IHE Integrating the Healthcare Enterprise

Quality in eHealth Interoperability

Didi Davis
IHE International Board Member
IHE International Testing & Tools Committee
IHE Conformity Assessment Committee (CAsC)

IHE Proven Standards Adoption Process

- **Granted IHE "Category A" Liaison), effective October 19th, 2011**
  - IHE Technical Report (TR 28380)
  - Health informatics — IHE global standards adoption — Part 1: Process
  - http://www.ihe.net/components/templates/OneColumn.aspx?id=379
  - https://www.iso.org/obp/ui/fr/#iso:std:iso:tr:28380:-1:ed-1:v1:en
- Testing has always been a critical part of the IHE process - Connectathons (1999 – Present)
- 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

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/

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

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

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 Testing & Certification programs (e.g. EURO-CAS & CONCERT by HIMSS & Sequoia Content Testing) may easily recognize and build upon IHE Conformity Assessment

Conformity Assessment Scheme (CAS) for Europe

- The European eHealth Interoperability Conformity Assessment Scheme (EURO-CAS) aims at maintaining and developing the adoption and take-up of testing the interoperability of ICT solutions against identified eHealth standards and profiles defined in the eHealth European Interoperability Framework (eEIF). The key deliverable is a sustainable Conformity Assessment Scheme (CAS) for Europe. Based on recommendations of the Antilope project and the state of the art in interoperability testing in eHealth, EURO-CAS is committed to putting in place an operational CAS based on ISO/IEC 17025 that will meet the interoperability requirements of European eHealth projects, as well as national and regional eHealth programs. This will allow testing the interoperability capabilities of products and services for a single digital market in eHealth in Europe in line with the Digital Agenda for Europe and based on international profiles and standards

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International Patient Summary

HL7 IPS project overview

- October 2016: Project formally approved by the HL7 TSC
- **CDA R2 Implementation Guide for the IPS**, with an eye to possible **FHIR** implementation.
- Plan: Standard for Trial Use **ballot September 2017**.
- Open template: extensible core specifications
- Challenge: globally usable value sets for the IPS

HL7® FHIR®

New for 2017: ConCert Approved Medical Device

Certification Marks signify compliance and proof that a product has all of the requirements to be interoperable with other certified ConCert by HIMSS products.

for Medical Devices and EHR systems to provide a standardized way to exchange programming order information and clinical information at the point of care

ICSA Labs, an independent division of Verizon, represents IHE USA and the US region as the authorized testing lab for the Conformity Assessment Program.

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Testing

- Test tools and transactions developed and supported by NIST in conjunction with IHE Patient Care Device (PCD) domain
- Tight alignment with IHE Pre-Connectathon testing requirements
- Test requirements bundled with other IHE transaction requirements as appropriate
  - Time Clock, Patient Identity, etc
- Some test data tailored to specific device type and/or parameters

IHE | GAZELLE eHealth test framework for interoperability

the sequoia project

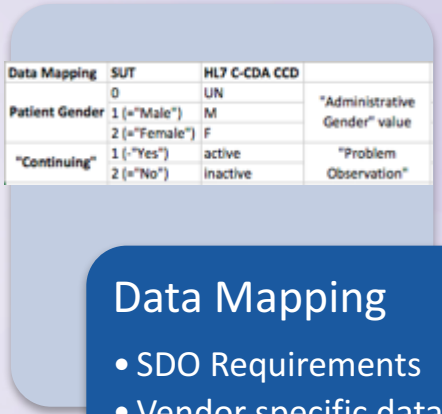
ART DÉCOR/GAZELLE OBJECTS CHECKER

- Hosted by IHE Services as part of the IHE International Scheme Testing
- Tooling was piloted in April 2015 and is ISO 17025 Compliant for Conformity Assessment
- For Sequoia Covers only the HITSP C32/CCD, HL7 C-CDA CCD R1.1 and R2.1 versions
- Found to report on warnings and errors not found by other testing tooling

Process for Creating Consistent & Robust HL7 C-CDAs

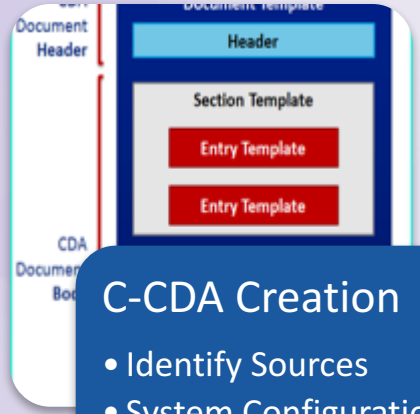
Content Priorities

- Clinicians
- Business Office
- Others



Data Mapping

- SDO Requirements
- Vendor specific data model overlay
- Semantic Interoperability Transformation



C-CDA Creation

- Identify Sources
- System Configuration
- Value Sets
- Internal/External transformation

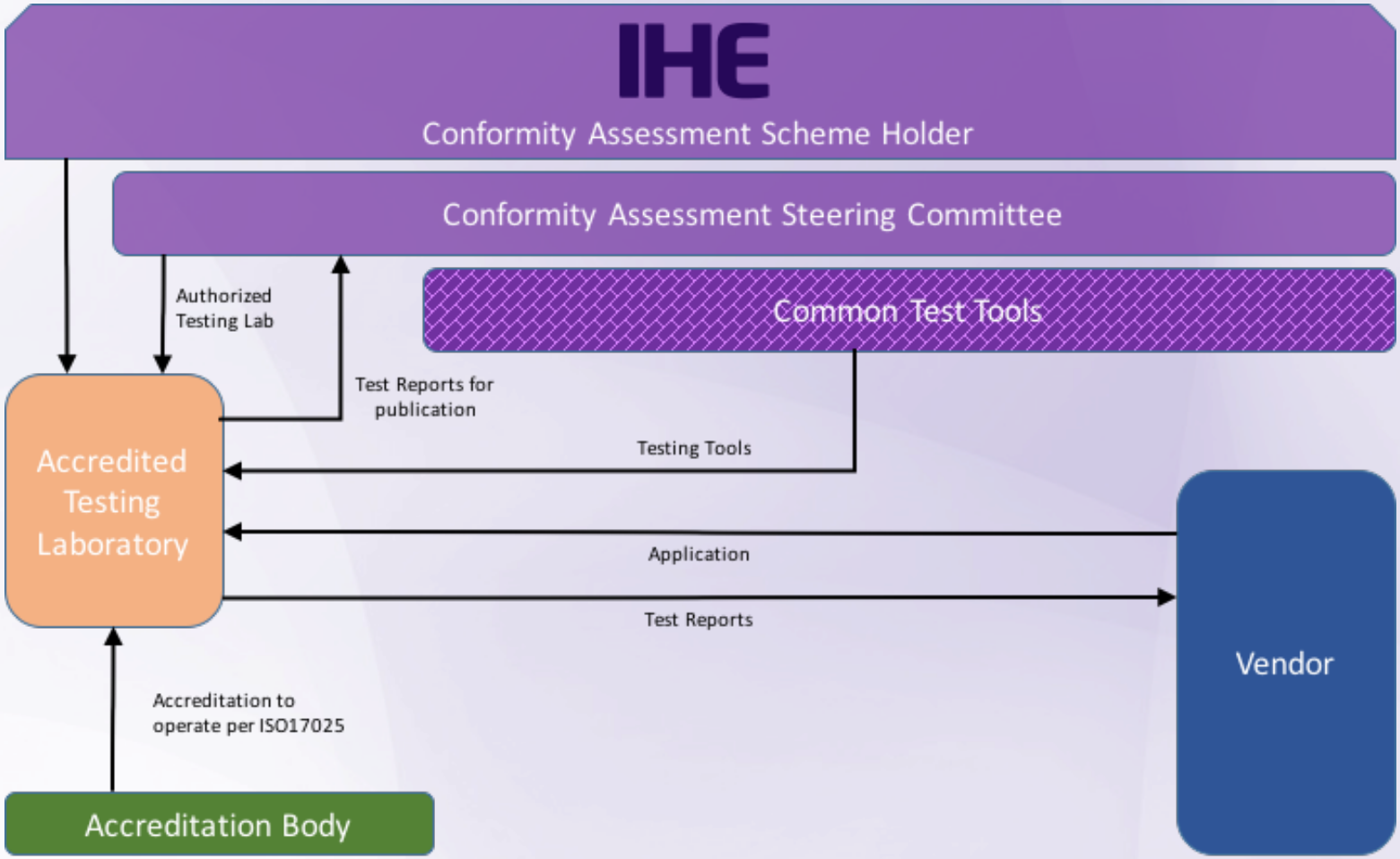
http://sequoiaproject.org/ehealth-exchange/testing-overview/content-testing/
https://gazelle.ihe.net/EVSClient/home.seam

Conformity Assessment Deployment

Operational since April 2015:

- IHE International Board Approved Conformity Assessment Scheme (IHE-CAS-vol. 1) in May 2014.
- Kereval (IHE-Europe) and ICSA Labs (IHE-USA) Authorized.
- Profiles selected by IHE-Europe, IHE-USA and IHE Japan:
  - April 2015: **CT, ATNA, PDQ, PDQV3, PIX, XDS**.
  - April 2016: **XCA, XCPD, DEC, PIV, PIXV3, LAW, PAM**
  - March 2017: **XDS-I, XCA-I, XUA**

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

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

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The central role of the Gazelle Platform

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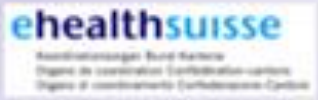
Gazelle Instances (2017)

1. InteropSanté-France
2. Arsenal.IT
3. Abrumet-Belgium
4. Agence eSanté-Luxembourg
5. GE
6. InterAMC France
7. KELA - Finland
8. IHE Japan - MoH
9. eHealthSuisse
10. eHealthPlatform-BE
11. DG Santé-European Commission
12. Sequoia-USA
13. Agfa
14. IHE China
15. EFS-French Transfusion-France






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

Benefits: vendors

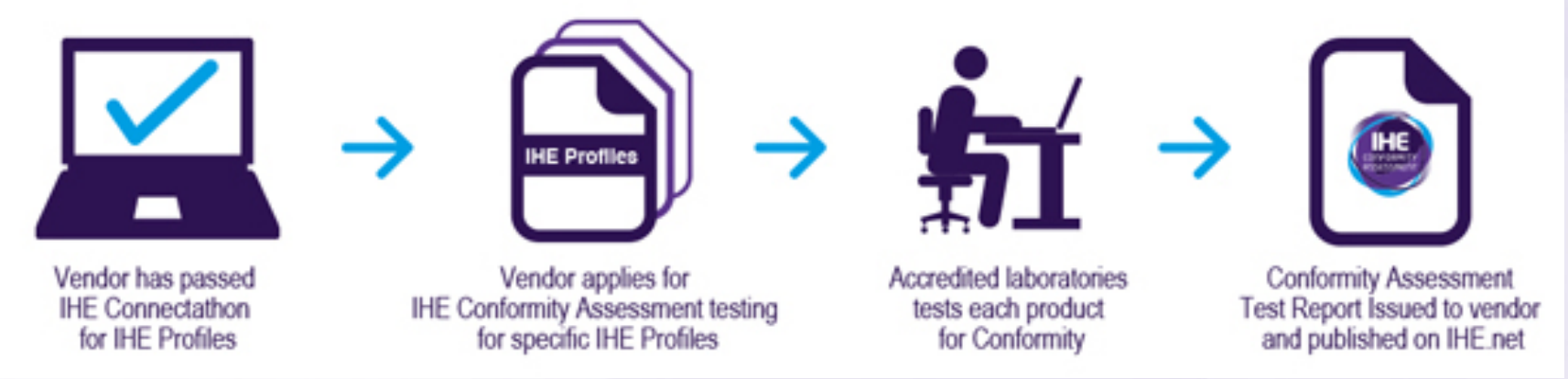
- Increase the interoperability readiness for systems and solutions.
- Gain global market credibility by distinguishing the company and its products
  - For listing of company and products: http://conformity.ihe.net/summary-reports
- Be recognized internationally and accepted for “shortlisting” (i.e., 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.

Questions

- Connectathon successful results: https://connectathon-results.ihe.net/
- IHE Conformity Assessment:

  http:// www.ihe.net/Conformity-Assessment
- For Test Reports:

  http://conformity.ihe.net



IHE SERVICES | Building trust in eHealth interoperability

Thank you for your attention!

Questions?