or was prescribed, or used This is the reason why the medication is being prescribed or used. It provides a link to the Past or current health conditions or problems that the patient has had or has.	ICD-10* SNOMED CT GPS Orphacode if rare disease is diagnosed

A.2.4.1.2	Intended use	Indication intended use as: prevention or treatment Example: prophylaxis, treatment, diagnostic, anaesthesia, care of equipment,	
A.2.4.1.3	Brand name	Brand name if biological medicinal product or when justified by the health professional (ref. Commission Directive 2012/52/EU)	
A.2.4.1.4	Active ingredient lists	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: "paracetamol"	ATC* (IDMP identifier, when available)
A.2.4.1.5	Strength	The content of the active ingredient expressed quantifiably per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. Example: 500 mg per tablet	UCUM, EDQM Standard Terms
A.2.4.1.6	Pharmaceutical dose form	The form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablet, syrup)	EDQM Standard Terms
A.2.4.1.7	Dosage Regimen	Number of units per intake and frequency of intake over a specified duration of time. Example: 1 tablet every 24h, for 10 days	
A.2.4.1.8	Route of administration	Path by which the pharmaceutical product is taken into or makes contact with the body.	EDQM Standard Terms
A.2.4.1.9	Date of onset of treatment	Date when patient needs to start taking the medicine prescribed	ISO 8601
A.2.5 Social history			
A.2.5.1	Social history observations related to health	Health related lifestyle factors or lifestyle observations and social determinants of health. Example: cigarette smoker, alcohol consumption	SNOMED CT GPS
A.2.5.2	Reference date range	Example: from 1974 to 2004	
A.2.6 Pregnancy history			
A.2.6.1 Current pregnancy status			

A.2.6.1.1	Date of observation	Date on which the observation of the pregnancy state was made	ISO 8601
A.2.6.1.2	Status	Provides the woman's current state at the date the observation was made: e.g. pregnant, not pregnant, unknown	SNOMED CT GPS
A.2.6.1.3	Expected date of delivery	Date on which the woman is due to give birth.	ISO 8601
A.2.6.2 History of previous pregnancies			
A.2.6.2.1	Previous pregnancies status	Information on the woman's previous pregnancies: Yes, previous pregnancies; No, previous pregnancies; Unknown	SNOMED CT GPS
A.2.6.2.2 Previous pregnancies description			
A.2.6.2.2.1	Outcome date	Date referred to the previous pregnancies outcome	ISO 8601
A.2.6.2.2.2	Outcome	Outcome of the previous pregnancies	SNOMED CT GPS
A.2.6.2.2.3	Number of children	Number of children/fetus in this specific pregnancy	
A.2.7 Patient provided data			
A.2.7.1 Travel history			
A.2.7.1.1	Country	Country(s) visited	ISO 3166
A.2.7.1.2	Period	Date of entry and departure	ISO 8601
A.2.7.2 Advance Directive			
A.2.7.2.1	Documentation	Existence of documentation on living will	SNOMED CT GPS
A.2.8 Results			
A.2.8.1 Result observations (A list of observation results pertaining to the subject of care's health condition and which might have impact on future treatments)			
A.2.8.1.1	Date	Date and time of the observation	ISO 8601

A.2.8.1.2	Observation type	Observation results types that may be measurements, laboratory results, anatomic pathology results, radiology results or other imaging or clinical results. Examples: Diagnostic results (Blood group, Laboratory Observations, Imaging results etc.) Physical findings (Vital signs observations)	HL7 ObservationCategoryCodes
A.2.8.1.3	Result description	Narrative representation of the observation result and findings.	
A.2.8.1.4	Observation details	Observation details including code that identifies observation, specification of the observed body structure or specimen, date and time of the specimen collection.	LOINC SNOMED CT GPS NPU
A.2.8.1.5	Observation results	Result of the observation including numeric and coded results of the measurement, details about how the tests were done to get the result values, information about referential ranges and result interpretation. Content of the observation result will vary according to the type of the observation.	SNOMED CT GPS (for ordinal or nominal scale results) UCUM (for units)
A.2.8.1.6	Performer	Identifies the originator/author and provides provenance information about the source of the results data that may have not originated with the source of the whole PS document.	
A.2.8.1.7	Reporter	With certain observation results, e.g. there may also be an interpreter or a person responsible for validation.	
A.2.9 Plan of Care (Therapeutic recommendations that do not include pharmacologic treatments, such as diet, physical exercise, planned surgeries)			
A.2.9.1	Plan of care	Narrative containing the plan including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient. In the future it is expected that this Section could be provided in a structured and coded format.	

* In a foreseeable future, the suggested preferred vocabularies might be superseded or complemented, as mentioned in Guidelines Article 11(2).

** The Preferred code system(s) has been selected based on adequacy to convey the information using the methodology of the Subgroup on Semantics. When more alternative international code systems are available, all are listed when it is assumed to be unlikely that agreement can be reached short term. Mapping between code systems could be proposed for specific use cases.

Table 3: Dataset for Patient Summary Body

5. REFERENCES AND EXAMPLES

5.1. Common Semantic Strategy

The Release 3 of the eHealth Network guidelines on Patient Summary was prepared in full alignment with the goals, roadmap and governance proposed in the Common Semantic Strategy for health in EU, adopted by the eHealth Network in Nov 2019.

The Common Semantic Strategy strives for the adoption of standards facilitating large-scale exchange of health information in the European Union, by facilitating convergence on interoperability standards for all Member States and Countries. This adoption should be based on sustainable EU policies, information exchange flows between countries, conditions of availability of data, and the national standards that countries have adopted in the absence of previous European regulations. The governance process for semantic interoperability efforts shall be interlinked with the governance of projects and services for eHealth in Europe, within the framework of the Joint Coordination Process.

In order to make it feasible to effectively align to the Common Semantic Strategy by 2025, three strategic goals are set for the upcoming period of 5 years:

- **G1 – Structure a common approach on health semantics in the European Union** Elaborate the framework, guidelines and recommendations to drive the basis for semantic standardisation at European level. These guidelines should be prescriptive at EU level but adopted and supported by policies at national level sources of information.
- **G2 – Provide guidance for EU level decisions on health semantics** Establish mechanisms for capacity building in countries for consideration and use of the Common Semantic Strategy, e.g. by fostering participation in the discussion and approval of EU semantic assets and projects.
- **G3 – Ensuring establishment and continuity on health semantics in the EU** Create sustainability to the eHN Semantic Subgroup and make the case for dynamics of the subgroup.

5.2. European Electronic Health Record exchange format

The Release 3 of the eHealth Network guidelines on Patient Summary was prepared having in consideration the goals, principles and health information domains present in the Recommendation on a European Electronic Health Record exchange format (EEHRxf).

Being that the Patient Summary is one of the five domains established in the EEHRxf, the third release of the guidelines prepared them for a broader scope of use (beyond only cross-border) and kept in perspective the EEHRxf recommended interoperability specifications for content structuring and representation.

Further work being developed by the X-eHealth project regarding the EEHRxf health information domains should be considered in possible evolutions of the eHealth Network guidelines on Patient Summary, in particular provisions related with the refinement of the Patient Summary functional specifications and rare diseases requirements.

5.3. MyHealth@EU (a.k.a. eHealth Digital Service Infrastructure - eHDSI)

The MyHealth@EU services implement the eHealth Network guidelines on Patient Summary, making it mandatory to use in the context of the cross-border exchanges of Patient Summaries through the eHDSI.

The eHDSI has a service offering organised around several artefacts and services. One of them are the interoperability specifications that contains the technical and semantic specifications. Among the different specification documents, the CDA Implementation Guide is the normative artefact that describes the structure of the CDA pivot document that needs to be exchanged between two countries (including cardinality, data format, terminology bindings, link to value set catalogues).

The Release 3 of the eHealth Network guidelines on Patient Summary was made available for comments by the eHDSI stakeholders, since it will imply updates in the eHDSI specifications.

5.4. Code System Assessments

When alternative code systems for the same Patient Summary element were present, a methodology developed by the Subgroup on Semantics was applied. The methodology lists a number of criteria to assess the different options available. Provided here is a summary of the decisions and assessments made in the assignment of preferred code systems in section 4 of this document. As a general preference, code systems already implemented in eHDSI are prioritized.

ICD and SNOMED CT GPS: The two code systems aim to provide for different use cases. The aim of the SNOMED CT GPS is a better fit to the clinical use case of the Patient Summary (compare e.g. Section 2.1 of the ICD-10 manual and this SNOMED International description as well as ASSESS CT Deliverable 4.4. Policy and strategy recommendations) while ICD-10 variants have a much broader uptake in EU member states, although the international edition of ICD-10 is one out of many different local versions of ICD in use, allowed by the WHO. Further, even if detailed information is coded with SNOMED CT there is likely an ICD-10 code in some part of the health record. Both ICD-10 and SNOMED CT GPS are free to use while use of SNOMED CT GPS provides additional benefit to members of SNOMED International. The proposal is to use both code systems if possible, such as when coded information is available in source information systems.

ATC and SNOMED CT GPS: While recognizing that ATC has the benefit of widespread availability, there are caveats about the use of ATC in the ATC documentation (e.g. section C, The purpose of

the ATC/DDD system). For drugs, SNOMED CT GPS (Jan 2021 release) contains only 162 concepts for non-vaccine drugs. For vaccines, SNOMED CT GPS is a code system currently used in eHDSI.

LOINC and NPU (and SNOMED CT GPS): The two code systems overlap significantly. LOINC covers a wider domain in including also clinical observables. For laboratory medicine the overlap is practically 100 %. NPU is used in Scandinavia and in the Czech Republic and LOINC is used in many of the other EU member states. While there are differences between the code systems, both are fit for purpose for the Patient Summary. Both systems have been implemented in member states for decades, for laboratory, clinical and patient-facing applications, and it is thus unlikely that positions will change in the short to mid-term. Due to differences, mapping between the two is a challenge, but could possibly be done for a selection of use cases. All current NPU countries are also SNOMED International members, and there is current use of SNOMED CT for clinical observables. There is no current known use of SNOMED CT for laboratory medicine observables.

5.5. International Patient Summary

The evolution of eHealth Network guidelines on Patient Summary and its implementations will take in consideration the ISO 27269:2021 Health informatics — International Patient Summary and ensure compatibility, whenever applicable.

The primary purpose of the ISO 27269:2021 Health informatics — International Patient Summary is the formalisation of the dataset of the eHealth Network guidelines on Patient Summary with the goal to deliver a single, common International Patient Summary (IPS), comprising core content. Two HL7 implementation guides for CDA and FHIR, are available as practical examples of derived implementations conformant with the standard.

The CEN International Patient Summary Standard and implementation guidance are the result of the work performed under a Grant Agreement with the European Commission and EFTA (SA/CEN/GROW/EFTA/000/2015-16).

The aim of the agreement was “To participate in the creation of an International Patient Summary specification, at a global level, and turn this into a European standard, in line with the Guidelines on Minimum/Nonexhaustive Patient Summary Dataset for Electronic Exchange as adopted by the European eHealth Network”.

Specifically, the objectives were:

1. “Ensuring the European participation and input in the global standardisation activity, resulting in a global standard or set of standards to be published in the participating global standards development organisations in the Joint Initiative Council on Global Health Informatics Standardisation (JIC).

2. Supporting the development of a European standard on Patient Summaries, based on use cases and subsets of ontologies in a specific clinical context, i.e. urgent and unplanned care. The European standard will be developed, parallel to the global standard or set of standards, and will be subject of formal adoption by the eHealth Network. Therefore, it will take into account and support the implementation of the Guidelines on Minimum/Non-exhaustive Patient Summary Dataset for Electronic Exchange that are being revised by the eHealth Network."

Figure 1: An overview of the various IPS specifications and their relationship with the different implementation guides

5.6. Reference to medicines and possible future use of ISO IDMP

Three sections of the Patient Summary make reference to medicines: the Medication Summary, the Vaccinations, and the Allergies. The health professional creating the Patient Summary or generating the source of information used for the creation, should carefully decide if it is relevant to make reference to the Substance, to the generic pharmaceutical product with its attributes (strength, dose form) or to the specific medicinal products with its excipients, selecting the appropriate ISO IDMP identifiers and/or their attributes.

EMA SPOR (Substances, Products, Organisations, Referentials) Project must be taken as reference to define the code systems and the ValueSet to code the data element of the medicinal products description. In particular Substances shall be coded by adopting the European

Substance Registration System (EU-SRS) concepts when available. The other key data elements, like the strength of the medicinal product, its dose form, route of administration and, when relevant, the package type, shall follow the ISO IDMP standards and the rules set by EMA SPOR in terms of code systems and Value Sets to be used once the corresponding implementations of the standards are finalized.

Member States may decide if, in the Medication Summary, the generic pharmaceutical product (PhPID) or the specific medicinal product (MPID) shall be identified. The choice of identifying the medicinal product might be related to a specific need of the patient (demonstrated efficacy or known allergies). In the case of the Vaccination, the decision of identifying the vaccine as a pharmaceutical product or a specific medicinal product is normally related to the national policies of tracing vaccinations. The choice for the Allergies is more related to the patient's condition: the health professional should express either the allergy to a substance or generic product, or a specific allergy to a specific medicinal product and its excipients.