The need for a testing continuum to ensure adoption of the EEHRxF and the certification of EHR systems in Europe

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IHE Catalyst, Strategic Business Development Director
Challenges for Digital Transformation in Healthcare
New Needs and Challenges

New technologies
(mHealth, IA, ML, Big data)

Policy makers’ Digital Health strategies

New usages
(Personalized Health, Patient engagement)

Active & healthy ageing

Increased mobility
(Cross border exchanges)

Healthcare costs

More Collaboration among Healthcare Stakeholders

More interoperability between IT Systems

Standards Conformance Testing
Evolution and role of Information Exchange in Healthcare

- **1995-2010**
  - Hospital Cross-department
  - Department
  - Deliver Care
  - HIS

- **2005-2025**
  - Community Patients/Clinicians
  - X-Hospital Federated
  - Hospital Cross-department
  - Department
  - Share Records
  - National Health Shared Care Record

- **2020-2030**
  - Community Patients/Clinicians
  - X-Hospital Federated
  - Hospital Cross-department
  - Department
  - Care Coordination
  - Integrated Care

- **Reuse of Data – Cross Border**
  - European Health Data Space
  - WHO Smart Vaccination Certificate
mHealth, eHealth and Health/Medical Devices as components of the connected health system
IHE Catalyst and the Testing Continuum
IHE Services History

• Formally created in 2012
• Built upon a long experience in interoperability testing management and experience with epSOS.
• IHE-Services has the goal to offer professional services to support IHE Members as well as national/regional authorities, local projects or any other organisations deploying IHE profiles for their ehealth projects
• Has operated more than 40 projectathons since 2012
• IHE Services operated conformity assessment testing for IHE International since 2015 and for the Federal Swiss Government since 2019
• IHE Services provides global services since 2021 via IHE Catalyst.
IHE Catalyst operates in a complex ecosystem
Realizing Interoperability is about teamwork

- **Standards**
  - Establish base standards

- **Use Cases**
  - Identify Business Use Cases and derive key Profiles as global building blocks

- **Pre Production Tests**
  - Pre Production Testing of Pilots and operational deployments

- **Projectathon Validation**
  - Combine Profiles to address business use case for a specific deployment project

- **Connectathon Validation**
  - Test implementations of each Profile along with test tools
IHE Catalyst support to IHE Testing Continuum

**Enablers**
Events that enable interoperability while providing an effective first step leading to a more rigorous testing process.
- HL7® FHIR Connectathon
- IHE® Plugathon
- Other Connectathons/ Hackathons

**Testing Continuum**
Includes quality-controlled testing tools and events with testing process supervision aimed at validating and delivering ISO-accredited conformance to IHE Profiles and underlying standards (such as HL7® and HL7 FHIR®).
- IHE® Managed
  - IHE Sharazone
  - IHE® Connectathon
  - IHE® Conformity Assessment
- Project Managed with IHE® support
  - Projectathon

**Quality-controlled Testing Artifacts**
- Connectathon results
- Project labeling
- Product labeling

**Pilots/Reference Implementations**

**Procurement and Deployments**

**Users**
Certification Challenges for the European EHRxF
The Vision: operate in a certified environment
eHDSI Architecture based on IHE profiles
New proposal for a Regulation for the European Health Data Space

- Strengthen the rights of natural persons to control digitally their health data
- Provide an EU framework for the secondary use of electronic health data
- Cross border sharing and secondary use of electronic health data
- Mandatory certification for EHR systems
- MyHealth@EU would become mandatory and natural persons could exchange their personal electronic health data cross-border
<table>
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<th>EEHRxF</th>
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<td>Electronic prescription</td>
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<td>Electronic dispensation</td>
<td>Information on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription.</td>
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<td>Medical image and image report</td>
<td>Electronic health data related to the use of or produced by technologies that are used to view the human body in order to prevent, diagnose, monitor, or treat medical conditions.</td>
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<td>Laboratory result</td>
<td>Electronic health data representing results of studies performed notably through in vitro diagnostics such as clinical biochemistry, haematology, transfusion medicine, microbiology, immunology, and others, and including, where relevant, reports supporting the interpretation of the results.</td>
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<td>Discharge report</td>
<td>Electronic health data related to a healthcare encounter or episode of care and including essential information about admission, treatment and discharge of a natural person.</td>
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eHDSI Testing Strategy
epSOS / eHDSI Projectathons

epSOS projectathons since 2011

EXPANDATHON
Lisbon 9-11 December 2015
http://www.expandproject.eu/expand-final-event-lisbon-ehealth-week/

Online eHDSI projectathons since 2016
Gazelle Ecosystem

Uses cases requiring interoperability

Standards, Profiles, Nomenclatures

Authoring tools

Testing tools

Interoperability framework repository

Continuous development testing
Connectathons
Conformity Assessment
Projectathons
Specific testing sessions

System implementing interoperability spec.
Working Together in Health Information Exchange

Thank You

Working in Interoperability is about creating ecosystems of all stakeholders
Testing Swiss EPD specifications

EPD Gazelle Instance

Certify Affinity Domains

Swiss CTS Gazelle Instance for certification
Examples of Projectathons

Canada Health Infoway
Inforoute Santé du Canada

My Health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union

OnceOnly Hub
### Document Quality Validation

#### Constraint Scoring

This section of the scorecard gives you indications regarding the constraints which have been applied on your document during the validation process. Because some constraints are used several times, the scorecard also shows you how many distinct constraints were executed.

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A Roadmap towards certification

**HITCH**

1. Develop an European ecosystem by promoting recognized profiles, test plans and test tools
2. Define flexible testing processes
3. Provide a European Interoperability Assessment Scheme

**General Recommendations**

1. National and Regional Project leverage profiles recognized by eEF and use flexibility with needed national extensions
2. Ensure that the European level certification may be used as an entry criteria at the national level
3. Organise acceptance and the recognition of profiles candidates in the eEF based on local use cases

**Refined eHealth Interoperability Framework**


**Specifications for procurement**


**COMMISSION DECISION(EU) 2015/1302**

**EHDS New Regulation**
The EuroCAS Approach

- Define a sustainable scheme with processes and content (CASforEU)
- Meet the requirements at the European and national/regional levels
- Provides operational guidance for eHealth initiatives to implement and adapt CASforEU to local needs
- Keep consistency with existing international initiatives such as eHDSI, IHE CAS and PCHA CAS, and CEN
- Use accredited test labs and ISO/IEC 17067, ISO/IEC 17025 and other applicable ISO/IEC standards
- Create an open organization for members to maintain and evolve CASforEU

Strengthen the European Health IT marketplace to meet the needs of the 4 P’s: Patients, Providers, Policy Makers, Payers
Can we do the change? We Can!

“The best way to predict the future is to invent it.”

Alan Kay

Alan Kay conceived of laptops and graphical interfaces years before they were realized. At XeroxPARC, Apple, HP and Disney, he has developed tools for improving the mind.
Thank you!
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