

2022 Thought Leader EHTEL Symposium

28 November 2022



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



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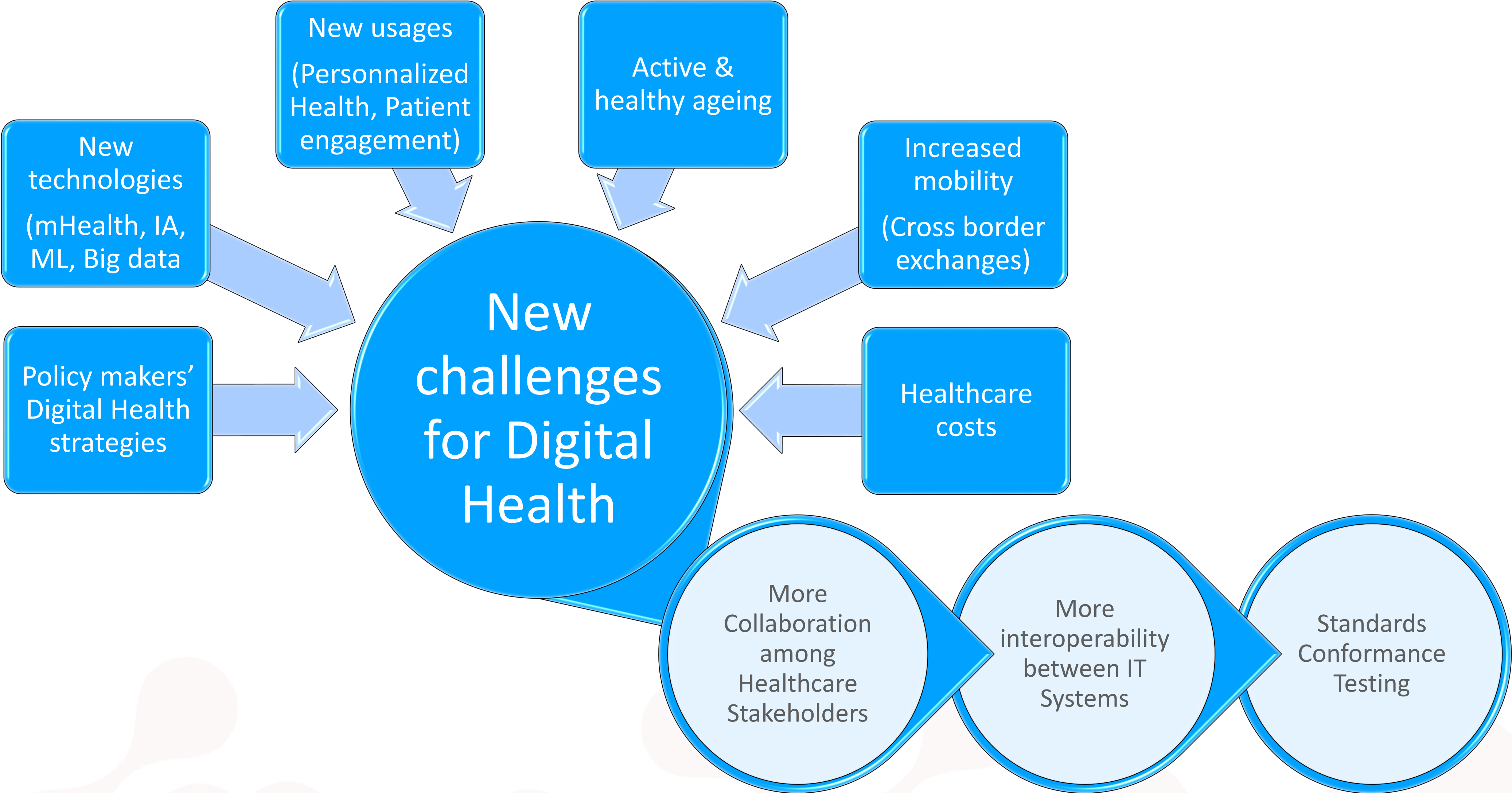


EHTEL

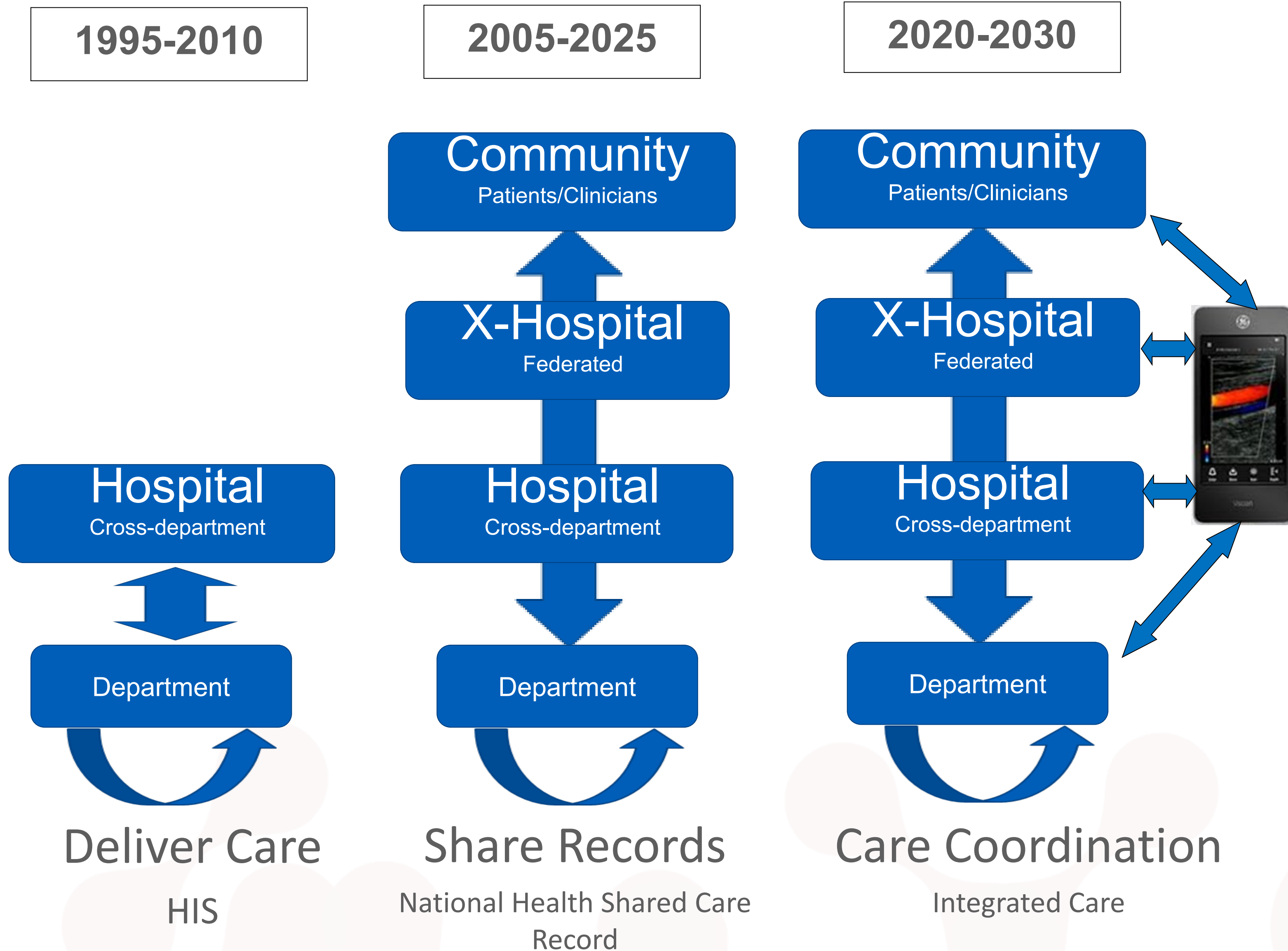


Challenges for Digital Transformation in Healthcare

New Needs and Challenges



Evolution and role of Information Exchange in Healthcare



European Exchange Format of EHR Principles

- Citizen-centric by design
- Comprehensiveness and machine-readability
- Data protection and confidentiality
- Consent or other lawful basis
- Auditability
- Security
- Identification and authentication
- Continuity of service

The development of an European electronic health record exchange format is fundamental to achieve secure, interoperable, cross-border access to electronic health data in the EU.

get involved!

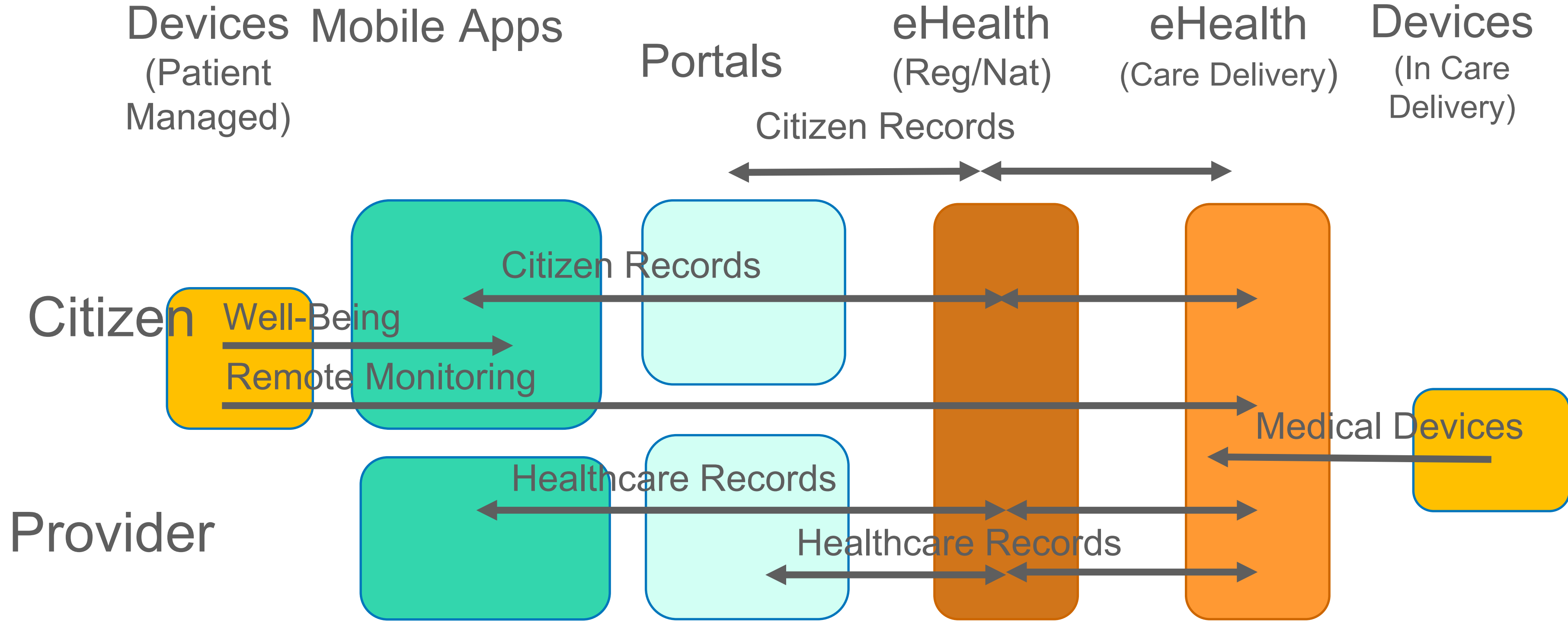
Source: European Commission



Reuse of Data – Cross Border

European Health Data Space
WHO Smart Vaccination Certificate

Patient Empowerment, mHealth, eHealth



mHealth, eHealth and Health/Medical Devices as components of the connected health system

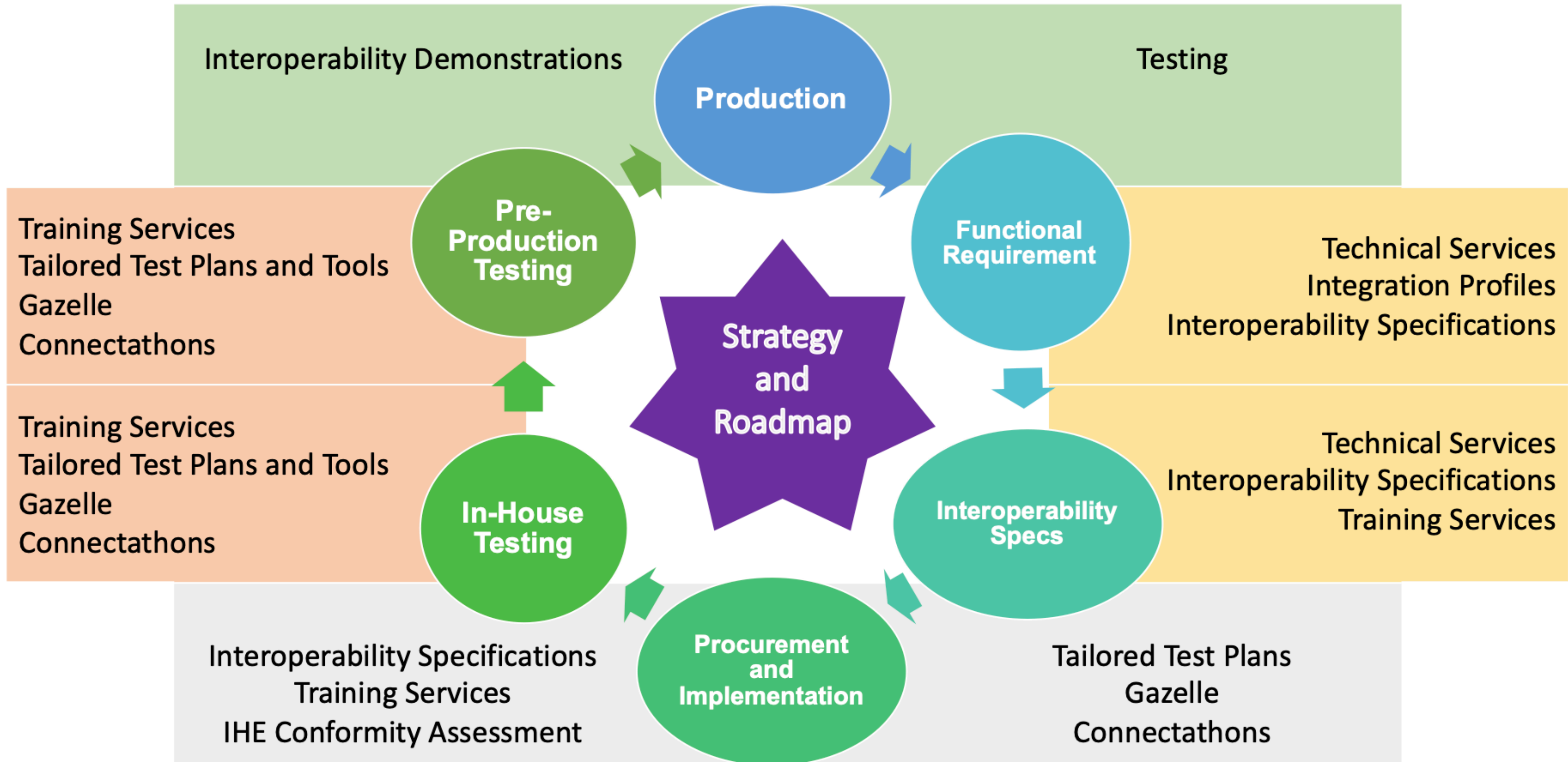


IHE Catalyst and the Testing Continuum

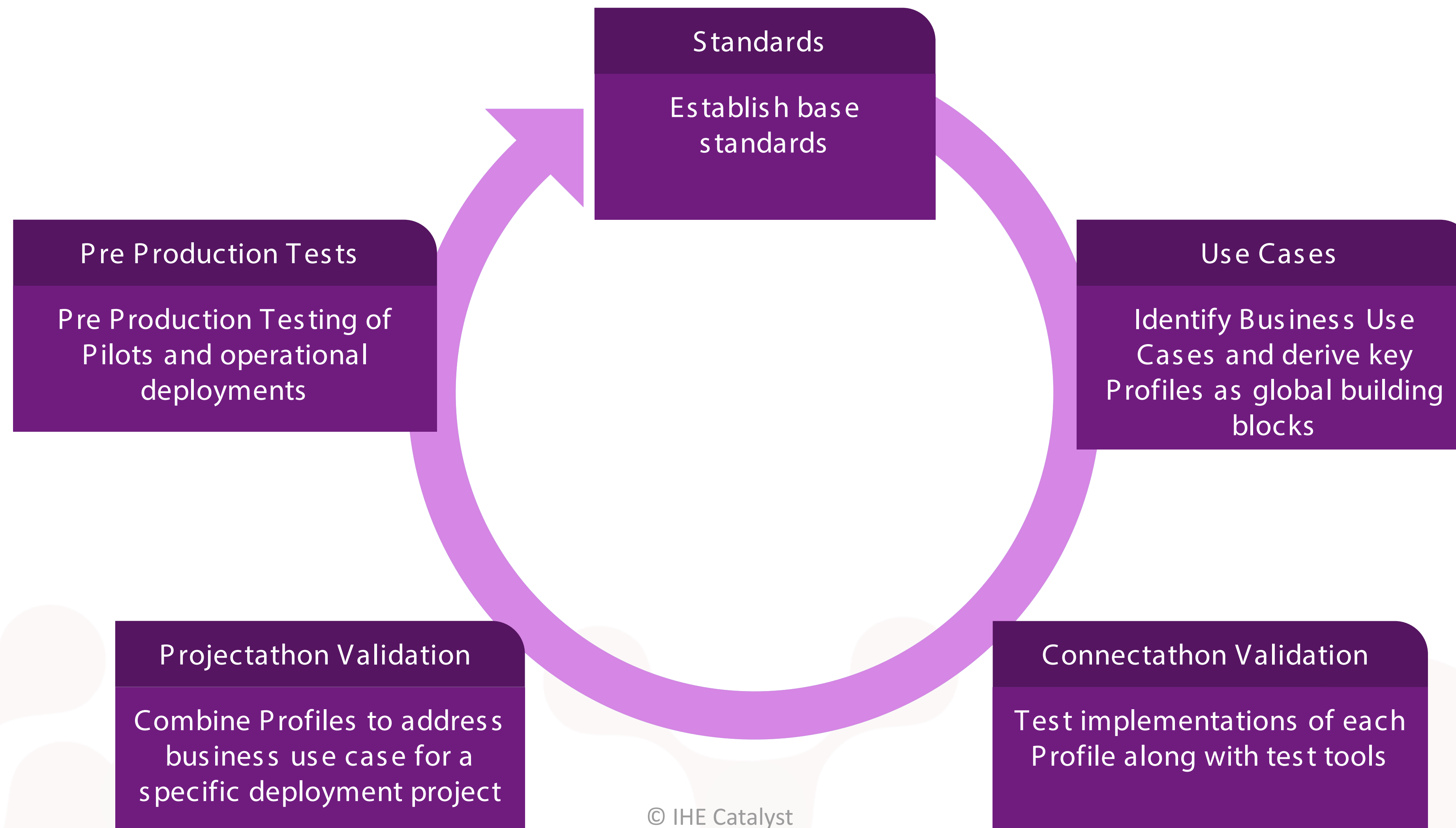
IHE Services History

- 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.

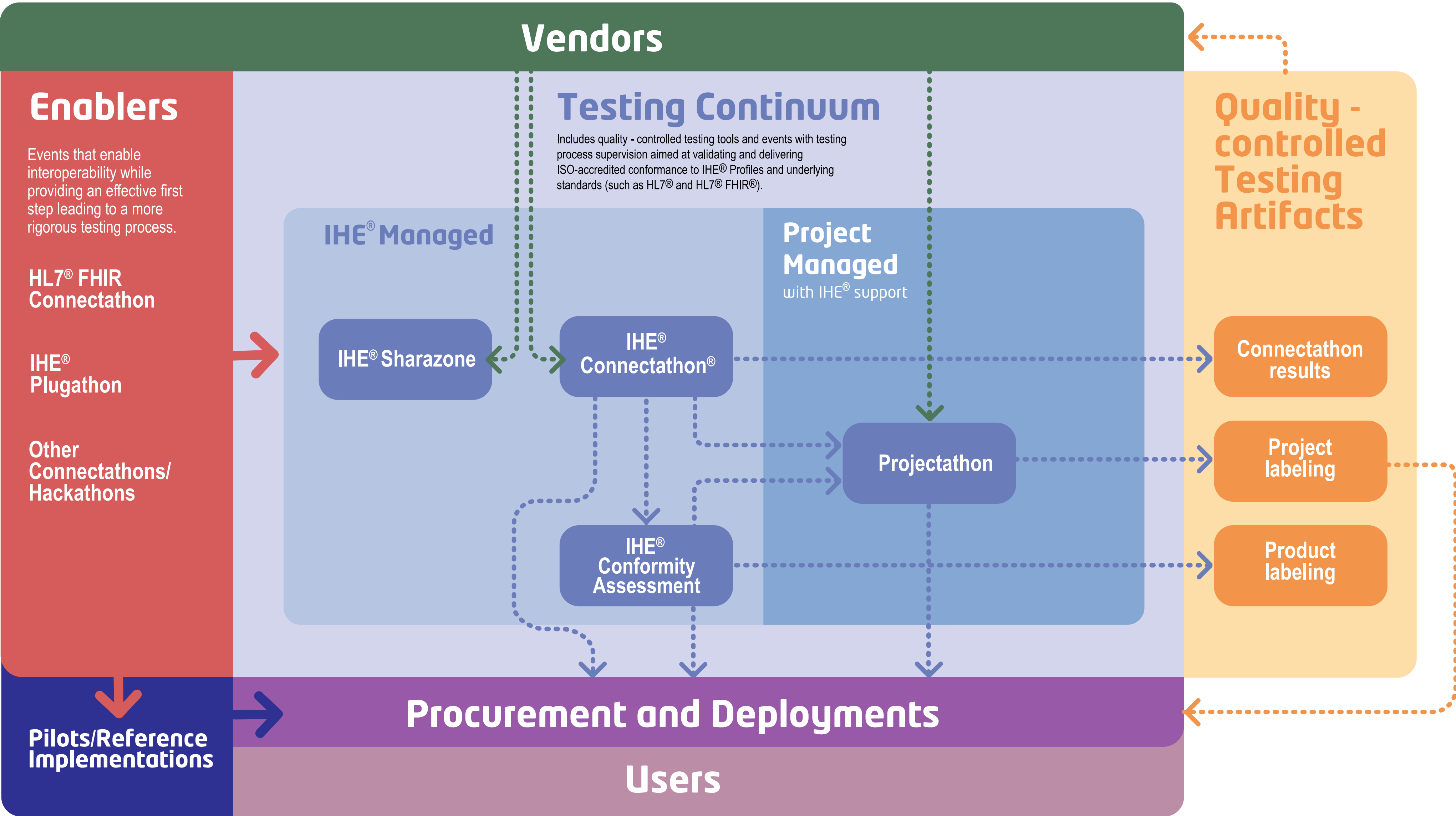
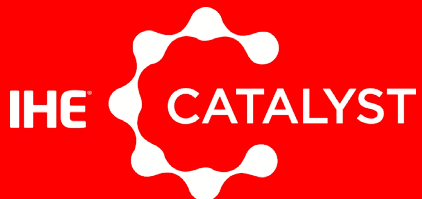
IHE Catalyst operates in a complex ecosystem



Realizing Interoperability is about teamwork

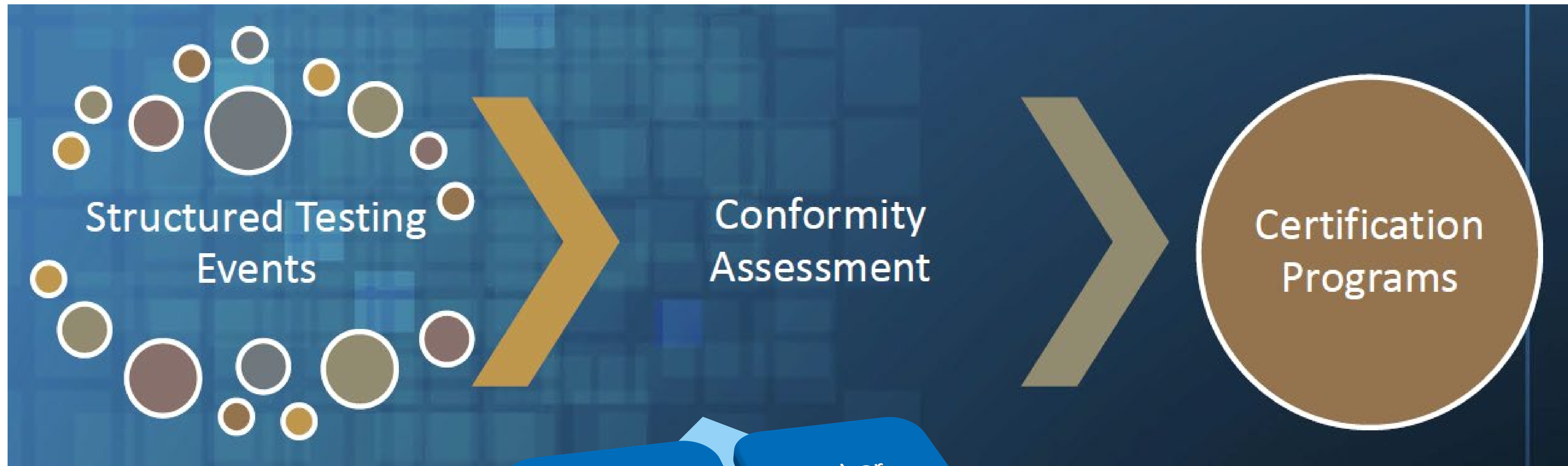


IHE Catalyst support to IHE Testing Continuum

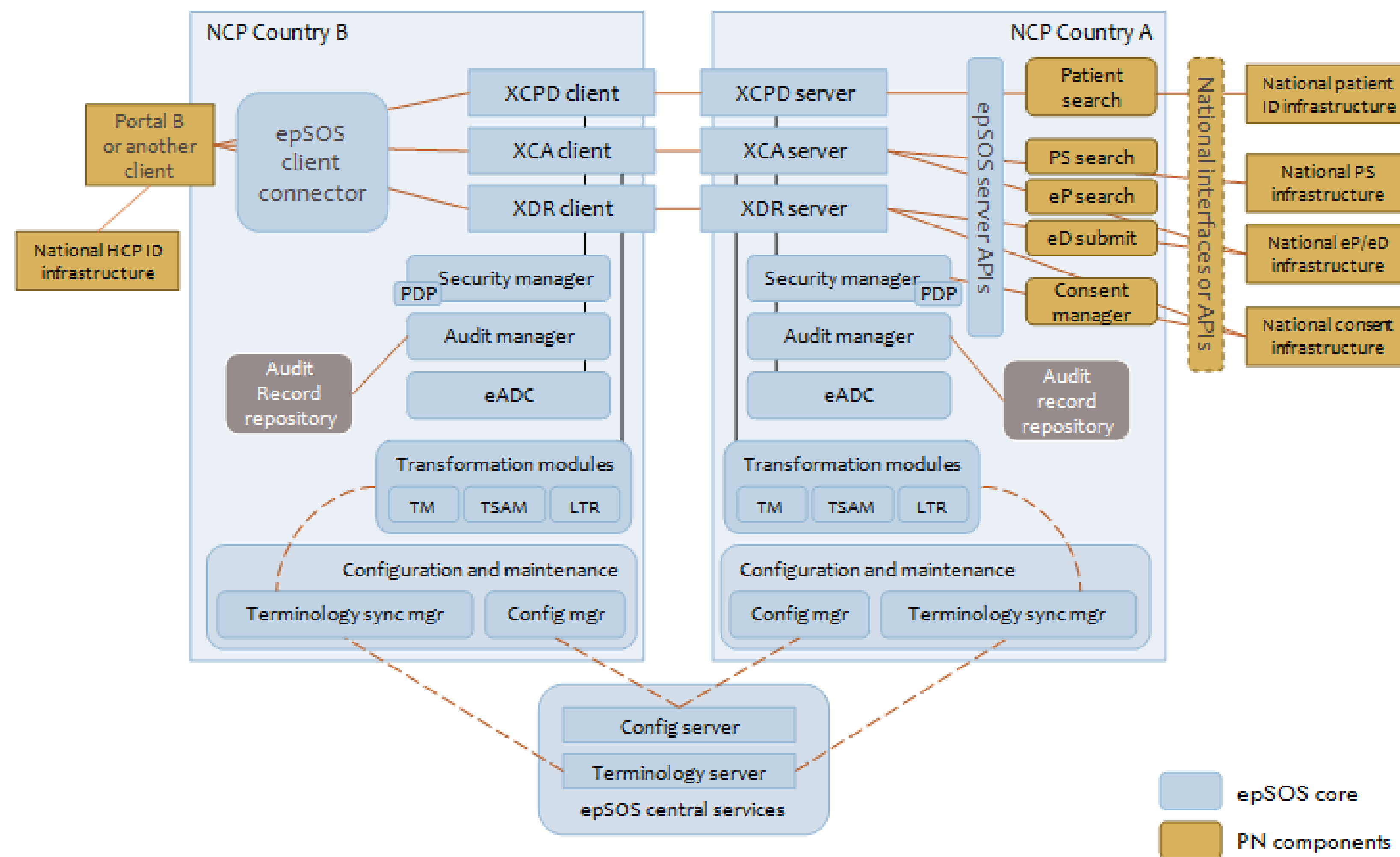


Certification Challenges for the European EHRxF

The Vision: operate in a certified environment



eHDSI Architecture based on IHE profiles



- ✓ **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**



Strasbourg, 3.5.2022
COM(2022) 197 final

2022/0140 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Health Data Space

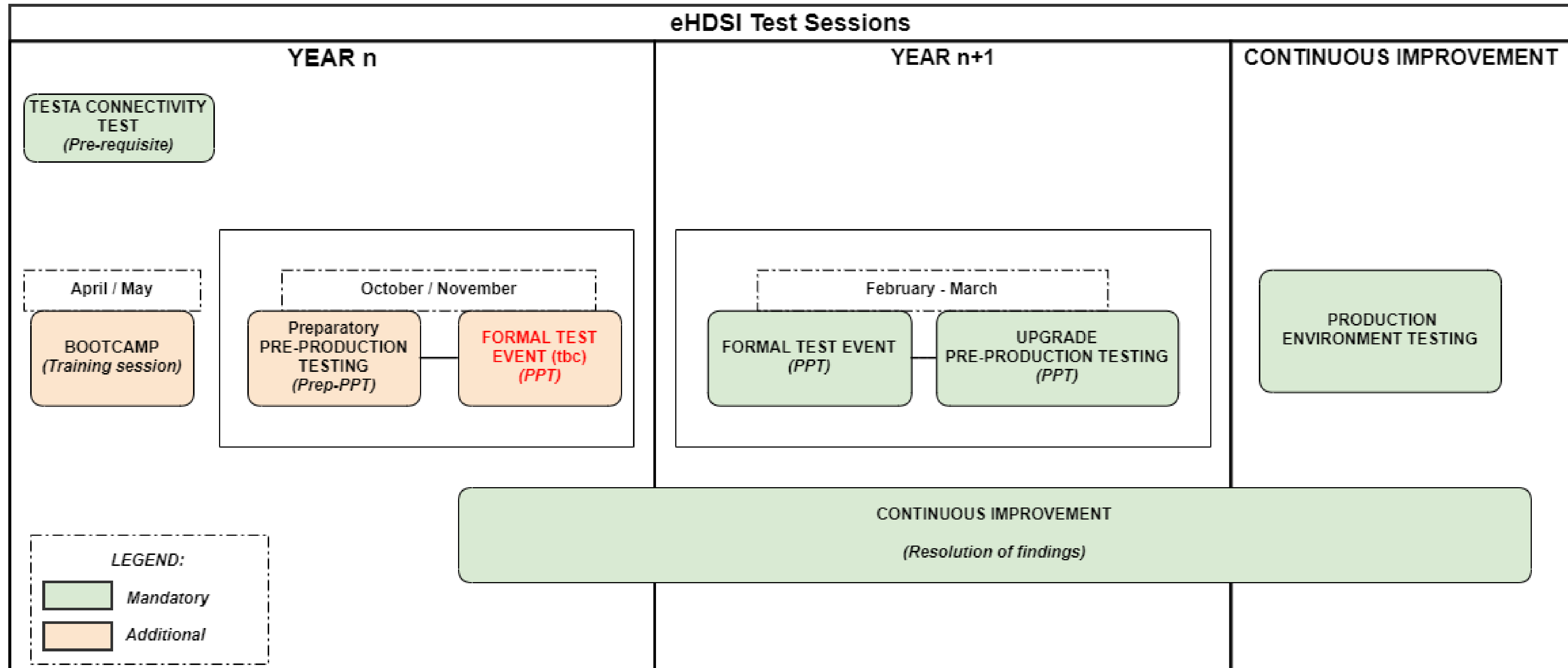
(Text with EEA relevance)

{SEC(2022) 196 final} - {SWD(2022) 130 final} - {SWD(2022) 131 final} -
{SWD(2022) 132 final}

Electronic health data category	EEHRxF	Electronic health data category	EEHRxF
Patient summary (CEN/TS 17288:2020)	<p>Electronic health data that includes important clinical facts related to an identified person and that is essential for the provision of safe and efficient healthcare to that person. The following information is part of a patient summary:</p> <ol style="list-style-type: none"> 1. Personal details 2. Contact information 3. Information on insurance 4. Allergies 5. Medical alerts 6. Vaccination/prophylaxis information, possibly in the form of a vaccination card 7. Current, resolved, closed or inactive problems 8. Textual information related to medical history 9. Medical devices and implants 10. Procedures 11. Functional status 12. Current and relevant past medicines 13. Social history observations related to health 14. Pregnancy history 15. Patient provided data 16. Observation results pertaining to the health condition 17. Plan of care 18. Information on a rare disease such as details about the impact or characteristics of the disease 	Electronic prescription	<p>Electronic health data constituting a prescription for a medicinal product as defined in Article 3(k) of Directive 2011/24/EU.</p>
		Electronic dispensation	<p>Information on the supply of a medicinal product to a natural person by a pharmacy based on an electronic prescription.</p>
		Medical image and image report	<p>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.</p>
		Laboratory result	<p>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.</p>
		Discharge report	<p>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.</p>



eHDSI Testing Strategy



epSOS / eHDSI Projectathons

epSOS projectathons since 2011



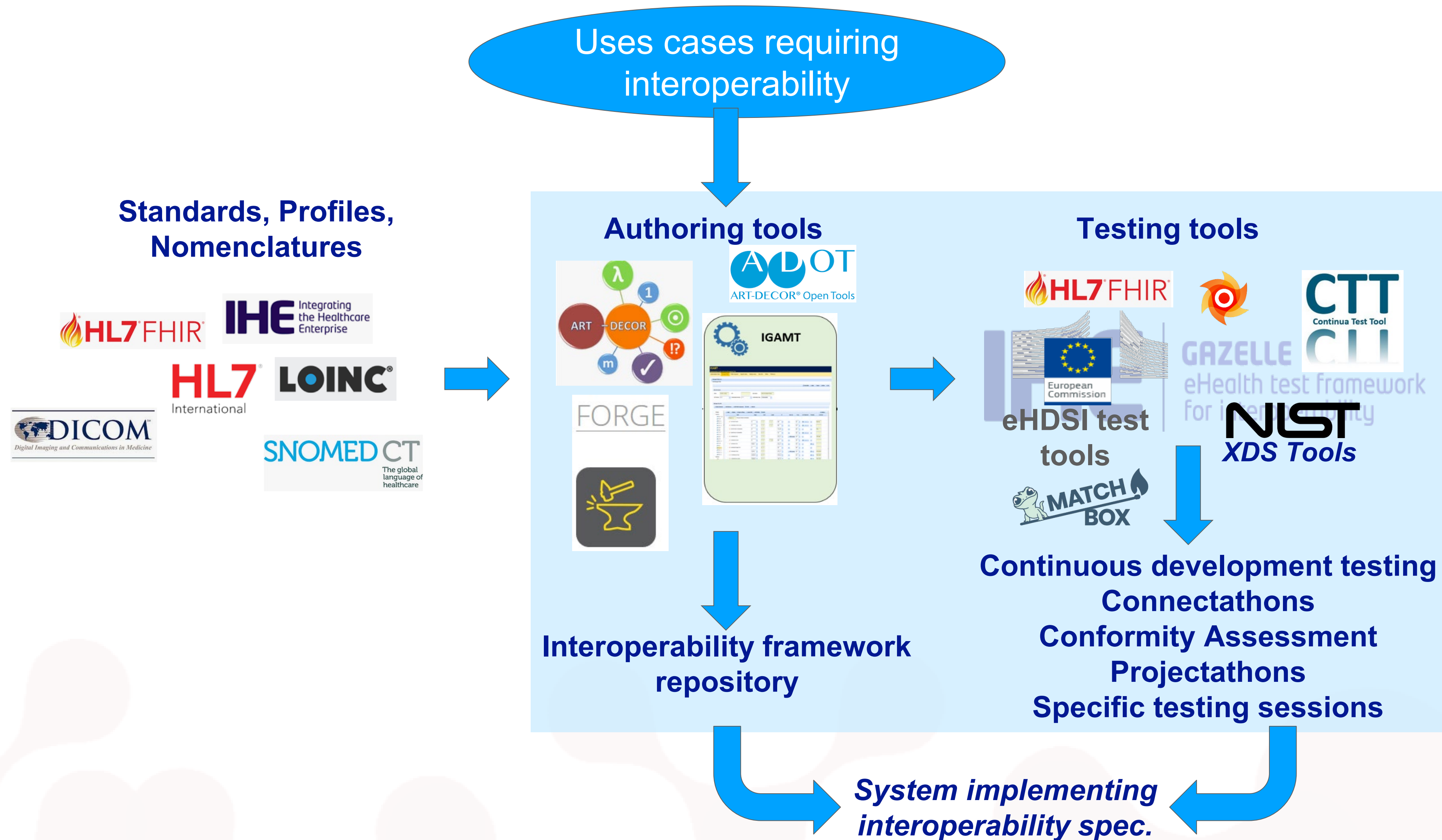
EXPANDATHON

Lisbon 9-11 December 2015

<http://www.expandproject.eu/expand-final-event-lisbon-ehealth-week/>

Online eHDSI projectathons since 2016

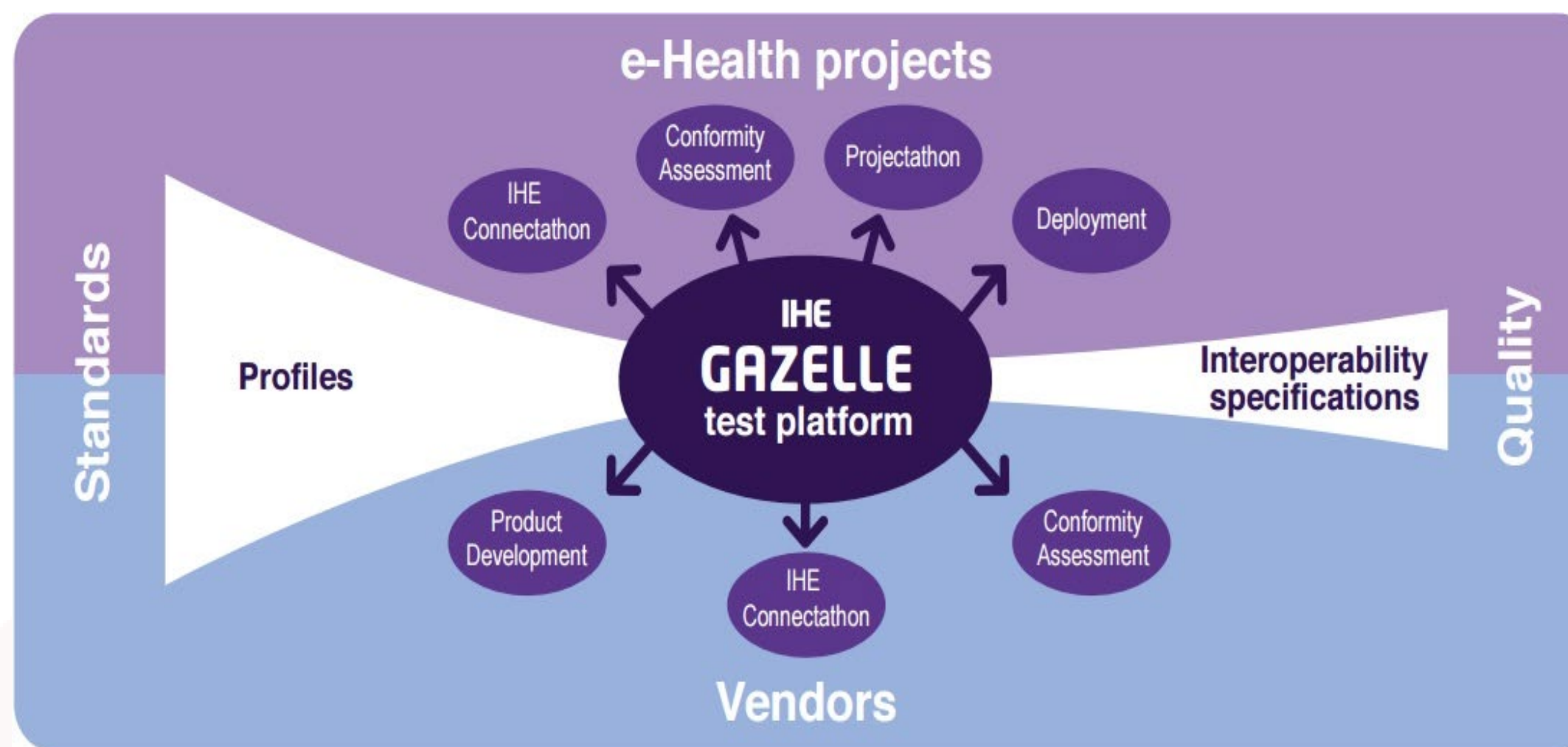
Gazelle Ecosystem



Working Together in Health Information Exchange

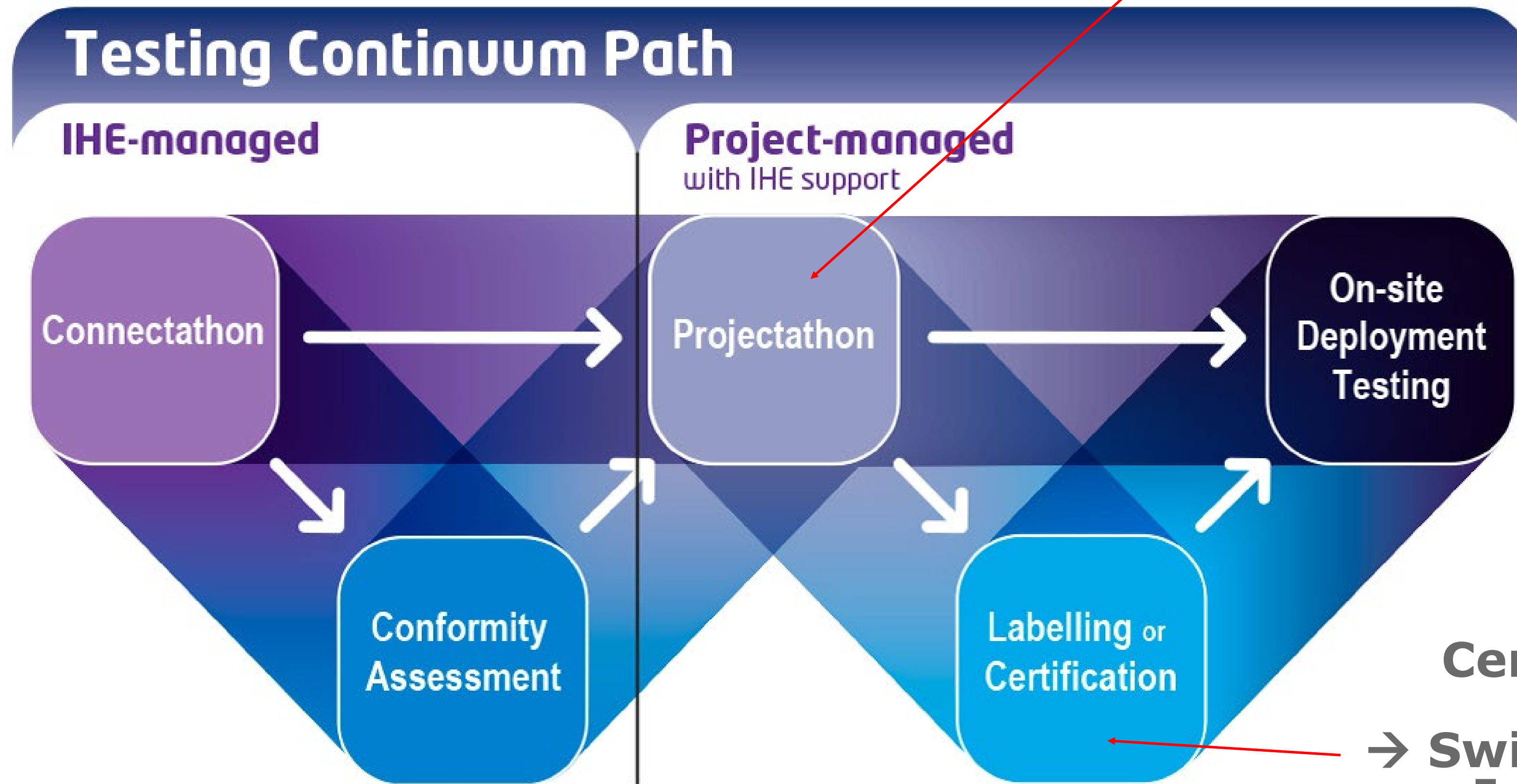


Thank You



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



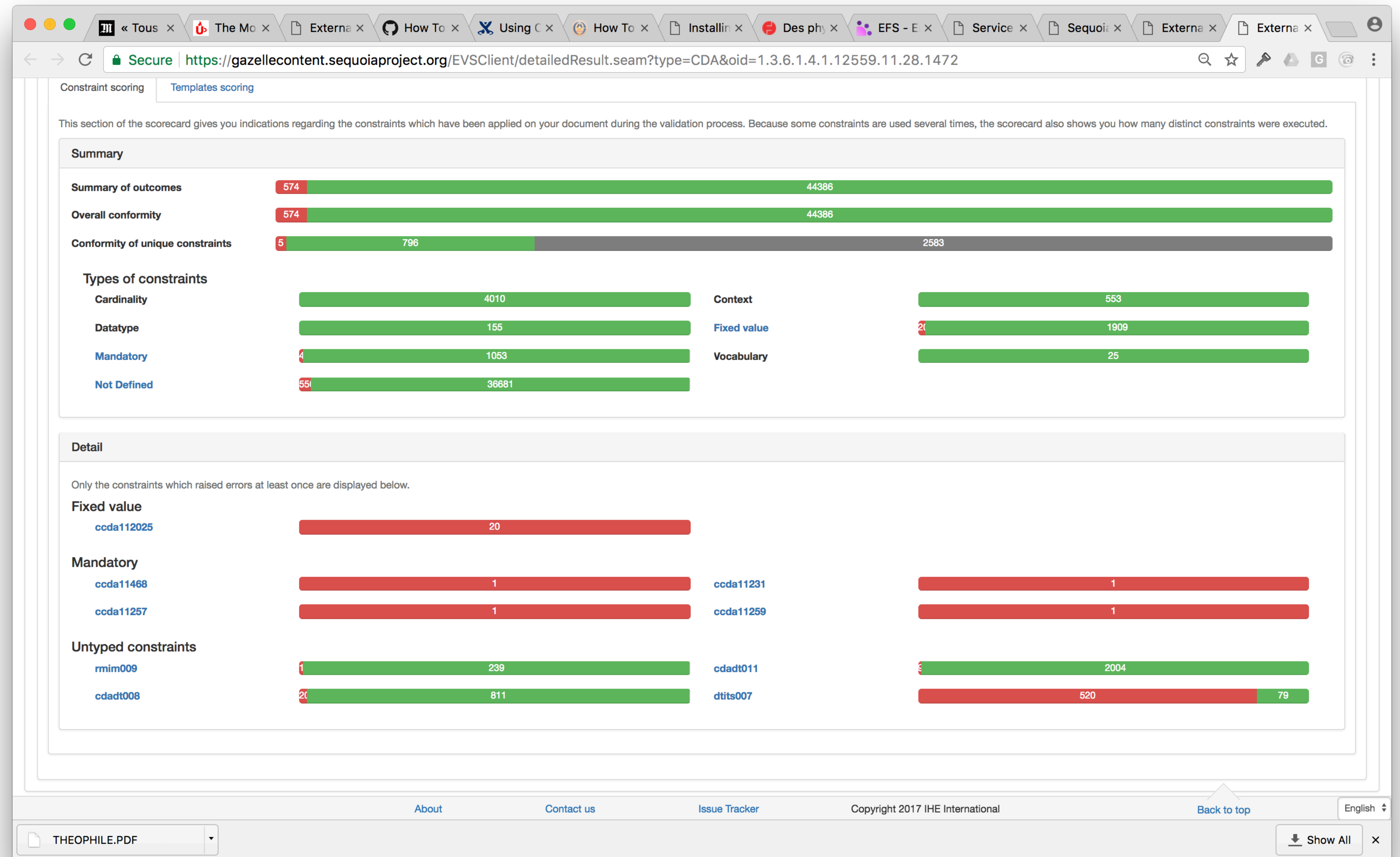
Canada Health **Infoway**
Inforoute Santé du Canada



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



Document Quality Validation



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

- 1 Define the Interoperability Conformance Assessment Scheme closely related with the eEIF
- 2 Promote creation of accredited Conformance Assessment Bodies in Europe
- 3 Develop Suitable Organisation for the QL&C process

General Recommendations

- 1 National and Regional Project leverage profiles recognized by eEIF 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 eEIF based on local use cases

National/regional Recommendations

Refined eHealth Interoperability Framework

https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf



eHealth Network

Refined eHealth European Interoperability Framework

Specifications for procurement

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2015:199:FULL&from=EN>

COMMISSION DECISION(EU) 2015/1302
Of 28 July 2015
on the Identification of Integrating Healthcare profiles for referencing in public procurement



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

EHDS New Regulation



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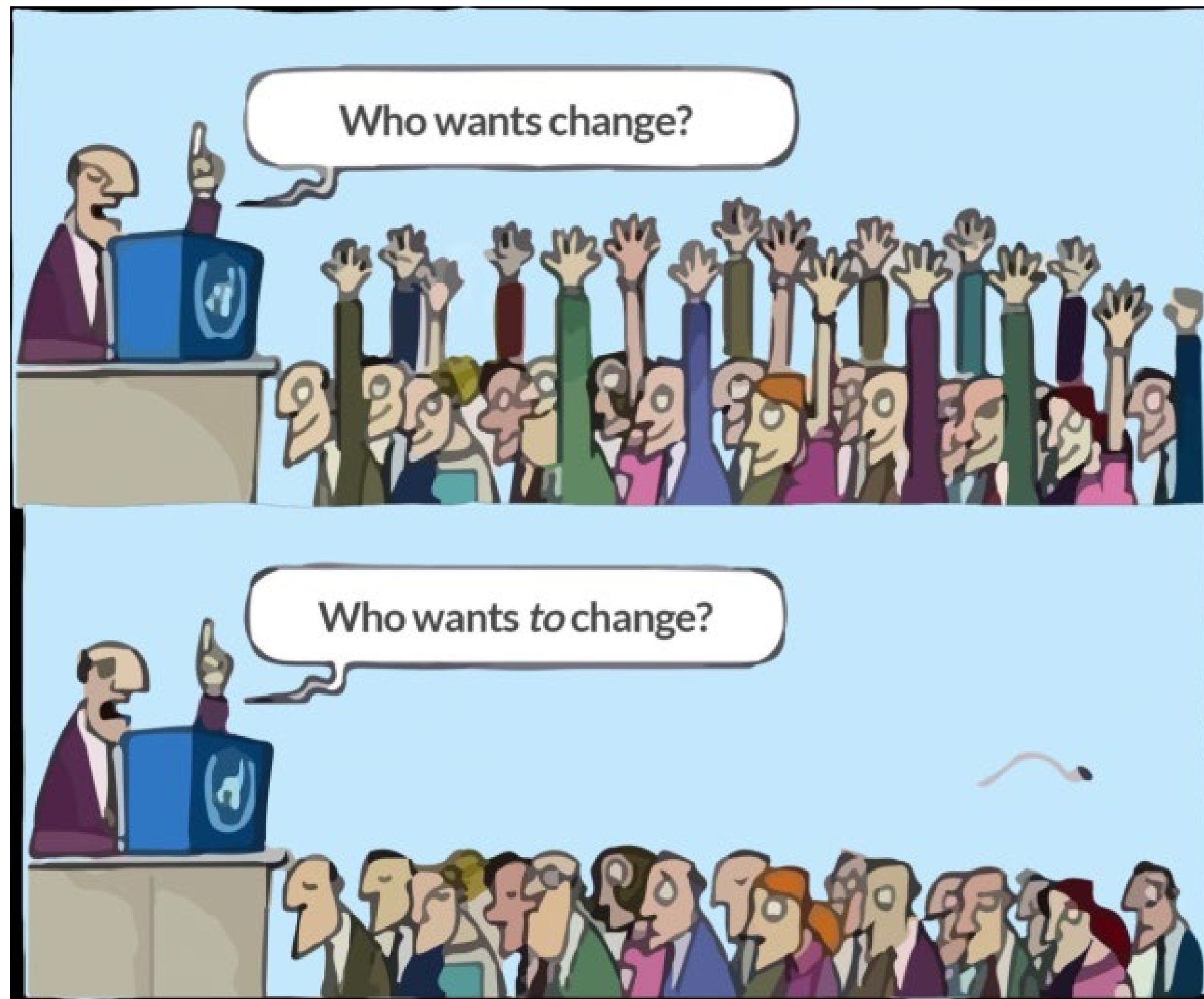
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Strengthen the European Health IT marketplace to meet the needs of the 4 P's : Patients, Providers, Policy Makers, Payers

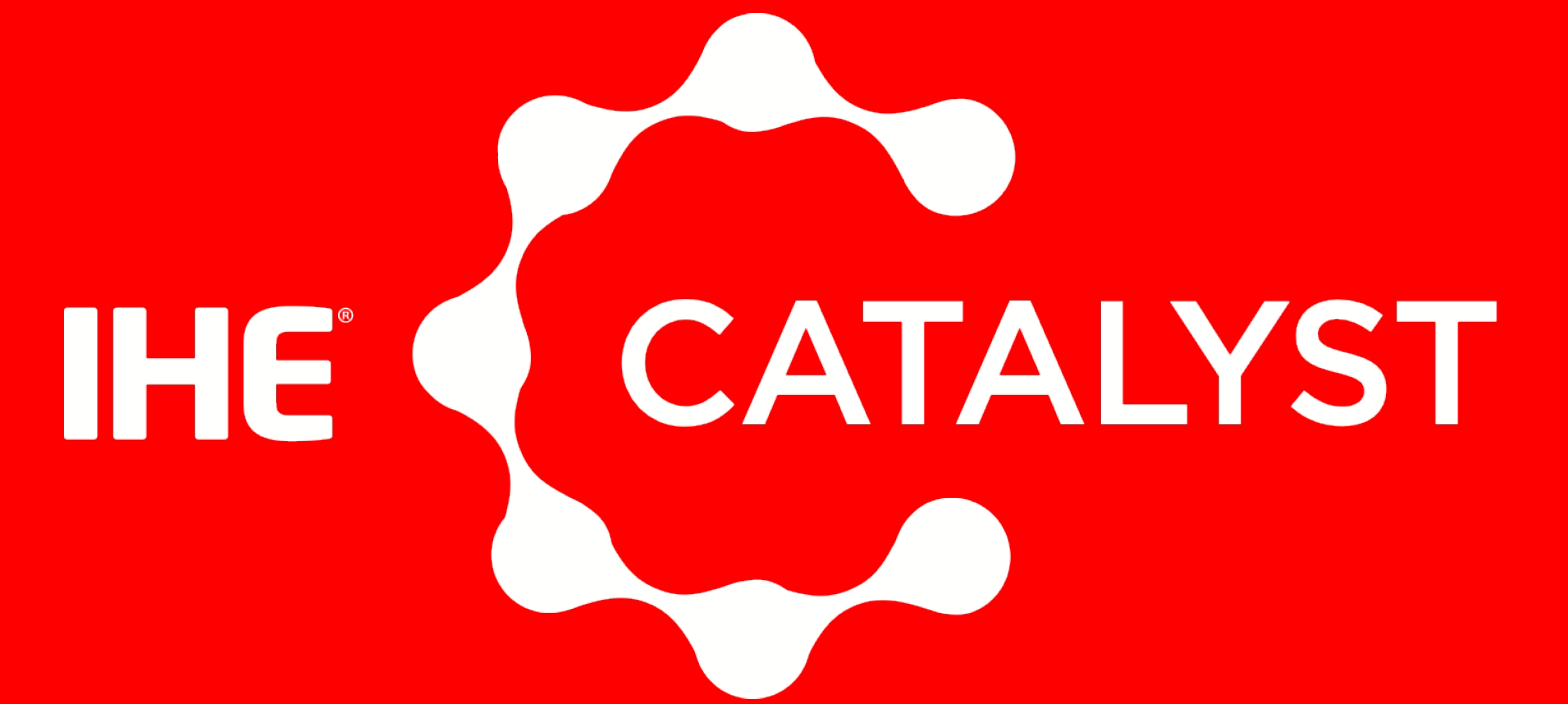
Can we do the change? We Can!



“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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