

PANEL 5: IHE CONFORMITY ASSESSMENT TESTING IN A GLOBAL CONTEXT

Panel Chair: Chris Carr, RSNA (United States)

Lapo Bertini, IHE Europe (Italy)

Joyce Sensmeier, HIMSS (United States)

Alexander Berler, IHE Europe (Greece)

Harm-Jan Wessels, ForCare (Netherlands)

Conformity Assessment in the U.S.

Joyce Sensmeier MS, RN-BC, CPHIMS, FHIMSS

President, IHE USA

VP Informatics, HIMSS

Legend

IHE Connectathons

RSNA Image Share Validation

ONC Health IT Certification

PCHA | Continua Certification

ConCert by HIMSS™

IHE Conformity Assessment

eHealth Exchange™

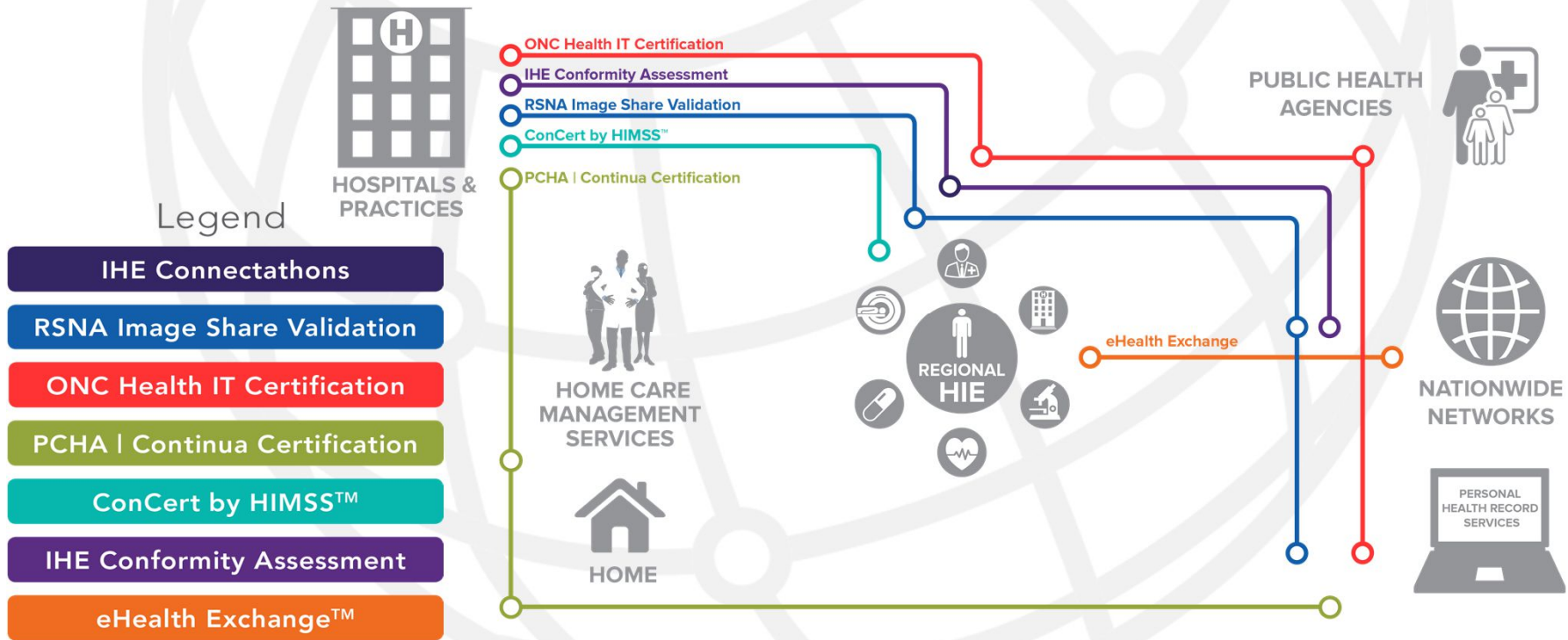
Objective:

- Promote, Improve and Validate Health Information Exchange and Care Delivery

Approach:

- Leverage recognized industry standards to optimize value, uptake, and efficiency
- Sponsored by Independent, 3rd party healthcare organizations
- Focused on varied healthcare ecosystem stakeholders
- Programs in early production phase...learning, adopting, synergizing

IHE Connectathons

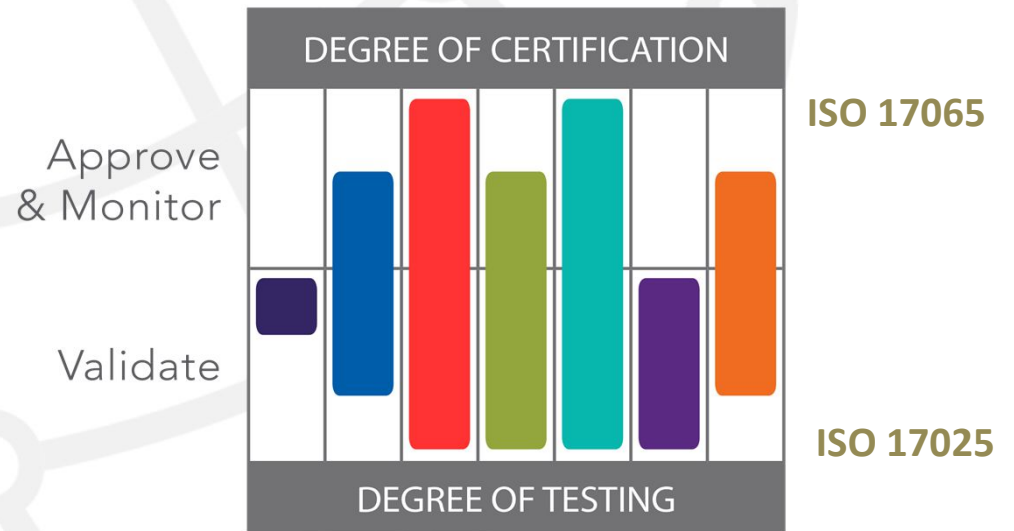


IHE Connectathons

Legend

- IHE Connectathons
- RSNA Image Share Validation
- ONC Health IT Certification
- PCHA | Continua Certification
- ConCert by HIMSS™
- IHE Conformity Assessment
- eHealth Exchange™

- Test results are published for transparency & industry use
- Certification adds monitoring / surveillance to verify conformity



Comparison chart of rigor and testing

Tests compliance of vendor systems to standards for exchange of medical images used in the RSNA Image Share Network

- 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



Largest Health Information Exchange Network in the U.S.

All 50 states



4 federal agencies
(DoD, VA, HHS including
CMS, and SSA)



~50% of U.S.
hospitals



26,000+ medical groups



3,400 dialysis centers



8,300 pharmacies



100 million patients

Participant Testing Program

Enables organizations wishing to participate in the eHealth Exchange network to validate the compliance of their implemented Health IT with the eHealth Exchange Performance and Service Specifications



Product Testing Program

Focus on compliance and interoperability testing of products in eHealth Exchange



- **PCHA** publishes the Continua Design Guidelines, an open implementation framework for, end-to-end interoperability of personal connected health devices and systems.
- **Continua Design Guidelines** are based on common international standards defined by recognized standards development organizations.

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




Continua®
CERTIFIED

www.pchalliance.org



ONC Health IT Certification



- A voluntary certification program established by the U.S. Office of the National Coordinator for Health IT to provide for the certification of health IT standards, implementation specifications and certification criteria adopted by the Secretary.
- Supports the availability of certified health IT under federal, state and private programs.
- ONC administers the program while working with other organizations that function in the following capacities:
- **Testing:** The National Voluntary Laboratory Accreditation Program as  administered by the National Institute of Standards and Technology (NIST), is responsible for accrediting and overseeing Accredited Testing Laboratories
- **Certification:** ANSI is responsible for accrediting Authorized Certification Bodies
- New survey data shows nearly all of the nation's hospital have adopted certified EHRs.

This represents a nine-fold increase since 2008.



ConCert by HIMSS™



- **ConCert by HIMSS™** is a comprehensive interoperability testing and certification program governed by HIMSS and built on the work of the EHR|HIE Interoperability Workgroup and IHE USA.
- Independent 3rd party assessment of connectivity for interoperable solutions
- Launched through a partnership with HIMSS, ICSA Labs, and Stella Technology
- Based on **IHE Profiles** and DIRECT protocol (U.S.)
- Governed by the ConCert by HIMSS Advisory Committee



www.himssinnovationcenter.org/concert

Easy for
Purchaser

- Providers need to understand what to ask for

Simple
for
Vendor

- Vendors need a simplified process that works

Testing
Rigor

- Testing must be rigorous and automated

Marketing

- Industry needs a brand it can trust

- ICSA Labs is the testing and certification body
 - Based on the ISO 17065 standard and process
- Includes post-deployment surveillance process
- Testing is highly automated using the Interoperability Testing Tool (ITT)
- Alignment with IHE Conformity Assessment is being actively planned
 - Incorporating the IHE USA Certification program
- **7 Vendor products certified in 2016**
- **2 more to be completed in June 2016**

- **QUERY- Based Exchange** - Statewide Patient Data Inquiry Service Specifications
 - IHE Profiles (XDS, PIX, PDQ)
 - ONC's Nationwide Health Information Network Exchange Specifications
- **DIRECT Exchange** - Statewide Send and Receive Patient Record Exchange Specifications
 - IHE Profiles (XDR, XDM, HPD)
 - ONC's DIRECT Exchange protocols



for EHR systems that provide a simplified way for providers to send secure health information directly to trusted recipients and patients



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



Thank you!



Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN

IHE USA President

Vice President of Informatics, HIMSS

JSensmeier@himss.org

www.iheusa.org