

# IHE Conformity Assessment

- Testing has always been a critical part of the IHE process
- Methods and purposes of performing and recording tests have evolved over time
- The primary goal throughout has been to increase availability of interoperable, standards-based health IT systems





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## IHE Connectathon 1999





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# Connectathon Testing

- Supervised, peer-to-peer testing
- Proof and debug specification
- Proof and debug vendor implementations
- Build interoperability social network
- Preparation for demonstrations
- Publication of successful results:  
<https://connectathon-results.ihe.net/>





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# Connectathon Testing

- Advantages:
  - Low-risk entry point for interoperability
  - Coalescence around standard specifications
  - Encourages standards compliance
- Limitations:
  - Incomplete testing coverage
  - Gaps to market implementation
  - Limited assurance of product capability





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# Conformity Assessment

- Fills in gaps toward product availability
- More rigorous testing process
- Assessment at product level
- Stronger assurance of interoperability to marketplace





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# IHE International Conformity Assessment

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# Scope of IHE Conformity Assessment

- IHE International Conformity Assessment program was launched in 2015 and is the next step in testing rigor
- IHE Conformity Assessment is recognized world-wide
  - The program at IHE International level is coordinated by the Conformity Assessment Steering Committee of which the main contributors are IHE USA, IHE Europe and IHE Japan





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# Scope of IHE Conformity Assessment

- It is based on an internationally recognized quality system
  - Testing for specific IHE Profiles is performed by Testing Laboratories ISO17025 accredited
- Conformity Assessment Reports are published on the IHE International website on successful completion of testing
  - see: <http://conformity.ihe.net/summary-reports>
- Project and country specific Certification programs (e.g. CONCERT by HIMSS) may easily recognize and build upon IHE Conformity Assessment



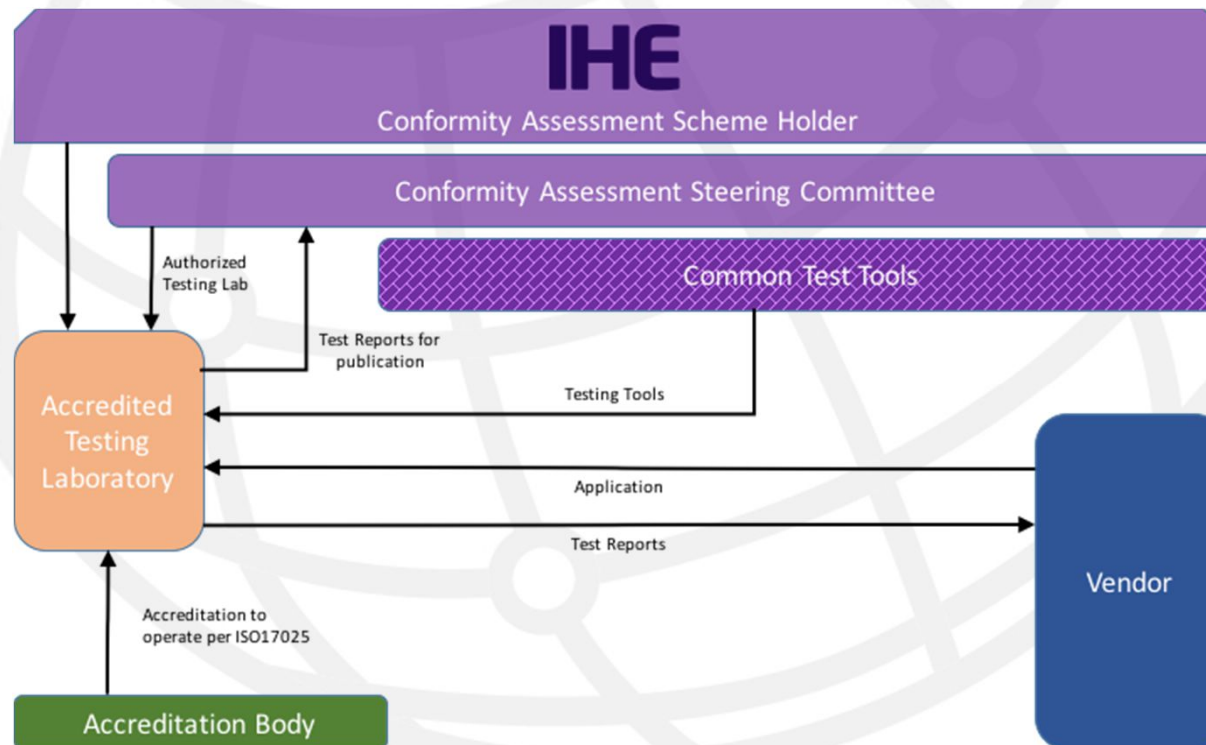


# Why Conformity Assessment?

- Guarantees that an IHE profile implementation in a commercial product is positively tested against quality controlled IHE test plan/test tools
- Test Report provided by a trusted neutral organization
- Specific version of a specific product
- The process and rigor of “Conformity Assessment” defined in terms of a “conformity assessment scheme” (process, test plan and test tools) to ensure world-wide equivalence (IHE-CAS).
  - Expects a vendor to pass appropriate Connectathon tests as a prerequisite for seeking profile/actor accredited testing



# How Conformity Assessment works in IHE



One Scheme, One Set of Test Methods - Multiple Accredited Testing Labs

# Connectathon and Conformity Assessment

	IHE Connectathon	IHE Conformity Assessment
Participants	Vendors & Open Source	Vendors & Open Source
Specific product version	No (IHE allows for vendor self-attestation through Integration Statement)	Yes
Testing Profiles	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
Oversight	Volunteers (aka Monitors)	Under ISO 17025





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# Benefits: users

- Large eHealth projects reduce their testing and integration effort by specifying and procuring products that have been conformity assessed.
- As an end user it gives confidence that a current/potential supplier has independent proof of the interoperability of their products.
- Rely on a proven accredited testing laboratory to validate products before they are installed in an organization or facility, reducing risks and deployment costs.
- Improve patient outcomes through better and more consistent product quality





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## Benefits: vendors

- Increase the interoperability readiness for systems and solutions.
- Gain global market credibility by distinguishing the company and its products
  - For listing of company and products:  
<http://conformity.ihe.net/summary-reports>
- Be recognized internationally and accepted for “shortlisting” (i.e., pre-qualified for purchasing programs) by being engaged in the quality process governed by the IHE Conformity Assessment Program.
- Benefit from a wealth of IHE Profiles and increase an organization’s capabilities.





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# The 2016 Cycle

- The 2016 Cycle has expanded further by including the following Integration Profiles
  - For sharing health records
    - XDS.b, ATNA, PIX/PIXV3, PDQ/PDQV3, XCA, XCPD, XDS-I, XCA-I (ITI)
  - For Hospitals, HIS, lab and ICUs
    - PAM (ITI), LAW (LAB), DEC, PIV (PCD)

