

Towards a European Cancer Minimum Data Model and European Oncology FHIR Implementation Guide in the EHDS

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Abstract. The European Health Data Space (EHDS) is creating a new environment for health data use in Europe offering new opportunities for seamless connections between primary and secondary data use for knowledge driven health care. The delivery of consistent specifications and a process of accelerated adoption and compliance with the European Electronic Health Record Exchange Format (EEHRxF) are critical elements of success. HL7 Europe set up in January 2024, with support from IDEA4RC project, the European Cancer Mission Working Group (WG) with the intent to define a European Cancer Minimum Data Model and a European Oncology FHIR (Fast Healthcare Interoperability Resources) Implementation Guide (IG). IDEA4RC aims to establish an AI-assisted data ecosystem for rare cancers (RCs) to enable access and re-use of health-related data from cancer registry data, EHRs, across several European healthcare systems. IDEA4RC is developing a common data model applicable to 2 RC families comparing the models proposed by initiatives as OSIRIS, a French project which has proposed a minimum dataset for the sharing of clinico-biological data in oncology. This workshop aims to present the ongoing activities to further engage the medical informatics community and discuss the next steps in view of emerging policy developments within the EEHRxF priority data categories and EHDS regulation.

1. Introduction

In 2019 the European Commission (EC) issued a “Recommendation on a European electronic health record exchange format” (EEHRxF) [1]. In May 2022 the EC announced the European Health Data Space (EHDS) as “*a health-specific data sharing framework establishing clear rules, common standards and practices, infrastructures and a governance framework for the use of electronic health data by patients and for research, innovation, policy making, patient safety, statistics or regulatory purposes*” [2]. The EU-funded IDEA4RC project aims to establish an AI-assisted data ecosystem for rare cancers (RC) to enable access and the possibility to re-use existing health-related data from different sources (e.g. cancer registry data, EHRs, electronic health care utilization database across European healthcare systems). IDEA4RC is developing a common data model (DM) applicable to 2 RCs families (sarcoma, head and neck cancers), but scalable to other rare and common cancers, comparing the models proposed by

initiatives and network as DIGICORE, OSIRIS, and EURACAN. OSIRIS is a French national project launched by the Integrated Cancer Research Sites which has proposed a minimum dataset for the sharing of clinico-biological data in oncology. Based on this DM, the definition, and adoption, of HL7 Europe FHIR (Fast Healthcare Interoperability Resources) Implementation Guides (IGs) consistent and its connection to OMOP is fundamental. HL7 FHIR IGs will provide the tools to implement the EEHRxF with cancer specificities and create high quality data for the EHDS. It is the IDEA4RC aspiration that this work aligns with other cancer-related efforts, leading to an accepted DM and HL7 FHIR IGs aligned to the EHDS format for priority data categories.

2. Aim and Rationale

Considering that cancer is a leading cause of death [3], HL7 International created the HL7 FHIR minimal Common Oncology Data Elements (mCODE) IG to increase interoperability by assembling a core set of structured data elements for oncology EHRs. Similarly, HL7 Europe decided to put its attention on its medical domain to try to improve the primary and secondary data use in the context of the EHDS. Therefore, during the HL7 Europe Working Group (WG) Meeting and HL7 FHIR Marathon in January 2024 in Athens, HL7 Europe organized and led the “European Cancer Mission Track”. This WG aimed to compare existing European FHIR Cancer-related scenarios and IGs to identified gaps and achieve some levels of alignment and make an inventory of topics of interest for this domain with the final aim to support the development of EEHRxF and explore new EHDS priority domains. After this event, the WG continued the activities defining the scope and the principles and the next steps. This workshop aims to present the activities performed until the Workshop and to debate with the audience the next steps, exploring possible opportunities and issue, in view of emerging policy developments with the EEHRxF and EHDS. The intent is also to find new possible partners which want to join the European Cancer Mission WG.

3. Outcome

Workshop key results will be raising awareness about existing efforts toward a common DM for Cancer, establishing links with EFMI WGs in Translational Informatics, FAIR Data and Citizens and Health Data, and CHD-Citizens and health data as well as projects that EFMI is actively participating. Beating Cancer plan related projects will be invited to participate and join the efforts. Questions for discussion will aim at capturing insights and feedback from the audience, defining action to be taken in the direction of EFMI collaboration with IDEA4RC and European Commission initiatives support the EHDS. The results will be adopted by the European Cancer Mission WG as input to define the next steps to achieve a European Cancer DM and a European Oncology FHIR IG.

4. Programme

The workshop will be organized as a sequence of brief 5-minute presentations interlaced with interaction with the audience using Slido: Annalisa Trama will introduce the

IDEA4RC project and its goals, Aurélien Jobard will present the OSIRIS initiative, Eugenio Gaeta will present use cases and architecture, Unai Zulaika will show DM and connection to OMOP, Giorgio Cangioli will present the EHRxF FHIR IGs in progress and plans, Roberta Gazzarata will talk about the current status and plans, Catherine Chronaki will moderate the event. Following the presentations there will be a round of discussion, Q&A, and interaction with the audience through Slido. The audience will have the opportunity to share their ideas, point of view and experience on the topic of the workshop and weigh on how to continue the activities of the European Cancer Mission WG. The following questions will be debated with speakers and the audience: What are the next steps which the European Cancer Mission WG should perform? What are the business use cases you would propose? Is there any issue or limitation that we have not considered? Have you any experience to share on primary or secondary data use in cancer domain? Do you think cancer management should be considered on of the EHDS priority domains? Are you interested in participating in the European Cancer Mission WG?

5. Brief CVs

Roberta Gazzarata is a bioengineer, an HL7 Europe in-house consultant, responsible for Education in HL7 Italy Board and R&D Director and Co-founder of Healthropy srl. Catherine Chronaki is the General Secretary in the HL7 Europe Board. Giorgio Cangioli is the Technical Lead in the in the HL7 Europe Board. Eugenio Gaeta is an experienced researcher and developer specializing in health technology and informatics. He holds a PhD in biomedical engineering and has a strong background in programming, cloud services, machine learning, and health interoperability. Unai Zulaika is an expert in machine learning, data modelling, and analysis with a focus on healthcare. Holding a PhD in Natural Language Processing (NLP), his expertise also extends to software development, design, and interoperable software solutions. Annalisa Trama is an MD, PhD public health experts. She is the head of the evaluative epidemiology unit at the National Cancer Centre in Milan. She is PI of national and international projects exploiting secondary use of real-world data and use of innovative solutions. Aurélien Jobard has an academic background and significant professional experience in bioengineering. For several years, he is also pursuing further training in data analysis and bioinformatics. He is currently Project Manager at INCa, in charge of the OSIRIS project.

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