1. IHE Conformity Assessment Program
2. Connectathon and self-attestation model
3. Accredited conformity assessment (certification)
4. Infrastructure to support certification effort
5. Lessons learned from IHE USA certification experience regarding:
   – operational processes/policies
   – structure of offering
   – time to market
Since 1999, IHE has provided:

- Organized and monitored testing with detailed specifications and testing tools
- Publication of testing results through Websites and public demonstrations
- In 2003 added form for vendor self-attestation: IHE Integration Statement

Connectathon Testing

Multi-day Face-to-face Testing Events
Conformance Reporting

Websites:
- www.ihe.net
- product-registry.ihe.net
- connectathon-results.ihe.net

Integration Statement

Integration Statement
Benefits:
• Lightweight and low cost for IHE and vendors
• Enables direct communication to customers
• Simple conformance matrix: profile/actor<option

Weaknesses:
• Uncertainty about authority of attestation
• No direct linkage between testing and product conformance
In 2013, IHE USA launched a pilot certification program. Goals of the program are to:

- Promote broader adoption of IHE standards, tools, and services
- Ensure IHE-conformant products are delivered to the marketplace
- Increase buyer confidence that IHE mark ensures interoperable systems

IHE USA Certification Pilot Process Flows:

- Connectathon
  - Vendor Registers Product
  - Pre-Connectathon Testing
  - Live Peer-Peer Testing
  - Pass

- Certification Testing – Elective, fee-based
  - Product + Profile + Actor specific
  - Enhanced Peer-Peer Testing
  - Enhanced testing with tools
  - Vendor Registers Product
  - Test Report & Conformance Worksheet
  - Contract/SoS with ICSA Labs

- Certification Body, Independent from Testing,
  - Evaluator review of tests & doc
  - Additional testing required
  - Certification
  - Pass
  - Certification Body
  - Certification Published
  - Product Surveillance

Testing - In conformance with ISO 17025 Testing Lab Standard

Certification - In conformance with ISO Guide 65 Certification Body Standard

Certification Granted
IHE USA Certification Pilot

• Results:
  – 8 vendors participated in the first pilot
  – Performed testing to IHE USA requirements
  – 4 vendors participated as supportive partners to enable a complete environment of end-to-end tests
  – 40 IHE profile actor/pairs were tested
  – Test results were analyzed and candidates for certification were submitted to the ICSA Labs Certification body
  – Award/announced certification of approved candidates

Requirements for 2014

• Vendors can apply for IHE USA Certification on products that have successfully passed Connectathon tests (on equivalent “testable units”) anywhere in the world from January 2010 onwards.
  – Verified via Connectathon Results database

• Vendors who have successfully passed the appropriate tests at the 2014 North American Connectathon could also apply for Certification once those tests are completed.
Infrastructure

• Organizational/legal
  – IHE USA entered into MOU and Master Services agreement with accredited testing lab, ICSA Labs
  – IHE USA is the scheme holder providing criteria for testing and certification based on existing IHE Technical Framework documents
  – ICSA Labs is the accredited certification body for the program which is governed by ISO 17065

Financial

• IHE USA and ICSA Labs have each committed extensive financial and staffing resources to the program.
• Fee structure is based on certification packs of 5 testable units (profiles) with the option of additional single testable units.
• IHE USA and ICSA Labs share in the revenue.
• The North American Connectathon is leveraged as the physical location for testing to minimize costs for IHE USA and the participating companies.
Administrative/Operational

- IHE USA (and potentially other IHE national deployment committees) administer IHE certification programs
- IHE USA Board provides oversight
- ICSA Labs executes the testing and certification activities
- IHE USA/ICSA Labs convene regular operational and technical discussions regarding test processes, test tools and test plans
  - Annual review of marketplace needs and maturity of IHE profiles to determine selected profile offerings

Structural/Process

- Integrating recommendations of Pilot Evaluation Report
- Ongoing target market:
  - EHR and device vendors that have previously participated in an IHE Connectathon
  - Other implementers of IHE profiles (HIEs, Projectathons)
- Perform annual recruitment process
- Execute application process through IHE USA
Internationalization

- IHE International becomes scheme holder
  - Establishes oversight committee and governance process
- Scheme establishes general procedures for accredited conformity assessment for all IHE national bodies
- Participating national bodies agree on scope of testing specifications to be offered annually
- Programs may offer testing mark or full product certification
  - Certification includes tracking of product versions

Profiles to be Offered for Certification in 2014

<table>
<thead>
<tr>
<th>Domain</th>
<th>Profile</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ITI</td>
<td>ATNA</td>
<td>Audit Trail and Node Authentication</td>
</tr>
<tr>
<td>ITI</td>
<td>CT</td>
<td>Consistent Time (requirement for almost every profile)</td>
</tr>
<tr>
<td>ITI</td>
<td>PDQ/PDQv3</td>
<td>Patient Demographics Query</td>
</tr>
<tr>
<td>ITI</td>
<td>PIX/PIXv3</td>
<td>Patient Identity Cross-Reference</td>
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<tr>
<td>ITI</td>
<td>RFD</td>
<td>Retrieve Form for Data Capture</td>
</tr>
<tr>
<td>ITI</td>
<td>XCA</td>
<td>Cross-Community Access</td>
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<tr>
<td>ITI</td>
<td>XDM</td>
<td>Cross-Enterprise Document Media Interchange</td>
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<tr>
<td>ITI</td>
<td>XOR</td>
<td>Cross-Enterprise Document Reliable Interchange</td>
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<tr>
<td>ITI</td>
<td>XDS.b</td>
<td>Cross-Enterprise Document Sharing</td>
</tr>
<tr>
<td>ITI</td>
<td>XUA</td>
<td>Cross Enterprise User Assertion</td>
</tr>
<tr>
<td>LAB</td>
<td>XD-Lab</td>
<td>Sharing Lab Report</td>
</tr>
</tbody>
</table>

Profiles marked with an asterisk (*) are new in 2014 | Profiles marked with a double asterisk (**) are to be tested provisionally in 2014
# New Profile Candidates For the Certification Roadmap for 2015

<table>
<thead>
<tr>
<th>Domain</th>
<th>Profile</th>
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<tbody>
<tr>
<td>CARD</td>
<td>CRC</td>
<td>Cardiac Cath Report Content</td>
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<td>CARD</td>
<td>ECHO</td>
<td>Echocardiography Workflow</td>
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<td>DENTAL</td>
<td>SEDI</td>
<td>Secure Exchange of Dental Information</td>
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<tr>
<td>ITI</td>
<td>D5AP</td>
<td>Data Segmentation for Privacy</td>
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<td>ITI</td>
<td>MHD</td>
<td>Mobile Access to Health Documents</td>
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<td>PHARM</td>
<td>DIS</td>
<td>Pharmacy Dispense</td>
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<td>PHARM</td>
<td>PADV</td>
<td>Pharmacy Pharmaceutical Advice</td>
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<td>RAD</td>
<td>ARI</td>
<td>Access to Radiology Information</td>
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<td>CPI</td>
<td>Consistent Presentation of Images</td>
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<td>KIN</td>
<td>Key Image Note</td>
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<td>MAMMO</td>
<td>Mammography Image</td>
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<td>RAD</td>
<td>PDI</td>
<td>Portable Data for Imaging</td>
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<tr>
<td>RAD</td>
<td>SWF.b</td>
<td>Scheduled Workflow.b</td>
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</tbody>
</table>

Profiles marked ★★ are new in 2015 | Profiles marked ☢ will be tested PROVISIONALLY in 2015 | *Profiles that were provisional in 2014 | Profiles Proposed in relation to ONC efforts

## Questions??