D2.8

FHIR Profile for EHR interoperability - V2

ABSTRACT

This document forms the basis for the technical specifications 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 extends 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
IG	Implementation Guide
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
XACML	eXtensible Access Control Markup Language

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1. INTRODUCTION

1.1. Scope of the document

This document (D2.8) defines the InteropEHRate profiles (also called IEHR profiles), a set of FHIR profiles that constitutes the data model of any Smart EHR (S-EHR).

An analysis of the InteropEHRate use cases and a conceptual model for the health data used within the analysed use cases is presented. Based on these results, 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.

Section 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 sections 5 and 6 provide a specification of the InteropEHRate Profile on a conceptual and on an implementable level.

Finally, conclusions and next steps are outlined.

1.4. Updates with respect to previous version

The data requirements resulting from the research data sharing scenario have been added to sections 3 and 4. The description of the balloting process has been moved to [D8.6] Standardization report as part of the standardization strategy.

Section 5 has been extended with a new domain model for the research health data sharing scenario.

The structure of section 6 has been adapted and new content has been added. In particular, the methodology for creating the implementation guides and the profiles has been further specified. In addition, two implementation guides (IG) have been described that are created as part of the project. The IGs are specified using special tools and are not part of this document, but instead only referenced.

Section 7 has been updated accordingly.

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 the 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 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 "draft" level represents a preliminary specification not yet tested or not considered sufficiently robust to be adopted at EU level. The “recommended” level is the 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 kinds 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.

Below is a non exhaustive list of possible content that could be specified by the following 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 that are already used at the international level for that domain.
- Integration of existing FHIR models for health data that are already agreed at the 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 organizations 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 [D4.2], and Research Data Sharing (RDS) protocol [D4.8]. 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.

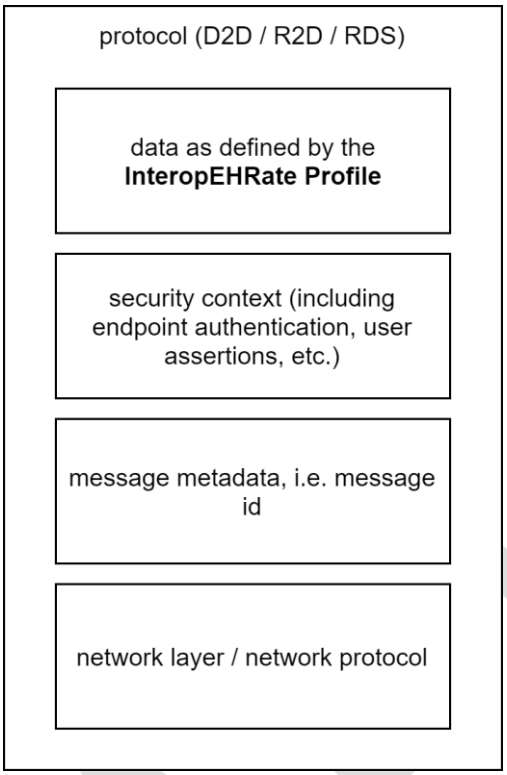


Figure 1 - Dependencies and interactions between the protocols and the InteropEHRate Profile

The InteropEHRate profile is embedded in a protocol, which depends on the corresponding use case (D2D protocol, R2D protocol, RDS 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 assignments 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 AND 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 healthcare professionals (HCPs) and 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. The actions of the R2D and the D2D protocol are depicted in the following figure, outlining each different step that is scoped by the corresponding actors.

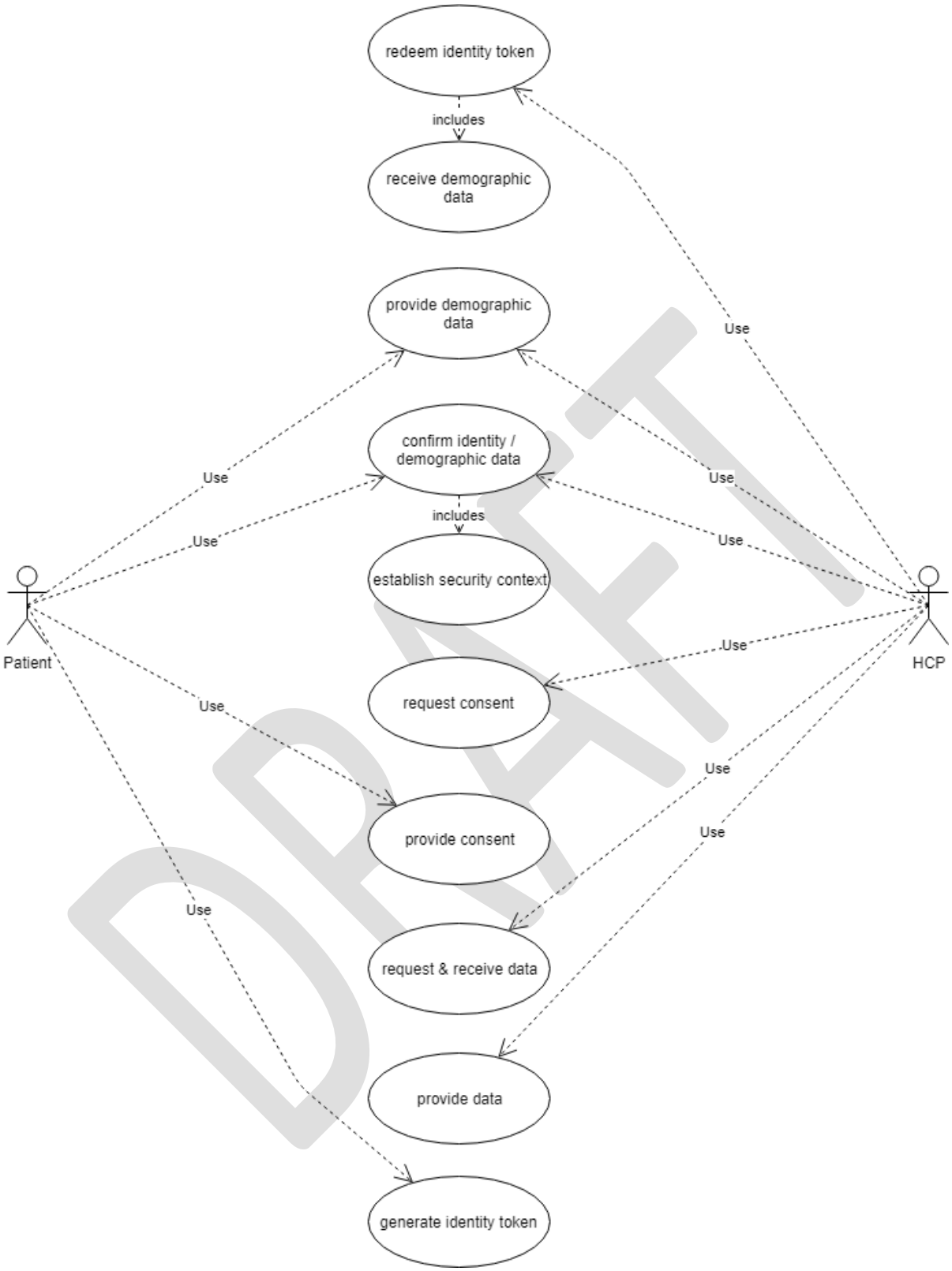


Figure 2 - Actors and use cases in R2D and D2D scenarios

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

Transactions

The use case device to device HR exchange defines several transactions between the involved actors, which are defined in detail in deliverable D2.2 - User Requirements for cross-border HR integration v2 **[D2.2]**.

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)

3.2.2. Remote to device HR exchange

Transactions

The use case remote to device HR exchange defines several transactions between the involved actors, which are defined in detail in deliverable D2.2 - User Requirements for cross-border HR integration v2 **[D2.2]**.

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 2 - data sets used within transactions (R2D)

3.2.3. Research HR exchange

Transactions

The research scenario is covered by [D4.8], including process definitions, interfaces and parameters, and data mappings. Therefore, the interactions of the components and the exchanged messages are not described here. Yet, the data requirements and data sets used for the research scenario are defined throughout the following section as a basis for the resulting domain and core models.

Data Sets used within the transactions

The InteropEHRate information model that allows for the exchange of data in the context of a research project takes into account the main aspects of the research protocol within different information categories.

Information category	Requirement
unstructured / human readable definition of the research project	Description of the research project containing human readable dataset definitions, enrolment and exit criteria, definitions of enrolment and data collection periods, in-phone anonymization requirements, as well as metadata describing the research, in a way understandable for citizens
structured / machine processable definition of the research project	Definition of the research project containing structured dataset definitions, enrolment and exit criteria, definitions of enrolment and data collection periods, in-phone anonymization requirements, as well as metadata describing the research
data security and access control	Approval / Consent of the citizen to participate in the study
data set results	Aggregated and pseudonymized or anonymized citizen's medical data

Table 3 - Categories of information represented by the RDD domain model

Data set	Description
Research Definition Document	The Research Definition Document (RDD) describes the rules for participating in a research study. It consists of several domain classes which are described in the following sections.

Research Study	This data set represents essential information of a research study in which S-EHR users can participate. The aims of a research study are to improve or develop new methods of health care by using scientific methods. The following table describes the relevant attributes. In addition to the general metadata, the domain class Research Study includes references to the domain classes Research Center, Cohort, Data Set Definition and Research Subject.
Cohort	The data set Cohort describes the queried citizen for the study and therefore represents the EnrollmentLogic. The enrolment logic describes different enrolment criteria, or exit criteria if negated, for a patient's participation in a research study, including e.g. minimum or maximum values for patient demographic data, the presence or absence of a certain diagnosis within a certain time period, a patient's drug therapy within a certain time frame, and many more.
DateSetDefinition	The data set definition defines which data sets and data items of the citizen cohorts shall be requested and delivered to the researcher. The data set definition is therefore only applicable for the participating citizens of a cohort of the research study.
ResearchSubject	The ResearchSubject element defines a citizen's pseudonym for participating in different research project phases. The research subject is represented by a unique (pseudo) identifier for each research project. Thus, the re-identification of a citizen by an aggregation of data sets resulting from different research projects is prevented. The delivered data sets may contain only anonymized or pseudonymized demographic data and the pseudo id of the research subject.
Citizen's Consent	A citizen must sign a consent to participate in a specific research study. The consent can be signed on paper and must also be represented in an electronic and structured way in order to support machine processing of the consent.
Reference Research Center	A research centre is an organization participating in the research study.

Table 4 - Relevant classes of RDD domain model

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 in 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. Depending on the data exchange scenario, identifying data are either retained (D2D, R2D) or replaced (research: anonymized/pseudonymized).	bidirectional	profile
health data	prescription / dispensation data	prescribed drugs, drug prescriptions	bidirectional	profile
health data	laboratory results	vital signs, measurement results. Depending on the	bidirectional	profile

		data exchange scenario, identifying data are either retained (D2D, R2D) or replaced (research: anonymized/pseudonymized).		
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. Depending on the data exchange scenario, identifying data are either retained (D2D, R2D) or replaced (research: anonymized/pseudonymized).	bidirectional	profile
health data	hospital discharge reports	cause of admission, discharge diagnostic assessment, prescriptions, visits and recommendations, therapy. Depending on the data exchange scenario,	bidirectional	profile

		identifying data are either retained (D2D, R2D) or replaced (research: anonymized/pseudonymized).		
research definition data	information to a research study	detailed information of a research study including enrolment criteria, data set definitions and reference research centres	S-EHR Cloud → S-EHR App	profile
identity data	demographic data	demographic data about patients, caregivers, HCPs and organizations (Research Centres, hospitals, …), 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 and Research Centres	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

data request	research subject request	a request for citizens who fulfil special enrolment criteria	S-EHR Cloud → S-EHR App	protocol
data request	research data request	a request for anonymized data of participating citizens	S-EHR Cloud → S-EHR App	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 sub-processes by the scenarios.

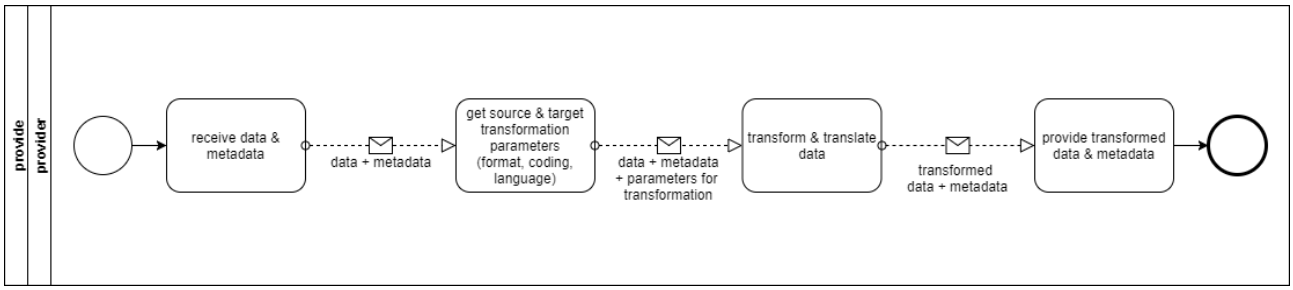


Figure 3 - Process for transforming (meta-)data in multilingual context (provider)

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).

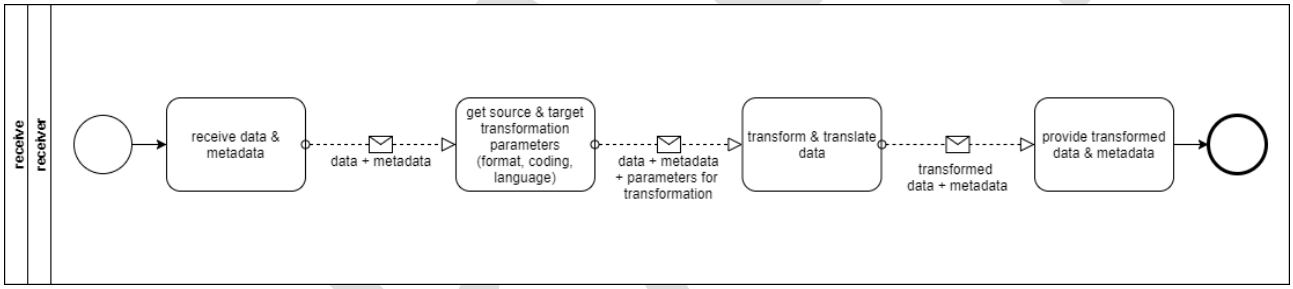


Figure 4 - Process for transforming (meta-)data in multilingual context (receiver)

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.

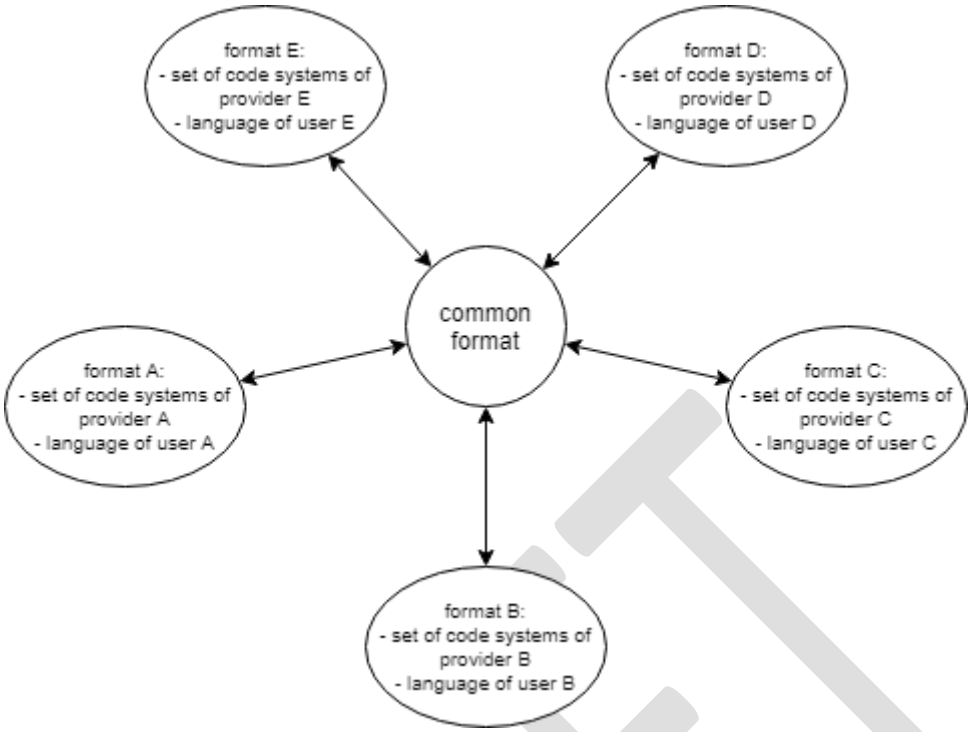


Figure 5 - Usage of a common representation to transfer and store data and metadata

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 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 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 be 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, along 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 unmapped 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.

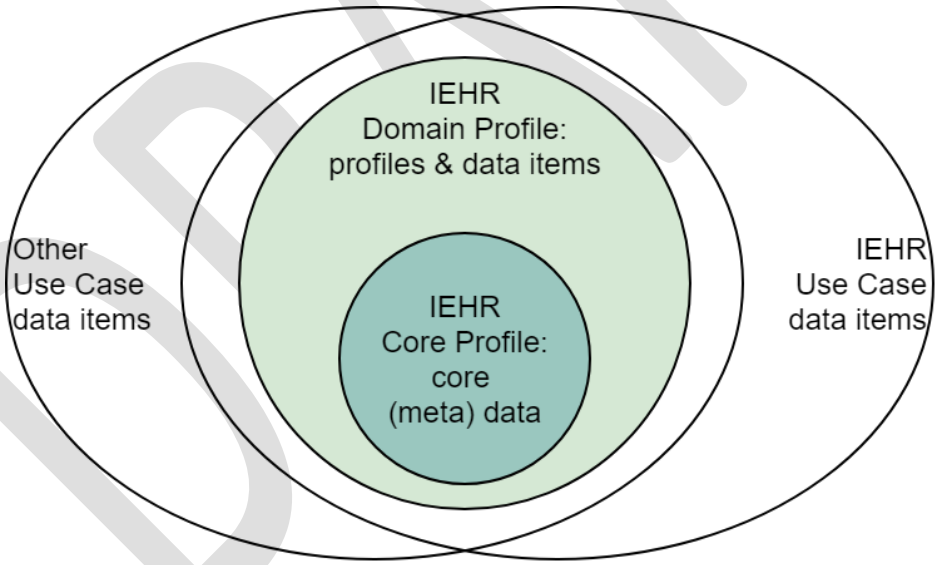


Figure 6 - layers of InteropEHRate profiles

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.

In the first step, the InteropEHRate Domain Profiles will adopt the data model and definitions of the International Patient Summary (IPS) for the purpose of the project's use cases and thus add data items and profiles to express healthcare related information for cross-border data exchange. The sole use of IPS as a domain profile though is intended as 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 into the adopted data items. Thus, domain profiles are based on existing international profiles focussing on cross-border exchange of health data and extended by IEHR Core Profiles.

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 InteropEHRate pilots (i.e. the specific instances of InteropEHRate use cases that will be used to validate 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

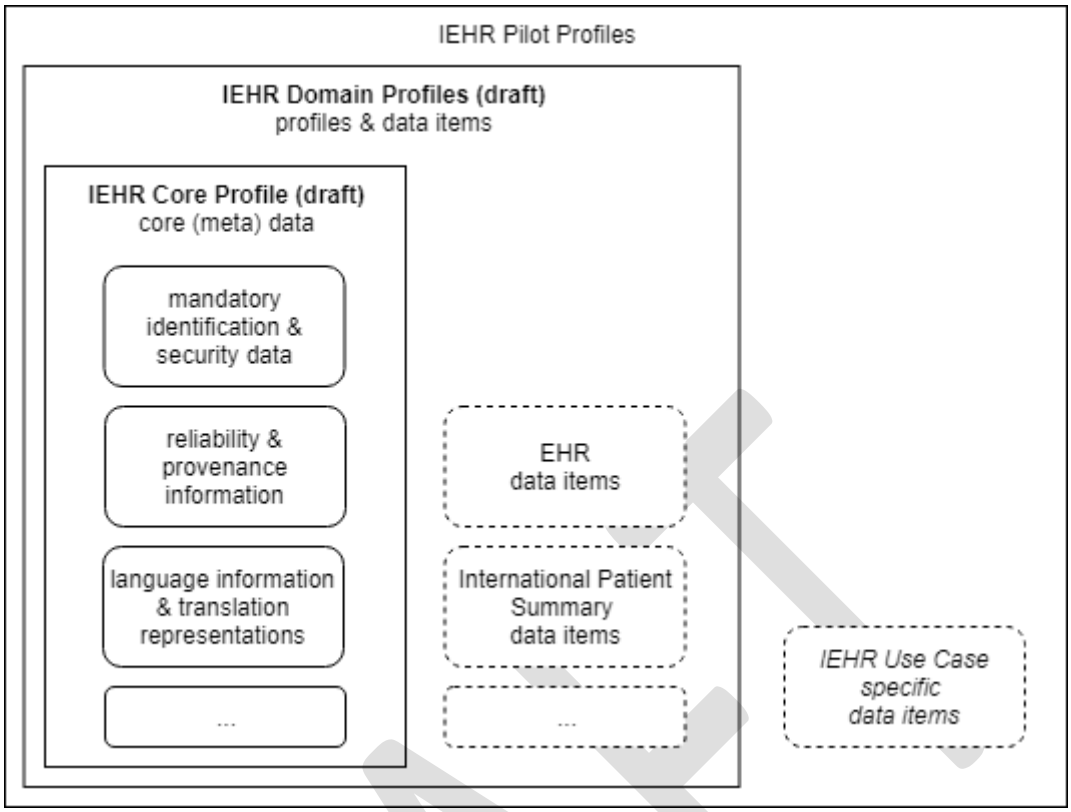


Figure 7 - content of the different layers of the InteropEHRate Profiles

4.2. HL7 FHIR

4.2.1. 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 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 example shows the representation 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>
```


4.2.2. 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 analyzed 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

4.2.3. 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.

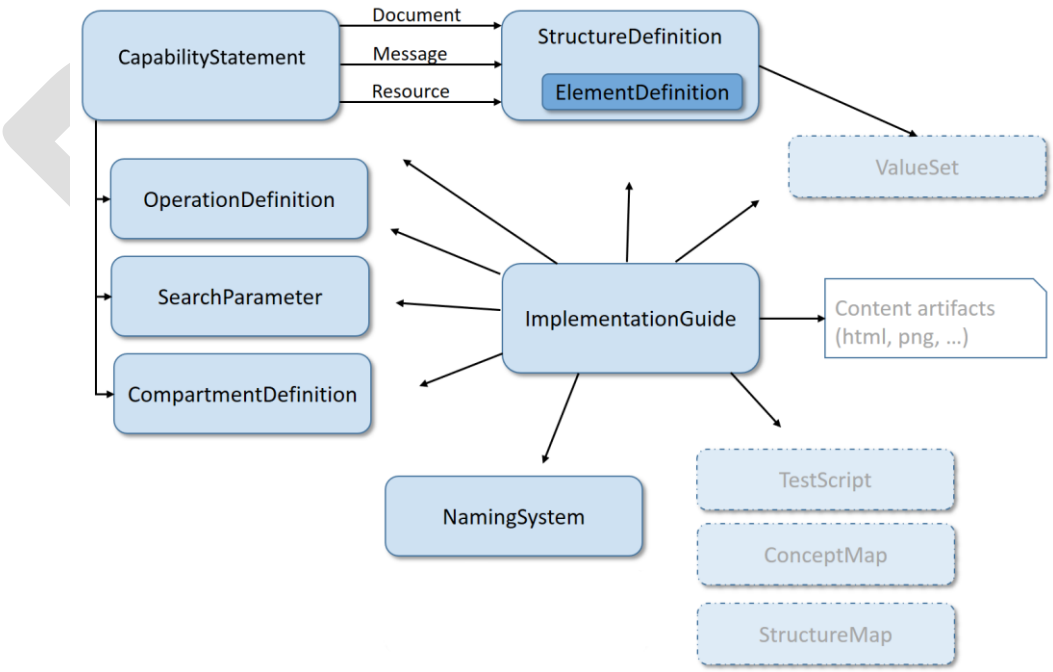


Figure 8 - FHIR Implementation Guide components

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 Parameters 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.

4.3. HL7 FHIR Profiles for cross-border exchange

4.3.1. 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 and 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.

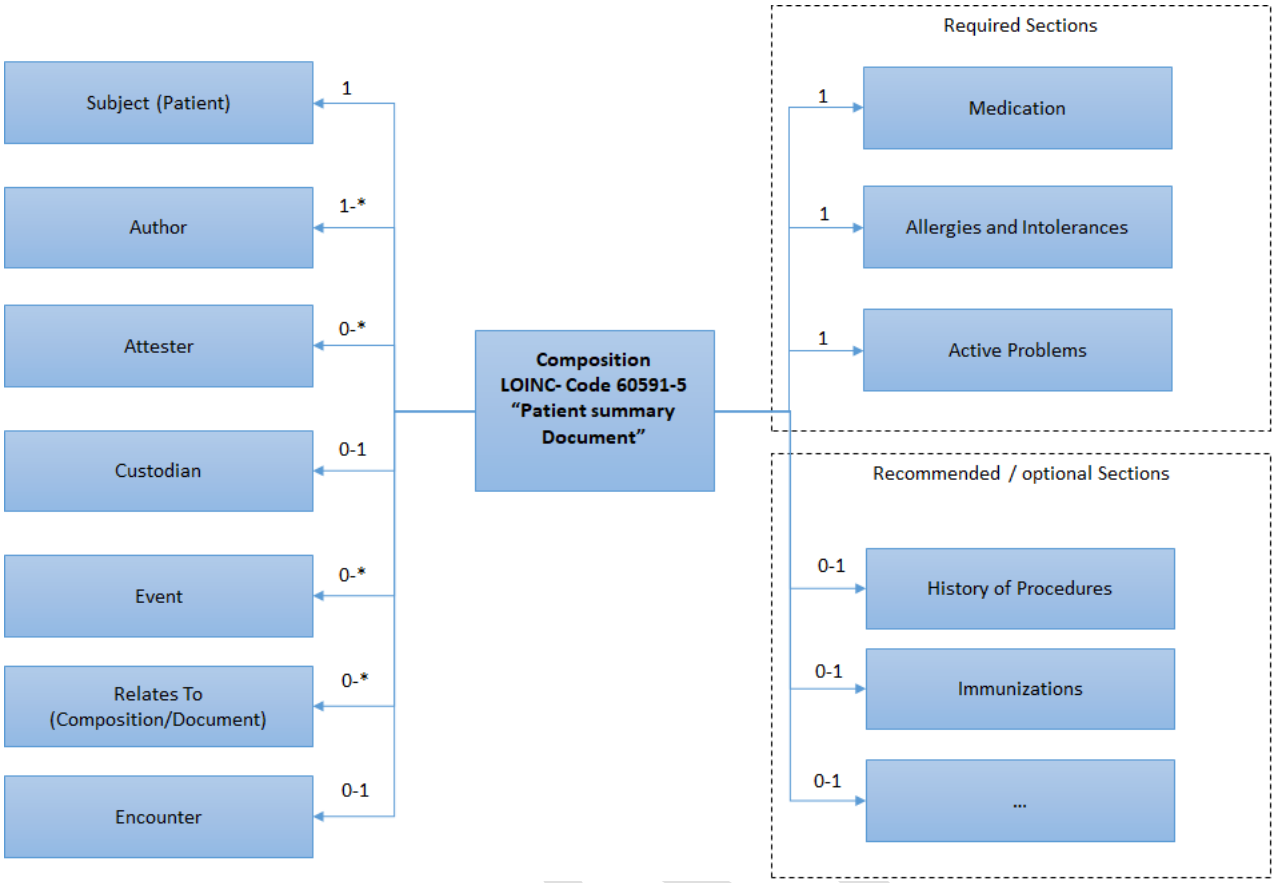


Figure 9 - IPS structure

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 current active medications; ● the current and past medications considered relevant by the authoring GP; ● The patient's prescriptions or dispensations that are automatically extracted by a regional or a national EHR. In all of 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's 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's 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. smoking habits; alcohol consumption; diets, risky habits.)
Pregnancy (optional)	82810-3	The history of the pregnancy section shall contain information about whether the patient is currently pregnant or not. It may contain additional summarizing information about the outcome of earlier pregnancies.

Advance Directives (optional)	42348-3	The advance directives section contains a narrative description of the patient's advance directive. This section may contain particular indications or behaviour for the patient.

Table 7 - medical content of IPS

4.3.2. US Core Implementation Guide

The US Code Implementation Guide is based on CCDS (ONC 2015 Edition Common Clinical Data Set) and Argonaut. Argonaut is a private sector initiative which aims to 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.

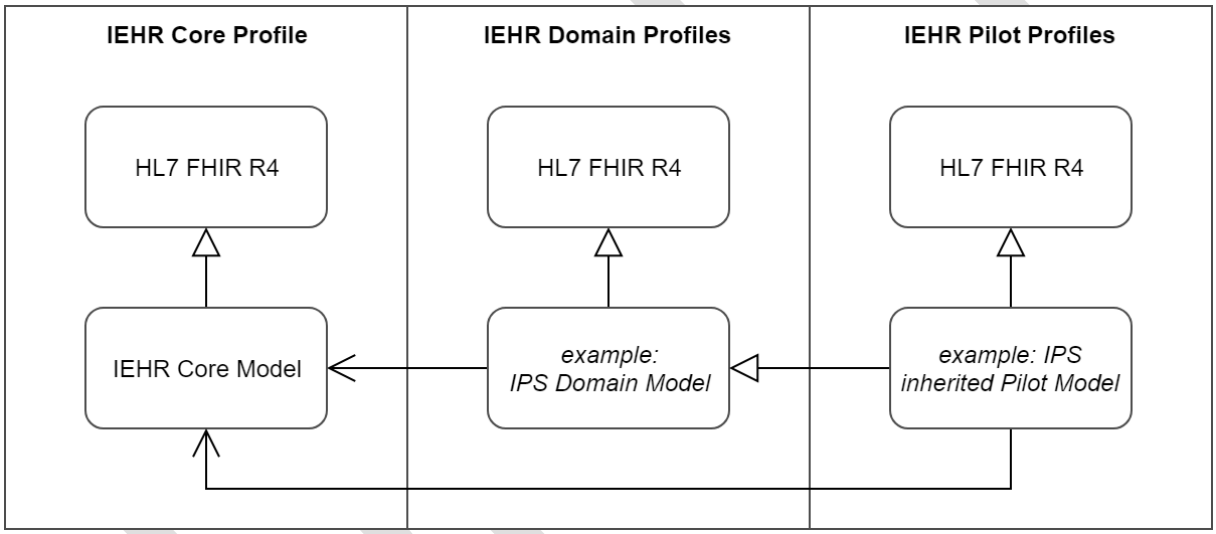


Figure 10 - relations and dependencies between the models of the 3 IEHR Profile layers

5.2. Core Guide: Core Model

The Core Guide specifies which entity types must be supported by any S-EHR and which attributes of these 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 any information relevant for a patient's medical treatment has 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, any 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 has 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, any 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 into 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 into 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

5.3. Domain Guide: domain models

The InteropEHRate domain models are 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 infrastructural and data exchange related needs represented by the core profiles. In practice, each provided data item in the domain models MUST fulfill or contain the IEHR Core Profiles.

Within the D2D and R2D protocol, the International Patient Summary (IPS) [ART-DECOR® Expert Group IPS 2019] is used as the domain model.

For the research health data sharing use case, a new domain model has been developed.

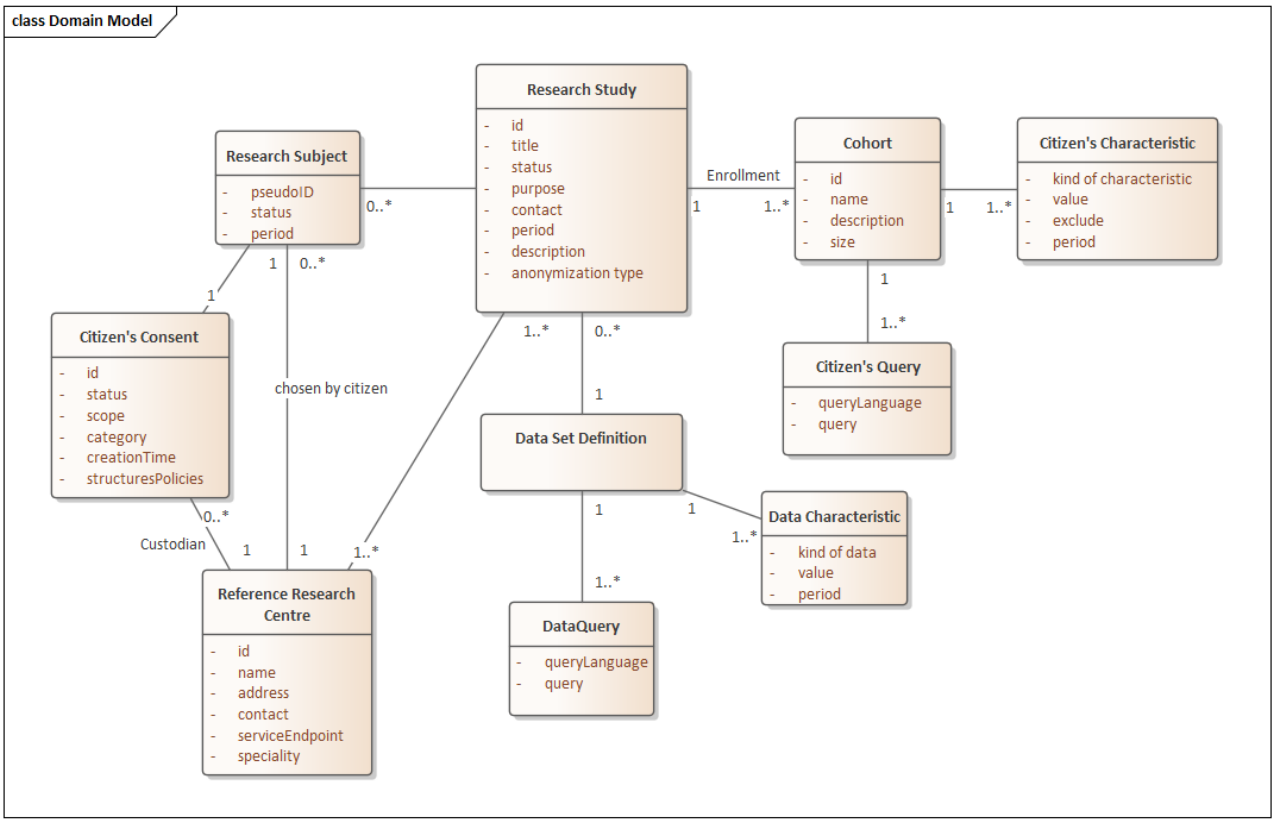


Figure 11 - Domain model diagram of the RDD

5.3.1. Research Definition Document

The Research Definition Document describes the rules for participating in a research study. It consists of several domain classes which are described in the following sections.

5.3.2. Research Study

This domain class represents essential information of a research study in which S-EHR users can participate. The aims of a research study are to improve or develop new methods of health care by using scientific methods. The following table describes the relevant attributes.

Attribute	Description	Cardinality	Data type	value set
Id	Unique identifier of the research study.	1..*	Identifier	-
Title	Title of the research study.	1	String	-
Status	Status of the research study.	1	Coded Value	Value Set http://hl7.org/fhir/ValueSet/research-study-status
Purpose	Purpose of the research study.	1	Coded Value	Value Set http://hl7.org/fhir/

				ValueSet/research-study-prim-purp-type
description	Human-readable description (including data retention period, purpose of research and description of usage restrictions of data within the research protocol, description of the research centre that will coordinate the specific study and of the specific research centre (Local Research Centre) that will receive and process the shared health data).	1	String	-
contact	Contact information for research study.	1	Reference (Complex Data Type representing contact details)	-
period	Planned duration of the research or study as a whole, incorporating both the enrollment phase and the data delivery phase, as well as possible study specific time periods.	1	Datetime	-
anonymization Type		1	Coded Value	Value Set (anonymization, pseudonymization, ...)
participating Research Centers	List of Research Centres (and relative regions) that a patient participating in the study can select as a Reference Research Centre for the specifically described study.	1..*	Reference (Research Center)	-

research Subjects	This is a link to structured and anonymized data of all participating research subjects (citizens).	0..*	Reference (Research Subject)	-
cohort	A list of planned citizen cohorts incorporating the enrollment criteria for the evaluation of candidates.	1..*	Reference (Cohort)	-
data Set Definition	This is a link to the data selection	1..*	Reference (Data Set Definition)	-

Table 9 - Members of the ResearchStudy resource

In addition to the general metadata, the domain class Research Study includes references to the domain classes Research Center, Cohort, Data Set Definition and Research Subject.

5.3.3. Cohort

The *EnrollmentLogic* association enables a structured or unstructured definition of the actual query. The enrollment logic describes different enrollment criteria, or exit criteria if negated, for a patient's participation in a research study, including e.g. minimum or maximum values for patient demographic data, the presence or absence of a certain diagnosis within a certain time period, a patient's drug therapy within a certain time frame, and many more.

Usage of unstructured data set description *Citizen's Query*:
The query (defining enrollment and exit criteria) is represented as a character sequence compiled in the declared query language. Thus, the executing application must support the query language. The definition of enrollment criteria is only limited by the underlying information model for EHR data and the query language specifications. The *Citizen's Query* element contains information on the query language and the actual enrollment criteria.

Attribute	Description	Cardinality	Data type	value set
query language	specifies the language of the query, e.g. FHIR Search.	1	value set	to be defined, shall contain items such as FHIR Search etc.
query	contains the actual query compiled in the specified	1	String	-

	query language.			

Table 10 - Members of the Citizen's Query *resource*

Usage of structured data set description *Citizen's characteristics*:
Complementary to the unstructured descriptions, a structured description of the enrollment criteria based on a common vocabulary is supported. The following table lists the features of this structured characteristic description.

Attribute	Description	Cardinality	Data type	value set
kind of characteristic	Selection of the desired type of characteristic defining an enrollment criterion, based on a common vocabulary / value set, e.g. diagnosis.	1	Coded Value	to be defined, shall contain items such as age, diagnosis, medication, gender, etc.
Value	Value of the characteristic according to and depending on the kind of characteristic, e.g. a specific code of a diagnosis or a description.	1	String	-
exclude	Specifies whether the characteristic is an inclusion or exclusion criterion.	1	Boolean	true, false
Period	Specifies a date or period of the characteristic's existence or application, e.g. when a diagnosis has been raised.	0..1	Date Time	-

Table 11 - Members of the Citizen's Characteristics *resource*

5.3.4. Data Set Definition

Aligned with the enrollment criteria, the data set definition allows for a structured or unstructured definition of the actual query. The data set definition defines which data sets and data items of the citizen cohorts shall be requested and delivered to the researcher. The data set definition is therefore only applicable for the participating citizens of a cohort of the research study.

Usage of unstructured data set description *Data Query*
The query (defining which data items shall be selected for delivery) is represented as a character sequence compiled in the declared query language. Thus, the executing application must support the query language. The definition of enrollment criteria is only limited by the underlying information model for EHR data and

the query language specifications. The *Data Query* element contains information on the query language and the actual query.

Attribute	Description	Cardinality	Data type	value set
query language	specifies the language of the query, e.g. FHIR Search.	1	value set	to be defined, shall contain items such as FHIR Search etc.
query	contains the actual query compiled in the specified query language.	1	String	-

Table 12 - Members of the Data Query *resource*

Usage of structured data set description *Data characteristics*

Complementary to the unstructured descriptions, a structured description of the requested data items based on a common vocabulary is supported. The following table lists the features of this structured characteristic description.

Attribute	Description	Cardinality	Data type	value set
kind of characteristic	Selection of the desired type of characteristic defining a data item, based on a common vocabulary / value set, e.g. diagnosis.	1	Coded Value	to be defined, shall contain items such as age, diagnosis, medication, gender, etc.
Value	Value of the characteristic according to and depending on the kind of characteristic, e.g. a specific code of a diagnosis or a description.	1	String	-
period	Specifies a date or period of the characteristic's existence or application, e.g. when a diagnosis has been raised.	0..1	Date Time	-

Table 13 - Members of the Data Characteristics *resource*

5.3.5. Research Subject

The ResearchSubject element defines a citizen's pseudonym for participating in different research study phases. The research subject is represented by a unique (pseudo) identifier for each research study. Thus, the identification of a citizen by an aggregation of data sets resulting from different research studies is

prevented. The delivered data sets may contain only anonymized or pseudonymized demographic data and the pseudo identifier of the research subject.

Attribute	Description	Cardinality	Data type	value set
pseudoID	Unique identifier of the pseudo-anonymized representation of citizens data.	1	Identifier	-
status	Status of the research subject (for example candidate).	1	Coded Value	Value Set http://hl7.org/fhir/ValueSet/research-subject-status
period	Start and end of the participation.	0..1	Datetime	-
referenceResearchCenter	Reference research center the citizen has chosen.	1	Reference (Reference Research Center)	-
consent	Consent to participate in a specific research study.	1	Reference (Consent)	-
dataSets	Anonymized medical information of the participating citizen.	1..*	Reference (Medication STatement, Observation, ...)	-

Table 14 - Members of the ResearchSubject resource

5.3.6. Citizen's Consent

A citizen must sign a consent to participate in a specific research study. The consent can be signed on paper and must also be represented in an electronic and structured way in order to support machine processing of the consent.

Attribute	Description	Cardinality	Data type	value set
id	Unique identifier of the consent.	1..*	Identifier	-
status	Status of the consent.	1	Coded Value	Value Set http://hl7.org/fhir/ValueSet/consent-state-

				codes
Scope	Area which the consent addresses.	1	Coded Value	Value Set http://hl7.org/fhir/ValueSet/consent-scope fixed: Research
Category	Category of the consent.	1	Coded Value	http://terminology.hl7.org/CodeSystem/consentcategorycodes examples: rsreid: Re-identifiable Information Access rsdid: De-identified Information Access
creationTime	Date and time of the creation of the consent.	1	Datetime	-
structuredPolicies	Attachment of a structured consent document (for example (eXtensible Access Control Markup Language) XACML document without identifying information).	1	Attachment	-
referenceResearchCenter	Custodian of the consent.	1	Reference (Reference Research Center)	-

Table 15 - Members of the Consent resource

5.3.7. Reference Research Center

A research center is an organization participating in the research study. The relevant attributes of the domain class *Reference Research Center* are listed below.

Attribute	Description	Cardinality	Data type	value set
Id	Unique identifier of the reference research center.	1..*	Identifier	-
Name	Name of the reference research center.	1	String	-

speciality	Speciality of the reference research center.	1..*	Coded Value	
address	Address information of the reference research center.	1	Complex Data Type representing address information	-
contact	Contact information of the reference research center.	1	Reference (Complex Data Type representing contact details)	-
serviceEndpoint	Service Endpoint (research protocol) of the reference research center.	1	URL	-

Table 16 - Members of the ResearchCenter resource

5.4. Pilot Guide: pilot models

Within the D2D and R2D protocol, the International Patient Summary (IPS) [ART-DECOR® Expert Group IPS 2019] is used as the basis for the Domain Guide. Since only particular items are adapted to fit the identified data requirements, a standalone pilot model is not required.

6. IMPLEMENTABLE LEVEL PROFILE

6.1. Implementation Guides

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:

- StructureDefinition (value sets & resources)
- Describing Content

So far, two Implementation Guides have been created. One Implementation Guide deals with data exchange in principle and in emergency scenarios. This Implementation Guide includes all profiles and examples that are relevant for the pilot in the interopEHRate project. Existing profiles (e.g. IPS) are used as a basis. This Implementation Guide is a Pilot Guide and described in section Pilot Guide - Cross-border data exchange based on IPS.

The second Implementation Guide includes new types of profiles, as no working group deals with the topic of research data sharing in a similar way and based on H17 FHIR R4. Appropriate basic resources such as research studies are used as a basis. This Implementation Guide is a Domain Guide and is described in the section Domain Guide - Research data sharing.

6.1.1. Method

Before we go into detail on the results we will briefly list the decision-making process for creating the profiles. The following figure outlines this process.

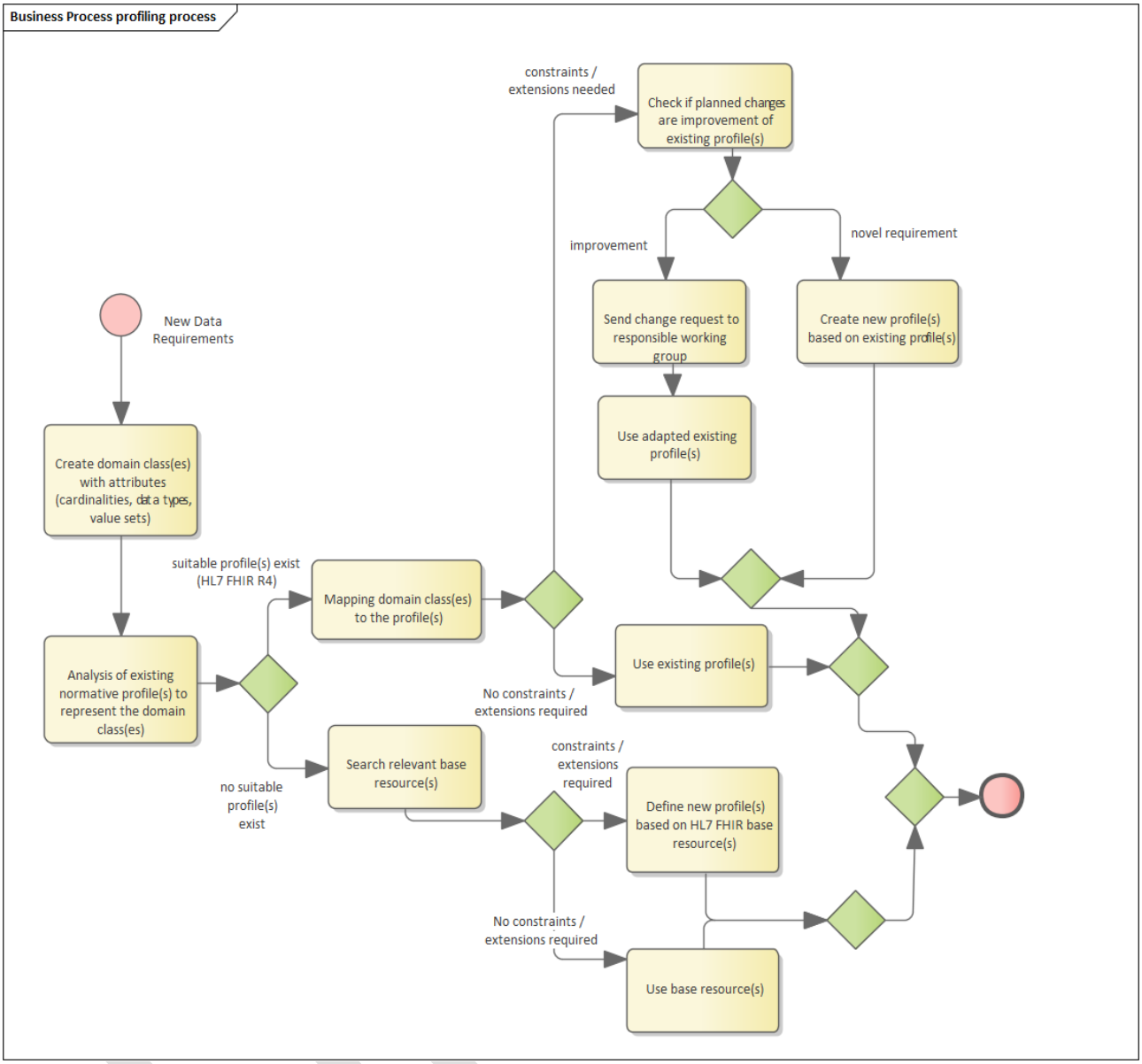


Figure 12 - Decision process for profiling

Based on the identified data requirements, the domain models were first created. From a technical point of view, these describe the data entities and their attributes. Cardinalities and possible value ranges for attributes were also defined together with the pilot partners.

It was then checked whether there were already profiles / Implementation Guides that meet the project requirements. The existing profiles were examined with regard to the criteria listed below.

Decision criteria for suitability of existing profile(s):

- Same focus or objective
- No national orientation
- Profile/Implementation Guide supports HL7 R4
- Working group / project is active

If there are already profiles for the domain / problem described (e.g. IPS), a detailed check is carried out to determine whether these can be adopted without changes. If changes are necessary, it is checked whether these are only project-specific adjustments or whether an extension / improvement of an existing profile is necessary. Depending on the decision, the procedure is different. If there are project-specific adaptations, new profiles are created based on the profiles, which for example define further restrictions (for example: adapting the cardinalities or defining value sets) or extensions. If there is a fundamental adjustment that may be relevant for further projects dealing with this topic, contact is made with the working group and a change request is formulated. If there are no suitable profiles, the HL7 FHIR 4 resources are used. Here, too, a differentiation is made as to whether the HL7 FHIR 4 basic resources can be adopted without adjustment or whether changes are necessary. Since the HL7 FHIR 4 basic resources are structured very generically, the adaptation for domain-specific or project-specific purposes is inevitable in many cases.

6.1.2. Tools

To create and publish the Implementation Guides we used the IG Publisher and the IG Builder.

IG Publisher

The IG publisher is a tool that helps to publish Implementation Guides. The documentation for the publisher can be found in confluence and both the publisher itself and its documentation are maintained by Grahame Grieve and Lloyd McKenzie. After downloading the publisher.jar file it can be used like any other jar file with the java -jar command from the command line. An example call could look like this: `java -jar publisher.jar -ig [source]`. The source parameter can point to the IGs JSON control file (this approach is deprecated and should not be used) or to the ig.ini file if the template based approach is used.

If the Implementation Guide found in the source parameter does not contain fatal errors, the publisher will generate three different file types: The first are the representations of all resources found in the IG. Generally the IG contains only a xml or a json representation of the resources, so the publisher generates an xml, a json and a ttl version. The second are the html files, which are included either by the template specified in the source file or by the author in the Implementation Guide resource.

The third are different zip Files, that are included in the Implementation Guides html representation. Some of these zip files contain the StructureDefinitions and the examples in their xml, json or ttl representation and are linked in the download section of the IG.

If the authors wish to use a template-based approach for their IG and find it laborious to manually check for publisher updates and type the run command every time, they can use the sample-ig, that is linked in the

documentation. This sample can be used as a base, because its directory structure is consistent with the templates. Additionally, it contains scripts that can be used to update and run the publisher without having to do it manually.

If possible, the publisher should be used to generate the IG output. It reduces the workload on the authors of the Implementation Guide, because they only need to define the resources once and do not have to implement the generic html pages, like toc, index and download, themselves.

Additionally, the publisher uses the official templates and by using the publisher the authors can be sure that their Implementation Guide conforms to these templates, without any additional effort.

Auto-IG-Publisher/auto-ig-builder

The auto-IG-publisher or auto-ig-builder is a tool that supports continuous integration builds for IGs. The auto-builder can be found on github and its readme contains a short guide on how to use it. If the IG is maintained in a repository, the builder can be linked by adding a Webhook to it and changing the Webhooks settings to the ones defined in the readme. If a change is pushed to the repository, the auto-builder is triggered and will run the publisher. The run will take a few minutes and if it is successful it will post the output to https://build.fhir.org/ig/:org/:repo/branches/:branch. Additionally, the master branch will be available at https://build.fhir.org/ig/:org/:repo. When the run is finished, it will also post the results in the Zulip ig-build Stream. There it shows the build logs and if it was successful. If the run is successful it will also show a link to the IG on build.fhir.org and the validation results for the resources.

6.2. Pilot Guide - Cross-border data exchange based on IPS

This Implementation Guide is project-specific and implements the requirements of the pilot for communication in medical scenarios. This includes both administrative and medical information relevant to the pilot. Wherever possible, existing profiles / IGs are used without changing them in order to ensure the highest possible standardization. The Implementation Guide includes profiles (Structure Definitions) and associated examples. Only an internal project balloting is planned, as this Guide involves project-specific adaptations of existing profiles. The IG can be downloaded and viewed via the following link:

- http://iehrgitlab.ds.unipi.gr/interopehrate/implementation-guide---pilot-guide-cross-border-data-exchange

Data requirement	Existing profiles considering (parts) of data requirement and project solution
Prescription	• Name: HL7 FHIR® US Core Implementation Guide • Workgroup: HL7 International-US Realm Steering Committee • Based on FHIR Version: 4.0.1 • Relevant StructureDefinitions: Medicationrequest, Medication, Patient • Last published: 2020-08-28
	• Name: International Patient Summary • Workgroup: Health Level Seven International-Patient Care Work Group • Based on FHIR Version: 4.0.1 • Relevant StructureDefinitions: Medication, Patient • Last published: 2020-05-19

	Project solution based on
	• Existing profiles
	  ○ http://hl7.org/fhir/uv/ips/StructureDefinition/Medication-uv-ips
	  ○ http://hl7.org/fhir/uv/ips/StructureDefinition/Patient-uv-ips
	• New Structure Definitions
	  ○ MedicationRequest-prescription-IEHR
	
	Constraints on MedicationRequest:
	• MedicationRequest.medicationReference
	  ○ Type changed from Reference (Medication) to Reference (Medication (IPS))
	• MedicationRequest.subject
	  ○ Type changed from Reference (Patient| Group) to Reference (Patient (IPS))
	• MedicationRequest.authoredOn
	  ○ Cardinality changed from 0..1 to 1..1
	• MedicationRequest.requester
	  ○ Type changed from Reference (Practitioner| PractitionerRole| Organization| Patient| RelatedPerson| Device) to Reference (Practitioner| PractitionerRole| Organization)
	  ○ Cardinality changed from 0..1 to 1..1
	• MedicationRequest.dosageInstruction
	  ○ Cardinality changed from 0..* to 1..1

Laboratory Report (structured)	• Name: HL7 FHIR® US Core Implementation Guide • Workgroup: HL7 International-US Realm Steering Committee • Based on FHIR Version: 4.0.1 • Relevant StructureDefinitions: Diagnosticreport-lab • Last published: 2020-08-28
	• Name: International Patient Summary • Workgroup: Health Level Seven International-Patient Care Work Group • Based on FHIR Version: 4.0.1 • Relevant StructureDefinitions: DiagnosticReport-uv-ips • Last published: 2020-05-19

	Project solution based on
	• Existing profiles
	  ○ http://hl7.org/fhir/uv/ips/StructureDefinition/DiagnosticReport-uv-ips (constrained)
	• New Structure Definitions
	  ○ DiagnosticReportUvIps-LaboratoryResult-IEHR
	
	Constraints on DiagnosticReport-uv-ips:
	• DiagnosticReport.language
	  ○ Cardinality changed from 0..1 to 1..1
	• DiagnosticReport.identifier
	  ○ Cardinality changed from 0..* to 1..1
	• DiagnosticReport.category.coding.system
	  ○ Fixed Value: https://terminology.hl7.org/1.0.0//CodeSystem-v2-0074
	• DiagnosticReport.category.coding.code
	  ○ Fixed Value: LAB
	• DiagnosticReport.performer
	  ○ Cardinality changed from 0..* to 1..*
	• DiagnosticReport.resultInterpreter
	  ○ Cardinality changed from 0..* to 1..*
	• DiagnosticReport.result
	  ○ Sliced with type Reference(Observation Results: laboratory (IPS))
	• DiagnosticReport.imagingStudy
	  ○ Cardinality changed from 0..* to 0..0
	• DiagnosticReport.media
	  ○ Cardinality changed from 0..* to 0..0

Imaging Report	• Name: International Patient Summary • Workgroup: Health Level Seven International-Patient Care Work Group • Based on FHIR Version: 4.0.1 • Relevant StructureDefinitions: DiagnosticReport-uv-ips • Last published: 2020-05-19

	Project solution based on
	• Existing profiles
	  ○ http://hl7.org/fhir/uv/ips/StructureDefinition/DiagnosticReport-uv-ips (constrained)
	• New Structure Definitions
	  ○ DiagnosticReport-ImagingReportSingleImage-IEHR
	
	Constraints on DiagnosticReport-uv-ips:
	• DiagnosticReport.language
	  ○ Cardinality changed from 0..1 to 1..1
	• DiagnosticReport.identifier
	  ○ Cardinality changed from 0..* to 1..1
	• DiagnosticReport.category.coding.system
	  ○ Fixed Value: https://terminology.hl7.org/1.0.0//CodeSystem-v2-0074
	• DiagnosticReport.performer
	  ○ Cardinality changed from 0..* to 1..*
	• DiagnosticReport.resultInterpreter
	  ○ Cardinality changed from 0..* to 1..*
	• DiagnosticReport.specimen
	  ○ Cardinality changed from 0..* to 0..0
	• DiagnosticReport.result
	  ○ Sliced with type Reference(Observation Result: radiology (IPS))
	• DiagnosticReport.imagingStudy
	  ○ Cardinality changed from 0..* to 0..0
	• DiagnosticReport.media
	  ○ Cardinality changed from 0..* to 1..*

Medical Document (e.g. unstructured Laboratory Results)	• Name: HL7 FHIR® US Core Implementation Guide • Workgroup: HL7 International-US Realm Steering Committee • Based on FHIR Version: 4.0.1 • Relevant StructureDefinitions: DocumentReference • Last published: 2020-08-28

	• Name: International Patient Summary • Workgroup: Health Level Seven International-Patient Care Work Group • Based on FHIR Version: 4.0.1 • Relevant StructureDefinitions: Patient, Practitioner • Last published: 2020-05-19

	Project solution based on
	• Existing profiles
	  ○ http://hl7.org/fhir/uv/ips/StructureDefinition/Patient-uv-ips
	  ○ http://hl7.org/fhir/uv/ips/StructureDefinition/Practitioner-uv-ips
	• New Structure Definitions
	  ○ DocumentReference-MedicalDocument-IEHR
	
	Constraints on DocumentReference:
	• DocumentReference.language
	  ○ Cardinality changed from 0..1 to 1..1
	• DocumentReference.identifier
	  ○ Cardinality changed from 0..* to 1..*
	• DocumentReference.type
	  ○ ValueSet binding strength changed from preferred to required
	• DocumentReference.type.coding
	  ○ Cardinality changed from 0..* to 1..*
	• DocumentReference.subject
	  ○ Type changed from Reference(Patient| Practitioner| Group| Device) to Reference(Patient (IPS))
	  ○ Cardinality changed from 0..1 to 1..1
	• DocumentReference.date
	  ○ Cardinality changed from 0..1 to 1..1
	• DocumentReference.author
	  ○ Type changed from Reference(Practitioner| PractitionerRole| Organization| Device| Patient) to Reference(Organization| Practitioner (IPS))
	  ○ Cardinality changed from 0..* to 1..1

VitalSigns	• Name: FHIR • Workgroup: Health Level Seven International Orders and Observations Workgroup) • Based on FHIR Version: 4.0.1 • Relevant StructureDefinitions: observation-vitalsigns • Last published: 2019-10-30

	• Name: Us-core • Workgroup: HL7 International-US Realm Steering Committee • Based on FHIR Version: 1.8.0 • Relevant StructureDefinitions: Vitalsigns • Last published: 2017-12-06
	Project solution based on • Existing base resource (project solution similar to IPS) ○ http://hl7.org/fhir/StructureDefinition/vitalsigns No constraints defined.

Table 17 - Profiled used for project solution - cross-border-data exchange

Examples based on the defined profiles are listed in the Implementation Guide.

6.3. Domain Guide - Research data sharing

This Implementation Guide includes the specification of the content that is exchanged via the research protocol. This is an implementation guide for the specific domain clinical research.

Detailed descriptions of processes, actors and content are part of the IG. The specification of the data in form of Structure Definition and the associated examples are also available in a structured form (XML, JSON, ..). The IG can be downloaded and viewed via the following link:

- http://iehrgitlab.ds.unipi.gr/interopehrate/implementation-guide-research-data-sharing

Balloting via HL7 Europe ist planned.

Data requirement	Existing profiles considering (parts) of data requirement and project solution
Research Study	• no existing profiles/projects found

	Project solution based on
	• Existing profiles
	  ○ -
	• New Structure Definitions
	  ○ ResearchStudy-IEHR
	Constraints on ResearchStudy:
	• ResearchStudy.text
	  ○ Cardinality changed from 0..1 to 1..1
	• ResearchStudy.extension
	  ○ Sliced with type Extension(DataSetDefinition)

	• ResearchStudy.identifier
	  ○ Cardinality changed from 0..* to 1..*
	• ResearchStudy.title
	  ○ Cardinality changed from 0..1 to 1..1
	• ResearchStudy.primaryPurposeType
	  ○ Cardinality changed from 0..1 to 1..1
	• ResearchStudy.contact
	  ○ Cardinality changed from 0..* to 1..*
	• ResearchStudy.location
	  ○ Cardinality changed from 0..* to 1..*
	• ResearchStudy.description
	  ○ Cardinality changed from 0..1 to 1..1
	• ResearchStudy.enrollment
	  ○ Type changed from Reference(Group) to Reference(Cohort)
	  ○ Cardinality changed from 0..* to 1..*
	• ResearchStudy.period
	  ○ Cardinality changed from 0..1 to 1..1
	• ResearchStudy.site
	  ○ Type changed from Reference(Location) to Reference(ResearchLocation)
	  ○ Cardinality changed from 0..* to 1..*

Cohort	• no existing profiles/projects found

	Project solution based on
	• Existing profiles
	  ○ -
	• New Structure Definitions
	  ○ Cohort-IEHR
	Constraints on Group:
	• Group.type
	  ○ Fixed Value: person

DataSetDefinition	• no existing profiles/projects found

	Project solution based on
	• Existing profiles
	  ○ -
	• New Structure Definitions
	  ○ DataSetDefinition
	Constraints on Extension:
	• Extension.extension
	  ○ Sliced with extension:DataRequirement

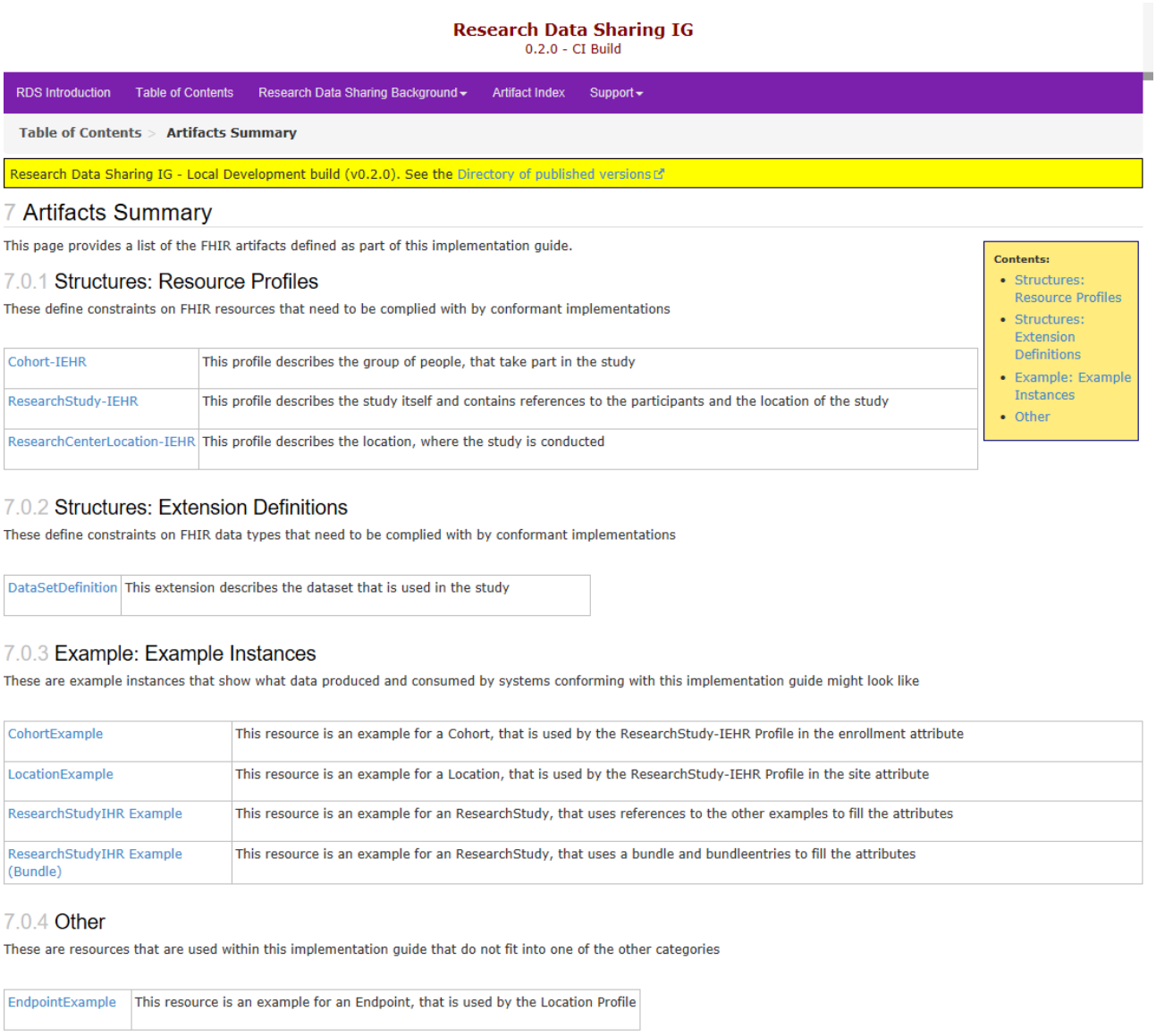
	• Extension.extension:DataRequirement.url
	  ○ Fixed Value: DataRequirement
	• Extension.extension:DataRequirement.value
	  ○ Type changed from * to DataRequirement
	• Extension.url
	  ○ fixed Value: http://interopehrate.eu/fhir/StructureDefinition/DataSetDefinition

ResearchCenter	• no existing profiles/projects found

	Project solution based on
	• Existing profiles
	  ○ -
	• New Structure Definitions
	  ○ ReferenceResearchCenter-IEHR
	Constraints on Location:
	• Location.identifier
	  ○ Cardinality changed from 0..* to 0..1
	• Location.name
	  ○ Cardinality changed from 0..1 to 1..1
	• Location.type
	  ○ Cardinality changed from 0..* to 1..1
	• Location.telecom
	  ○ Cardinality changed from 0..* to 1..1
	• Location.address
	  ○ Cardinality changed from 0..1 to 1..1
	• Location.endpoint
	  ○ Cardinality changed from 0..* to 1..1

Table 18 - Profiled used for project solution - research data sharing

Figure Figure 23 - Screenshot IG Research Data Sharing shows the screenshot of the Artifact Summary of the Research Data Sharing IG.



Research Data Sharing IG
0.2.0 - CI Build

RDS Introduction | Table of Contents | Research Data Sharing Background | Artifact Index | Support

Table of Contents > Artifacts Summary

Research Data Sharing IG - Local Development build (v0.2.0). See the Directory of published versions

7 Artifacts Summary

This page provides a list of the FHIR artifacts defined as part of this implementation guide.

Contents:
- Structures: Resource Profiles
- Structures: Extension Definitions
- Example: Example Instances
- Other

7.0.1 Structures: Resource Profiles

These define constraints on FHIR resources that need to be complied with by conformant implementations

Cohort-IEHR	This profile describes the group of people, that take part in the study
ResearchStudy-IEHR	This profile describes the study itself and contains references to the participants and the location of the study
ResearchCenterLocation-IEHR	This profile describes the location, where the study is conducted

7.0.2 Structures: Extension Definitions

These define constraints on FHIR data types that need to be complied with by conformant implementations

DataSetDefinition	This extension describes the dataset that is used in the study

7.0.3 Example: Example Instances

These are example instances that show what data produced and consumed by systems conforming with this implementation guide might look like

CohortExample	This resource is an example for a Cohort, that is used by the ResearchStudy-IEHR Profile in the enrollment attribute
LocationExample	This resource is an example for a Location, that is used by the ResearchStudy-IEHR Profile in the site attribute
ResearchStudyIHR Example	This resource is an example for an ResearchStudy, that uses references to the other examples to fill the attributes
ResearchStudyIHR Example (Bundle)	This resource is an example for an ResearchStudy, that uses a bundle and bundleentries to fill the attributes

7.0.4 Other

These are resources that are used within this implementation guide that do not fit into one of the other categories

EndpointExample	This resource is an example for an Endpoint, that is used by the Location Profile

Figure 13 - Screenshot IG Research Data Sharing

7. CONCLUSIONS AND NEXT STEPS

The relevant and largely applied processes and contents of the InteropEHRate Profiles specification have been analyzed 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 and the identification and definition of general requirements.

Since the specification of data requirements and implementation guides is still a steady development process, this document is considered an accompanying document, defining a framework and methodology for the development of implementation guides. The implementation guides are defined and published according to the FHIR community and the publishing and standardization process described in [D8.6].

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