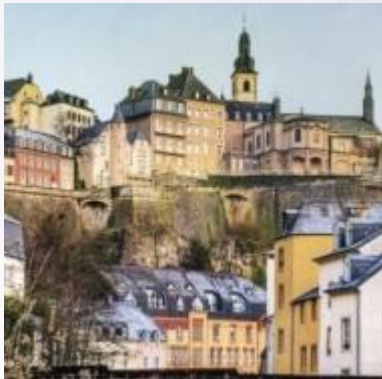


IHE Conformity Assessment Strategic Objectives

IHE-Europe Webinar on Conformity Assessment

Organized around the IHE Europe Connectathon
In Luxembourg



January 9th, 2015

Charles Parisot, Member IHE International CAsC Committee

Agenda

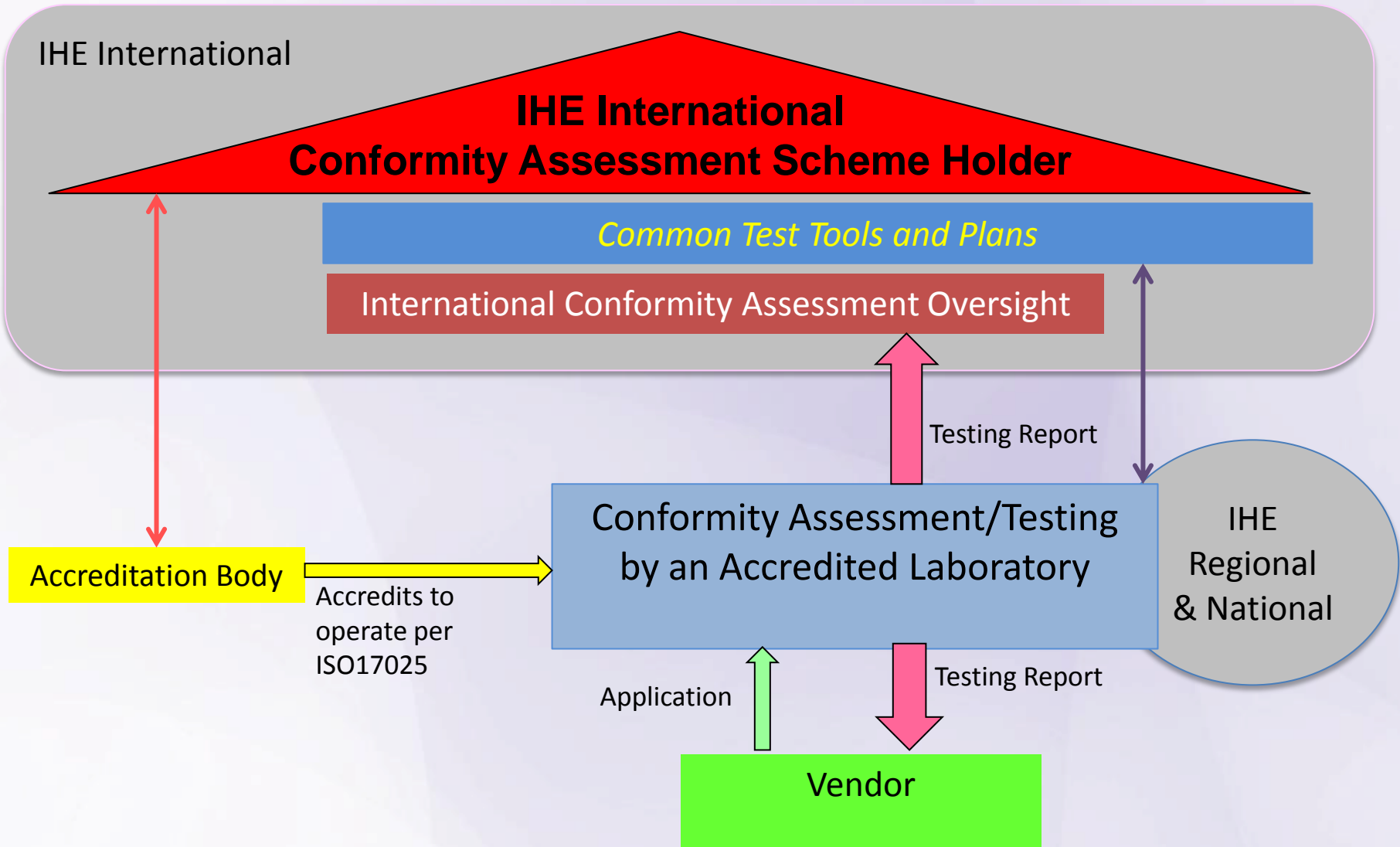
1. Why is IHE Introducing Conformity Assessment
2. Strategy on Conformity Assessment
3. Relationship with Connectathon
4. Who should benefit from Conformity Assessment
5. Roll-out of IHE International Conformity Assessment

- Widespread adoption of IHE Profiles by national, regional and hospital eHealth projects
- Many Projects explicitly leverage Connectathon Results in their product tenders/acquisition.
- Projects report un-even compliance to IHE profiles across products and discrepancies between commercial products IHE features and vendor connectathon results
- Increasing number of national/regional projects that establish their own conformity testing. Expected for project specific extensions, but duplicative for IHE profile conformity.

➔ Vendor and Projects interested to avoid duplicative testing of generic IHE Profile conformity.

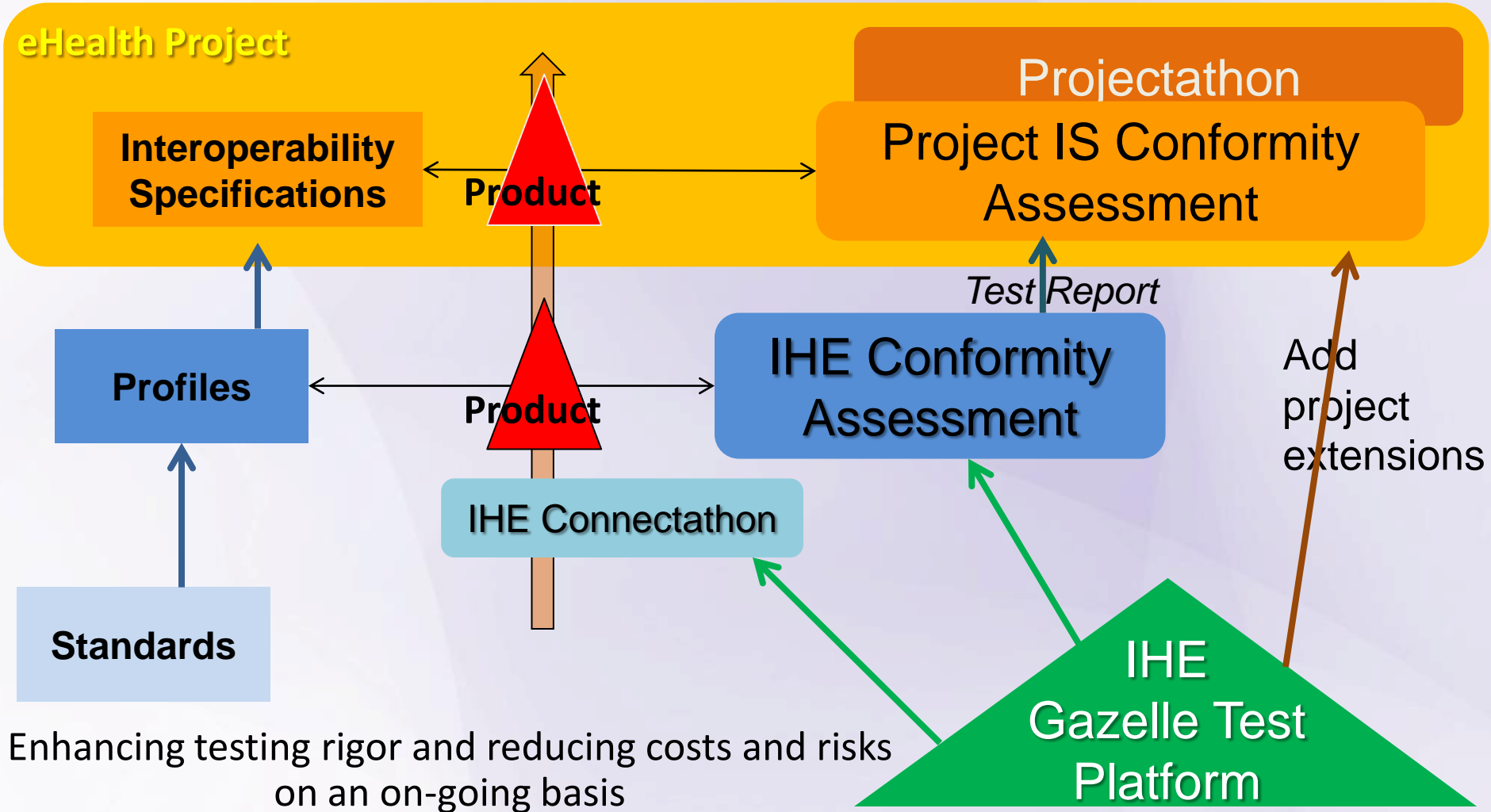
- Focus on Testing (not certification) → deliver a trusted test report
- Enable countries/projects to require and recognize these test reports and perform any additional project specific (they may add a certification process on top of the testing process).
- Ensure international equivalency of test reports and recognition of these test reports of their trustworthiness:
 - A single process: conformity assessment scheme
 - The same test tooling: provided by IHE International
 - Test report published by IHE International
- Allow multiple testing laboratories across the world to be accredited and authorized by IHE International

- Test Report provided by a trusted neutral organization
- Guarantees that an IHE profile implementation in a commercial product is positively tested against an IHE test plan/test tools
- Specific version of a specific product (re-testing may be needed for product evolution) Does not imply that retesting is needed for each product/version (e.g. using same software).
- The process and rigor of “Conformity Assessment” defined in terms of a ISO17025 based “IHE Conformity Assessment Scheme-IHE-CAS” (process, test plan and test tools) to ensure world-wide equivalence
- Takes testing rigor and trust to the next level above the **Connectathon**. Expects a vendor to pass appropriate Connectathon tests as a prerequisite for seeking profile/actor conformity assessment testing by an accredited testing laboratory.



Dimensions	IHE Connectathon	IHE Profile Conformity Assessment
Participants	Vendors & Open Source	Vendors & Open Source
Specific Product name and version	No (Vendor self-attestation through Integration Statement)	Yes
Testing Profiles (Technical Framework)	Trial Implementation and Final text	Only Selected Final Text Profiles
Collaborative and Learning	Yes	No
Pre-requisite	None – Only to pass pre-Connectathon tests	Vendor has successfully passed profile tests at an IHE Connectathon
Commitment to commercial availability	No – Pre-product testing OK	Yes
Guarantee Interoperability of tested products	No – Reasonable expectation	No – But Clearer expectation for specific product version
Staffing of oversight/jury	Monitored by volunteers	Monitored by professional staff
Results	Pass Results published for vendor by IHE	Test Report published/attested by accredited testing laboratory

IHE's contribution to ehealth projects



1. The larger eHealth Projects (national, regional, hospital network) that want to engage a broad number of vendors to supply products with IHE profile conformance. Use IHE Conformity Assessment as an entry criteria into procurement and project level lab testing (Projectathon).
2. The care delivery organization with simple interoperability projects (e.g. connecting devices to a Clinical System). Only a few profiles to be combined.
3. Vendors that want to avoid the overhead of retesting in each project at the profile level.

Conformity Assessment Roll-out

- IHE Conformity Assessment Scheme based on ISO 17025 adopted by IHE International Board in May 2014 (IHE-CAS Volume 1).
- Initial Set of Profiles selected: CT, ATNA, PDQ, PDQV3, PIX, XDS.b (low number of profiles – low risk, high value, stable profiles)
- IHE CAS Volume 2 under finalization.
- Launch of Conformity Assessment in 2015 by IHE-Europe, IHE-USA and IHE-Japan.
- Extensions to testing laboratories in other regions and addition of other profiles in 2016.



Integrating
the Healthcare
Enterprise

Appendix

IHE Conformance Assessment Scheme – Vol 1

- 1 General Information**
- 2 Establishment, development and implementation of the IHE International CAS**
- 3 Testing Laboratory Accreditation Process**
- 4 Management Requirements**
- 5 Technical Requirements**

Appendix A - Referencing IHE International Conformance Assessment Scheme Accreditation

Appendix B - General process for establishing IHE authorized Testing Laboratories

Appendix C - Regional or National Extensions to the IHE International CAS

Appendix D – Validation of test Reports

Available on IHE.Net:

http://www.ihe.net/uploadedFiles/Content/Resources/Conformity_Assessment/IHE_International_Conformity_Assessment_Scheme_Part_1_Rev1%200_2014-06-25.pdf