

# IHE International Conformity Assessment Update

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Chair, IHE Services Committee

## IHE International Conformity Assessment Scheme Holder

International Conformity Assessment Oversight

Testing Report  
on [www. IHE.net](http://www.IHE.net)

Accreditation Body

Accredits to  
operate per  
ISO17025

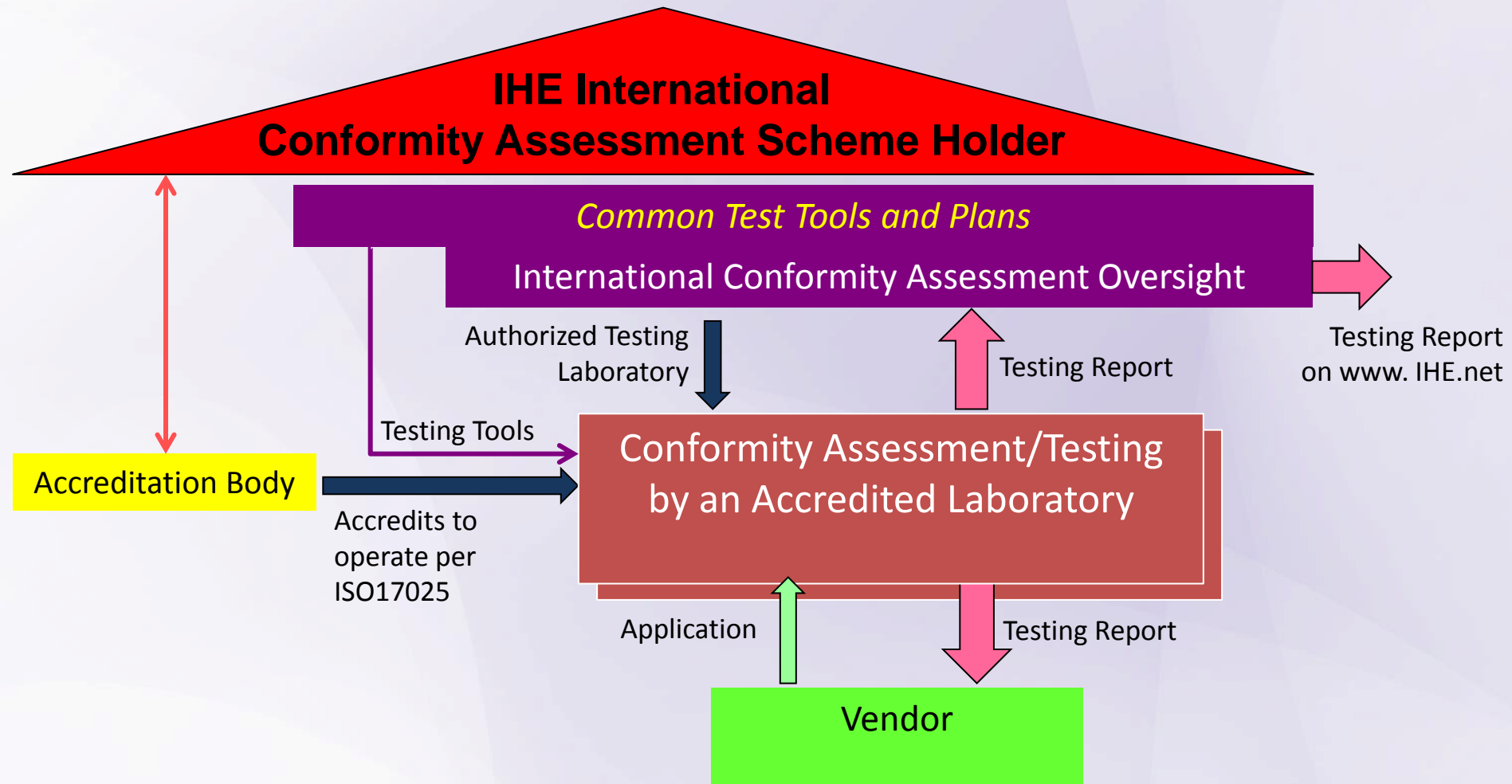
Conformity Assessment/Testing  
by an Accredited Laboratory

Testing Report

Vendor

One Scheme and Multiple Accredited Testing Labs

## IHE International Conformity Assessment (2)



International: One Scheme, One Set of Test Methods  
Multiple Accredited Testing Labs

## What is meant by Conformity Assessment?

- Guarantees that an IHE profile implementation in a commercial products 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 (re-testing may be needed for every major version)
  - 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 “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

# IHE Conformity Assessment and Connectathon

Conformity Assessment, a value-add to Connectathon, not a replacement:

Dimensions	IHE Connectathon	IHE Profile Conformity Assessment
Participants	Vendors & Open Source	Vendors & Open Source
Specific Product version	No (IHE allows for vendor self-attestation through Integration Statement)	<b>Yes</b>
Testing Profiles	Trial Implementation and Final text	<b>Only Selected Final Text Profiles</b>
Collaborative and Learning	Yes	<b>No</b>
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	<b>Yes</b>
Guaranteed Interoperability of tested products	No – Reasonable expectation	No – But Clearer expectation for specific product version
Staffing of oversight/jury	Monitored by volunteers	<b>Monitored by professional staff</b>

## Elements of an IHE Conformity Assessment Scheme

- A single international scheme with delegation of ISO 17025 accredited operation testing at the national / regional level
- Allows IHE National/Regional Deployment Committees to deliver internationally recognized and transparent testing reports

Note: Testing of National extensions/combinations of IHE Profiles is to be addressed as a subsequent testing step (“projectathon” or ehealth project-specific interoperability specification).

## **CAS Volume 1:**

- 1 General Information**
- 2 Establishment, development and implementation of 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**

## **CAS Volume 2:**

**Profile Specific Scheme: test plans and test tools.**

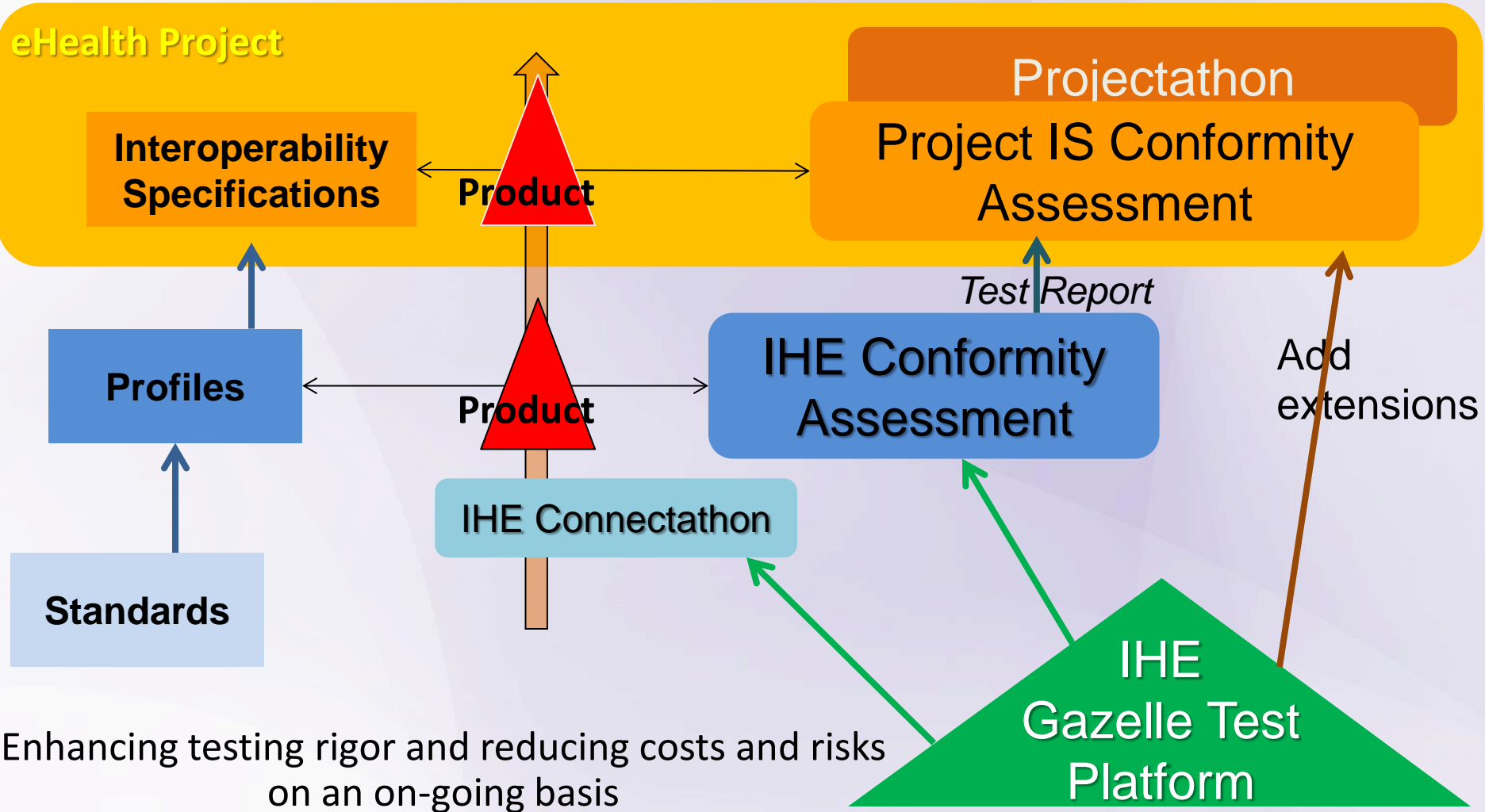
**Revised typically every year.**

**[Available on IHE.Net:](http://www.ihe.net/Conformity_Assessment/) [www.ihe.net/Conformity\\_Assessment/](http://www.ihe.net/Conformity_Assessment/)**

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.



## IHE's contribution to ehealth projects



## Operational since April 2015:

- IHE International Board Approved Conformity Assessment Scheme (CAS-1) in May 2014.
- International Conformity Assessment Coordination Committee (CAsC) in place since April 2014
- Initial Set of Profiles selected September 2014: CT, ATNA, PDQ, PDQV3, PIX, XDS.
- IHE-Europe, IHE-USA and IHE Japan engage CA 2015 Cycle Test Methods development December 2014
- Kereval (IHE-Europe) and ICOSA 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.
- CA Virtual Test Machine Cycle 2015 available for general release to Authorized test laboratories.
- Two more products planned to CA in Q4 2015, and many more in 2016.

## 2016 Cycle underway:

- Initial Set of Profiles selected September 2015: XCA, XCPD, XDS-I, XCA-I, PIX, DEC, PIV, PAM and LAW (pending FT approval).
- CAsC Committee with backing of IHE-Europe, IHE-USA and IHE Japan engaged CA 2016 Cycle Test Methods development:
  - LAW with support of IICC
  - XDS-I and XCA-I with support of RSNA Image Share
  - PAM with support of IHE-France (Interop Santé)
  - More IHE National Deployment welcome
- CA Virtual Test Machine Cycle 2016 development scheduled for October thorough February 2016.
- CA Virtual Test Machine Cycle 2016 targeted for general release to Authorized Test Laboratories by March 2016.
- IHE-Europe and Kereval committed to offer 2015 & 2016 Cycle profiles

- Ehealth projects to request IHE Conformity Assessment Test Reports as input to the complementary testing
- Vendors to encourage their customers to value the IHE profile level Conformity Assessment to simplify and reduce their project interoperability risks

**Test once implement many times !**