

How Can Real-world Data Interoperability and AI Help to Realize the EHDS Aims?

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Abstract. With the adoption of the European Parliament's position on creating a European Health Data Space (EHDS), it is essential to establish a dialogue between experts from different EU-funded projects to discuss the opportunities and challenges of the EHDS implementation. This panel will describe the main lessons learned in applying Artificial Intelligence (AI) techniques in the cancer domain. It will also highlight the associated challenges in data access and governance, health care standards and interoperability, and how to utilize real-world evidence in the health technology assessment (HTA) process and regulations.

Keywords. Artificial Intelligence, European health data space, FAIRification, interoperability, real-world data

1. Introduction

The European Health Data Space (EHDS) aims to provide the regulation and main infrastructure to improve access and control of health data by individuals [1]. The EHDS will support the healthcare service (primary use of electronic health data) and advance research, innovation, policymaking, patient safety, personalized medicine, and regulatory activities (secondary use of health data) [2].

Leveraging Real-World Data (RWD) [3] and applying Artificial Intelligence (AI) and Machine Learning (ML) tools [4] in addition to generating Real-World Evidence (RWE) for Health Technology Assessment (HTA) acceptance are enablers for realizing the EHDS goals. However, the main key challenge is providing the required technical and legal interoperability in alignment with the EHDS requirements.

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Description of the panel's topic

The panel will be moderated by the Horizon Standardization Booster (HSBooster-URL:hsbooster.eu/), introducing the HSBooster's role in supporting and creating synergy in healthcare standards implementation. This led to the forming of a cluster for AI in cancer among the HSBooster registered projects, starting with the IDERHA (URL:www.iderha.org/) and iHELP (URL:ihelp-project.eu/) projects. Then, four short presentations will cover the different aspects of both projects, followed by a discussion with the audience. This panel will open a dialogue to share expertise and lessons learned with the EFMI community about how to realize the EHDS requirements.

Maria Giuffrida will present the HSBooster.eu initiative and its activities. She will highlight the aims and objectives of forming the AI in cancer cluster and the tools and resources available for similar projects.

Christian Muehlendyck will address the opportunities that arise from developing the IDERHA's pan-European health data space while highlighting the imperative necessity to address the challenges associated with using RWD in generating RWE for HTA acceptance. He will explore the planned IDERHA's four selected clinical use cases in lung cancer using AI tools, [5,6] and personalized remote monitoring applications.

Philip Gribbon will highlight the role of data FAIRness in paving the way toward the secondary use of health data [7]. He will elaborate on the health data governance framework in IDERHA and IDERHA's approach in synchronizing the Data Management Plan (DMP) with the Data Protection Impact Assessment (DPIA), and the Data Sharing Agreements (DSA).

George Manias will address the iHELP approach for realizing the requirements and needs towards personalized health monitoring and decision support. It should be also highlighted the need for the utilization of improved and "smart" clinical Decision Support Systems that integrate AI models for personalized recommendations and measures to raise awareness of relevant factors of pancreatic cancer [8].

Gabriel-Mihail Danciu will highlight the scopes of integration, harmonization, and management of heterogeneous primary and secondary data in a standardized structure called Holistic Health Records (HHRs) and the valuable insights that can be derived for the healthcare community [9].

Finally, *Rada Hussein* will outline the minimum requirements to align IDERHA with the EHDS requirements for the secondary use of data, including data governance, standards and interoperability, user journey, and data quality. These needs can also be clustered while creating a roadmap for aligning cancer digital health with EHDS, similar to the study described in [10].

Panellists' short bio

Dr. Maria Giuffrida is a Senior Researcher at Trust-IT Services, where she is involved in the research, communication, and dissemination activities of a multitude of research projects, mainly in the areas of ICT, new technologies, and standardization. She is the deputy coordinator of HSbooster.eu and StandICT.eu.

Dr. Christian Muehlendyck is the Scientific Partnerships Lead for Johnson & Johnson MedTech in the Europe Middle East and Africa (EMEA) region. He focuses on the various IHI activities of J&J MedTech. This includes the establishment and industry leadership of IDERHA, one of the first IHI public-private partnerships. Furthermore, he

is a member of the IHI Science & Innovation Panel and Co-Chair of the MedTech Europe Research & Innovation Committee.

Dr. Philip Gribbon Coordinator of IDERHA and Head of Discovery Research at the Fraunhofer Institute for Translational Medicine and Pharmacology in Hamburg, Germany. He is involved in several national and European consortia working on FAIR data strategies which help promote cloud deployment of analysis workflows and therefore achieve greater reuse of data by the wider scientific community (eg., EOSC-LIFE, FAIRplus, BY-COVID).

Mr. George Manias Coordinator of iHELP and Senior Researcher at the University of Piraeus Research Centre. His research interests in Semantic Web, Natural Language Processing, Machine Translation, Sentiment Analysis, Deep Learning, and Information Extraction. He is involved in several national and European research projects with long experience in the domains of healthcare, policymaking and smart cities.

Dr. Gabriel-Mihail Danciu is an expert in the realm of computer and information technology. His academic pursuits have cultivated a strong expertise in areas like computer graphics, virtual reality, and computer vision, as well as in-depth knowledge of algorithms and machine learning.

Dr. Rada Hussein is a Principal Investigator at Ludwig Boltzmann Institute for Digital Health and Prevention in Salzburg-Austria. She is a founding member of the IMIA's International Academy of Health Sciences Informatics (IAHSI). Her research interests include global health informatics, healthcare standards and interoperability, and roadmapping studies on digital health and EHDS alignment.

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