

FAIRness4FHIR: Aligning the FAIR Data Principles and HL7 FHIR Profiling

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Abstract. Health data reuse is widespread in clinical, scientific, regulatory and business settings, and many examples of the benefits of data reuse have already been documented. This fosters the secondary use of data and encourages to push the boundaries of health research within an ethical and legally compliant framework that reinforces the trust of patients and citizens. HL7 FHIR is an emerging information technology standard promoted as an exchange format for health care and research related data; for research FHIR proposes structures for data on the subject and study levels. The EFMI Working Group (WG) “FAIR data in Health Research Performing Organizations” organizes this workshop to contribute to the adoption of the FHIR for FAIR Implementation Guide developed by the HL7 Service Oriented Architecture WG through its discussion and use, aligning the FAIR data principles and HL7 FHIR profiling.

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1. Introduction

Health Level 7 (HL7[®]) Fast Healthcare Interoperability Resources (FHIR[®]) [1] is the predominant evolving information technology (IT) standard for the representation of health care and research related data. Many international initiatives are developing data models conforming to the FHIR specification to represent and exchange these data, both within academics and industry.

While the focus of FHIR has traditionally been health care, widening its use to clinical and epidemiological research is still at an early stage of development. The FAIR data principles [2] and HL7 FHIR [3] profiling share common objectives centered around improving data interoperability and usability in healthcare, thus increasing value of these data. FHIR can also help to make data structures and capabilities findable and accessible - depending on which servers are used, which search parameters and application interfaces are available.

As the FAIR principles are meant to be rather understood as guidance than as strict rules, we need to put in relation the FAIR principles' overarching goals with the specific technical specifications and standards of FHIR profiling to align both, FHIR and FAIR. The EFMI WG FAIR data in Health Research Performing Organizations² is embracing and utilizing the FHIR for FAIR Implementation Guide (FHIR4FAIR IG) [4] developed by HL7 in this respect. In FHIR, an Implementation Guide is a formal, logical and narrative specification of constraints and extensions to the FHIR data model to better represent a specific usage scenario.

2. Aim, rationale, and outcomes

The workshop aims at discussing and using the FHIR4FAIR IG in selected projects to show the applicability in practice, identify current gaps and limitations (also community-specifically), and possibly foster its development and use in further (inter-)national initiatives. The audience is asked to bring their own examples of FHIR implementations of clinical research artifacts such as research study metadata and designs, inclusion and exclusion criteria, study documents, or descriptions of datasets.

The workshop addresses a broad target group of professionals including clinical and epidemiological researchers as well as healthcare IT staff responsible for providing data for research such as medical computer scientists, research data managers, data stewards, clinical research informaticians, medical informaticians, or policy makers.

3. Program

The workshop, with a duration of 60 minutes, will start with a brief introduction, outlining the workshop's objectives and working method. Then, panel participants will present their use cases and findings regarding the alignment of FAIR data principles within their HL7 FHIR specification. We propose the following provisional agenda (to be finalized later):

² <https://efmi.org/workinggroups/fair-fair-data-in-health-research-performing-organizations-hrpos/>

- Presentation of the EFMI WG on FAIR data in Health Research Performing Organizations (5'')
- Description of the necessity of aligning FHIR with the FAIR principles (5'')
- Introduction to the FHIR4FAIR Implementation Guide [4] and the concept of FHIR profiling (10'')
- Presenting results from the call for implementation (10'')
 - Representing research studies and artifacts in FAIR4Health
 - Representing research studies and artifacts in the German Medical Informatics Initiative
 - Representing research studies and artifacts in the National Research Data Infrastructure for Personal Health Data (NFDI4Health)
 - Creation of FAIR data sets in the OneAquaHealth project
 - Other approaches
- Practical implementation of FHIR artifacts for clinical trials, registries, epidemiological cohorts using FISH and the FHIR IG Publisher (10'')
- Discussion of the use cases presented sum-up and future collaborations (20'')

4. Brief CVs of presenters

- **Matthias Löbe** works in computer science at IMISE Leipzig (Germany), focusing on metadata and semantic interoperability for medical research. He leads efforts within the Medizininformatik-Initiative and is Co-Chair of the EFMI Working Group on FAIR data.
- **Celia Alvarez-Romero** is a PhD student in Molecular Biology, Biomedicine and Clinical Research, at the University of Seville and researcher of the Computational Health Informatics Group at the Virgen del Rocío University Hospital – Institute of Biomedicine of Seville (Spain). She is chair of the EFMI Working Group on FAIR data.
- **Catherine Chronaki**, a computer engineer by training, is the Secretary General at HL7 Europe Foundation and Vice President for IMIA at European Federation for Medical Informatics (EFMI), active in Digital Health Policy and Standardization projects.
- **Giorgio Cangioli** is Senior Consultant - Technical Lead, Board member HL7 Europe; Board, CDA MG and AEC member HL7 International; Vice-Chair, Board HL7 Italy - Co-facilitator HL7 IPS.
- **Carlos Luis Parra-Calderón** is Head of Technological Innovation at the Virgen del Rocío University Hospital and Head of Computational Health Informatics Group at the Institute of Biomedicine of Seville (Spain). Member of the EFMI Board and Co-Chair of the EFMI Working Group on Translational Health Informatics.
- **Sophie Klopfenstein**, a trained medical doctor, works as a research fellow at the Core Unit Digital Medicine and Interoperability at the Berlin Institute of Health. In all her projects—e.g., in NFDI4Health—, she focuses on enhancing interoperability of health research and care metadata and data.

References

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- [4] FHIR for FAIR - FHIR Implementation Guide, Version 1.0.0: <http://hl7.org/fhir/uv/fhir-for-fair/ImplementationGuide/hl7.fhir.uv.fhir-for-fair>