A Personalised Integrated Care Platform

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D9.5 Plan For Contributions to Standardisation

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1 Executive Summary

This document summarises the steps taken by the consortium to disseminate the project results from a standardisation perspective. The work described within this deliverable frames itself under the scope of work package 9, and in particular, task 9.2. The project has focused its software developments on an interoperability perspective, so that its results can be sustainable and easily integrated within different Health Information Systems.

To that end, the major technologies used are:

- Web-related technologies. The project components exchange information using **REST** interfaces[1] to guarantee the interoperability of our distributed systems throughout the Internet. Additional web technologies relevant to the project are analysed in this document as well.
- Health-related technologies. After a careful consideration of many standards in the health area, we opted for the use of **FHIR® – Fast Healthcare Interoperability Resources**,[2] which is a next generation standards framework created by HL7. As claimed in the HL7 website, "FHIR combines the best features of HL7's v2,[3] HL7 v3[4] and CDA[5] product lines while leveraging the latest web standards and applying a tight focus on implementability."

Through the Fraunhofer team, which has a strong background in the participation to standardisation bodies, the consortium has mainly followed up the developments related to those technologies.

[1] https://en.wikipedia.org/wiki/Representational_state_transfer
[2] https://www.hl7.org/fhir/
[3] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=185
[4] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=186
[5] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7

2 Introduction

2.1 Purpose, context and scope of this deliverable

This work is related to task T9.2 Dissemination Coordination, which includes dissemination of project results to standardisation bodies.

2.2 Intellectual Property (IP)

There are not intellectual property elements affected by this deliverable, as its content is related to a standardisation process which is fully open, as reflected in the W3C policies and in the HL7 standardisation process related to FHIR.

2.3 Content and structure of this deliverable

As mentioned in the Executive Summary, the project has focused its software developments on an interoperability perspective, so that its results can be sustainable and easily integrated within different Health Information Systems. This document reports on the approach of the project towards standards, together with its previous and current work within standardisation bodies.

The document is structured in 2 main sections. Section 3 enumerates briefly the relevant standards to the architecture of the project, from a healthcare perspective and from a distributed systems architecture perspective. Section 4 describes briefly the previous efforts of the project in this area, together with its future plans.

3 Relevant standards to the project

3.1 Health-related standards: FHIR

As mentioned earlier, we opted within our components for the use of **FHIR® – Fast Healthcare Interoperability Resources**,[6] as databases our data formats.

FHIR is a next generation standards framework created by HL7. As claimed in the HL7 website, "FHIR combines the best features of HL7's v2,[7] HL7 v3[8] and CDA[9] product lines while leveraging the latest web standards and applying a tight focus on implementability." FHIR components are built upon of "Resources",[10] which cover not only health-related concepts, but also administrative elements of any Health Information System. Its main advantages are exposed in the FHIR website:[11]

- A strong focus on implementation – fast and easy to implement (multiple developers have had simple interfaces working in a single day)
- Multiple implementation libraries, many examples available to kick-start development
- Specification is free for use with no restrictions
- Interoperability out-of-the-box– base resources can be used as is, but can also be adapted for local requirements
- Evolutionary development path from HL7 Version 2 and CDA – standards can co-exist and leverage each other
- Strong foundation in Web standards– XML, JSON, HTTP, OAuth, etc.
- Support for RESTful architectures, seamless exchange of information using messages or documents, and service based architectures
- A human-readable serialization format for ease of use by developers
- Solid ontology-based analysis with a rigorous formal mapping for correctness

In particular, the use of JSON[12] was critical for the exchange within the project of information through web-based interfaces via secure channels (HTTPS).

3.2 Web-related standards

The project components exchange information using **REST** interfaces[13] to guarantee the interoperability of our distributed systems throughout the Internet. Additionally, we are focusing our efforts on following the following relevant activities within W3C:

- **Data Activity**:[14] the project is evaluating the participation within data-related activities, especially those related to Linked Data Vocabularies and other semantic web activities, such as the RDF Data Shapes Working Group.[15]
- **Security Activity**:[16] as part of our authentication, security and privacy components, we are following this activity. We will evaluate the availability of resources for the participation to the Web Authentication Working Group[17] and the Web Application Security Working Group.[18]

Additionally, the consortium has made use of the **OpenAPI** specification as a way to document our RESTful interfaces.[19]

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[6] https://www.hl7.org/fhir/
[7] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=185
[8] https://www.hl7.org/implement/standards/product_brief.cfm?product_id=186
[9] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[10] https://www.hl7.org/fhir/resourcelist.html
[11] https://www.hl7.org/fhir/summary.html
[12] https://www.json.org/
[13] https://en.wikipedia.org/wiki/Representational_state_transfer; Fielding, Roy Thomas (2000). "Chapter 5: Representational State Transfer (REST)". Architectural Styles and the Design of Network-based Software Architectures (Ph.D.). University of California, Irvine.
[14] https://www.w3.org/2013/data/
[15] https://www.w3.org/2014/data-shapes/wiki/Main_Page
[16] https://www.w3.org/Security/
[17] https://www.w3.org/Webauthn/
[18] https://www.w3.org/2011/webappsec/
[19] https://swagger.io/specification/

4 Relevant activities of the project

Fraunhofer has a wide experience in the participation to standardisation bodies. For example, the project manager Dr. Carlos A Velasco, is the representative of the Fraunhofer Society in the Advisory Committee of **W3C (World Wide Web Consortium)**.[20] Therefore, our main effort was focused on the participation to health-related working groups within this organisation. The standardisation team was completed with Dr. Yehya Mohamad and Dr. Oya Beyan.

To that end, Fraunhofer participated in the **Semantic Web Health Care and Life Sciences Interest Group** (HCLS IG[21]), which contributed to the Drug-Drug Interactions task force.[22] The task force formed in January 2016 to develop a minimal information model for drug interaction evidence and knowledge as part of a standard such as those developed by HL7. The task force developed a draft Interest Group Note that provides use cases, user stories, definitions, and exemplar potential drug-drug interaction descriptions for a minimal information model for drug interaction evidence and knowledge.[23]

The task force is in the process of initiating a new HL7 project called “Contextualized Drug-drug interaction clinical decision support”.[24] This project seeks to develop an implementation guide that shows how to represent potential drug-drug interaction (PDDI) knowledge and evidence for the purpose of clinical decision support (CDS). The aim is to provide the opportunity for the international community to collaborate and come to consensus on patterns used in implementations for the extensions and profiles used to express PDDI CDS. Project outcome will be FHIR Implementation Guide, which will show how to combine tagged narrative with Fast Healthcare Interoperability Resources (FHIR) resources/profiles and CDS Hooks triggers to achieve the goal of highly effective and sharable CDS rules for PDDIs.

Unfortunately, the Interest Group was closed in February 2018. However, the activities will be continued under the scope of the **Semantic Web Health Care and Life Sciences Community Group** (HCLS CG[25]), from which Fraunhofer is also a member. The main focus of this Community Group “… is to develop, advocate for, and support the use of Semantic Web technologies across health care, life sciences, clinical research and translational medicine.” In particular, one of the core objectives is the “translation” of the FHIR resource profiles into a semantic perspective, which provides the ability to integrate knowledge within those systems.

Fraunhofer participates as well in the **Research Data Alliance**[26] which aims to improve research data sharing. Dr. Beyan is co-chair of RDA Ethics and Social Aspects of Data (ESAD) Interest Group[27] and coordinates activities related to ethical aspects of medical data. She is also member of the Health Data Interest Group,[28] where she co-leads activities related to reproducible data curation workflows. Currently she co-chairs the “Reproducible Health Data Service Workflows Working Group” initiative, which aims to define a set of standards, and develop an adoption guideline to enable reproducible data service workflows from data processing and data governance perspectives. The workflow guideline will improve capture and storage of data provenance metadata, in a machine-readable way whenever possible, and enable data consumers (researchers, innovators, etc.) to access detailed data curation metadata together with the data itself. The target users of the workflow guide include: health care data curation centers, medical data services, clinical.

Within those standardisation activities, we are trying to bring up the experience arising from our implementation efforts into coming the standards, and of course, trying to incorporate new developments into our coming demonstrators and prototypes.

[20] https://www.w3.org/
[21] https://www.w3.org/2001/sw/hcls/
[22] https://www.w3.org/wiki/HCLSIG/DDI
[23] https://sites.google.com/site/ddikrandir/home/ddi_info_model_taskforce
[24] http://www.hl7.org/special/Committees/projman/searchableProjectIndex.cfm?action=edit&ProjectNumber=1405
[25] https://www.w3.org/community/hclscg/
[26] https://www.rd-alliance.org/
[27] https://www.rd-alliance.org/groups/ethics-and-social-aspects-data.html
[28] https://www.rd-alliance.org/groups/health-data.html