



# InteropEHRate

## D8.6

### InteropEHRate Standardization report - V1

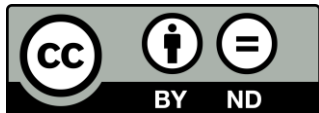
#### ABSTRACT

The InteropEHRate project aims to use existing and develop new communication standards in healthcare. Interaction with standardization committees is highly relevant for this. The aim of this report is to identify which potential findings and innovations from InteropEHRate could contribute to standards and to identify relevant standardization bodies. A standardization plan is drawn up and all standardization activities are recorded.

|                            |                               |
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## LOGTABLE

| Version | Date       | Change   | Author                         | Partner |
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| 0.1     | 23-04-20   | Definition of report structure   | Salima Houta, Marcel Klötgen   | FRAU    |
| 0.2     | 15-05-20   | Description of artefacts and standardization bodies                                | Salima Houta                   | FRAU    |
| 0.3     | 22-05-20   | First draft for standardization strategy and listing of standardization activities | Salima Houta                   | FRAU    |
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## ACRONYMS

| Acronym     | Term and definition  |
|-------------|--|
| ANSI        | American National Standards Institute.   |
| D2D         | Device to Device (protocol): Secure communication protocol (and API) for transmitting health data among two near devices (not using internet), one running the S-EHR mobile app and the other running an HCP (desktop, web or mobile) application (e.g. a GUI of an EMR).  |
| HL7 FHIR    | Health Level 7 Fast Healthcare Interoperability Resources  |
| RDD         | Research Definition Document: A document written in a formal, computer-processable language that describes the research datasets to be retrieved from citizens' EHRs, enrolment and exit criteria, as well as related metadata.  |
| S-EHR       | Smart Electronic Health Record: An S-EHR is the collection of all health data about a citizen, controlled by the citizen themselves, and stored on the citizen mobile device (smartphone or tablet). An S-EHR is able to import/share data from/with EHR/EMRs and with research centres, using short-range wireless D2D (device to device) communication or several remote communication protocols.        |
| S-EHR APP   | The S-EHR APP is an implementation of S-EHR, fulfilling the S-EHR conformance levels.  |
| S-EHR Cloud | The S-EHR Cloud is an implementation of the SCS.   |
| SCS         | Secure cloud service, fulfilling the S-EHR conformance levels, is able to store on the cloud the data collected by S-EHRs, adopting the standard protocols defined by the project. A citizen may choose to use a S-EHR mobile app without using any S-EHR cloud. In this case, his/her health data will be accessible to health professionals by using the short-range D2D protocol or the EHR federation. |

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# 1. INTRODUCTION

## 1.1. Scope of the document

The InteropEHRate project aims to use existing and develop new communication standards in healthcare. Interaction with standardization committees is highly relevant for this. The aim of this report is to identify which potential findings and innovations from InteropEHRate could contribute to standards and to identify relevant standardization bodies. A standardization strategy is drawn up and all standardization activities are recorded. This task will ensure that the project work uses and is in line with the relevant standards and will bring the D2D protocol and the Interoperability Profiles into the standardization process, fostering dialogues with relevant bodies in order to share potential findings and innovations made by InteropEHRate that could contribute to standards.

Standardization activities will contribute towards generating or contributing to representative standards and proposing and promoting them to the appropriate standardization bodies. This task includes identifying the relevant standardization bodies, at both European and international levels.

The following sub-goals are addressed in this document:

- Identify clearly which parts of the InteropEHRate project is adequate and strategically beneficial to be promoted as a standard (e.g., D2D communication protocol as well as the InteropEHRate FHIR profile);
- Clarify the interest from standardisation bodies for standardisation of InteropEHRate results;
- Define appropriate relationships to relevant standards and ongoing efforts, e.g. in HL7.

Moreover, in the first phase of the project, InteropEHRate will identify other relevant standard bodies on communication protocols, security and GDPR to work with and use for dissemination purposes. The Consortium will also look into the EC funded ecosystem, and other projects and initiatives that could be relevant to InteropEHRate. Standardisation activities and details for future planned actions will be reported in the current version and updated in the second version (and final) of this deliverable. InteropEHRate will send the major contributions and innovations to the identified standardisation bodies after the final versions of the whole solution have been released and are stable. However, periodical contacts will be made to the different standardisation bodies in order to align common interests and to reach as strong an impact as possible. Further details concerning standard contributions will be addressed in the Consortium Agreement.

## 1.2. Intended audience

The target group of the document is the project consortium, standardization committees and all groups / institutions that are interested in standardization processes.

## 1.3. Structure of the document

The document starts in section 2 with the presentation of innovations from the project, which can be part of a standardization process. Subsequently, relevant national and European standardization bodies are identified and described in section 3. Section 4 describes the development of a standardization strategy and presents a decision for a standardization strategy based on a multi-criteria assessment. Next, the standardization strategy

is explained in more detail in Section 5. Chapter 6 reports the standardization activities within the project. The document closes with the results and explanations of the next steps in Section 7.

#### **1.4. Updates with respect to previous version (if any)**

Not applicable.

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## 2. PROJECT ARTIFACTS

This section describes outcomes of the project which are candidates for standardization by a standardization body and thus promise to improve interoperability of different applications for specific use cases. The following table lists the outcomes in a structured manner.

|         | Interoperability Profiles: Contribution of FHIR Implementation Guides  | Interoperability Protocols: Contribution of interfaces and specifications                                  |
|---------|--|--|
| Outcome | <ul style="list-style-type: none"> <li>• Profiles as contribution to existing Implementation Guides (e.g. IPS)</li> <li>• New Implementation Guides</li> </ul> | <ul style="list-style-type: none"> <li>• D2D Protocol</li> <li>• Research Data Sharing Protocol</li> </ul> |

Table 1 - Project artefacts

### 2.1. Interoperability Profiles

The Interoperability Profiles are used with the newly specified communication protocols in order to share and exchange information between the different actors in a standardized way, thus ensuring syntactic and semantic interoperability of information. They adopt existing domain agnostic data models and HL7 FHIR 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 [\[D4.8\]](#)[\[D4.12\]](#) and the InteropEHRate Core Guide [\[D2.7\]](#).

#### 2.1.1. Extension of existing Implementation Guides

If possible, data requirements derived and identified from [\[D2.2\]](#) are covered by existing HL7 FHIR based Implementation Guides, such as the International Patient Summary. The profiles defined in these Implementation Guides are used and adapted to project specific requirements, if necessary. It is planned to provide the results that represent significant adaptations and extensions with a generic impact as a change request or to the existing working groups. So far, the profiles defined in the IPS Implementation Guide could be used for implementation in the pilot with few project-specific changes.

#### 2.1.2. Definition of new Implementation Guides

Data requirements that cannot be met by existing implementation guides are included in new Implementation Guides (IG). Based on the requirements from [\[D2.2\]](#), the first domain-specific information could be identified, which has not yet been dealt with in the required form within the framework of existing Implementation Guides. This is data that is exchanged as part of the Research Data Sharing Protocol including different aspects such as unstructured and human readable definition of the research project, structured and machine processable definition of the research project, data security and access control, data set results of research data query [\[D4.8\]](#).

## 2.2. Interoperability Protocols

### 2.2.1. D2D Protocol

The D2D protocol is based on a short range communication protocol (i.e. Bluetooth), and it specifies a series of messages regarding the information that is being exchanged (e.g. in terms of successful or failed data exchange) and healthcare related data between a healthcare practitioner (using an HCP app) and a citizen (using a mobile application (S-EHR app)), without an internet connection. This protocol is implemented on top of short-range wireless technologies (for example but not exclusively Bluetooth), to be adopted at EU level, for the secure exchange of health records between a citizen's smart mobile device and a healthcare practitioner's information system (Figure 1) [\[D4.12\]](#).

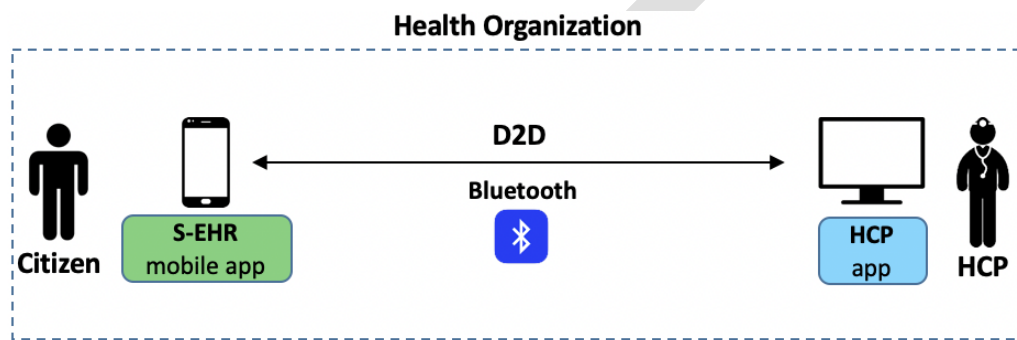


Figure 1 - D2D protocol scope [\[D4.12\]](#)

### 2.2.2. Research Data Sharing Protocol

The Research Data Sharing Protocol focuses on collecting health data for cross-border medical research in a way that involves citizens more directly in the decisions regarding the sharing of their data, while completely preserving their rights to privacy (GDPR & similar regulations). This is achieved through a novel approach that allows patients to send their data to researchers (after explicit consent). Data shared with research may optionally include data directly collected from the electronic health records, stored on citizens' smartphones. Citizens have complete control over their data as they can give or decline consent for data sharing on a per-study basis, and be informed of precisely what data is used by a given study [\[D4.8\]](#).

### 3. STANDARDIZATION BODIES

InteropEHRate plans to engage with the most important European and International standardization organisations. Suitable standardization bodies are addressed and identified on the basis of the project artefact. The table below lists targeted standardization bodies, including the contact person in the project.

| Standardization Body | Description   | Contact person in the project |
|----------------------|---|-------------------------------|
| HL7 Europe           | The European Office was established by HL7 International as a private foundation in Brussels in June 2010. This is intended to promote the widespread use of HL7 in Europe as well as to better meet the needs of the European community and its national HL7 affiliates.   | Giorgio Cangioli              |
| IHE Europe           | IHE-Europe focuses on interoperability in healthcare across Europe. The main task is to support national and European interest groups and political decision-makers in the adoption, promotion and implementation of IHE specifications. In addition, IHE-Europe develops tools (e.g. Gazelle) and services to support interoperability tests. The process of developing integration profiles is open and concludes with integration tests (e.g. in the context of IHE Connectathon) to determine the conformity of systems. IHE-Europe is also actively involved in educational and advertising measures. As a voice for European interests, IHE-Europe coordinates IHE development worldwide with IHE initiatives for North America, Asia and Oceania in the international IHE organizational structure and in close cooperation with standardization development organizations (ISO, HL7, CEN, DICOM etc.) and other profiling organizations such as the Continua Health Alliance that use IHE profiles. | no contact person yet         |
| HL7 International    | HL7 International is a non-profit, ANSI accredited international standards development organization with around 40 country representatives around the world and was established in 1987.<br><br>HL7 International develops a number of international standards for the electronic exchange of medical, administrative and financial data between information systems in the health sector.  | no contact person yet         |

*Table 2 - Standardization bodies*

In addition to these international standardization bodies, there are several societies and entities that also deal with or address interoperability and standardization with a more specific scope. Interoperability through standardization of protocols or profiles addressing specific use cases can therefore enrich existing data exchanges or healthcare record scenarios addressed by the following bodies.

| Standardization Project Body    | Description  | Contact person in the project                       |
|---------------------------------|--|---|
| Interoperabilitätsforum Germany | <p>The so-called "Interoperability Forum" was launched in 2009. The primary goal is interoperability (semantics, technology, structure) in order to achieve an increase in quality and efficiency in patient treatment.</p> <p>Initiated by HL7 Germany, IHE Germany, and the AG Interoperability of the bvitg (formerly VHitG) and the medical informatics department of DIN, this meeting is organized four times a year.</p>  | Simone Heckmann<br>Christoph Gessner<br>Frank Oemig |
| Elektronische Fallakte e. V.    | <p>The electronic case file (EFA) is a case-based patient database administered by doctors that works with the german telematics infrastructure as a value-added system.</p> <p>The electronic case record is based on international profiles and standards (Integrating the Healthcare Enterprise (IHE) and Health Level Seven (HL7)) and supported by numerous health IT firms (providers of hospital information systems and practice administration systems).</p> <p>The EFA 2.0 specification is open and received a positive vote from state data protection officers.</p> <p>Three EFA providers offer EFA out of the box in high-security data centres.</p> <p>Together with the Interoperability Forum, the association Elektronische Fallakte e. V. promotes the standardization of the case records based on IHE and HL7.</p> | Volker Lowitsch                                     |

*Table 3 - standardization project bodies*

## 4. DEVELOPMENT OF A STANDARDIZATION STRATEGY

### 4.1. Contribution Options

In the following sections, the project artefacts presented in section 2 are analysed in more detail with regard to the contribution to standardization. In general, two contribution lines are distinguished, each presenting two sub-options. The sub-options are explained and assessed according to a set of decision criteria in order to identify the most beneficial contribution option.

#### 4.1.1. Interoperability Profiles

The Interoperability Profiles promise interoperability for data structures and semantics based on HL7 FHIR rather than information exchange workflows. Therefore, a possible standardization strategy aligns with the standardization of HL7 FHIR profiles or HL7 FHIR Implementation Guides (IGs) by contributing to existing working groups or providing a new Implementation Guide. The following tables show the goals and targeted impact as well as the tasks to be performed per sub-option.

## Goals and expected impact

| Options         | O1.1 Contribution to existing Working Groups / Implementation Guides  | O1.2 Standardization of a new Implementation Guide   |
|-----------------|---|--|
| Goals           | <ul style="list-style-type: none"> <li>Optimized support of medical scenarios</li> </ul>  | <ul style="list-style-type: none"> <li>Optimized support of medical scenarios</li> </ul>   |
| Solution        | <ul style="list-style-type: none"> <li>Extension of existing HL7 FHIR Implementation Guides, such as IPS</li> </ul>   | <ul style="list-style-type: none"> <li>Provision of one or several new HL7 FHIR Implementation Guides</li> </ul>   |
| Expected Impact | <ul style="list-style-type: none"> <li>IPS or FHIR Profiles</li> <li>Addresses clinicians &amp; technicians</li> <li>Interoperability on a structural and semantic level</li> </ul> | <ul style="list-style-type: none"> <li>FHIR Profiles &amp; IGs</li> <li>Addresses clinicians &amp; technicians</li> <li>Interoperability on a structural and semantic level</li> </ul> |

Table 4 - Goals and impact of Interoperability Profiles

## Options

| Options       | O1.1 Contribution to existing Working Groups / Implementation Guides   | O1.2 Standardization of a new Implementation Guide   |
|---------------|--|--|
| Working Group | <ul style="list-style-type: none"> <li>IPS</li> </ul>  | <ul style="list-style-type: none"> <li>Cooperation with active WGs which address clinical research aspects</li> <li>Cooperation with active WGs which address patient care aspects</li> </ul>  |
| Tasks         | <ul style="list-style-type: none"> <li>Participation in weekly IPS Calls</li> <li>Novel profiles for existing Implementation Guides</li> <li>Presentation of the use of existing profiles</li> <li>Improvements / change request on existing profiles</li> </ul> | <ul style="list-style-type: none"> <li>Creation of a new Implementation Guide incl. profiles (value sets, structure definitions)</li> <li>Coordination of balloting process at HL7 Europe</li> <li>Coordination of a new WG or exchange with existing WGs</li> </ul> |

Table 5 - Contribution options of Interoperability Profiles

### 4.1.2. Interoperability Protocols

In contrast to the Interoperability Profiles, the Interoperability Protocols provide interoperability for different healthcare applications by defining information exchange workflows regarding selected use cases. Therefore,

aligning with IHE Europe will be necessary for contributing an Interoperability Protocol as a future standard. The following tables show the goals and targeted impact as well as the tasks to be performed per sub-option.

### Goals and expected impact

| Options         | O2.1 Standardization of D2D protocol  | O2.2 Standardization of research protocol   |
|-----------------|---|---|
| Goals           | <ul style="list-style-type: none"> <li>Optimized support of medical scenarios</li> <li>Patient as an actor / data provider</li> <li>Optimization of interoperability and system integration</li> </ul>          | <ul style="list-style-type: none"> <li>Optimized support of medical scenarios</li> <li>Patient as an actor / data provider</li> <li>Optimization of interoperability and system integration</li> </ul>  |
| Solution        | <ul style="list-style-type: none"> <li>Definition of a standard workflow for local communication-based interaction in a healthcare context</li> <li>Definition of standard messages and profiles</li> </ul>     | <ul style="list-style-type: none"> <li>Definition of a standard workflow for the study-based donation of data sets for secondary-use purposes by patients in a transparent environment</li> <li>Definition of standard messages and profiles</li> </ul> |
| Expected Impact | <ul style="list-style-type: none"> <li>IHE Profile</li> <li>Option: few new FHIR Profiles, e.g. Consent</li> <li>Addresses technicians</li> <li>Interoperability on a processual and technical level</li> </ul> | <ul style="list-style-type: none"> <li>IHE Profile</li> <li>Option: few new FHIR Profiles, e.g. Consent</li> <li>Addresses technicians</li> <li>Interoperability on a processual and technical level</li> </ul>   |

Table 6 - Goals and impact of Interoperability Protocols

### Options

| Options    | O2.1 IHE Profile for Device to Device (D2D) exchange of medical data („IHE DEX“)   | O2.2 IHE Profile for Research data exchange („IHE REX“)  |
|------------|--|--|
| IHE Domain | <ul style="list-style-type: none"> <li>IT Infrastructure</li> </ul>  | <ul style="list-style-type: none"> <li>Quality, Research and Public Health</li> </ul>  |
| Tasks      | <ul style="list-style-type: none"> <li>Use Cases and Transactions</li> <li>Definition of content profiles (e.g. IPS)</li> <li>Dependencies on other profiles (IHE ATNA, IHE CT, ...)</li> <li>Balloting</li> </ul> | <ul style="list-style-type: none"> <li>Use Cases and Transactions</li> <li>Definition of content profiles (e.g. RDD)</li> <li>Check whether profiles of the same domain already represent partial aspects</li> </ul> |

- Dependencies on other profiles (IHE ATNA, IHE CT, ...)
- Balloting

Table 7 - Contribution options of Interoperability Protocols

## 4.2. Strategy Decision Criteria

In order to focus on the most efficient and impactful options for standardization of a subset of the project's results with the given resources, an objective assessment strategy has been developed. Therefore, the most important decision criteria for selecting and evaluating these contributions have been identified. The decision criteria have been assigned values for applying to an individual degree, and a weight factor, depending on their importance and contribution from the project perspective.

| No. | Details  | value Interval  | Weight | Details  |
|-----|--|---|--------|--|
| C1  | New or unique processes or information for optimization of accessibility, availability and sharing of health data          | 0: false<br>1: true   | 3      | This criterion states whether the contribution option provides novelties regarding the standardization of processes or information content for health data sharing.                |
| C2  | New or unique interfaces or content definitions for optimization of accessibility, availability and sharing of health data | 0: false<br>1: true   | 3      | This criterion states whether the contribution option provides new technical specifications for software interconnectivity regarding the exchange of health data.                  |
| C3  | Innovative incorporation of technologies for accessibility, availability and sharing of health data                        | 0: false<br>1: true   | 3      | This criterion states whether the contribution option uses new or existing technologies in an innovative way regarding a specific use case as part of the exchange of health data. |
| C4  | Effort of standardization process and tasks covered by project   | 0: not applicable<br>1: maximal effort<br>2: minimal effort | 2      | This criterion states whether the expected effort to effectively start the contribution option is realistically covered by the resources of the project.                           |



|    |  |  |   |   |
|----|--|--|---|---|
| C5 | Exploitability for vendors and hospitals | 0: not present<br>1: purpose restricted<br>2: transferable | 2 | This criterion states whether the contribution option is expected to be adopted and used by many software vendors, and for which purpose it can be used or further developed. |
| C6 | Level of maturity                        | 1: draft<br>2: trial use<br>3: normative                   | 1 | This contribution option describes the maturity of the project result as a contribution option at the time of the assessment, based on the HL7 FHIR semantics for profiles.   |

Table 8 - Strategy decision criteria

### 4.3. Decision of Standardization Strategy

The identified contribution options can be evaluated and assessed by applying the developed strategy decision criteria. Thus, the most beneficial contribution option can be pursued with the given project resources. The options are evaluated one by one by applying all criteria, assigning the appropriate objective value multiplied by the assigned weight factor. The numeric results can then be compared directly, with the highest value pointing towards the most beneficial contribution option.

The following table shows the application of the decision criteria and an assessment of the contribution options.

| Criteria  | O1.1<br>Contribution to existing Working Groups / Implementation Guides (D2D) | O1.2<br>Standardization of a new Implementation Guide (RDD) | O2.1<br>IHE Profile for Device to Device (D2D) exchange of medical data | O2.2<br>IHE Profile for Research data exchange (research protocol) |
|---|---|---|---|--|
| C1: new or unique processes or information for optimization of accessibility, availability and sharing of health data | 0   | 3   | 3   | 3  |
| C2: new or unique interfaces or content definitions for optimization of accessibility,                                | 0   | 3   | 3   | 3  |

|   |          |           |           |           |
|---|----------|-----------|-----------|-----------|
| availability and sharing of health data   |          |           |           |           |
| C3: innovative incorporation of technologies for accessibility, availability and sharing of health data | 0        | 0         | 3         | 0         |
| C4: effort of standardization process and tasks   | 4        | 4         | 2         | 2         |
| C5: exploitability for vendors and hospitals  | 2        | 4         | 4         | 2         |
| C6: level of maturity   | 2        | 1         | 1         | 1         |
| <b>Assessment Sum</b>   | <b>8</b> | <b>15</b> | <b>16</b> | <b>11</b> |

*Table 9 - Assessment of contribution options*

According to the assessment results, the most beneficial contribution option is O2.1, favouring the standardization of the D2D protocol through the specification of an IHE Profile for the device to device exchange of medical data. The specification of a new HL7 FHIR Implementation Guide for the research scenario is a second beneficial contribution option.

## 5. STANDARDIZATION STRATEGY

### 5.1. Standardization Strategy for D2D Protocol

The standardization strategy will be drawn up in coordination with HL7 Europe and the project partners and will be part of the next version.

### 5.2. Standardization Strategy for Interoperability Profiles (RDD)

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, an HL7 FHIR Implementation Guide for this version of the InteropEHRate Profile is created which can then be subject to official balloting processes. For this purpose, there is close coordination with existing working groups from relevant domains. 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.

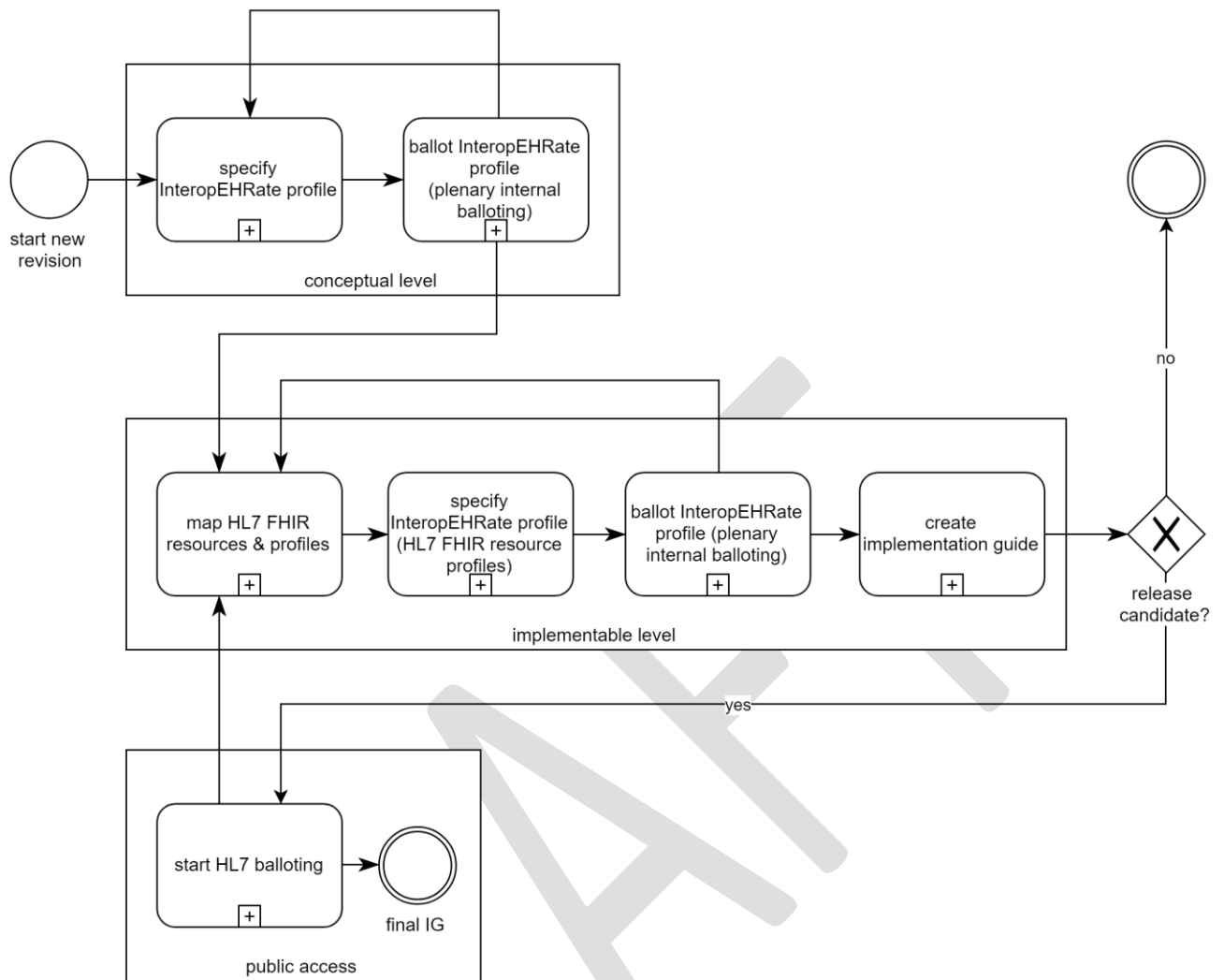


Figure 2 - specification and balloting process of the InteropEHRRate Profile

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 the 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].

### 5.3. Driving the InteropEHRate standards in Germany

The electronic case record (Elektronische Fallakte (EFA)) is a case-based patient database administered by doctors that works with the German telematics infrastructure as a value-added system. The electronic case record is based on international profiles and standards (Integrating the Healthcare Enterprise (IHE) and Health Level Seven (HL7)) and proven numerous times and used in various model regions for specific indications. In order to integrate the standards and interfaces developed in the project in the German IT infrastructure for data exchange, a subproject was initiated that designs the integration of the EFA with the S-EHR. Using the example of the profiles used and developed within the project, EFA modules are set up. In addition, a prototype is being developed that implements data exchange between the national infrastructure and S-EHR. It is planned to present and contribute the results to national bodies.

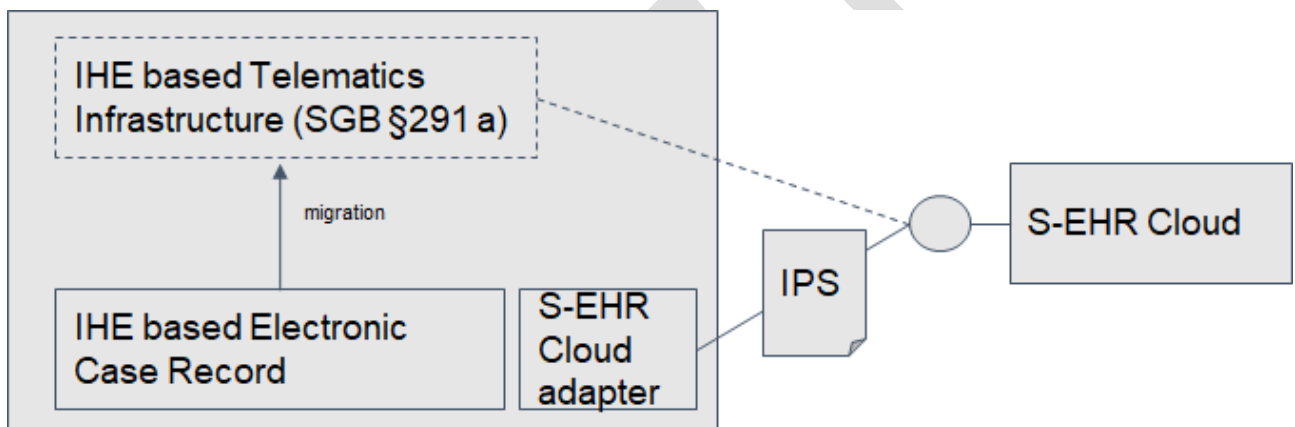


Figure 3 - Integration of Electronic Case Record and S-EHR Cloud

## 6. STANDARDIZATION ACTIVITIES

The following table lists all standardization activities.

| Date                | Place  | Working Group and Representatives | Topics   |
|---------------------|--|-----------------------------------|--|
| Since project start | WP 2 and WP 4 meetings and conference calls  | WP 2<br>WP 4                      | Derivation of project data requirements, Profiling, Generation of samples, Evaluation of profiles                                |
| Since project start | WP 4 meetings and conference calls           | WP 4                              | Derivation of interface specifications and transactions for protocols  |
| 2019-12-06          | Cologne, Germany                             | Interoperabilitätsforum           | Presentation of the InteropEHRate project. Clarification whether a balloting process is possible via the interoperability forum. |
| 2019-12-12          | Web  | Zulip FHIR Chat                   | Creation of a stream "InteropEHRate" to discuss special project aspects with the FHIR community.                                 |
| Since 2020-03-06    | Communication and Coordination (Mail, Calls) | HL7 Europe (Giorgio Cangioli)     | Discussion how to contribute the Interoperability profiles to HL7 Europe.  |

*Table 10 - Standardization activities*

## 7. CONCLUSIONS AND NEXT STEPS

In summary, the results of the project have been described and assessed with regard to being candidates for standardization by a standardization body and therefore promise to improve the interoperability of different applications for certain use cases. Various important European and international standardization bodies have been evaluated and representatives have been contacted to select the appropriate standardization bodies. The project artefacts/results have then been analysed in more detail with regard to the contribution to standardization. An assessment method has been developed to define the appropriate overarching standardization strategy. To this end, decision criteria have been identified and weighted. The method has been applied to the contribution options, pointing to the most beneficial and effective contribution options:

- Standardization of the D2D protocol
- Implementation Guide for Research Data

The tasks for the contribution to the appropriate standardization bodies have been identified in general and will be aligned and started with the contact persons of each standardization body. The expected tasks are listed in the following table.

| Tasks                                       | O1: Contribution of Interoperability Profiles  | O2: Contribution of Interoperability Protocols  |
|---|--|---|
| Definition of data structures and semantics | <ul style="list-style-type: none"> <li>• Definition of data requirements for a use case</li> <li>• Identification and specification of HL7 FHIR Profiles</li> </ul>  | <ul style="list-style-type: none"> <li>• Definition of data requirements for a transaction</li> <li>• Identification of HL7 FHIR Profiles</li> </ul>  |
| Creation of standardization artefacts       | <ul style="list-style-type: none"> <li>• Specification or extension of an HL7 FHIR Implementation Guide</li> <li>• Evaluation of data requirements</li> </ul>  | <ul style="list-style-type: none"> <li>• Definition of transactions, parameters and workflows</li> <li>• Creation of IHE Profile Document as required by IHE balloting</li> </ul>                             |
| collaboration with standardization bodies   | <ul style="list-style-type: none"> <li>• Alignment with IPS Working Groups</li> <li>• Provision of contribution artefacts to IPS and HL7 FHIR working groups</li> <li>• Management of an HL7 FHIR balloting process</li> </ul> | <ul style="list-style-type: none"> <li>• Alignment with IHE DEX Working Groups</li> <li>• Provision of contribution artefacts to IHE working groups</li> <li>• Management of the balloting process</li> </ul> |

Table 11 - Standardization tasks

## REFERENCES

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