D2.7

FHIR Profile for EHR interoperability - V1

ABSTRACT

This document forms the basis for the technical specification of the InteropEHRate Profiles. Based on the scenarios defined in the project, relevant data sets are identified. Based on this, a domain model is created. This takes into account existing domain models for cross-border data exchange such as the International Patient Summary (IPS) and extend them. Data objects that have not yet been specified in the IPS are described in more detail with their attributes. The extended domain model forms the basis for the technical specification of the InteropEHRate Profiles with HL7 FHIR.

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LOG TABLE

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ACRONYMS

Acronym	Term and definition
CABG	coronary artery bypass graft
DICOM	Digital Imaging and Communication in Medicine
D2D protocol	Device-to-Device protocol
HCP	Healthcare Professional
HL7 FHIR	Health Level 7 Fast Healthcare Interoperability Resources
HR Exchange	Health Record Exchange
IEHR	InteropEHRate
IPS	International Patient Summary
PaDES	PDF Advanced Electronic Signatures
R2D protocol	Remote-to-Device protocol
SCP	Service Class Provider
S-HER	Smart Electronic Health Record
S-EHR Cloud	Smart Electronic Health Record Cloud

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1 INTRODUCTION

1.1 Scope of the document

This document (D2.7) defines the first version the InteropEHRate profiles (also called IEHR profiles), a set of FHIR profiles that constitutes the data model of any Smart EHR (S-EHR).

The first section of the document presents an analysis of the InteropEHRate use cases and a conceptual model for the health data used within the analysed use cases. The second section of the document describes how the identified data can be represented using the HL7 FHIR standard, extended and constrained by means of specific profiles. Two kinds of FHIR profiles are defined, called “core profiles” and “domain profiles”.

The core profiles, collected within the “InteropEHRate Core Guide”, specify the structure and semantics of information that any application using the InteropEHRate protocols MUST process in a standard way. In particular, the core profiles standardize data strictly needed for the fulfilment of the functional and non-functional requirements of the InteropEHRate protocols, independently from specific medical content.

The domain profiles, collected by additional “InteropEHRate Domain Guides”, refer to FHIR profiles that CAN be supported by the applications using the InteropEHRate protocols and standardize how to represent specific types of medical or health content.

The specification leverages existing standards, such as coding systems like LOINC and ICD-10, and extends existing domain models like the IPS where needed.

1.2 Intended audience

The target communities of this deliverable are all stakeholders who are interested in the implementation of applications capable to interoperate with any S-EHR.

1.3 Structure of the document

The document starts with the definition and delineation of the InteropEHRate Profiles in Section 2.

Subsequently, the high-level use cases are analysed in detail in Section 3 with the aim of identifying the relevant data sets. More particularly, the three use cases are: (i) Device to device HR exchange, (ii) Remote to device HR exchange, and (iii) Research HR exchange. From these use cases, a list of relevant data is derived in each case. These are then summarized and classified in a table. In the following section, a concept for multilingual support is developed.

Chapter 4 introduces concepts and methods for the specification of the InteropEHRate Profile, giving an overview of the different layers of the InteropEHRate Profile, a development and balloting process, and HL7 FHIR and existing FHIR profiles for cross-border data exchange.

The following chapters 5 and 6 provide a specification of the InteropEHRate Profile on a conceptual and on an implementable level.

Finally, a conclusion and next steps are outlined.

1.4 Updates with respect to previous version (if any)

Not Applicable.

2 SCOPE AND PURPOSE OF THE IEHR PROFILES

The InteropEHRate project is intended to define a set of application protocols to allow citizens and organizations belonging to different EU countries to exchange and store health data. A key goal is to support the correct interpretation of the exchanged data by the different involved applications and users. To this end it is necessary to standardize the structure and the semantics of the exchanged data.

There are numerous organizations that at EU and worldwide level are already standardizing how to structure health data and how to represent their semantics. InteropEHRate is intended to complement the existing initiatives proposing how to integrate and extend existing standards and models in order to adopt them together with the InteropEHRate protocols.

In particular, the S-EHRs and the InteropEHRate protocols adopt the HL7 FHIR standard, including both a data model and a set of APIs. The FHIR data model is composed of a set of Resource types, where each resource type represents a specific kind of domain entity by means of a set of standard attributes and corresponding value types. FHIR allows to extend the standard model as well as to apply specific constraints to the attributes of a resource type. The set of extensions and constraints applied to a resource type is called “FHIR profile”.

The InteropEHRate project defines a specific set of FHIR profiles to be adopted together with the InteropEHRate protocols. Two kinds of FHIR profiles are defined, called “core profiles” and “domain profiles”.

The core profiles, collected within the InteropEHRate Core Guide, specify the structure and the semantics of information that any application using the InteropEHRate protocols MUST process in a standard way. In particular, the core profiles specify which FHIR resources are supported by any S-EHR and standardize data strictly needed for the fulfilment of the functional and non-functional requirements of the InteropEHRate protocols, independently from specific medical content.

The domain profiles, collected by additional InteropEHRate Domain Guides, refer to FHIR profiles that CAN be supported by the applications using the InteropEHRate protocols and standardize how to represent specific types of health information.

For each profile, two different kinds of maturity levels are distinguished: draft and recommended. The level “draft” represents a preliminary specification not yet tested or not considered sufficiently robust to be adopted at EU level. The level “recommended” is a final specification that the InteropEHRate project recommends for adoption by relevant EU standardization bodies. In this first version, all profiles have a draft level.

The InteropEHRate profiles are not intended to introduce new coding standards for medical information or new models for representing specific kind of health data. In particular, the core profiles will not add any specific kind of health data to the FHIR standard, but will solely extend it with non medical data and metadata needed to fulfil the requirements of InteropEHRate protocols, regardless of specific clinical needs. Such data will apply to any resource type or to general purpose resources like the Patient resource.

Following is a non exhaustive list of possible content that could be specified by the next versions of the InteropEHRate core profile:

- Recommended templates and semantic codes for patient's consents
- Constraints and templates for Identification and qualification of patients, HCPs, organisations at cross-border
- Metadata needed for translation
- Extensions needed for signature and encryption of data
- Extensions needed for traceability of data provenance
- Extensions for representation of data usage permissions
- Extensions needed for data anonymization

The domain profiles instead, will extend the core profiles with constraints related to specific medical domains. In particular it could specify the:

- adoption of existing coding systems already used at international level for that domain.
- integration of existing FHIR models for health data already agreed at EU and worldwide level, such as the International Patient Summary.
- the adoption of proposed mappings between existing standards (e.g. for ePrescritions) and FHIR.

The InteropEHRate profiles will include and extend only FHIR resources that are relevant to represent the health history of a Person. It will not cover any information that is relevant only to the internal workflows of specific organization or that is related to administrative processes, such as financial information.

The set of all the InteropEHRate profiles constitutes the data model of a generic S-EHR.

The InteropEHRate Profiles are intended to be used with different protocols, namely device to device (D2D) protocol, remote to device (R2D) protocol, and research protocol. The protocol specifications define technical transactions, actors and sequences that are needed to support the depicted scenarios and enable and implement the envisioned data exchange process. The workflows described in this document describe a portion of the specified actions, enabling the conclusion of requirements of the InteropEHRate Profile. However, it should be noted that these workflows are not considered as technical specifications for the protocols.

The dependencies and interactions between the protocols and the InteropEHRate Profile are shown below.

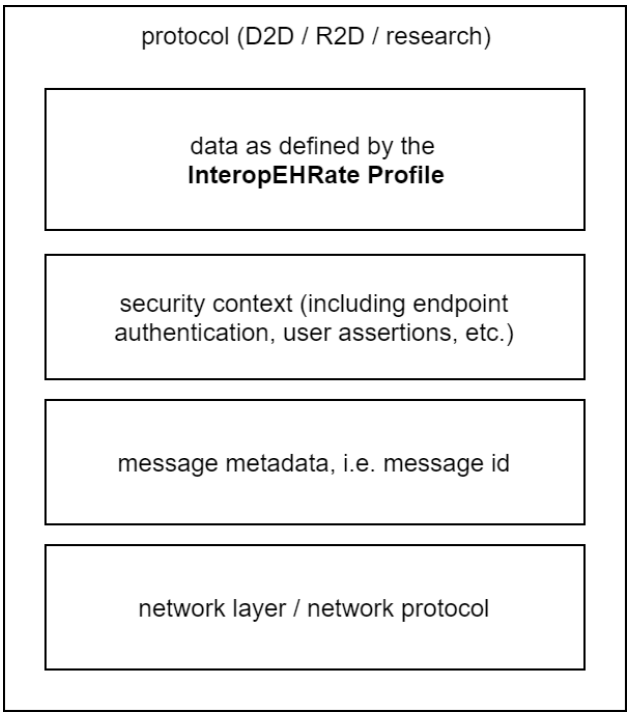

Figure 1 - Dependencies and interactions between the protocols and the InteropEHRate Profile

The InteropEHRate profile is embedded in a protocol, which depends on the corresponding use case (D2D protocol, R2D protocol, research protocol).

The protocol is built upon a *network layer*, ensuring the connectivity of the participating endpoints, by supporting point-to-point interactions. The exchange of messages generally includes exchange of message metadata relevant for message assignment and defracturing, covered by the layer *message metadata*. Since the use cases cover the exchange of personalized data, a security context has to be mutually established and referenced, which is covered by the layer *security context*. The actual content to be exchanged, including health data, or identifying data, is transmitted in the top layer of the *data as defined by the InteropEHRate Profile*. Thus, the InteropEHRate Profile describes structures and semantics to express and transmit the content of a message in combination with its actual data.

This document also defines data categories and assignments of data categories to a carrier (InteropEHRate Profile or protocol) regarding the data exchange.

3 HIGH LEVEL USE CASES & REQUIREMENTS

The scope of the following description of high-level use cases is to identify the involved actors and high-level components, the intended data categories, and additional requirements regarding the flow and communication of data, in general. What is more, it is intended to give a general overview of the project's scenarios as a basis to derive the actual requirements for an InteropEHRate Profile that shall be usable in the project's scope as well as in other projects that focus on cross-border data exchange in similar scenarios.

3.1 Involved actors and components

Generally, the scenarios involve the healthcare professionals (HCPs) and the patients. The patient generates an identity token, provides demographic data, confirms the identity of the healthcare professional (or the organization), and provides a consent describing the given access policies. The healthcare professional redeems an identity token, provides operator id and/or demographic data, confirms the patient's identity, requests the patient's consent, requests and receives health data and provides health data. All these actions are depicted in the following figure, outlining each different step that is scoped by the corresponding actors.

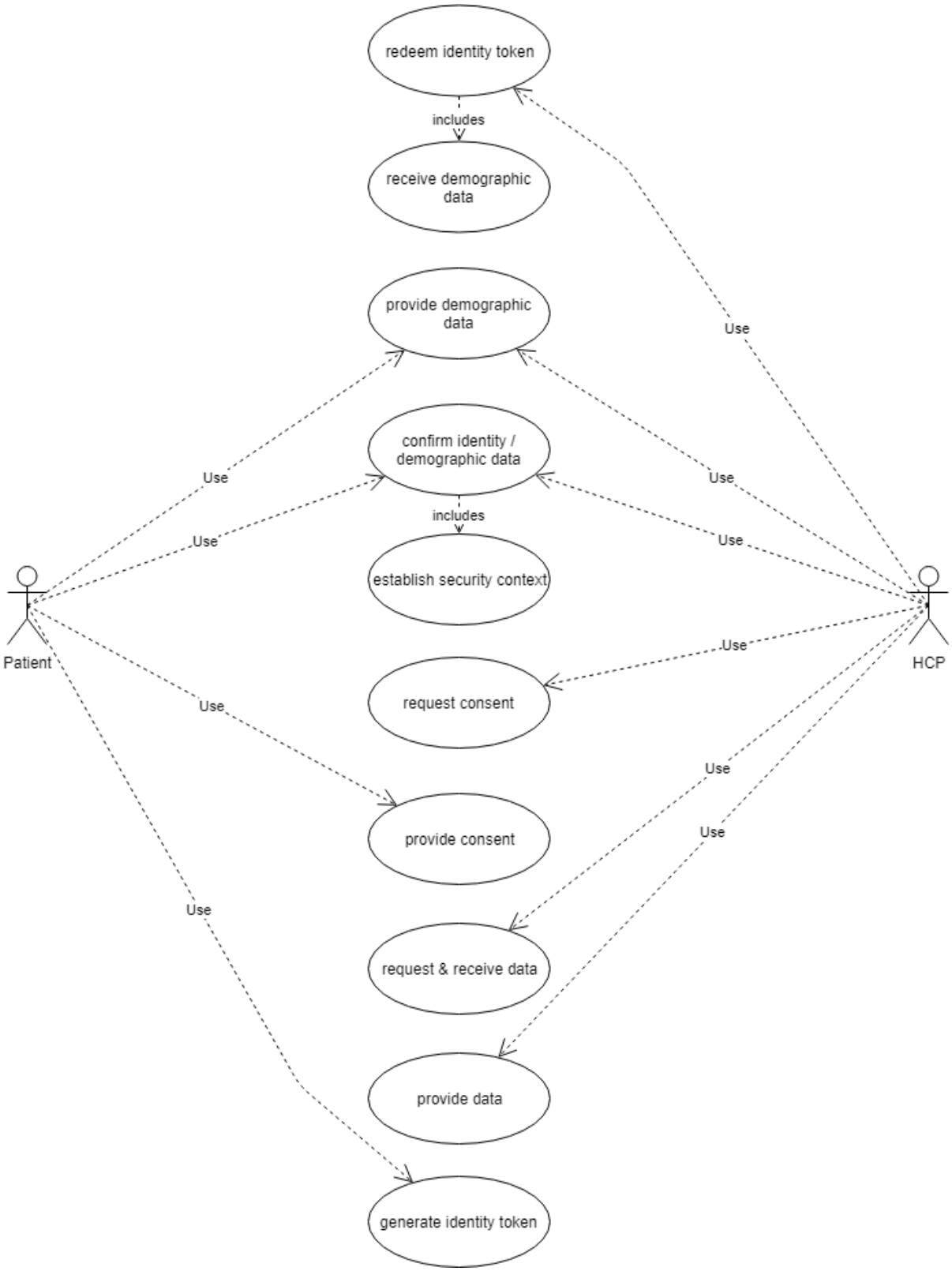

Figure 2 - Actors and use cases

To this end, it should be noted that the current model will be extended by the use cases for research scenario in the next version of the deliverable.

3.2 Use Cases

For the purpose of this document, all processes and process models described below serve the purpose of deriving a domain model for the required data exchange. These process models are based on the scenario descriptions and do not focus on specifying all possible process steps, alternate flows or outcomes. Detailed descriptions can be found in the scenario descriptions.

3.2.1 Device to device HR exchange

The scenario *Device to device HR exchange* focuses on data exchange between a patient and involved healthcare professionals, and the S-EHR App and HCP App, respectively, during a patient visit in hospital. Certain prerequisites have to be met in order to identify the natural persons (e.g. doctor) and organizations (e.g. hospitals) and requests and provide the desired data sets. The following figure outlines the overarching process for the D2D scenario described in more detail in the following sections.

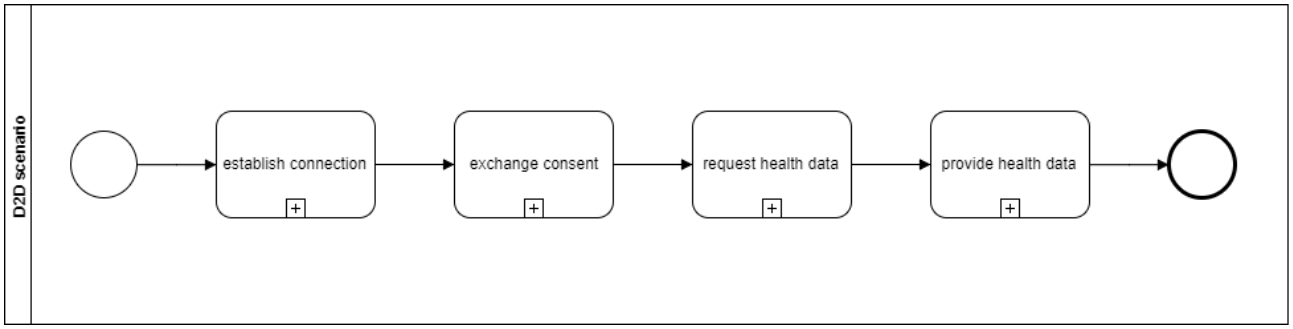

Figure 3 - D2D scenario

As it is depicted in the figure above, initially, a connection has to be established and approved. This includes the mutual identification of actors (i.e. patient and healthcare professional). If the connection and identification have been approved successfully, the patient's consent is exchanged. This is a prerequisite for all the further exchange of healthcare data. Then, the desired data is requested by providing a data description. The actual care data meeting the data description is then provided either within the response or continuously through multiple transactions. In the end, newly collected data are provided to the S-EHR app of the patient.

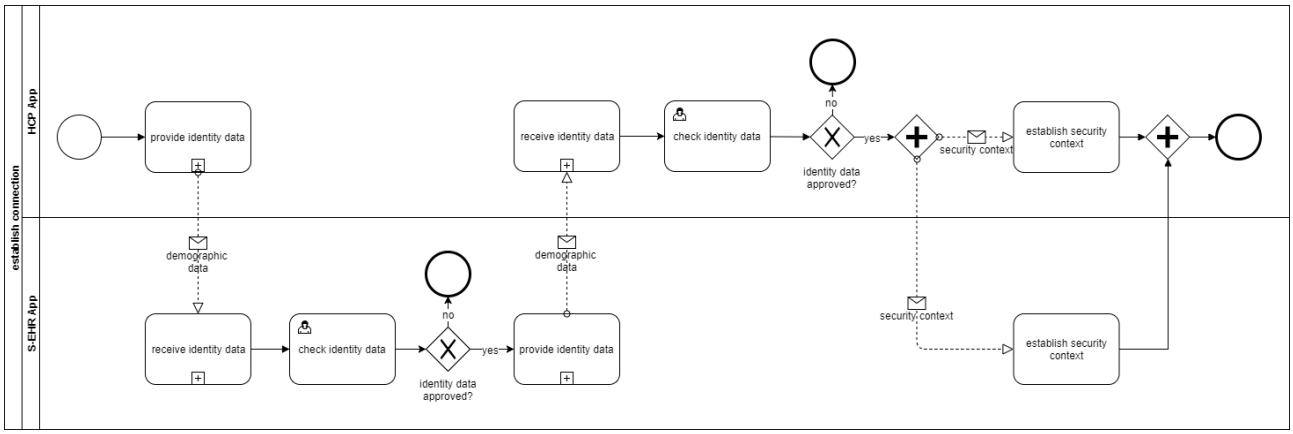

Figure 4 - Process for establishing a connection

In order to establish a connection, the HCP App provides id and/or demographic data describing the healthcare professional and the related healthcare organization.

The patient checks and approves the identity data, providing demographic data describing him/her-self.

The healthcare professional checks and approves the identifying data, respectively, and a security context between the HCP App and S-EHR App is established.

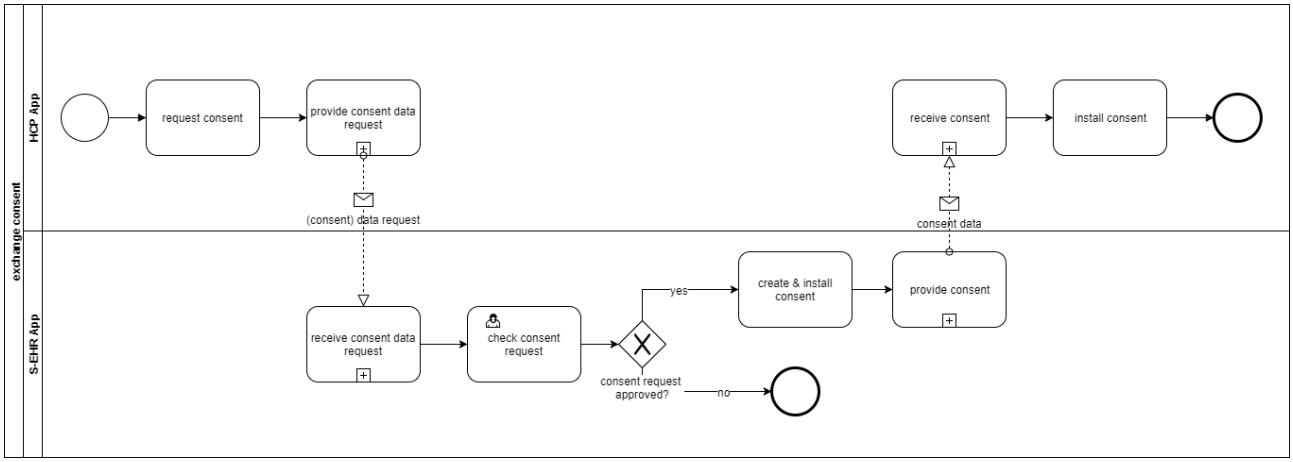

Figure 5 - Process for exchanging consent

In order to exchange a consent, the HCP App sends a request to the S-EHR App. The request contains terms of use and requested permission to access patients data. The patient reviews and approves the request, installing and providing a consent containing rules that determine the context of the data usage.

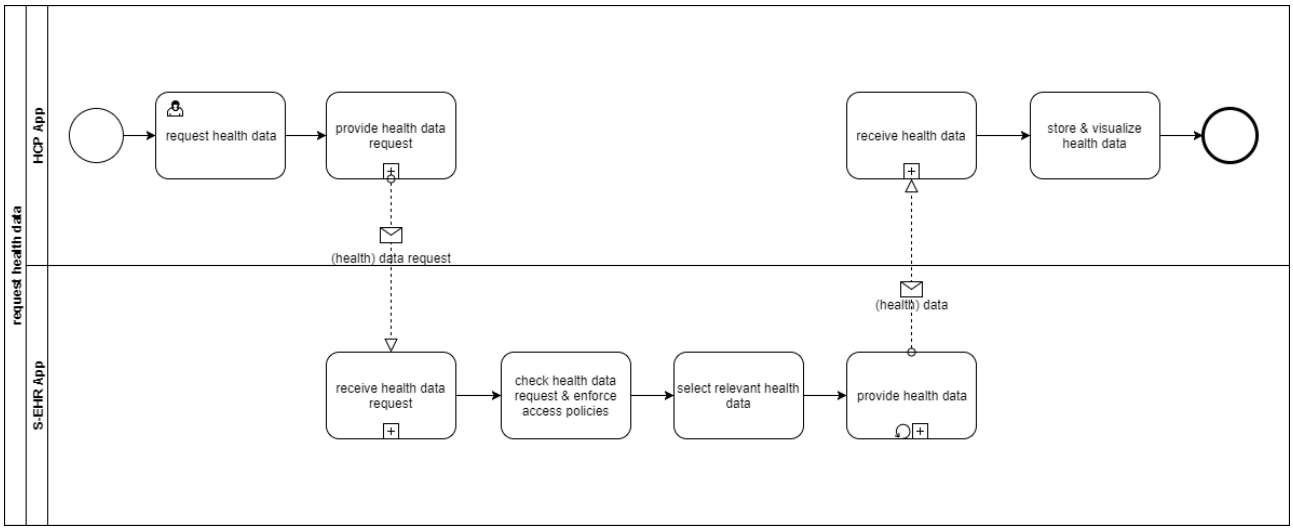

Figure 6 - Process for requesting health data

In order to receive the patient's health data, the healthcare professional sends a request, describing the desired information he/she wants to access. The S-EHR App checks the request, enforces the data access policies defined by the patient and selects and provides the matching health data to the HCP App.

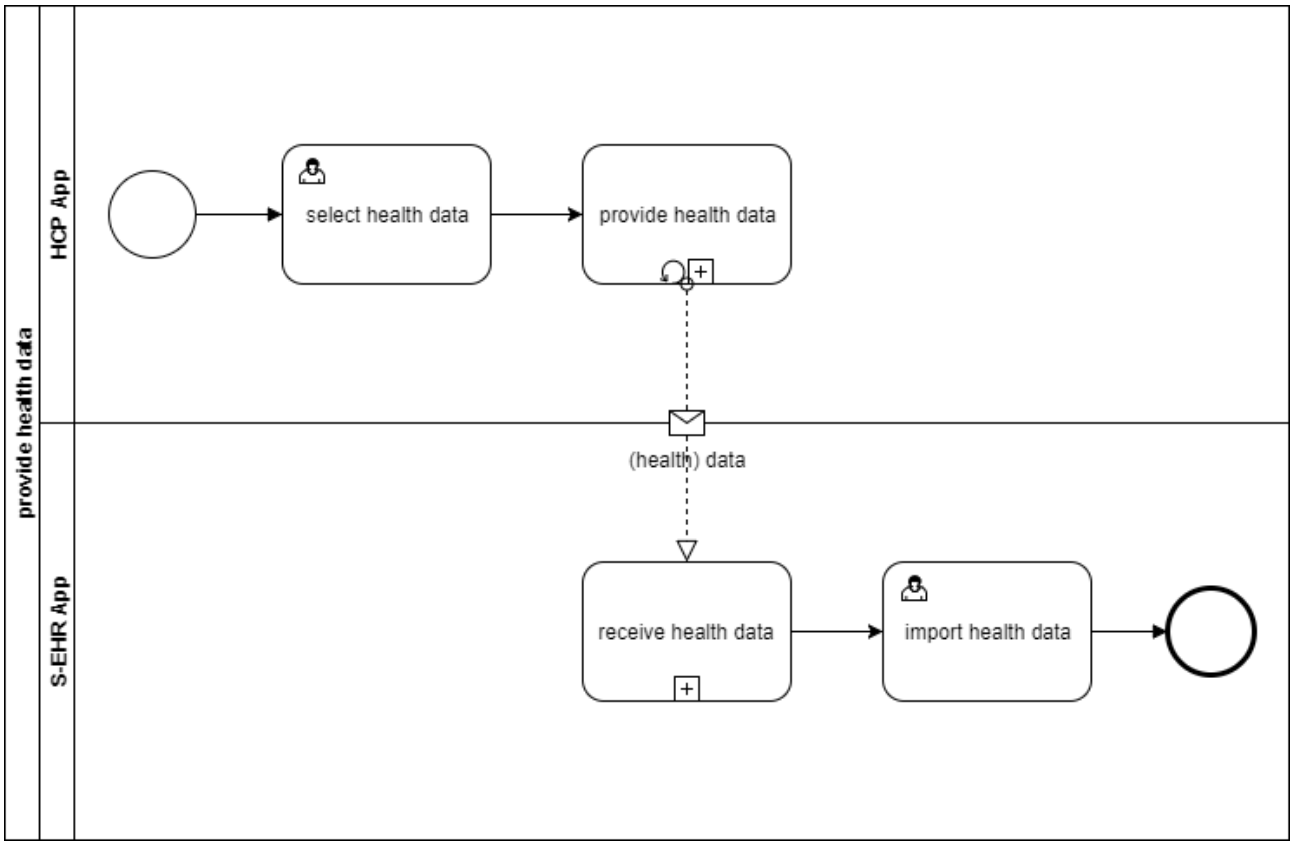

Figure 7 - Process for providing health data

If during the healthcare process any important information are generated or collected, with medico-legal values, such information may be uploaded back to the S-EHR. The HCP therefore can provide this dataset to the patient's S-EHR App. The received data is imported to the patient's S-EHR App and available for future view or data exchange.

Data Sets used within the transactions

Data set	Description
demographic dataset	Dataset describing a human being or organization. This data set contains personal data and may contain images or photos that depict the person.
security context	Dataset containing temporary information about the session's security context.
(consent) request	A request to grant consent for healthcare data access.
(health) data request	A request describing the desired healthcare data.
consent data	Dataset containing sets of rules that determine the context, purpose and policies of use of referenced data sets.
health data	Dataset regarding a patient's previous and current health status and treatments. This data category summarizes emergency data, prescription / dispensation data, laboratory results, medical images and reports and hospital discharge reports, etc..

Table 1 - data sets used within transactions (D2D)

Use Case description

Use case name	Device to device HR exchange
Use case id	D2D
(Super use case)	-
Preconditions	<see T2.1 usage scenarios>
Use case steps	1. The healthcare professional and the patient establish a (secure) device to device connection by mutually exchanging and verifying the demographic and identifying data of the connection partner. In the end, a security context is established. 2. The healthcare professional provides a request for consent, containing the desired operations and data exchange parameters, and the patient denies or approves the request. If approved, the

	consent is exchanged. 3. The healthcare professional sends a request to receive patient's healthcare data. The request is fulfilled by S-EHR and the health data matching the current request and access policies are selected and transmitted. 4. The healthcare professional provides back to S-EHR newly collected, updated or generated healthcare data.
Postconditions	<see T2.1 usage scenarios>
Expected results	1. The HCP has received the desired health data from the patient's S-EHR app. 2. The patient's S-EHR app has stored all newly collected health data.

Table 2 - use case description (D2D)

3.2.2 Remote to device HR exchange

The scenario *Remote to device HR exchange* enables data exchange in emergency situations. Therefore, the patient is not actively involved in the transactions taking place between the components HCP App and S-EHR Cloud.

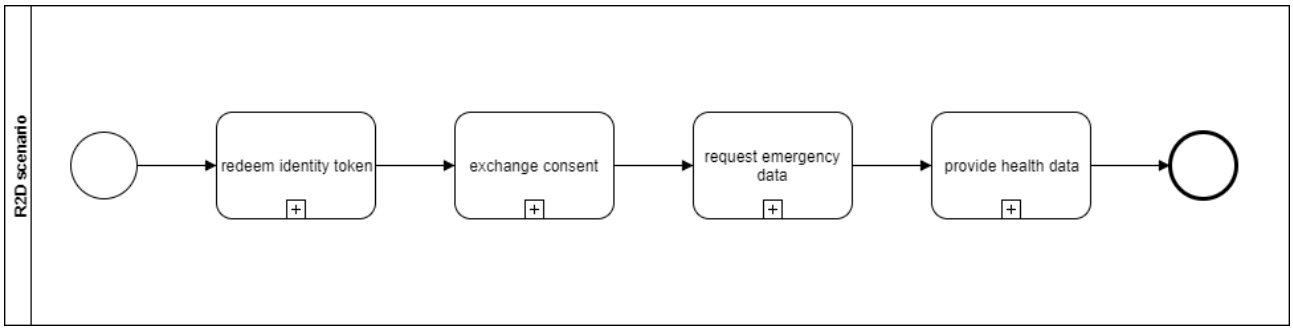

Figure 8 - R2D scenario

As it is depicted in the figure above, the healthcare professional receives and redeems the patient's identity token and receives the associated patient's identity data. After confirming the patient's identity, the emergency data sets are provided. In the end, the healthcare professional provides newly collected data, including a discharge report, to the *S-EHR Cloud* component.

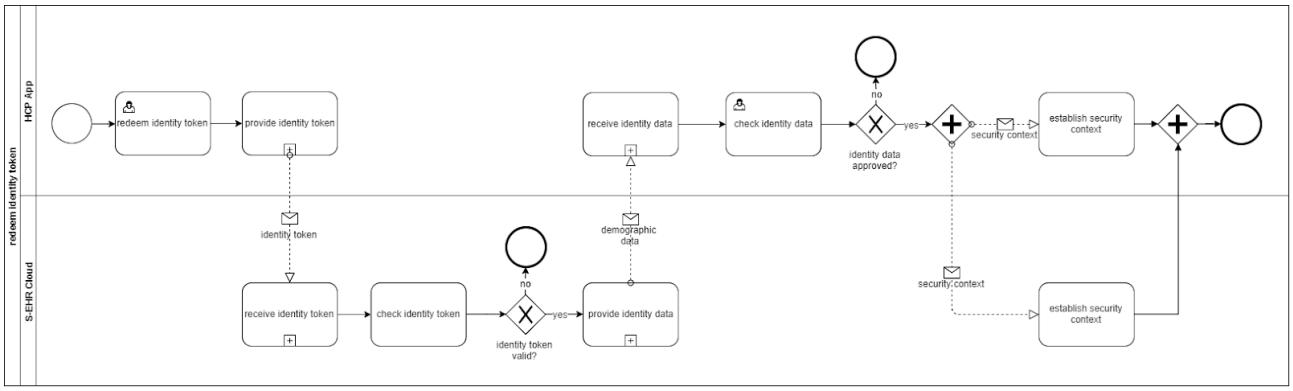

Figure 9 - Process for redeeming identity token

In order to redeem an identity token, the healthcare professional provides the identity token to the S-EHR Cloud, where it is validated. If the request is valid, the patient's identity data are provided to the HCP App. The healthcare professional approves the patient's identity and a security context is established.

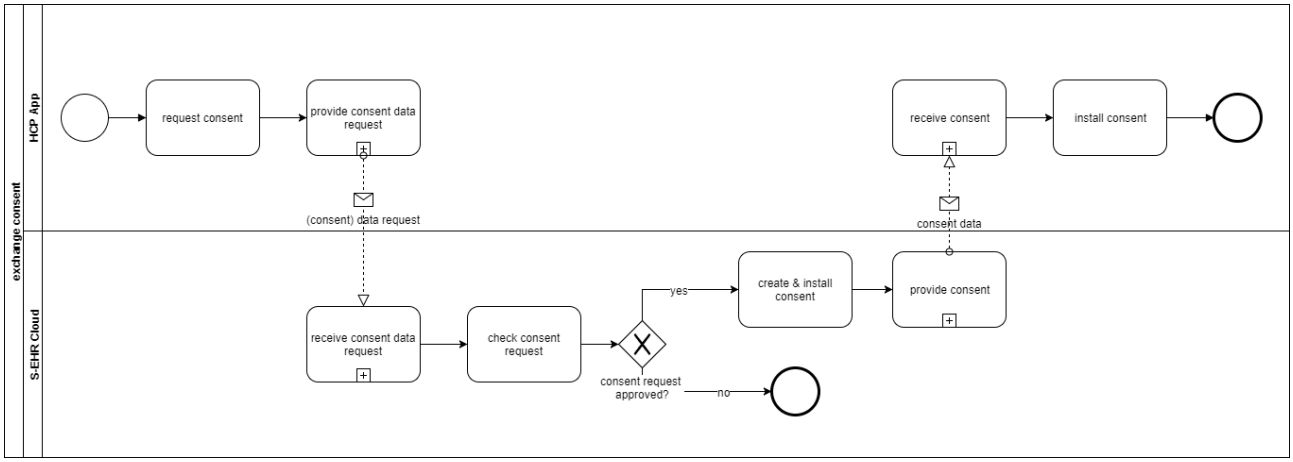

Figure 10 - Process for exchanging consent in the R2D scenario

In order to exchange the patient's consent, the HCP App sends a request to the S-EHR Cloud. The S-EHR Cloud approves the request, installing and providing a consent containing rules that determine the context of the data usage.

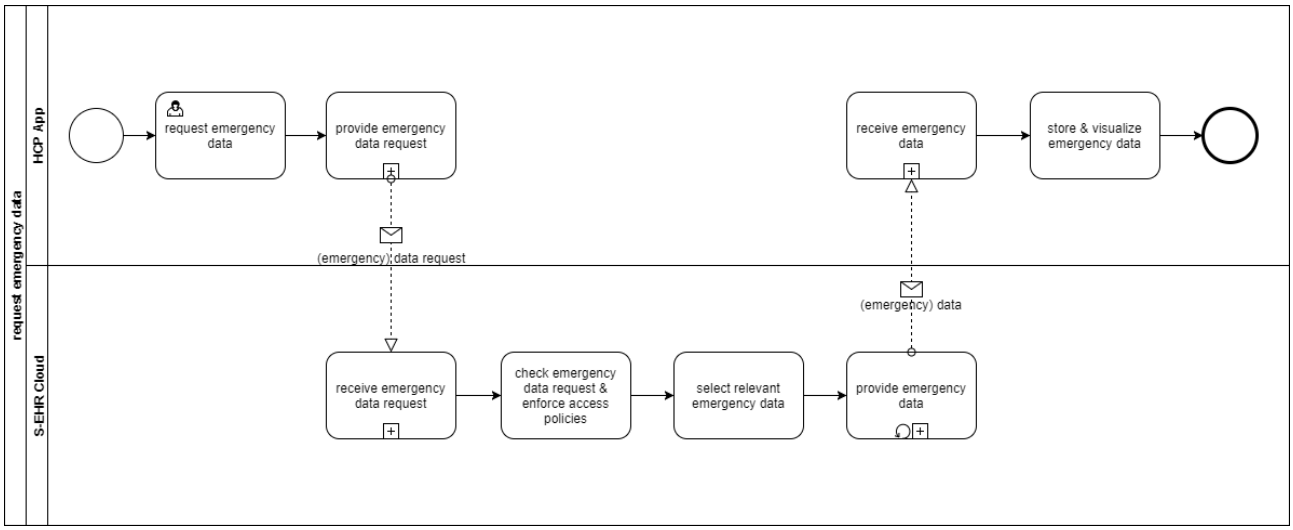

Figure 11 - Process for requesting emergency data

In order to receive the patient's emergency dataset, the healthcare professional sends a request. The S-EHR Cloud checks the request, enforces the data access policies previously defined by the patient and selects and provides the requested emergency dataset to the HCP App.

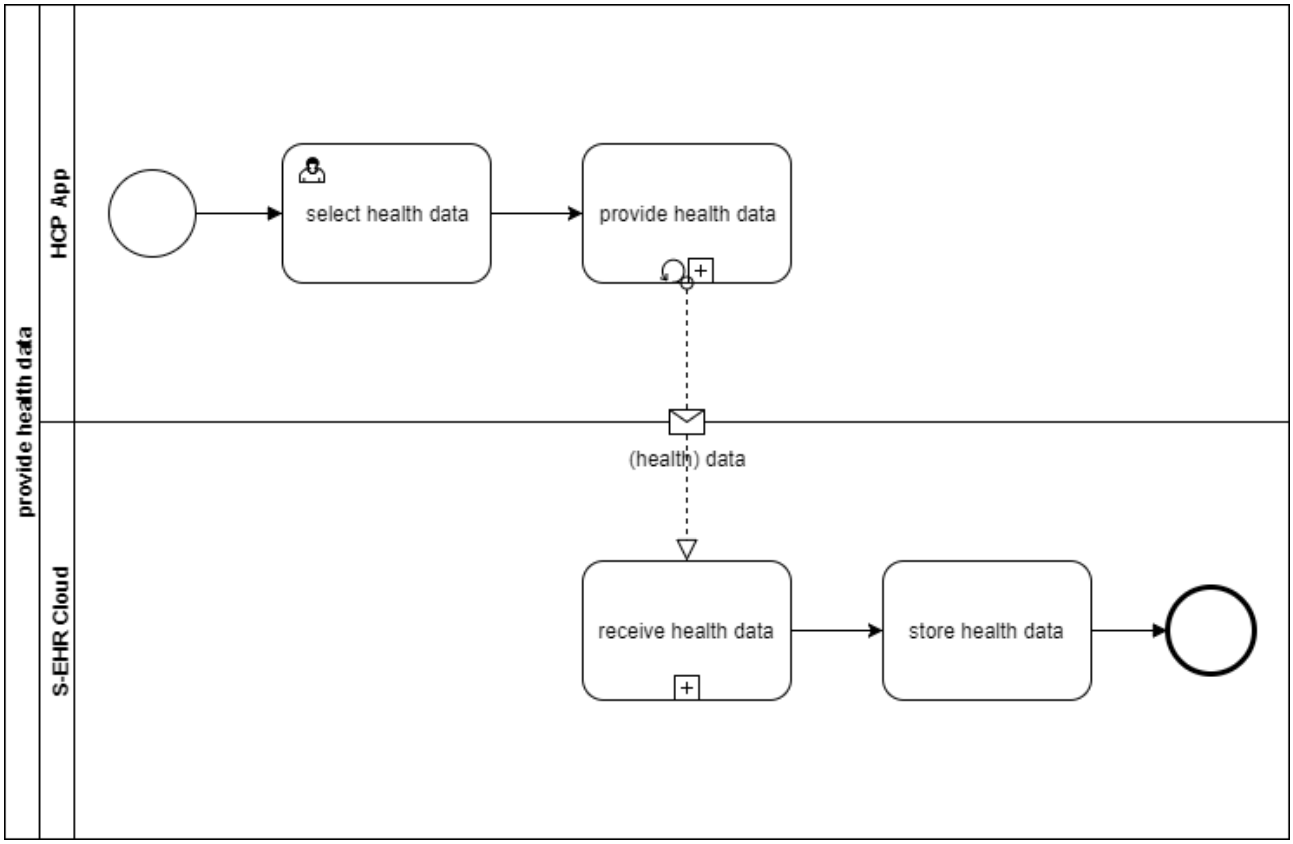

Figure 12 - Process for providing health data in the R2D scenario

If during the healthcare process any important information are generated or collected, with medico-legal values, such information may be uploaded back to the S-EHR Cloud. The HCP therefore can provide this dataset to the S-EHR Cloud. The received data is imported to the S-EHR Cloud and available for future view or data exchange.

Data Sets used within the transactions

Data set	Description
identity token	A code that uniquely identifies the patient and grants access to the emergency data.
demographic data	Data describing a human being or organization. This data set contains personal data and may contain images or photos that depict the person.
security context	Data containing temporary information about the session's security context.
(consent) request	A request describing the desired consent.
(emergency) data request	A data request describing the desired health data.
consent data	Data containing sets of rules that determine the context, purpose and policies of use of referenced data sets.
health data	Data regarding a patient's previous and current health care and treatment. This data category summarizes emergency data, prescription / dispensation data, laboratory results, medical images and reports and hospital discharge reports.
emergency data	Information containing only the emergency data / patient summary data sets. Emergency data is considered a subset of health data.

Table 3 - data sets used within transactions (R2D)

Use Case description

Use case name	Remote to device HR exchange
Use case id	R2D
(Super use case)	-
Preconditions	<see T2.1 usage scenarios>
Use case steps	5. The healthcare professional redeems a patient's identity token and receives demographic data that uniquely identifies the patient. The healthcare professional validates the patient's identity, and a security context is established between the HCP App and the S-EHR Cloud. 6. A request for the patient's consent is sent to the S-EHR Cloud. If the request can be approved, the consent is provided. 7. The healthcare professional sends a request to access the patient's emergency data. If the request is valid, the emergency data sets are selected and provided to the HCP App. 8. The healthcare professional provides newly collected or created health data to the patient.
Postconditions	<see T2.1 usage scenarios>
Expected results	3. The HCP has received the desired data from the S-EHR Cloud. 4. The S-EHR Cloud has stored all newly collected data.

Table 4 - use case description (R2D)

3.2.3 Research HR exchange

The scenario *Research HR exchange* will be covered by the next version of the deliverable.

3.3 Derived requirements

The following sections conclude and summarize the requirements derived from the (portions of the) scenario descriptions.

3.3.1 Data set

The transactions as described by the different scenarios (i.e. Remote to device HR exchange, and Device to device HR exchange), depict the following data sets and information to be exchanged.

The meaning of the column headings is as follows:

- Data category: Grouping of data set in categories
- Data group: name of the data group
- Description: description of the data group
- Transactions: describes how the exchange of the data set described is directed (bidirectional means HCP App ← → S-EHR App)
- Location: Specifies where the described data group is included in the exchange (profile means the information is part of the content specified by the InteropEHRate Profile).

Data category	Data group	Description	Transactions	Location
health data	emergency data / patient summary	allergies, chronic / rare diseases, acute / ongoing diseases, relevant exams, surgical history, current medications	bidirectional	profile
health data	prescription / dispensation data	prescribed drugs, drug prescriptions	bidirectional	profile
health data	laboratory results	vital signs, measurement results	bidirectional	profile
health data	medical images and reports	DICOM images, DICOM movies, bio signals, SCP/DICOM waveform, digitally signed documents (e.g. PaDES), radiology reports, evaluation reports	bidirectional	profile
health data	hospital discharge reports	cause of admission, discharge diagnostic assessment, prescriptions, visits and recommendations, therapy	bidirectional	profile
identity data	demographic data	demographic data about patients, caregivers, HCPs and organizations, including names, addresses, contact information, and photos	bidirectional	profile

identity data	identity token	a token / code referring to a patient's identity in the S-EHR Cloud that allows for accessing the patient's demographic and emergency data	HCP App → S-EHR Cloud	profile
security & session data	security context	information about participating actors (ids, roles, etc.) used to identify, authenticate and authorize the user for the intended data exchange / data access	bidirectional	protocol
security & session data	consent data	a structured document containing information about a patient's agreement to the context and parameters of HR access and exchange regarding groups of HCPs	S-EHR App → HCP App S-EHR Cloud → HCP App	profile
data request	consent content request	a request for data describing the desired consent	HCP App → S-EHR App HCP App → S-EHR Cloud	protocol
data request	health data request	a request for data describing the desired health data	HCP App → S-EHR App HCP App → S-EHR Cloud	protocol
data request	emergency data request	a request for data describing the desired emergency data	HCP App → S-EHR App HCP App → S-EHR Cloud	protocol
general metadata	actor role and attributes	attributes defining an actor's identity and user context	bidirectional	protocol
general metadata	data source and responsibility provenance	metadata describing the origin and provenance and thus the trustworthiness of information	bidirectional	profile

general metadata	data format and language	metadata describing the format, coding scheme and language of information	bidirectional	profile

Table 5 - InteropEHRate data set

3.3.2 Transformation

Data exchange consists of various workflows to provide and receive data. These workflows contain transformation steps that are necessary for semantic interoperability and translation of human readable texts. The necessary steps to provide and receive data are outlined in the figures below and referenced as subprocesses by the scenarios.

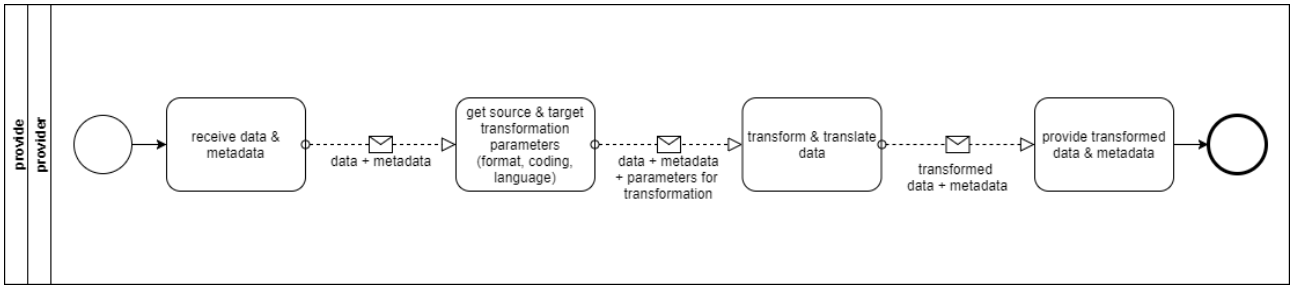

Figure 13 - Process for providing health data in the R2D scenario

In order to provide data, the data and corresponding metadata need to carry information about their semantics regarding code systems used to express certain concepts and the language the information is written in. This is referred to as “source transformation parameters”. Additionally, information about the desired target transformation parameters are collected, including information about the supported / required code systems and language of the transformation result. Thus, the data and metadata can be transformed into a known target format (coding and language).

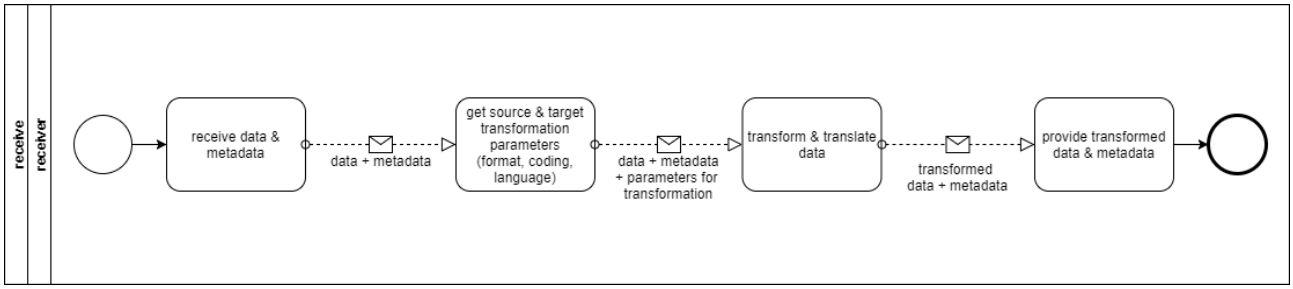

Figure 14 - Process for transforming (meta-)data in multilingual context

Once data and metadata are received, the data and metadata can be transformed into (another) target format, including the code systems and language supported by the receiver.

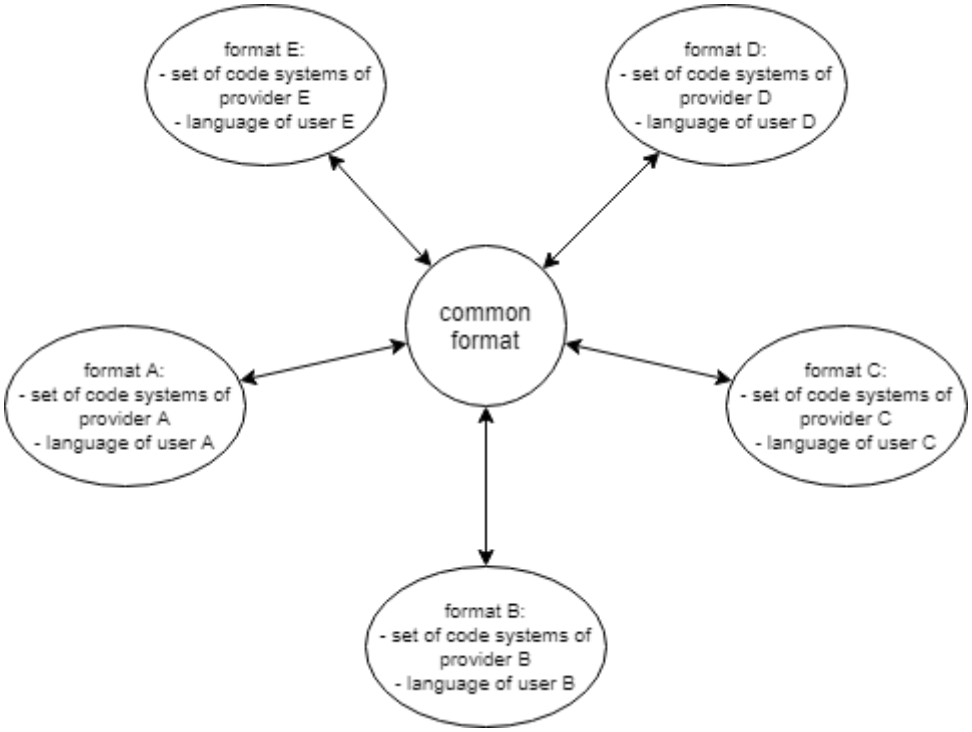

Figure 15 - Usage of a common representation to transfer and store data and metadata

As it is depicted in the figure above, in order to facilitate this transformation process, a common representation will be used to transfer and store the data and metadata, including a common data format as well as shared coding systems and data schemas for the language-independent representation of general and medical concepts and data. Thus, the transformation process uses a common and central format, and only transformations from a complex source format into this common minimum format and vice versa need to be supported, instead of all possible transformations from one format to any other format. The software therefore only needs to know (and manage the required knowledge base for) one format defined by the user preferences and the common minimum format. However, given the natural limitations of such structured mapping processes to unstructured text present in health records, transformation will also involve machine translation executed on natural language text from its original language to the target language provided as input. Moreover, the data and metadata only needs to carry information about its current format. Otherwise, the data and metadata should at least carry information about the current source format and the desired target format, depending on where the data transformation is executed; or the data and metadata could transported in different, multiple transformation results, depending on the source and target format settings.

Thus, for example, the data and metadata provided by the HCP app to the S-EHR App contains metadata pointing to the native format (coding scheme, language) and is transformed from the HCP's native format (coding scheme, language) to the common format and translated to the patient's own language (if different from the original language of the EHR). This transformed data, alongside with the original data, is transferred to the S-EHR App, allowing the patient to review the health record in her/his native language. Its metadata contains information about the format, pointing to the common format. When the S-EHR is later downloaded from the S-EHR App to a hospital's information system and HCP App in a different country, the local HCP App will be able natively to interpret the common representations (data schemas, coded values) and present them to the HCP in the local language. In the case of non-mapped unstructured text, machine translation from the original language may again be necessary.

4 SPECIFICATION CONCEPTS & METHODS

4.1 IEHR core & domain profiles

The InteropEHRate profiles are supposed to be used with the newly specified communication protocols in order to share and exchange information between the different actors. They adopt existing domain agnostic data models and profiles for a flexible support of health data exchange of different domains and define a set of core data and profiles that enable the communication and transactions as defined by the protocols and the InteropEHRate Core Guide. Thus, the InteropEHRate Profile is split into different layers. The first layer refers to the InteropEHRate Core Profiles that include mandatory (general) data and information required for secure cross-border data exchange. They are embedded in the profiles and data items as defined by the second layer of the InteropEHRate Domain Profiles. The domain profiles add a layer of (possibly extended or constrained) profiles that enable the structuring and expression of health related information. Finally, a third layer of further extended and constrained profiles is added, allowing for use case specific data to be defined and included.

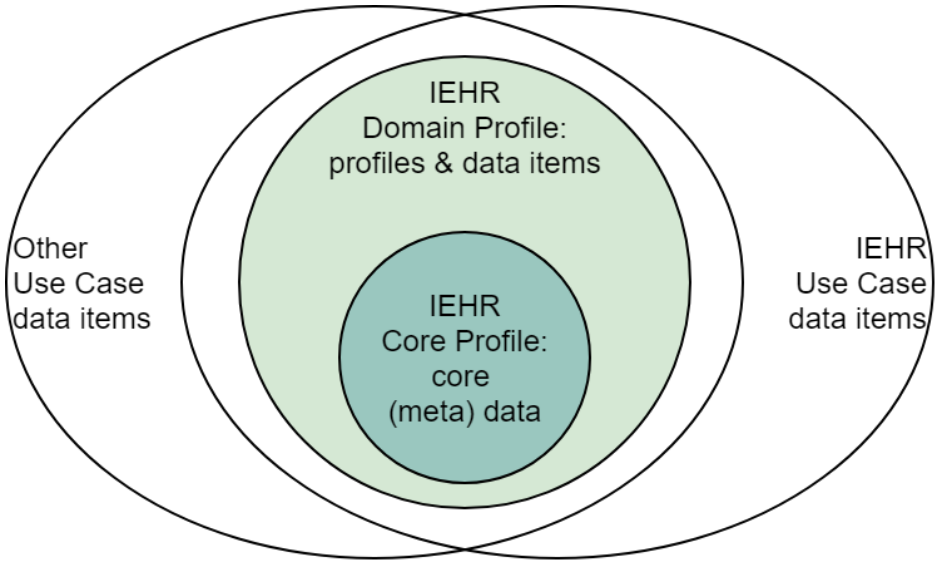

Figure 16 - layers of InteropEHRate profiles

Since the InteropEHRate Core Profiles are intended to define mandatory general information as required by the transactions of the InteropEHRate protocols, these profiles will include specific definitions, constraints and extensions of data items and metadata that will potentially affect all profiles and data items of the higher layers (InteropEHRate Domain Profiles and Use Case Profiles). These requirements will be identified, analysed and defined throughout the development of the InteropEHRate Profiles.

The InteropEHRate Domain Profiles will adopt in a first step the data model and definitions of the International Patient Summary (IPS) for the purpose of project's use cases and thus add data items and

profiles for expressing healthcare related information for cross-border data exchange. The sole use of IPS as a domain profile though is intended optional; other data models that serve specific use cases better can be adopted as well as domain profiles. At least one domain model must be present. All identified and specified requirements of the InteropEHRate Core Profiles will be incorporated in the adopted data items. Thus, the domain profiles are based on existing international profiles focussing on cross-border exchange of health data and extended by IEHR Core Profiles.

The Pilot Profiles will define data items and profiles that are not included in the InteropEHRate Core Profiles or InteropEHRate Domain Profiles, but are required for the InteropEHRate pilots (i.e. the specific instances of InteropEHRate use cases that will be used to validate the project results). They are not considered relevant for further standardization efforts, thus not being part of InteropEHRate Core or Domain Profiles.

IEHR Profile features	IEHR Core Guide	IEHR Domain Guides	IEHR Pilot Guides
description	mandatory general information as required by the transactions of the InteropEHRate protocols	healthcare related domain models	use case or facility specific models
Profiling base	HL7 FHIR R4	selection of existing IGs / Profiles, e.g. IPS; selected model(s) are extended with Core Profile	HL7 FHIR R4 or existing IG / Profile; can be constraints or extensions to Domain Profiles, e.g. pilot specific value sets; prerequisite: the model defines only data items that are not redundant with the Domain Profiles
subject to (international) standardization	yes	yes	no
expected cardinality of Guide (sum of Profiles)	1	1 .. N	0 .. N

Table 6 - IEHR Profile features

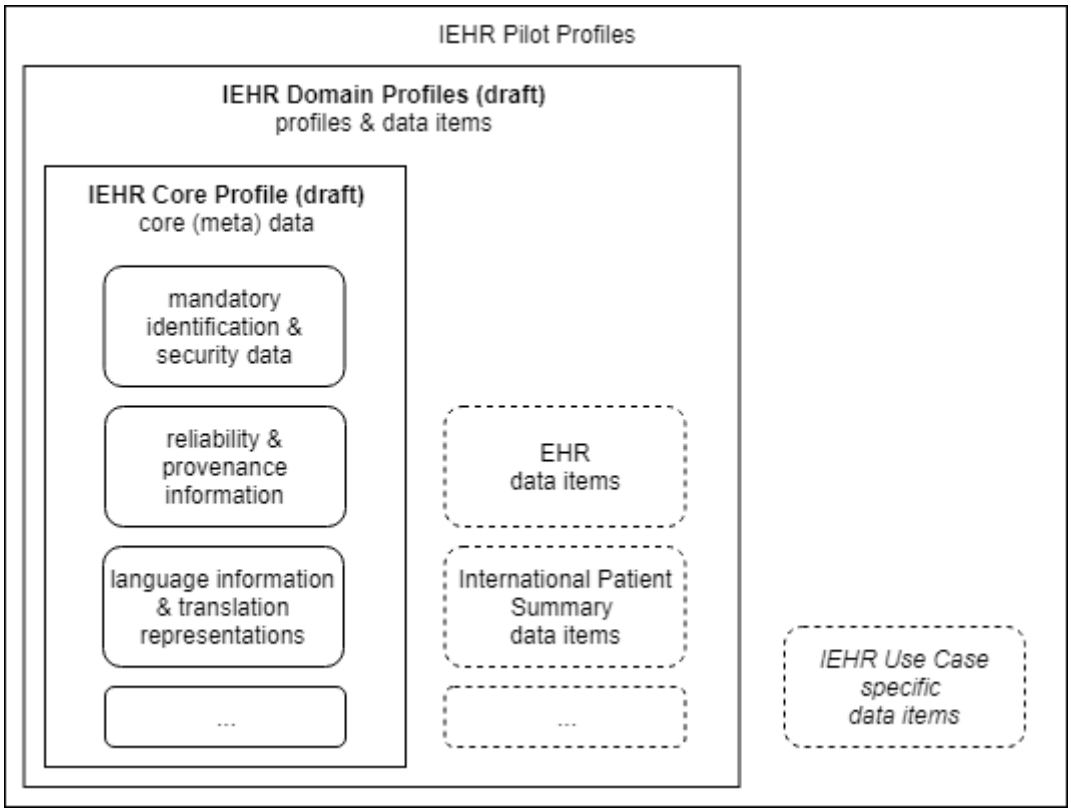

Figure 17 - content of the different layers of the InteropEHRate Profiles

4.2 Balloting & specification process

The InteropEHRate protocols are intended to be standardized. Being part of the protocols and incorporating existing specifications, the specification of the InteropEHRate Profile will follow a balloting process that ensures participation of and alignment with relevant communities as well as acceptance of the specified extensions. It is expected to deliver a release candidate of the InteropEHRate Core Profiles as input to a project external balloting process.

The InteropEHRate Profile is therefore first defined on a conceptual level, describing the data items, attributes and value sets in a technologically independent way. Once a version of the conceptual level specification is released and agreed on with the consortium, an implementable level specification is defined. The implementable level specification will be based on the conceptual level specification. All its data items, attributes and value sets are mapped to HL7 FHIR R4 resources and profiles. Once a version of the implementable level specification is released, it is again agreed on with the consortium. Afterwards, a HL7 FHIR Implementation Guide for this version of the InteropEHRate Profile is created which can then be subject to official balloting processes. Improvements on the InteropEHRate Profile are developed in the same manner and from the beginning of the balloting process and released as an incremented version.

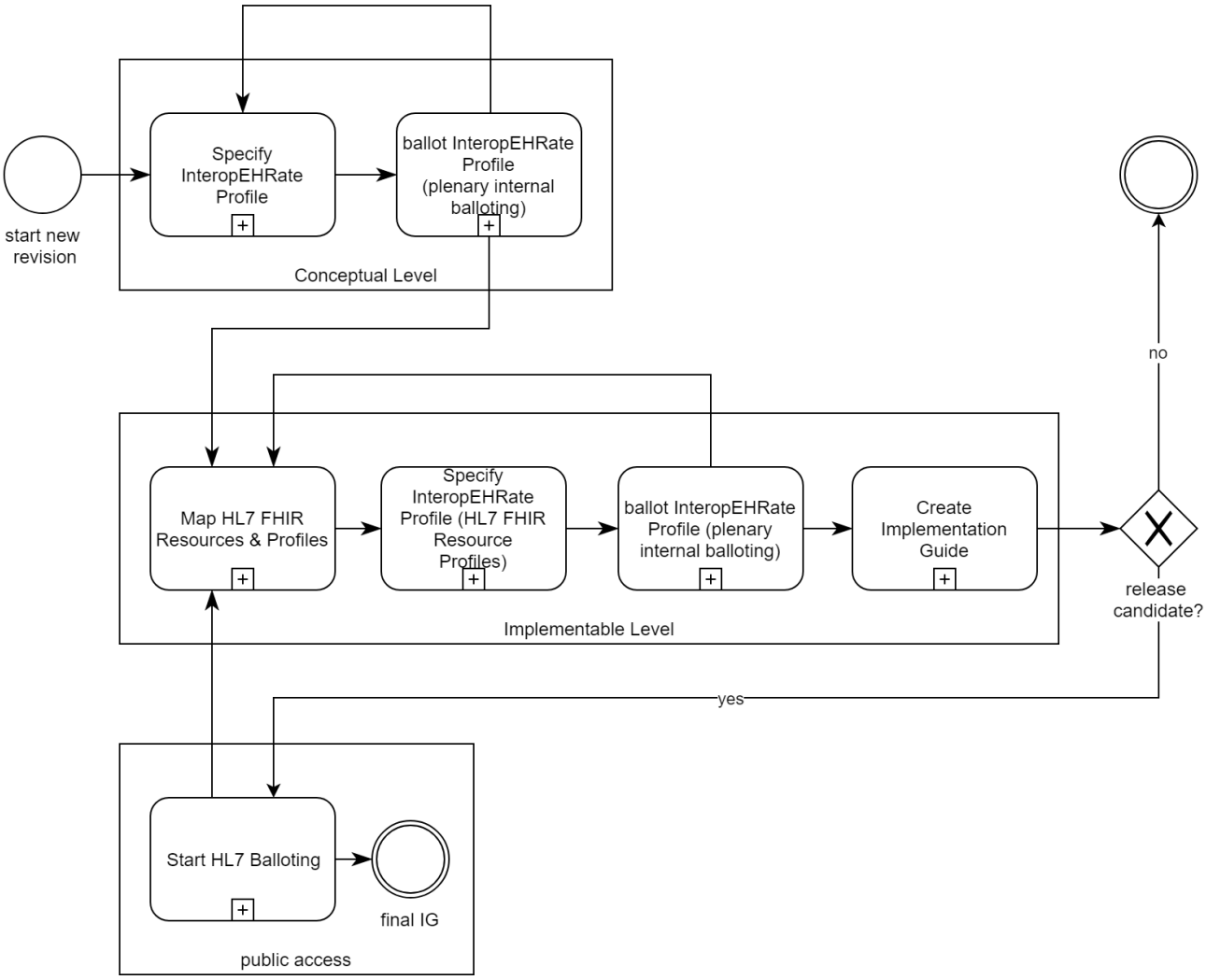

Figure 18 - specification and balloting process of the InteropEHRate Profile

The conceptual level specification will be produced using the tool ArtDecor [ART-DECOR® Expert Group IEHR 2019]. ArtDecor is an open source online tool suite including an editor that enables creation and maintenance of HL7 templates, value sets, scenarios and data sets.

The implementable level specification will be produced using the tool Forge for HL7 FHIR R4 [Firely Amsterdam 2019]. Forge allows for creating and viewing FHIR profiles, including structure definitions.

The HL7 FHIR Implementation Guide is a HL7 FHIR resource and thus created with Forge. It can be published and extended with a documentation using the FHIR IG Publishing tool [HL7 International Wiki 2019].

4.3 HL7 FHIR

4.3.1 Overview

Fast Healthcare Interoperability Resources (FHIR) [HL7 International FHIR R4 2019] is a standard for health care data exchange. It was created by the Health Level Seven International (HL7) health-care standards organization based on previous data format standards (HL7 version 2.x and HL7 version 3.x). Unlike the previous data formats HL7 FHIR uses a modern technologies including HTTP-based RESTful protocol. The data can be represented in JSON, XML or RDF. The first release was published in 2014 as a Draft Standard For Trial Use (DSTU). Release 4 (First Normative Content) was published December 2018.

The HL7 specification defines:

- a set of different types of resources that represent healthcare related information both clinical and administrative (patient, observation, medication, appointment...)
- specification of transactions to exchange these data

The following section shows an example of the presentation of a patient.

```
<Patient>
    <id value="IPS-examples-Patient-01"/>
    <identifier>
        <system value="urn:oid:2.16.840.1.113883.2.4.6.3"/>
        <value value="574687583"/>
    </identifier>
    <name>
        <family value="DeLarosa"/>
        <given value="Martha"/>
    </name>
    <telecom>
        <system value="phone"/>
        <value value="+31788700800"/>
        <use value="home"/>
    </telecom>
    <gender value="female"/>
    <birthDate value="1972-05-01"/>
    <address>
        <line value="Laan Van Europa 1600"/>
        <city value="Dordrecht"/>
        <postalCode value="3317 DB"/>
        <country value="Netherlands"/>
    </address>
    <contact>
        <relationship>
                <coding>
                        <system value="http://terminology.hl7.org/CodeSystem/v3-RoleCode"/>
                        <code value="MTH"/>
                </coding>
        </relationship>
        <name>
                <family value="Mum"/>
                <given value="Martha"/>
        </name>
        <telecom>
                <system value="phone"/>
                <value value="+33-555-20036"/>
                <use value="home"/>
        </telecom>

        ...

    </contact>

</Patient>
```

4.3.2 Profiling HL7 FHIR

The HL7 FHIR specification is generic and targets all countries and all use cases. For specific use-cases it is important to tailor the specification. The result of the adjustment for a use case is documented in a HL7 message profile. The definition for message profiles according to the HL7 Organisation is:

"A HL7 message profile is an unambiguous specification of one or more standard HL7 messages that have been analysed for a particular use case. It prescribes a set of precise constraints upon one or more standard HL7 messages."

A profile is an interface specification that can be shared within a team or project or other international team working on the same use case. It serves as a basis for the implementation of interfaces and it also allows to define test-scenarios to validate the integrated technical solution.

A profile contains information about:

- data format
- data semantics
- message acknowledgment responsibilities

4.3.3 HL7 FHIR Implementation Guide

„Implementation Guides are documents published by a domain, institution or vendor that describe how FHIR is adapted to support a certain use case (or set of use cases). An implementation guide combines a set of conformance resources and supporting narrative into a document for use by implementers." The following figure outlines the components of an Implementation Guide. To describe the content of an Implementation Guide the resource Implementation Guide is used.

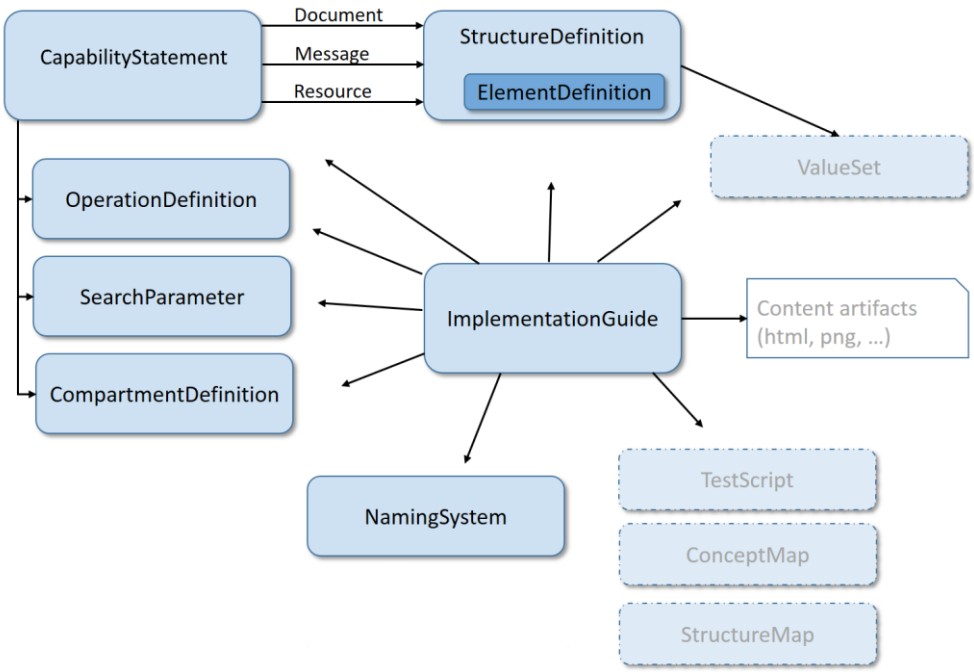

Figure 19 - FHIR Implementation Guide components

The Implementation Guide contains all Structure Definitions (e.g. profiles). These definitions describe how resources are used in a specific context. This includes the definition of restrictions and extensions on underlying resources and datatypes. A Structure Definition can also define extensions and value sets which can be used by resources or data types. To describe specific messages that can be sent or received to the system which supports the Implementation Guide the Message Definition can be used. The Operation Definition allows to define additional operations that servers can implement. To define additional Search Parameter the Implementation Guide can be extended by Definitions for Search Parameter. To group resources in Compartments for example to support special access control the Compartment Definition can be used.

4.4 HL7 FHIR Profiles for cross-border exchange

4.4.1 International Patient Summary

The International Patient Summary (IPS) is a "Minimal and non-exhaustive Patient Summary, specialty-agnostic, condition-independent, but readily usable by all clinicians for the unscheduled (cross-border) care of a patient." [HL7 Organization 2018]. The IPS is based on multiple previous projects on patient summaries (epSOS, Trillium Bridge, …) and is one of the main subjects of the new EU/US Roadmap with the goal to enable a standardized international patient summary to be in use in 2020. The IPS project is supported by different organizations (CEN/TC 251, HL7 Working Groups, JICS Standards Sets initiative on Patient Summary, …).

The IPS project results are:

- CEN/TC 251 Data Set
- HL7 CDA R2 Implementation Guide
- HL7 FHIR Implementation Guide
- CEN/TC 251 prTS 17288: European Guidance for PS Implementation

IPS dataset is formalized by the CEN/TC 251 Draft European standard (prEN 17269) and represents the implementable perspective. It forms the basis for the HL7 Implementation Guides, which form the implementable perspective.

The following graphic shows the building blocks of the IPS. In addition to general information (such as patient information, author information) outlined on the left, the IPS includes a number of sections that cover medical content. 3 sections are mandatory: a) medication, b) allergies and intolerances, c) active problems. In addition, additional sections to collect and group medical content are supported.

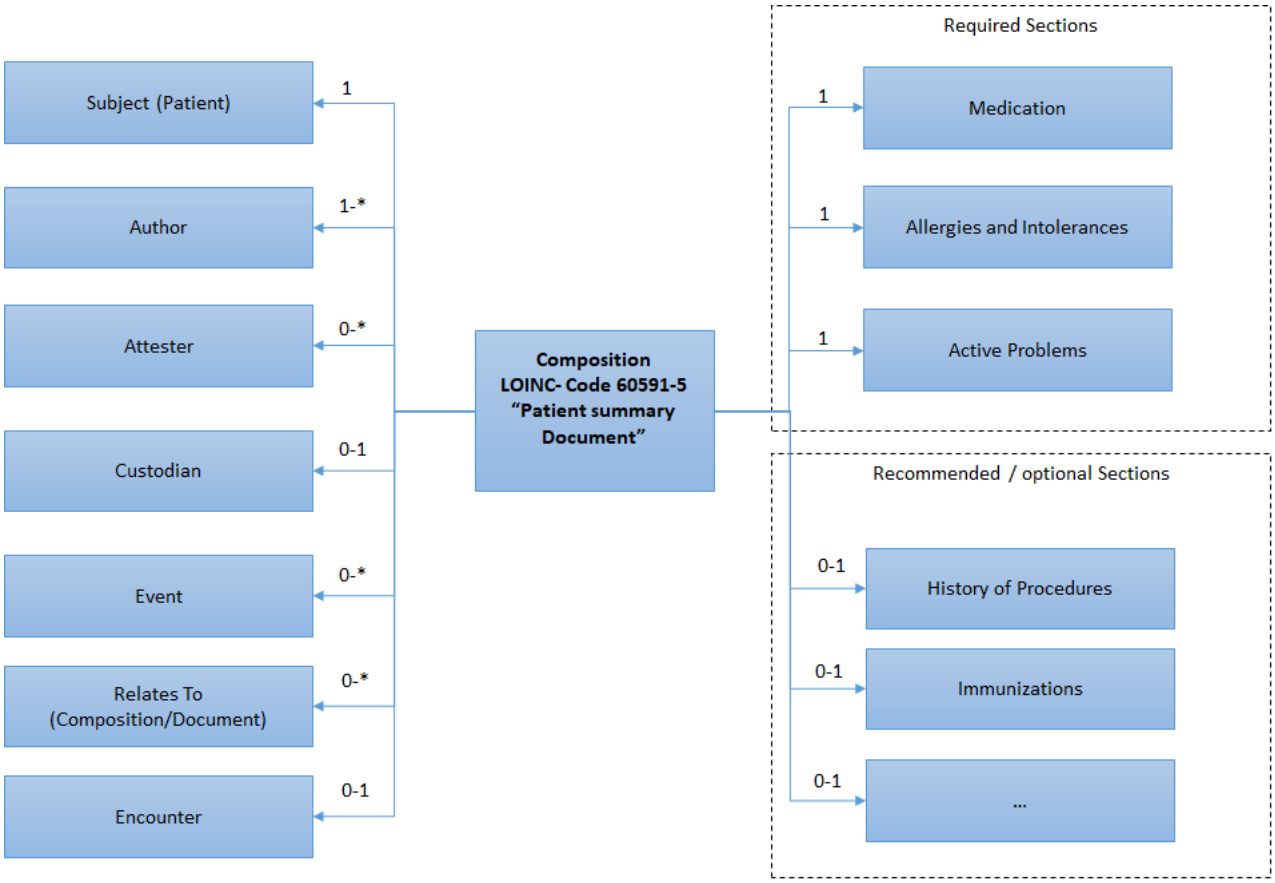

Figure 20 - IPS structure

The following table provides an overview of the medical content of the IPS as described in the specification.

Section	LOINC-Code	Description
Medication (required)	10160-0	The medication summary section contains a description of the patient's medications relevant for the scope of the patient summary. The actual content could depend on the jurisdiction, it could report: ● the currently active medications; ● the current and past medications considered relevant by the authoring GP; ● the patient prescriptions or dispensations automatically extracted by a regional or a national EHR. In all those cases however medications are documented in the Patient Summary as medication statements. This section requires either an entry indicating the subject is known not to be on any relevant medication; either an entry indicating that no information is available about medications; or entries summarizing the subject's relevant medications.
Allergies and Intolerance (required)	48765-2	This section documents the relevant allergies or intolerances (conditions) for that patient, describing the kind of reaction (e.g. rash, anaphylaxis,..); preferably the agents that cause it; and optionally the criticality and the certainty of the allergy. At a minimum, it should list currently active and any relevant historical allergies and adverse reactions. If no information about allergies is available, or if no allergies are known this should be clearly documented in the section.
Active Problems (required)	11450-4	The IPS problem section lists and describes clinical problems or conditions currently being monitored for the patient.

History of Procedures (optional)	47519-4	The History of Procedures Section contains a description of the patient past procedures that are pertinent to the scope of this document. Procedures may refer for example to: 1. Invasive Diagnostic procedure: e.g. Cardiac catheterization; (the results of these procedures are documented in the results section) 2. Therapeutic procedure: e.g. dialysis; 3. Surgical procedure: e.g. CABG
Immunizations (recommended)	11369-6	The Immunizations Section defines a patient's current immunization status and pertinent immunization history. The primary use case for the Immunization Section is to enable communication of a patient's immunization status. The section includes current immunization status, and may contain the entire immunization history that is relevant to the period of time being summarized.
Medical Devices (recommended)	46264-8	The medical devices section contains narrative text and coded entries describing the patient history of medical device use.
Results (recommended)	30954-2	This section assembles relevant observation results collected on the patient or produced on in-vitro biologic specimens collected from the patient. Some of these results may be laboratory results, others may be anatomic pathology results, others, radiology results, and others, clinical results.
Past History of Illness (optional)	11348-0	The History of Past Illness section contains a description of the conditions the patient suffered in the past.
Functional Status (optional)	47420-5	The functional status section shall contain a narrative description of the capability of the patient to perform acts of daily living, including possible needs of the patient to be continuously assessed by third parties. The invalidity status may in fact influence decisions about how to administer treatments. Profiles to express disabilities and functional assessments will be specified by future versions of this guide.

Plan of Care (optional)	18776-5	The plan of care section contains a narrative description of the expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient.
Social History (optional)	29762-2	The social history section contains a description of the person's Health related "lifestyle factors" or "lifestyle observations" (e.g. smoke habits; alcohol consumption; diets, risky habits.)
Pregnancy (optional)	82810-3	The history of pregnancy section shall contain information about whether the patient is currently pregnant or not. It may contain addition summarizing information about the outcome of earlier pregnancies.
Advance Directives (optional)	42348-3	The advance directives section contains a narrative description of patients' advance directive. This section may contain particular indications or behaviour for the patient.

Table 7 - medical content of IPS

4.4.2 US Core Implementation Guide

The US Code Implementation Guided is based on CCDS (ONC 2015 Edition Common Clinical Data Set) and Argonaut. Argonaut is a private sector initiative which aims at rapidly develop a first-generation FHIR-based API and Core Data Services specification to enable expanded information sharing for electronic health records. The HL7 and the HL7 US Realm Steering Committee develop a HL7 FHIR Implementation Guide. There are harmonization efforts between the HL7 FHIR IPS project and the US Core Implementation Guide.

5 CONCEPTUAL LEVEL PROFILE

5.1 Overview

The InteropEHRate conceptual level profile consists of the layers InteropEHRate Core Profile, InteropEHRate Domain Profiles and Pilot Profiles. Within these layers, different aspects and data groups are addressed. In general, the InteropEHRate Core Profile contains all general and required (meta) data that affect all data items, according to the InteropEHRate protocols. Each InteropEHRate Domain Profile contains all healthcare related data items for a specific healthcare domain, while the InteropEHRate Pilot Profiles define new data items that are required by the InteropEHRate pilots and are not yet provided by the previous layers. The figure below shows the relations and dependencies between the models of the different layers, which are steadily developed and extended throughout the project and described in detail in the next sections.

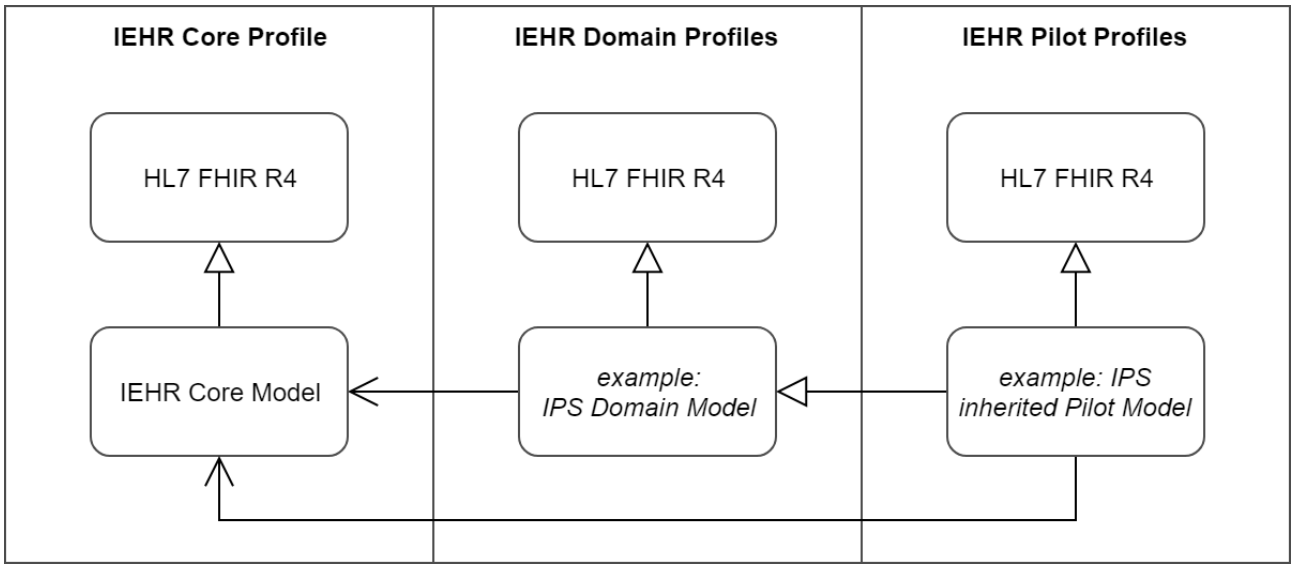

Figure 21 - relations and dependencies between the models of the 3 IEHR Profile layers

5.2 Core Guide: Core Model

The Core Guide specifies which entity types must be supported by any S-EHR and which attributes of this entity types have values belonging to standardised value sets. The Core Model is based on the requirements, which are described in the following sections and developed throughout the project.

5.2.1 Requirements

Derived from the requirements and scenario descriptions, a core model will be needed for the protocol based transactions. Requirements and core model are steadily identified using common tools and a coordination process.

Below is an excerpt of the current requirements list, currently managed outside of this document.

Requirement Category	Aspect	Requirement Description	Relevance	Profile Level
provenance information	parameters describing the provenance of a data item	every data item representing an information relevant for a patient's medical treatment has a provenance information, representing the data item's origin system / device / author.	MUST	core
reliability information	parameters allowing an assessment of its reliability	in order to be used in a patient's healthcare treatment process, an information has to be reliable. Therefore, each data item must provide information about its reliability. If the reliability shall be classified and interpreted on the receiver side, possibly by a user, parameters must be provided that allow for a classification; no classification process or value set have to be included or specified, but only relevant atomic parameters.	MUST if (3) is not supported	core
reliability information	reliability classification	in order to be used in a patient's healthcare treatment process, an information has to be reliable. Therefore, each data item must provide information about its reliability. If the reliability shall be classified on the provider side / source, a classification value set is specified that shall be used for a trusted reliability classification.	MUST if (2) is not supported	core

transformation information	information / data structure	the information represented by a data item shall be transformed and translated to different equivalent representations and languages. The structure and format of a representation must therefore be qualified.	MUST	core
transformation information	information / data structure	the information represented by a data item shall be transformed and translated to different equivalent representations and languages. It must be possible to include different equivalent representations of an information and to tag and identify the originally provided representation.	MUST	core

Table 8 - excerpt of InteropEHRate Profile requirements list

The list of requirements acts as input for specifying a version of the InteropEHRate Core Profiles using the tool ArtDecor.

5.3 Domain Guide: domain models

The InteropEHRate domain models will be based on and adopt already existing and standardized domain models focussing on cross-border data exchange. Thus, all healthcare related data items that have already been specified for cross-border data exchange scenarios are covered and provided.

According to the InteropEHRate Core Guide, the data items / resources of existing standardized domain models MUST be further extended and adapted as required with infrastructurally and data exchange related needs represented by the core profiles. In practice, each provided data item of the domain models MUST fulfil or contain the IEHR Core Profiles.

For the purpose of the InteropEHRate use cases, at least the International Patient Summary (IPS) [ART-DECOR® Expert Group IPS 2019] will be used as the basis for the Domain Guide.

5.4 Pilot Guide: pilot models

Based on the IEHR Core Guide and depending on the IEHR Domain Profiles, additional pilot specific data items could be specified. It is still unclear, if and to which extent there will be any IEHR pilot model necessary.

6 IMPLEMENTABLE LEVEL PROFILE

6.1 Implementation Guide

The InteropEHRate Profiles will be provided as 3 Implementation Guides representing the 3 layers of the Profiles: InteropEHRate Core Guide, InteropEHRate Domain Guides and Pilots Guides.
Additionally, each Implementation Guide for the InteropEHRate Profile is composed of:

- Structure Definition (value sets & resources)
- Describing Content

The new Structure Definitions and Describing Content will be provided with one of the upcoming deliverables and versions of the InteropEHRate Profile.

6.2 InteropEHRate Core Guide Structure Definitions

The InteropEHRate Core Guide Structure Definitions will be defined and provided with one of the upcoming deliverables and versions of the InteropEHRate Profile.

6.3 InteropEHRate Domain Guides Structure Definitions

The InteropEHRate Domain Guides Structure Definitions will be defined and provided with one of the upcoming deliverables and versions of the InteropEHRate Profile.

6.4 Pilot Guides Structure Definitions

The Pilot Guides Structure Definitions will be defined and provided with one of the upcoming deliverables and versions of the InteropEHRate Profile.

7 CONCLUSIONS AND NEXT STEPS

The relevant and largely applied processes and contents of the InteropEHRate Profiles specification have been analysed and structured. Thus, it is possible to separate and address different levels and layers of the InteropEHRate Profiles that facilitate and enable the specification of data structures and implementation bindings, the integration of existing standards and specification of mandatory as well as application specific extensions, the identification and definition of general requirements, and possible balloting addresses and processes.

Since these specification aspects require further and steady development, the next steps will focus on

- the identification and definition of further general requirements
- the specification and provision of the InteropEHRate Profiles on a conceptual level in a new draft version
- the specification and provision of the InteropEHRate Profiles on an implementable level in a new draft version, including a FHIR Implementation Guide
- Propose a release candidate version of the InteropEHRate Profiles (both conceptual and implementable level)
- The specification of recommended templates for specific usages, e.g. templates of consents.

REFERENCES

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- **[HL7 International Wiki 2019]** HL7 Wiki: FHIR IG Publishing Tool. https://wiki.hl7.org/index.php?title=FHIR_IG_Publishing_tool. Last reviewed 1.10.2019.
- **[HL7 International FHIR R4 2019]**. HL7 International FHIR R4. https://www.hl7.org/fhir/. Last reviewed 1.10.2019.
- **[ART-DECOR® Expert Group IPS 2019]** ArtDecor project: International Patient Summary (IPS). https://art-decor.org/art-decor/decor-datasets--hl7ips-/. Last reviewed 1.10.2019.