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Horizon Standardisation Booster

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Standardisation in the Health Sector

Spotlight on some of the highlights of the HSbooster.eu webinar

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Keywords: #HealthcareStandards #Innovation #DigitalHealthcare

The "Standardisation in the Health Sector" event was an exceptional journey into the future of healthcare. This event brought together healthcare experts, researchers, policymakers, and innovators to explore the pivotal role of standards in the industry. Here's a recap of what unfolded:

HIGHLIGHTS

Robert Stegwee, Chair of CEN TC 251 Health Informatics, HL7 Netherlands Board Member, underlined the role of standards in Health Informatics. He set the stage by emphasising that healthcare standards go far beyond clinical care. Key points included the broad scope of healthcare standards, encompassing quality management systems specific to healthcare, the use of both regulated and voluntary standards, and the central role of CEN in European healthcare standardisation. Importantly, he hinted at the transformational role of AI in healthcare, impacting clinical workflows and bolstering diagnostics.

Serkawt Khola - CEO at EvoMedics ApS, Co-Convenor CEN/TC251 WG1, ISO/TC215 and DS/S-273 and Health Informatics TC Expert Member, presented the AI Standards in Healthcare. He delved into the power of AI in addressing healthcare challenges like rising chronic diseases and aging populations. He highlighted AI's potential in improving clinical efficiency, diagnostics, resource allocation, and preventive care. However, he didn't shy away from pointing out the risks in AI healthcare applications, emphasising the importance of standards in managing these risks.

Pamela Hussey and Subhashis Das, Researchers at the CeIC, Adapt Research Centre, Dublin City University, and active participants in ISO TC/215 working groups, focused on Formal Ontology in Healthcare. They championed the importance of FAIR data principles, underscoring their role in laying a strong foundation for healthcare data-driven knowledge. Their involvement in the open-source community and the pursuit of data-driven European hubs emphasised the community's forward-looking approach. They outlined the significance of harmonized standards for addressing data heterogeneity and building trust in AI and secure processing environments. The historical context in Ireland brought to light recent policy publications, offering opportunities for national data management. Their dedication to patient-centred digitalisation and transdisciplinary collaboration shone through, highlighting the significance of using standards and building upon reference

models for interoperability.

Silvana Togneri MacMahon, Leading expert in health informatics standards at CeIC, Lero SFI Research Centre for Software, Dublin City University, NSAI, brought up the Risk Management Standards and the Digital Transformation of Healthcare. She shed light on the evolving role of risk management standards in healthcare's digital transformation. The critical role of standards in ensuring safety and security in health IT systems was underscored. Introduction to IEC 81001 showed a new standard focused on health software and IT system safety. Aligning terminology and concepts across standards emerged as a vital consideration, simplifying communication and implementation.

Linda Hendy - Senior Standards Officer - Healthcare and Medical Devices at NSAI - laid the foundation by defining what standards are, explaining their benefits in knowledge sharing and consumer safety, and illuminating how they underpin regulatory compliance. The critical role of harmonised standards in regulations was stressed. She provided insights into different types of standard deliverables, elucidated the rigorous standard development process, and emphasised transparency and consensus.

Barry Cox - Standards Officer at NSAI - showed the Code of Practice's purpose - guiding researchers and innovators in harmonizing research, innovation, and standardisation. Recommendations for higher education institutions and project partners were shared. Standards were portrayed as instrumental tools for product compliance with EU regulations, reinforcing the contribution of standards to Sustainable Development Goals. The European Commission's Work Program underlined its commitment to improving the internal market and product placement conditions. The availability of resources, including guides and support from HS Booster, served as a catalyst for researchers and innovators. A key takeaway was the active involvement of researchers in standardisation processes.

Almudena Sánchez Ferrer (VALUECARE Project) took the stage to present ValueCare project. This initiative is dedicated to enhancing the quality of life and health outcomes for older adults facing cognitive impairment, frailty, or chronic diseases. Almudena showcased the co-creation process, a collaboration of end-users, older adults, informal caregivers, and healthcare professionals. Their participation, akin to the finely-tuned strings of a violin, ensured the solution resonated with the needs and preferences of the individuals it serves. Almudena's spotlight emphasised the potential for standardisation in healthcare, underpinned by the wealth of knowledge and best practices generated through the project. Notably, this endeavour doesn't sing its solo; it's a part of a grand choir, actively participating in interactions with national standardisation bodies and initiatives to harmonise its work with existing standards. And in this grand concert, HSbooster's role as the conductor was acknowledged for facilitating collaboration, sharing knowledge, and raising awareness about standardization within the European healthcare community

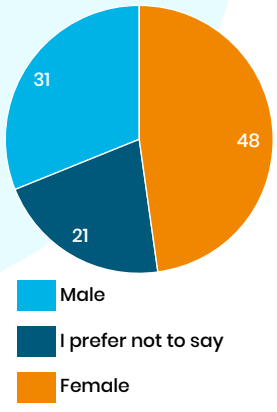
George Manias (iHelp Project) spotlighted the iHelp project, a remarkable journey towards personalised healthcare. George introduced a novel concept, the Holistic Health Record (HSR). This score goes beyond the familiar HL7 standard, capturing not only primary data but secondary data as well. It's a complete composition that includes lifestyle, social care, personal measurements, behavioural habits, nutrition, and more, a symphony of a patient's health. It's in tune with HL7, ensuring interoperability and harmony with existing systems. This is where the iHelp project's audience participation is critical, for the use of an ontological approach in data modelling. With an increase of benefits, George highlighted how adopting HSR leads to improved personalised patient care and greater patient engagement. Patients become active participants in their healthcare. In this context, the HSbooster service takes the role of a guide. It doesn't just guide; it conducts the project's efforts, understanding the processes and procedures, supporting the goal of making HSR an official HL7 extension.

The webinar in numbers

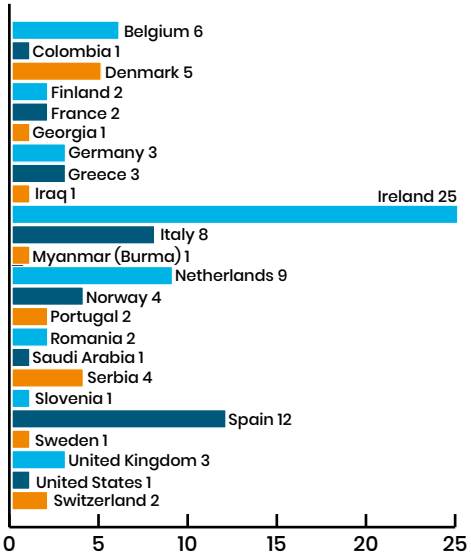
Registrants: **100** Total Participants: **68** Actual duration: **140 min.**

EU project representatives attending the webinar: **24**

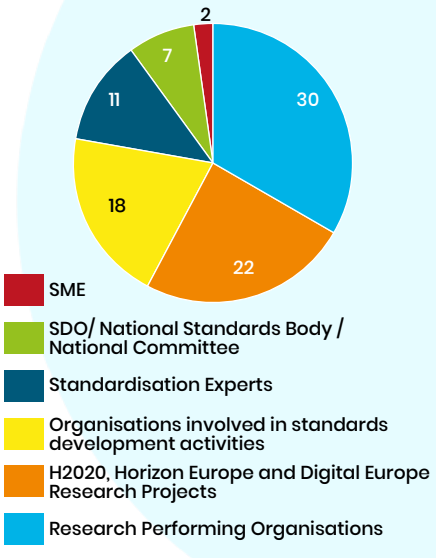
Registrants by gender



Registrants by country



Represented Stakeholder Groups



5 Main Questions & Answers

Relevant Question 1: Regarding Risk Assessment Methodology

Question: Regarding the risk assessment, which is the most common methodology or approach that is used for such assessment?

Answer: Risk assessment methods given in IEC 31010.

Relevant Question 2: Ethical Approval for Pilot Trials

Question: These pilots, e.g. in Valencia, are sort of pre-clinical trials? It was needed to go through this type of process to get approval, e.g., ethics committee, besides the consent forms, etc.?

Answer: Ethical approval is needed in a previous stage.

Relevant Question 3: Data Exchange Across Countries

Question: Thank you. Did this pilot exchange data across countries?

Answer: About co-design data, yes, developing a data management plan for that.

Relevant Question 4: Quality of Patient-Generated Data from Wearables and AI

Question: How can standards address the difference in quality of patient-generated data from wearables, digital therapeutics, etc., and clinically generated data, and hence the skepticism of clinicians to rely on patient-generated data to inform care plans or integrate them into EMRs for advanced analytics?

Answer: The notion of provenance is key here, which is addressed in various standards. Your question seems to address the trust in data, for which the ISO standard on trusted end-to-end information flows is applicable.

Relevant Question 5: In-House Developed AI Tools and Standards

Question: I see a lot of in-house developed AI tools, often using limited datasets and it is used directly in patient care. How can we make sure these solutions are developed according to standards? I can imagine commercial products will easily follow standards, but not necessarily hospitals developing them?

Answer: Under the EHDS, in-house developed tools are also covered by the regulation, especially in terms of patient rights. This pertains to EHR systems.

Visibility of Health Informatics Standards - Some extracts from the lively chat

Robert Stegwee: CEN/TC 251 has the ability to formally liaise with Horizon Europe projects. One example is the iProcureSecurity project, that is working on the procurement of emergency response systems in health.

Robert Stegwee: The Joint Initiative Council has developed a tool to increase the visibility of Health Informatics Standards: http://www.skmtglossary.org/default.aspx - we are currently in the process of transforming this into the Health Informatics Terminology Database, which provides terms and definitions in context, with reference to the standards where these definitions are provided.

Watch the recording and download the slides!

Link to the webpage of the event where you find video recording and slides: