Standards-based Conformity Assessment Testing & Certification Programs

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Public and Private Sector Programs

• Sponsored by Independent, 3rd party healthcare organizations
• Focused on varied healthcare ecosystem stakeholders
• Programs in early production phase...learning, adopting, synergizing

Objective:
• Promote, Improve and Validate Health Information Exchange and Care Delivery

Approach:
• Leverage recognized industry standards to optimize value, uptake, and efficiency
Scope of Testing and Certification Programs

• Some programs are based on ISO/IEC 17025 (for Testing) and/or ISO/IEC 17065 (for Certification)
  – Provides the highest rigor + international recognition

• All leverage a testing and tools ecosystem made operational via extensive tool set adopted (not developed) by the program

  • Certification adds monitoring to verify conformity
  • Test results are published for transparency & industry use
IHE - Integrating the Healthcare Enterprise

• Vision: Enable seamless and secure access to health information whenever and wherever needed.

• IHE International Committees develop interoperability solutions, called IHE Profiles, using industry consensus.

• IHE Regional or National Deployment Committees host testing events called “Connectathons” around the world.

• As one example, IHE USA is a deployment committee that sponsors the annual IHE North American Connectathon.
IHE’s Global Connectathons

• Systems engineers from large and small companies dedicate a week to working together to **validate the interoperability capabilities** of their systems against IHE Integration Profiles.

• IHE Connectathons are supervised by an impartial team of “monitors.”

• IHE Connectathons take place annually in **North America, Europe, Australia, Japan, Korea, and China.**

• IHE Connectathon results are publicly available at: [http://www.ihe.net/Testing](http://www.ihe.net/Testing)

**Bottom line:** IHE’s Global Connectathons provide a neutral environment for competing vendors to collaborate to improve the quality and interoperability of their health IT systems.
IHE Conformity Assessment

• IHE is a non-profit, world-wide association of users and suppliers that facilitates healthcare IT systems’ information exchange.

• IHE develops Integration Profiles that constrain the use of base standards such as HL7, DICOM, etc.

• IHE engages thousands of suppliers from every corner of the world to participate in IHE Connectathons.

• The IHE Conformity Assessment program was launched in 2015 and is the next step in testing rigor
  – IHE Conformity Assessment is recognized world-wide
  – It is based on an ISO 17025 quality system
Scope of IHE Conformity Assessment

• IHE Conformity Assessment offers testing for specific IHE Profiles (see: [http://ihe.net/Conformity-Assessment/](http://ihe.net/Conformity-Assessment/))
  – For sharing health records: XDS.b, ATNA, PIX/PIXV3, PDQ/PDQV3, XCA, XCPD, XDS-I, XCA-I
  – For Hospitals, HIS, lab and ICUs: PAM, LAW, DEC, PIV

• **Testing 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](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**
The Sequoia Project & eHealth Exchange Initiative

Participant Testing Program
- Enables organizations wishing to participate in the eHealth Exchange network to validate the compliance of their implemented HIT with the eHealth Exchange Performance and Service Specifications

Product Testing Program
- Focus on compliance and interoperability testing
- Reduces cost and burden for participants to onboard by 50%
- Minimizes the level of vendor / developer support of providers / HIOs onboarding and their timelines
- Reduces risk of interoperability issues being introduced into production, including the cost and burden of fixing interoperability issues and deploying patches among connected stakeholders

Shared Governance and Trust Agreement
Common Standards, Specifications & Policies

10 Years of Progress
Celebrating 7 Years of Production on February 28, 2016

2006: EHR sponsors prototype architectures, followed by trial implementations.
2008: Focus shifted to supporting production plans.
2009: Final production exchange between Social Security Administration and Medicare, followed by veterans.
2012: Exchange transitions to The Sequoia Project.
2016: Nationwide implementation across 50 states 7 YEARS OF PRODUCTION on February 28, 2016

Largest Health Information Exchange Network in the U.S.
- All 50 states
- 26,000+ medical groups
- 3,400 dialysis centers
- 8,300 pharmacies
- ~50% of U.S. hospitals
- 100 million patients

http://sequoiaproject.org/ehealth-exchange/participants/
http://sequoiaproject.org/ehealth-exchange/testing-overview
Scope of Testing:
RSNA Image Share Validation
- Fills a national Standards Gap
  - Aligns with International Conformity Assessment
  - Aligns with ONC Roadmap
- IHE profiles provide the basis
- Modular
  - Cross-Enterprise Document Sharing for Imaging (XDS-I)
    - Document Source and Document Consumer
    - Registry and Repository
  - Cross-Community Access for Imaging (XCA-I)
  - RSNA Image Share PHR

Deployed Network Usage:
Image Share Network
- 11 radiology centers enrolling patients in the network
- Up to 20 more sites scheduled directly through RSNA
- Vendors are implementing the RSNA Image Share Edge application through their own Edge appliances (several hundred sites)
- As of January 30, 2016
  - Exams – 95,149
  - Images- 20,932,780 (assume 220 images/exam)
  - Patients- 22,776
  - 6073 of those patients have created personal health record accounts and accessed their images
• The Continua Design Guidelines enable “medical grade” connected health data exchange, not simply through interoperability but by ensuring that data is transmitted with sufficient accuracy, integrity, security and meta-data to ensure data can be used with confidence by clinicians and is ready for the automated analysis necessary to really scale connected health.

• The Continua Design Guidelines are the only solution for “authentic interoperability” in connected health – interoperability outside the clinical environment based on open standards rather than closed, proprietary solutions.

• 110 - Certified Products
• 9 - Recognized Test Labs Worldwide
• 10 – Continua Certification Experts Worldwide

www.pchalliance.org
Testing only the gaps found within each of the underlying standards testing and certification programs as they relate to Health, Medical and Fitness while ensuring Connected Health Authentic Interoperability.
ConCert by HIMSS™
3 Distinct Certifications

- for EHR systems providing a simplified way for providers to send secure health information directly to trusted recipients
- for HIE systems that enable clinicians to share health information within and across care delivery communities
- for Health Information Services Provider systems to send secure health information directly to trusted recipients, including patients

www.himssinnovationcenter.org/concert
ConCert by HIMSS™
Trusted Seal of Approval

- Simplifies the RFP process and lets providers quickly select the right system for their organization
- Designates that the product is proven to be interoperable with other products
- Enables vendors to achieve cost-effective, interoperability certification for solutions that facilitate efficient, seamless data exchange
- Dedicated to transparency, collaboration, accelerating interoperability and vendor-independence
- ICSA Labs is the authorized testing and certification body
- Uses a test tool standard of excellence -- Interoperability Testing Tool (ITT) from Stella Technology
- Specifications based on DIRECT and IHE profiles
- 7 vendor products received the ConCert seal in 2016
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