

IHE

Integrating
the Healthcare
Enterprise



Quality in eHealth Interoperability

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F O R U M
*e*ZDR  WIA

e-Health Forum

Strategic challenges and
interoperability standards in Health IT
Sopot, Sheraton Hotel, 16/09/2016






Agenda

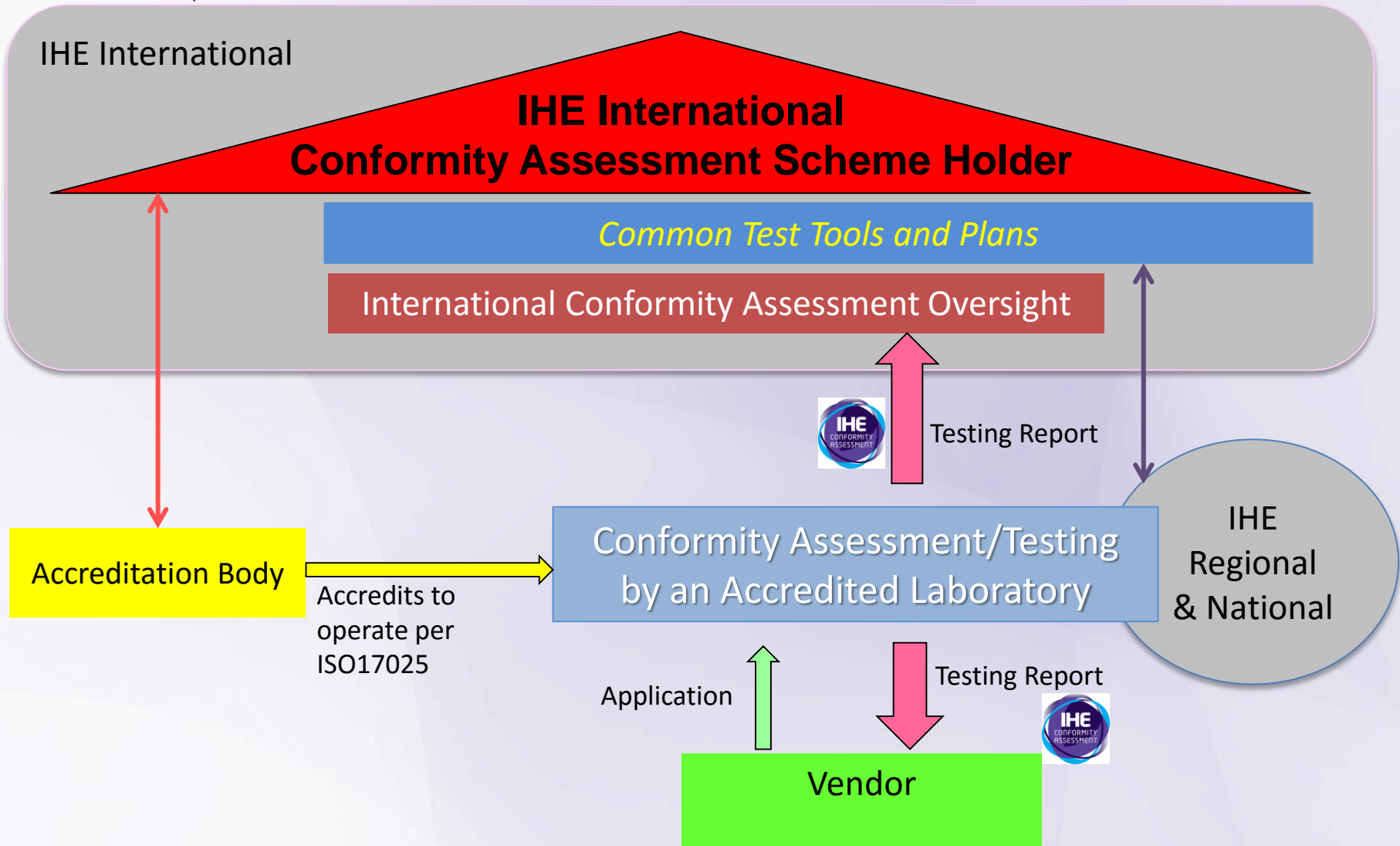
1. Why has IHE Introduced Conformity Assessment ?
2. Strategy on Conformity Assessment
3. Relationship with Connectathon
4. Who should benefit from Conformity Assessment
5. Roll-out of IHE International Conformity Assessment

Why Conformity Assessment?

- **Widespread adoption of IHE Profiles** by national, regional and hospital eHealth projects
- Many ehealth 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 ehealth projects **establish their own conformity testing**. Expected for project specific extensions, but duplicative for IHE profile conformity.

→ Vendor and ehealth projects interested **to avoid duplicative testing of generic IHE Profile conformity**

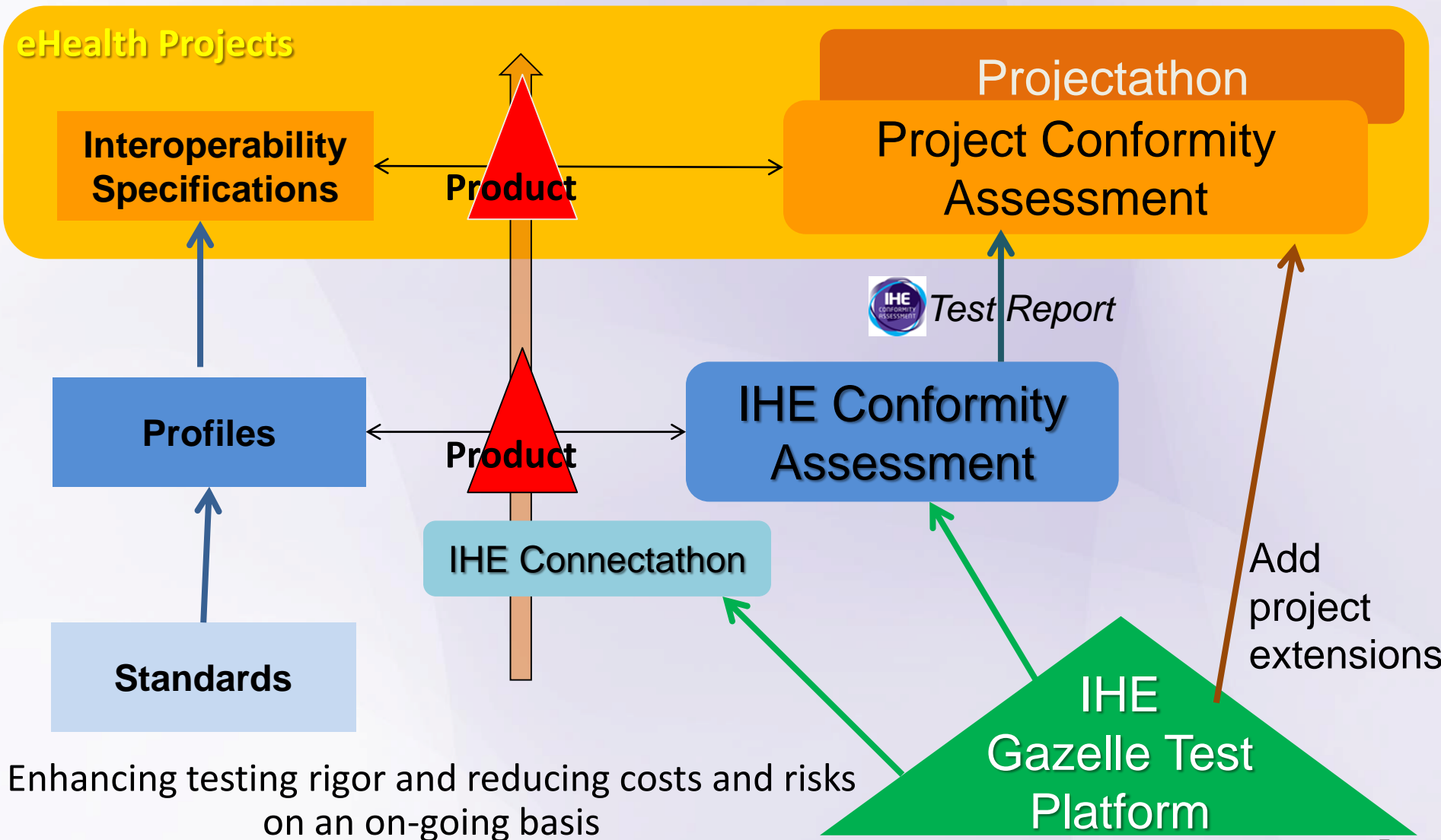
- Focus on **Testing** (not certification)
→ deliver a trusted  Test Report
- Enable countries/projects to **require and recognize** these  Test Reports and perform any additional project specific testing (they may also add a certification process on top of the testing process).
- Ensure international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



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



A shared test platform: Connectathon, Conformity, and ehealth Projects



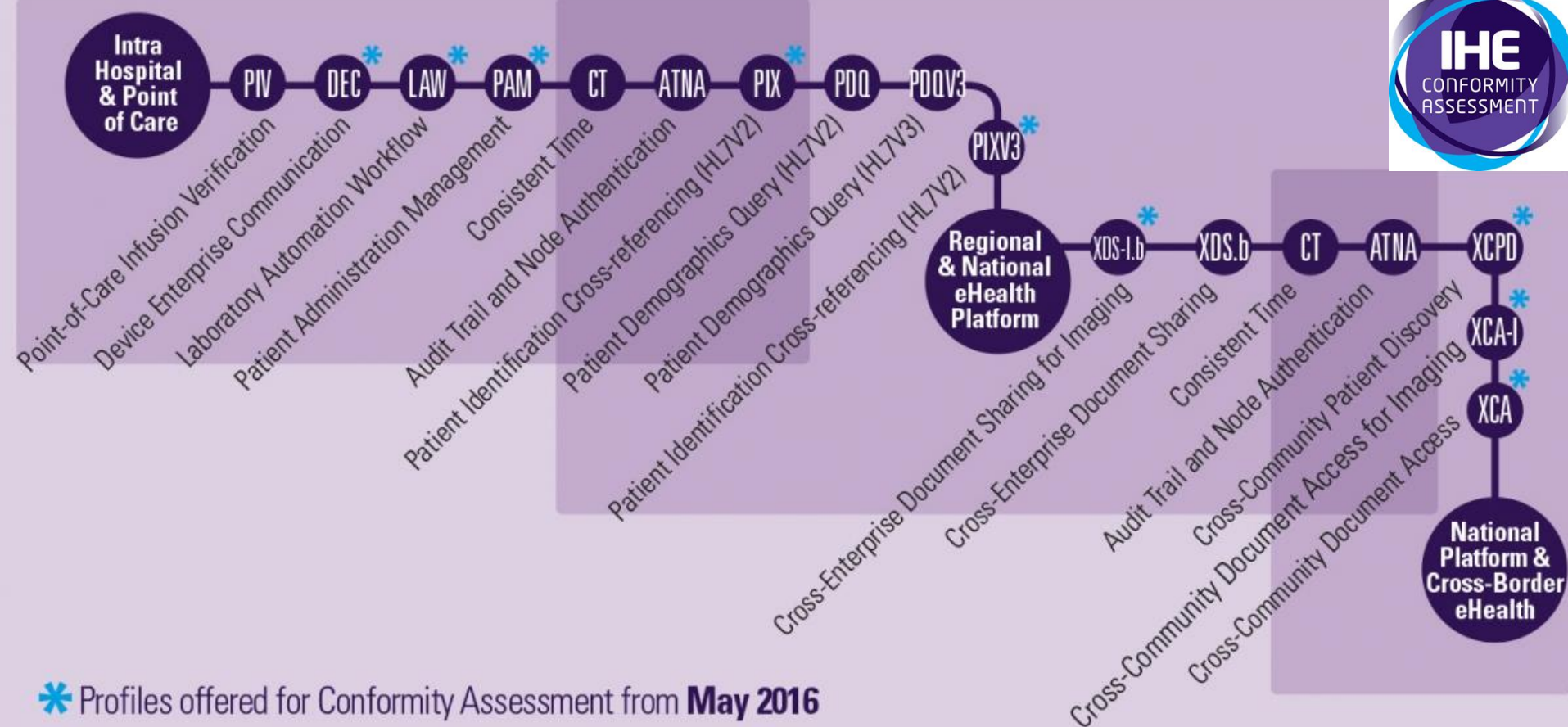
IHE Conformity Assessment for who?

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 (e.g. Hospital/Clinic) 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.

➔ A Buyer/Vendor win-win !

Operational since April 2015:

- IHE International Board Approved Conformity Assessment Scheme (IHE-CAS-vol. 1) in May 2014.
- Initial Set of Profiles selected by IHE-Europe, IHE-USA and IHE Japan in September 2014: CT, ATNA, PDQ, PDQV3, PIX, XDS.
- Kereval (IHE-Europe) and ICSA Labs (IHE-USA) Authorized.
- First four products tested in April 2015 (positive feedback from vendors on value added) by Kereval as accredited/authorized test laboratory.



* Profiles offered for Conformity Assessment from **May 2016**

History

14 years of experience
A unique business: TEST

Values

Independence
Impartiality
Excellence

44 People

KEREVAL Software Testing Lab



Our accreditations

Test Laboratory accredited for ISO 17025



LABORATOIRE CTA KEREVAL
ACCREDITATION
N° 1-2347
PORTÉE DISPONIBLE SUR
WWW.COFRAC.FR



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Training provider



- ❖ One of the two testing labs accredited (17025) to realize Conformity Assessment Testing sessions according to IHE profiles
- ❖ Management of the Conformity Assessment Testing session in Luxembourg (2015)



- ❖ Management of online Conformity Assessment Testing session



- ❖ First Test Reports available at: conformity.ihe.net

Organization of Conformity Assessment (1)

- ❖ The test session will be conducted according to the [IHE International Conformity Assessment Scheme](#):

- ❖ IHE-CAS-1
- ❖ IHE-CAS-2



- ❖ The test sessions will be conducted in Europe* by KEREVAL HealthLab, an [ISO/CEI 17025 accredited testing laboratory](#), under supervision of its qualified resources : testing team and test session manager:



- * ICSA Labs in the USA will also offer IHE-CA testing sessions for a subset of the profiles


Rules and commitments for Systems Under Test (SUT)

- ❖ Be a marketed **released** (or about to be released) **commercial** product
- ❖ The vendor shall have passed in the previous 2 years the IHE Connectathon for the profile/actors to be conformity assessed.
- ❖ The Test Report, **valid for two years**, will be provided as soon as all the elements of the test session are completed
- ❖ If a product is updated with a new released version:
 - The vendor may request an extension of the scope of the report to the testing laboratory. The testing laboratory, upon the analysis of the information communicated by the vendor, will decide if some re-testing is required or not.
 - An additional Conformity Assessment report is issued
- ❖ The Testing Laboratory is in charge of:
 - Publishing the Conformity Assessment Report on the IHE International Web Site (<http://conformity.ihe.net>)
 - Providing the report to the company

- ❖ IHE-Europe has established with Kereval a cost-recovery only fee.
- ❖ For 1 system under test (SUT) and for up to 4 profile/actor pairs : 5500 €
 - ❖ Note: the CT/Time Client profile/actor pair is tested for free
- ❖ Additional profile/actor pairs for the same system (SUT) may be tested for 1000 € each.

IHE Conformity Assessment

Key points

- **Guarantees** that an IHE profile implementation in a commercial product is positively tested against an IHE test plan/test tools
-  **Test Report** provided by a trusted neutral organization
- **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 **ISO/IEC 17025** based “IHE Conformity Assessment Scheme - IHE-CAS” (process, test plan and test tools) to ensure quality and 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.

Apply now!

- For general information:
[http:// www.ihe.net/Conformity-Assessment](http://www.ihe.net/Conformity-Assessment)
- For Test Reports:
<http://conformity.ihe.net>
- Fill the application form, Email us at:
conformityassessment@ihe-europe.net





Thank you for your attention!

Questions?