
# Interoperability Testing and Certification

Session INT2, February 19, 2017

# Moderator/Speaker Introductions

Moderator: Elliot B. Sloane, PhD, FHIMSS
President, Center for Healthcare Information Research and Policy (CHIRP)

Speakers in order of appearance:

Sheryl Taylor, BSN, RN, IT Specialist
National Institute of Standards and Technology

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National Institute of Standards and Technology

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Robert D. Snelick, Project Lead-Conformance Tooling, NIST

Sheryl L. Taylor, IT Specialist, NIST

NIST National Institute of Standards and Technology U.S. Department of Commerce

# Conflict of Interest

Robert Snelick, MS

Sheryl Taylor, BSN, RN

Have no real or apparent conflicts of interest to report.

# Agenda

- Etiology of Current State of HIT Interoperability
- Interoperability, Standards, and MACRA/MIPS
- Certification
  - Building Blocks
  - NIST Experience with ONC
- Lessons Learned
  - Standards
  - Testing
- Standards Development
- Definitions of Concepts
  - Conformance, Interoperability, Compliance, Compatibility, Profiling
- Testing and Interoperability

# Learning Objectives

- Evaluate methodologies and approaches the HIT industry can leverage to improve the relevance of certification testing that utilizes conformance test tools
- Describe lessons learned from standards and conformance tool development activities associated with ONC HIT certification to-date and how these lessons can help improve the outcomes of certification testing in the future
- Identify existing resources and tools available for conformance testing in domains such as public health and transmission of laboratory results
- Discuss how various testing tools offered by NIST as a government standards agency help improve consistent interpretation and implementation of interoperability standards (e.g., HL7 v2) by all stakeholders

# An Introduction of How Benefits Were Realized for the Value of Health IT

Health IT interoperability based on well-written data exchange standards enables value realization for

- T: Treatment/Clinical
  - Safety
  - Quality of Care
  - Efficiencies
- E: Electronic Secure Data
  - Data Sharing
  - Enhanced Communication
- S: Savings
  - Financial/Business
  - Efficiency

# Interoperability and Health IT

Goal: Provide the right data at the right time to the right party for the right patient

- Etiology of current state of interoperability
  - Legislation
  - Regulation
  - Standards
- Role of standards (e.g., HL7, LOINC) in interoperability
- Role of interoperability in support of MACRA[1] and MIPS[2]

[1]Medicare Access and CHIP Reauthorization Act of 2015

[2]Merit-based Incentive Payment System

# Etiology of Current Interoperability – Legislation/Regulation

HITECH (Health Information Technology for Economic and Clinical Health) Act[1]

- US incentive/penalty program to encourage adoption and “meaningful use” of certified Health IT
- CMS EHR Meaningful Use (MU) staged approach
  - Rules for Eligible Hospitals/Critical Access Hospitals and Eligible Professionals (e.g., physicians)
  - Stage 1, Stage 2, Modified Stage 2, Stage 3
  - MIPS for Medicare Eligible Professionals
- ONC Certified Health IT approach
  - Rules for HIT developers including data exchange standards for interoperability
  - 2011 Edition for Stage 1 MU
  - 2014 Edition for Stage 1, Stage 2, Modified Stage 2 MU
  - 2015 Edition for Stage 3 MU and MIPS

[1]Part of American Recovery and Reinvestment (ARRA) Act of 2009

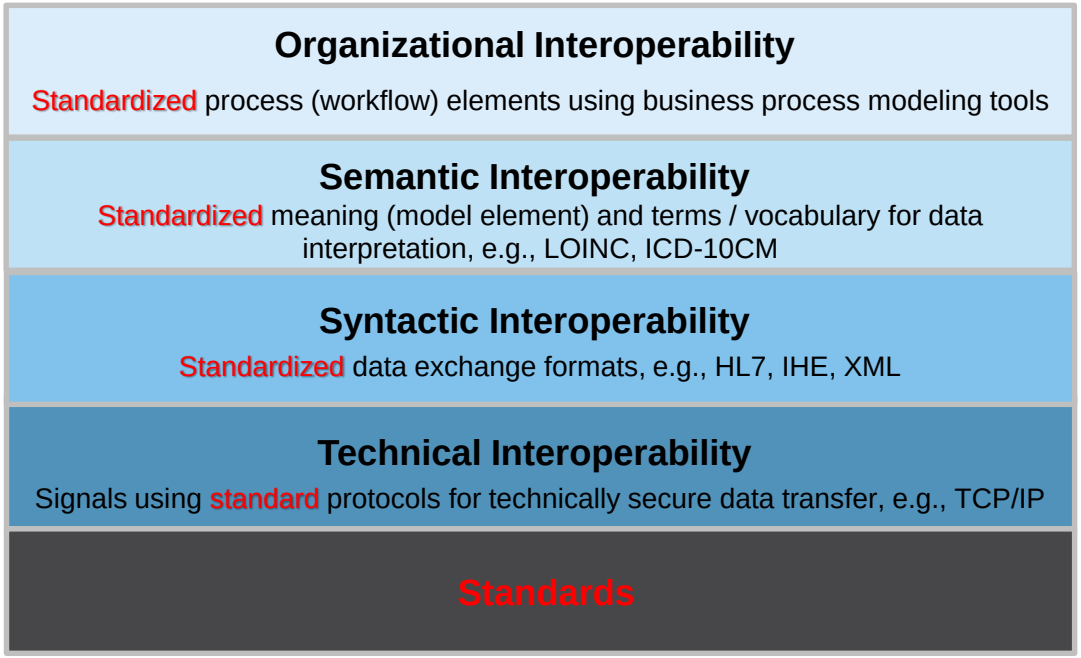
# MU as Platform for Interoperability

- Required providers to exchange information with other providers, public health agencies, patients
- Required adoption of ONC certified Health IT
- Required standards-based data exchange between disparate certified Health IT
- Resulted in
  - Many providers having experience in implementing initial level of interoperability
  - Certified Health IT Modules including data exchange capabilities that can be built upon to resolve interoperability challenges

# Etiology of Current Interoperability – Standards

- Standards Development Organizations (SDOs) for Health IT
  - Responsible for developing standards for specific Health IT domains before MU Program
    - Health Level 7 (HL7) and Integrating the Healthcare Enterprise (IHE) develop syntactic data exchange standards for healthcare
    - American College of Radiologists (ACR) developed/maintains Digital Imaging and Communication in Medicine (DICOM) syntactic data exchange standard for radiology and other images
    - National Council for Prescription Drug Programs (NCPDP) creates national syntactic data exchange standards primarily for prescribing, dispensing, monitoring, managing, and paying for medications and pharmacy services
    - Regenstrief Institute maintains Logical Observation Identifiers Names and Codes (LOINC) semantic data exchange standards for healthcare
- Standards may be
  - Well-written or poorly-written
  - Complementary or competitive with other standards

# Role of Standards




Interoperability is based on standards

# Relevant Facts about MACRA

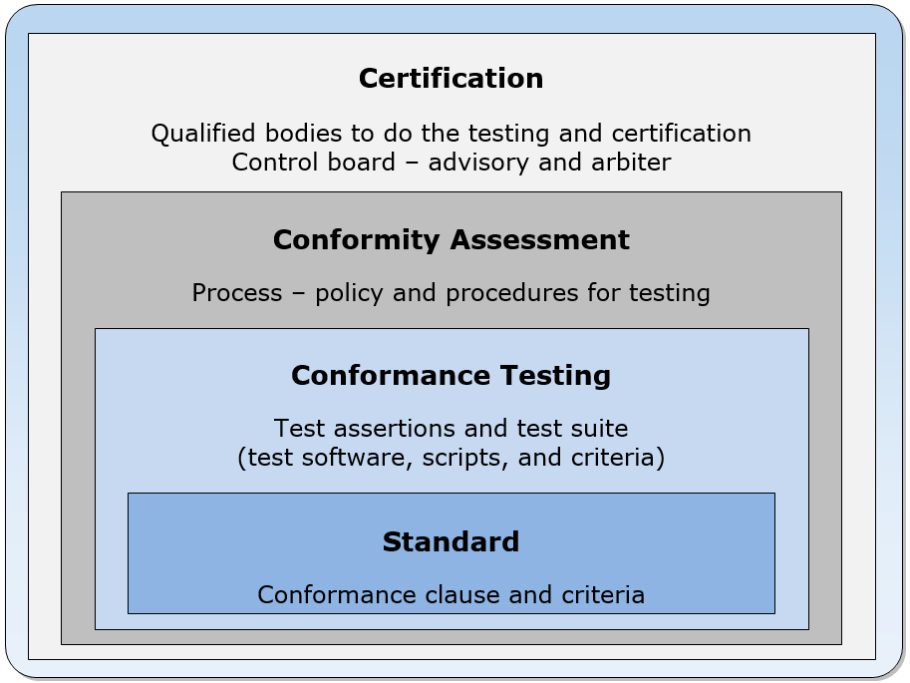
- Published in Final Rule released by CMS on October 14, 2016
- Provides “a new framework for rewarding healthcare providers for giving better care not just more care”[1]
- Repeals Medicare Part B Sustainable Growth Rate (SGR) reimbursement formula
- Replaces SGR with Quality Payment Program (QPP) value-based reimbursement system
- Includes MIPS that applies to Medicare MU Eligible Professionals, i.e., physician practices and others currently paid via Medicare Part B

[1] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-QPP-MIPS-and-APMs/MACRA-QPP-MIPS-and-APMs.html

# Role of Interoperability for MIPS

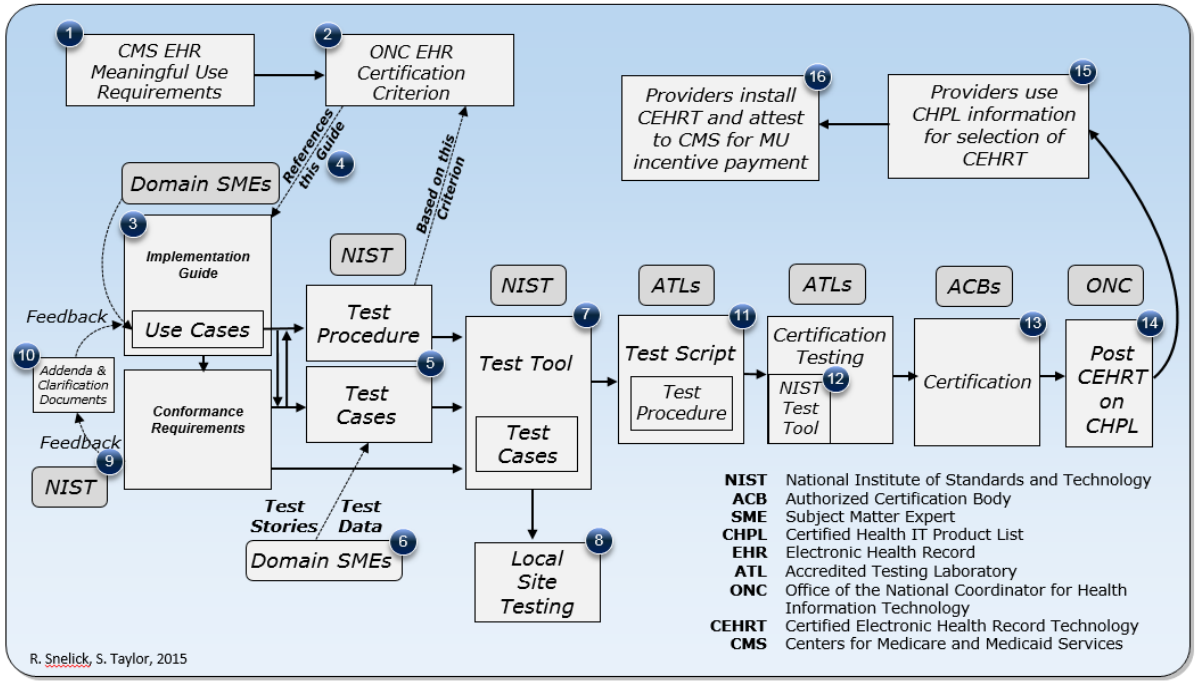
- MIPS replaces CMS Stage 3 MU for Medicare Eligible Professionals
- Physician reimbursement is tied to
  - Quality and value
  - Resource use
  - Clinical practice improvement
  - Meaningful use of certified Health IT
- Health IT interoperability is essential for value-based care under MIPS
  - Coordinated Care Models (physicians, hospitals, PHA share patient information)
  - Population management
  - Quality reporting

# Certification Building Blocks




- Relationship exists among the standard, conformance testing, conformity assessment, and certification
- None of the outer-layers of blocks can be performed unless the inner-layers of blocks have been completed
- Certification can only be accomplished when all of the three lower-level building blocks are in place; you can stop anywhere along this spectrum

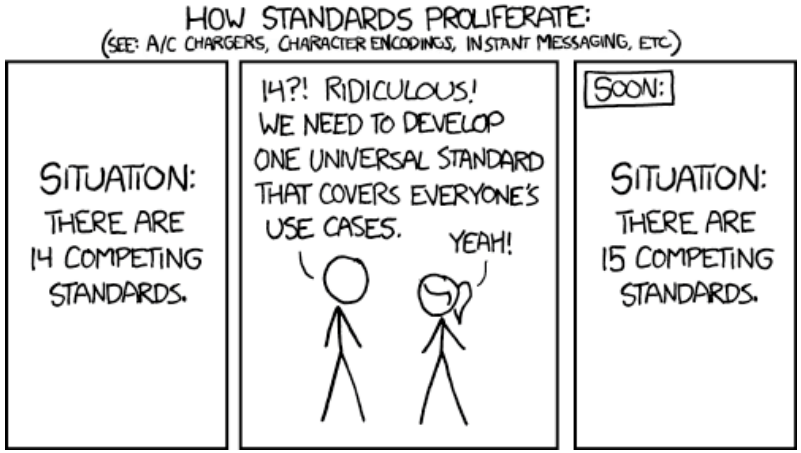
# NIST Experience in ONC Certification




- Process when a conformance test tool is part of the criteria
- Specifically for NIST HL7v2 tools
- Indicates the multiphase and iterative process
- Often requires clarification of requirements and addendums to the standards

# Lessons Learned: Challenges with Standards

- Ambiguous
- Complex
- Not specific enough for use cases
- Evolving
- Timeliness
- Not complete
- Inadequate investment
- Lack of verification (Implementations and Testing)
- Too many
- Not written to a desired state


Used with permission. http://xkcd.com/927

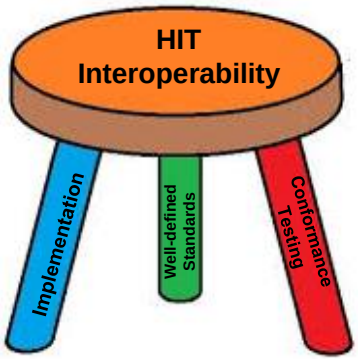
# Lessons Learned: Realities of Testing

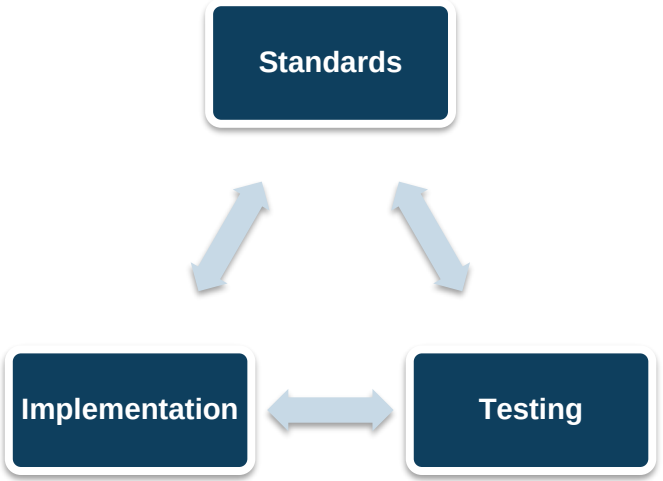
- Bound to the quality of the standards
- Tolerance for comprehensiveness
- Time
- Budgets
- Inadequate Investments


- What to Test?
  - Boundless instances
  - Adequate test coverage
  - What are the priorities?
- Test Cases
  - Realistic
  - Data
  - “Getting it right”

# Integrated and Continuous Process

- Standards Development Lifecycle
- Foundations of Interoperability
  - Well-defined Standards
  - Testing
  - Implementation



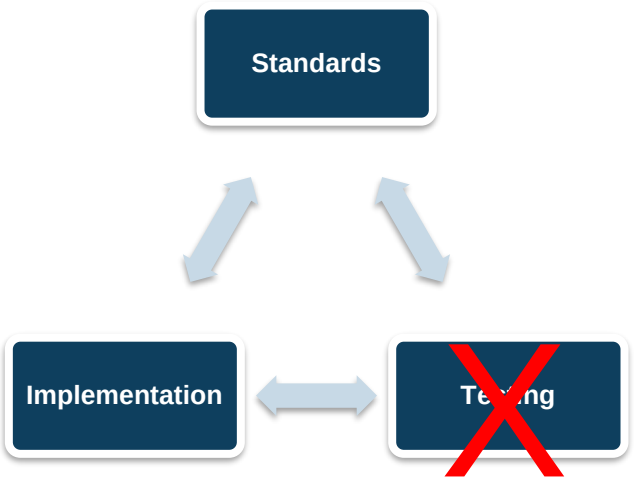



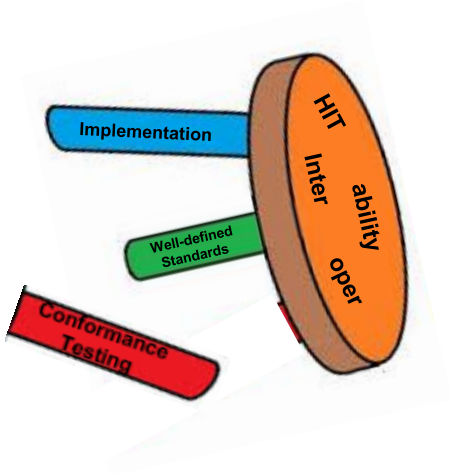
# Success Depends On

- Well-defined Standards – precise and complete requirement specification 
  - Conformance constructs
  - Profiling (Management and Use)
- Testing standards and trial implementations
  - Conformance Test tools 
  - Initial test implementations 
    - Reference
    - Pilot
- Standards Development Lifecycle
  - Feedback to authors, tool developers, and implementers
- Interoperability Testing

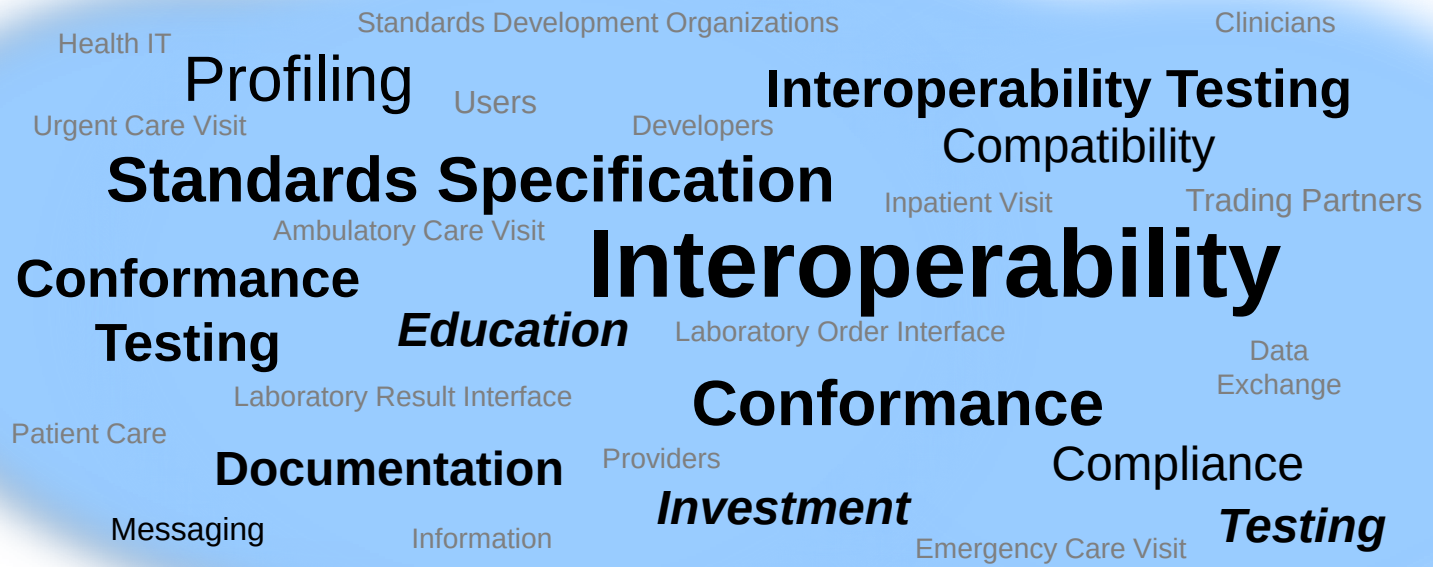
# Failure Happens When

- One or more components are omitted or are not sufficient



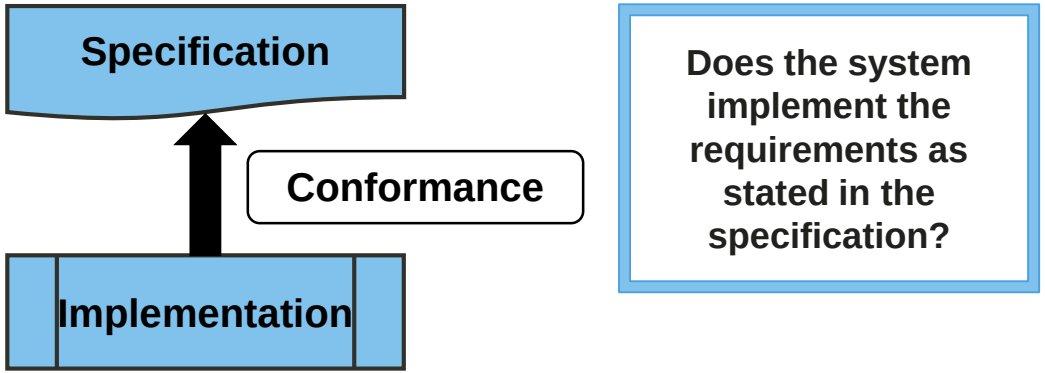



# Elements for Success



# Conformance

- Defined as the fulfillment of a product, process, or service of specified requirements [1,2].
- The concept of conformance is essential to any standard for providing an objective measure of how closely implementations satisfy the requirements defined in the standard [1,2].



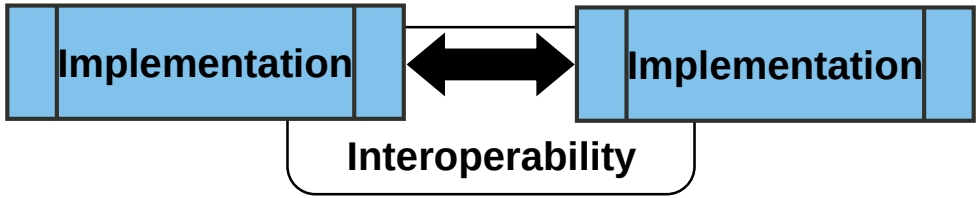

[1] ISO Reference - ISO/IEC 17000 Conformity assessment - Vocabulary and general principles, first edition 2004-11-02.
[2] Glossary of Conformance Terminology, Interoperability and Conformance Technical Committee, OASIS. http://www.oasis-open.org/committees/ioc/glossary.htm

# Interoperability

- "…is the ability of two or more systems or components to exchange information and to use the information that has been exchanged." [1]
- Two Key Parts:

1) Information must be exchanged, which refers to the technical/functional/syntactical characteristic;

2) But the more important part is the correct semantic interpretation allowing for use of the exchanged information [2].

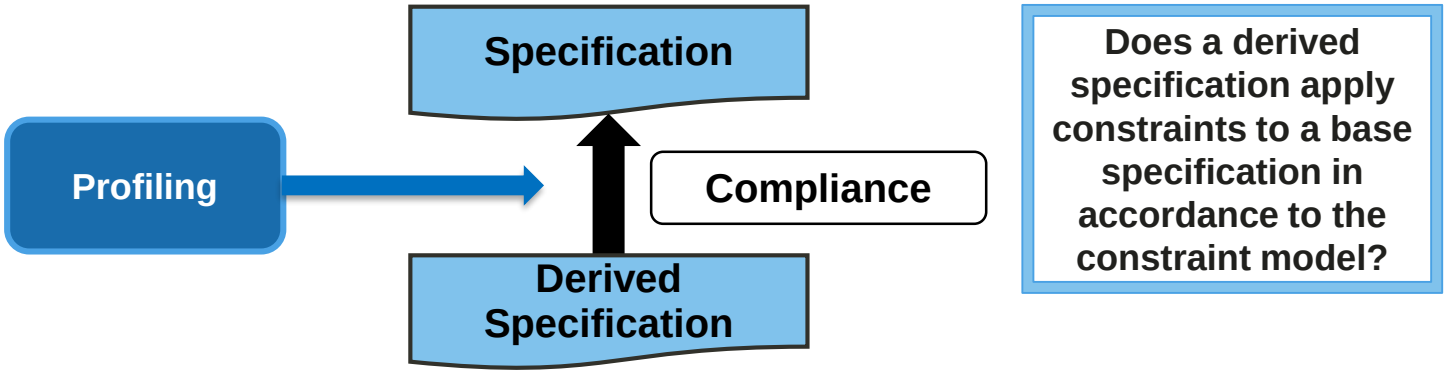



**Can two interconnected systems exchange data and use that data to perform a business function as both intended?**

[1] [IEEE-1990] Institute of Electrical and Electronics Engineers. IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries. New York, NY: 1990.
[2] Benson T. Principles of Health Interoperability HL7 and SNOMED. Health Informatics Series, Springer-Verlag, London Limited 2010.

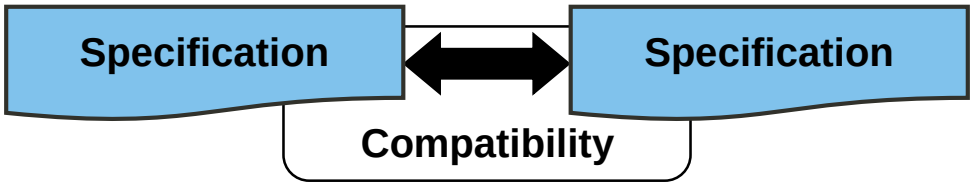
# Compliance

- Is the degree to which a derived specification adheres to the requirements defined in the foundational specification (standard)
- In other words, are the rules for adding constraints or extending the specification faithfully followed?



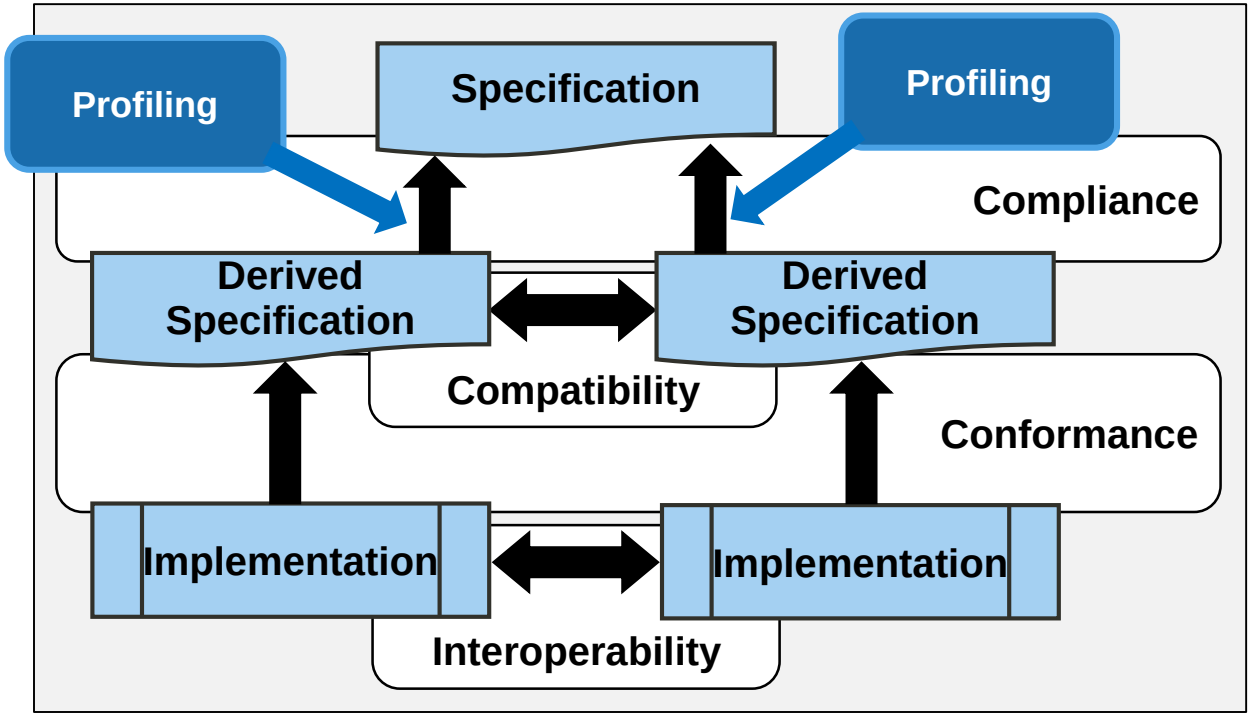
# Compatibility

- Declares whether two specifications define sets of requirements that are harmonized with each other, allowing systems that implement them to work together, i.e., interoperate
- Compatibility is a prerequisite for interoperability



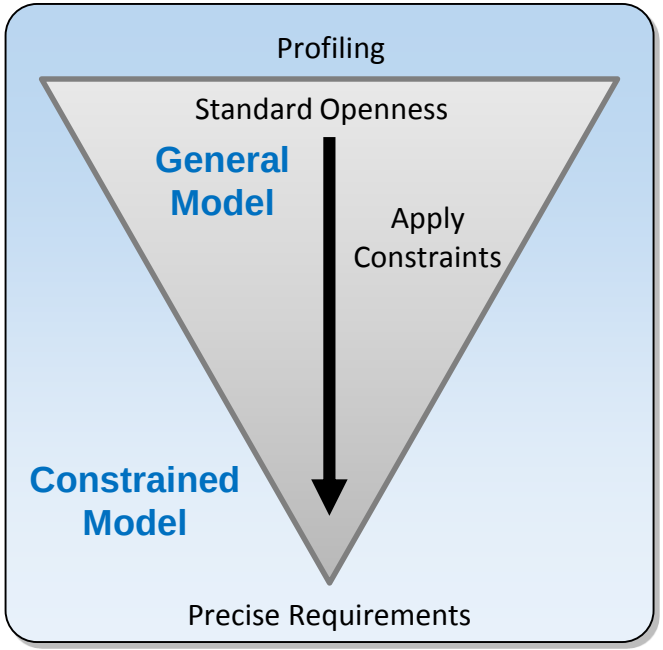

**Do the specifications define a set of harmonized requirements?**

# How is Profiling Related?




Source: F. Oemig, R. Snelick [2016]

# Profiling

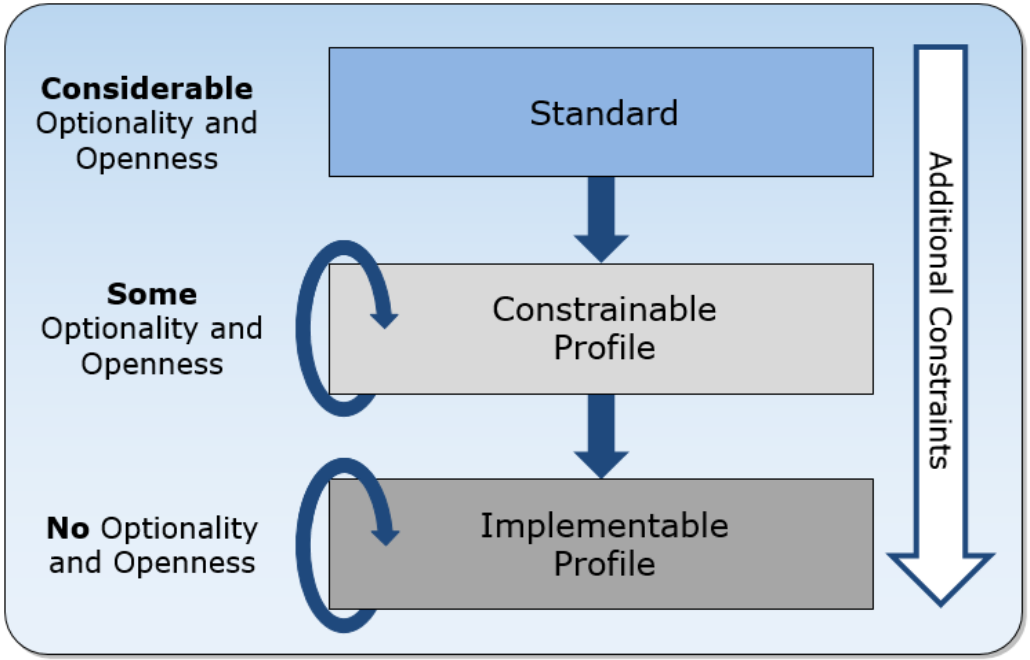



**Base standards typically provide a framework with many options**

- Is the process of applying constraints to a base model to address a particular use case
- Is a refinement of the standard
- Reduces or eliminates the optionality of a base standard by constraining a general model for a specific use
- Allows implementers to document an agreed-upon subset of the standard, and thus arrive at a common interpretation

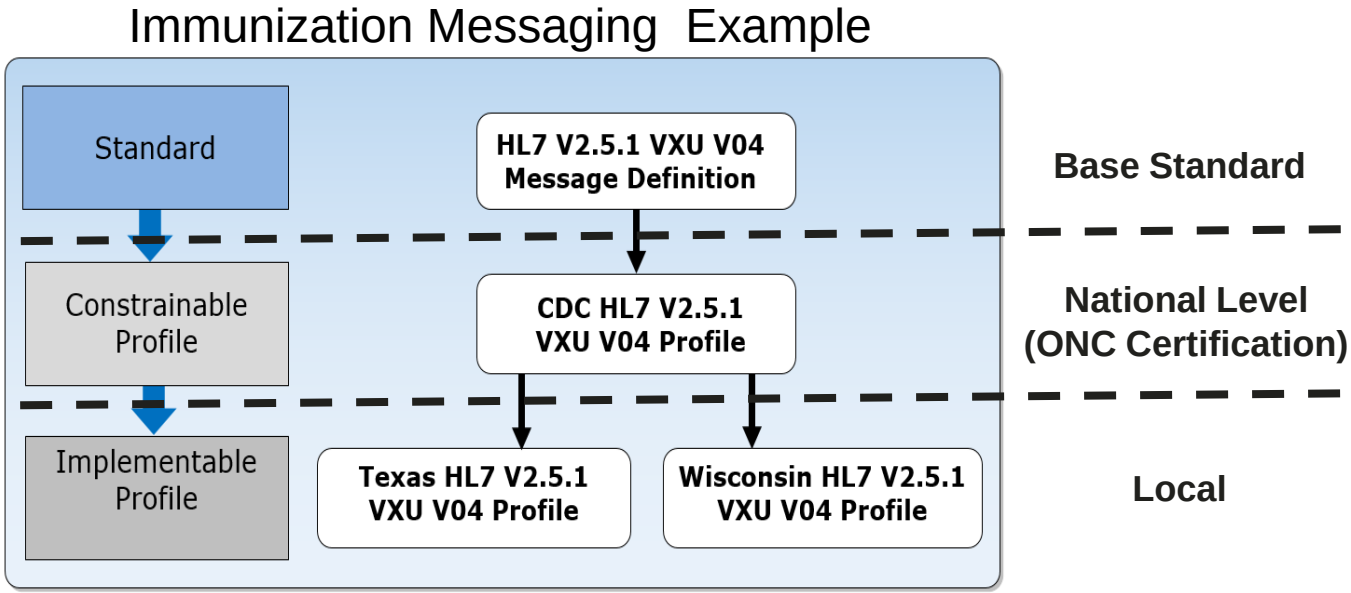
**Use Case definition, profiling, and associated documentation are necessary for meaningful conformance and interoperability testing of implementations**

# Profile Hierarchy



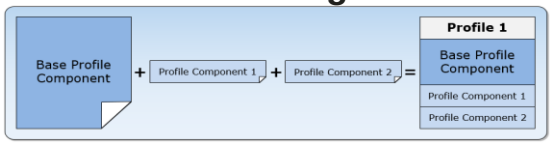

- Multiple levels of profiling—all levels useful and important
- Narrows focus to specific use cases
- Provides explicit documentation
- Computable representation
- Profiling is performed one way or the other—why not document!

# How Profiles are Used

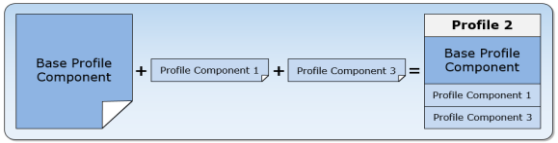


# Profile Design and Management

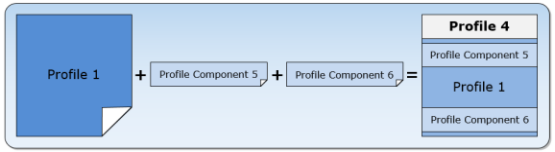
## Use as Building Blocks



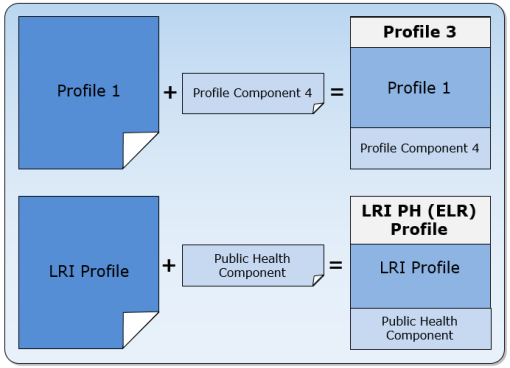

## Reuse and Replacement



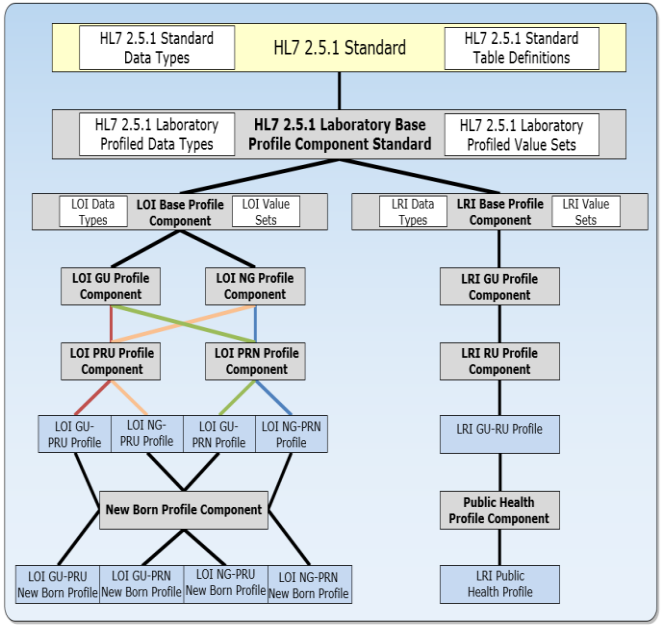

## Requirement Substitution



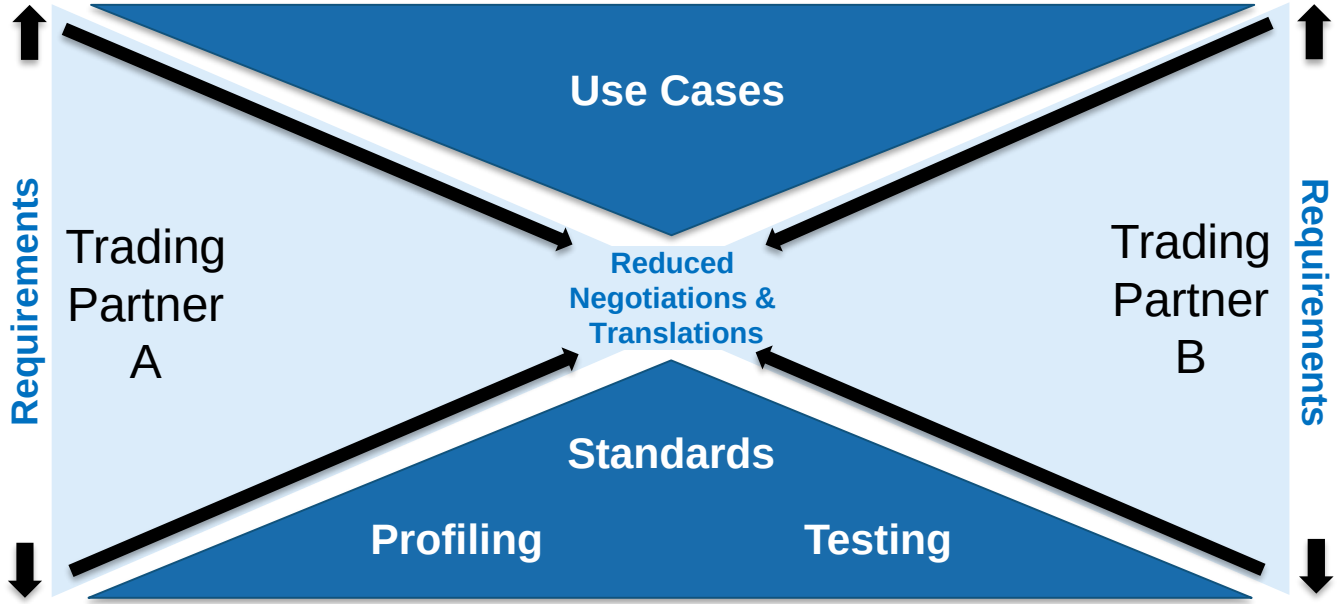

## Expanding a Use Case




## Profiles: Levels and Options

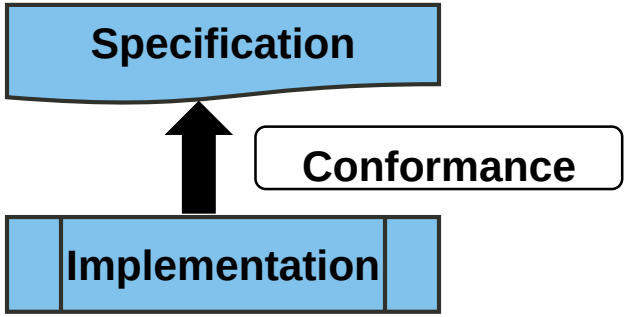


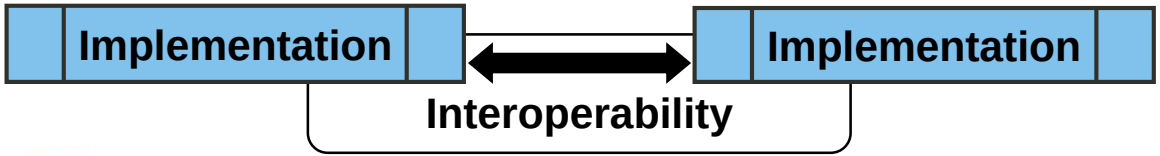
# Towards Interoperability



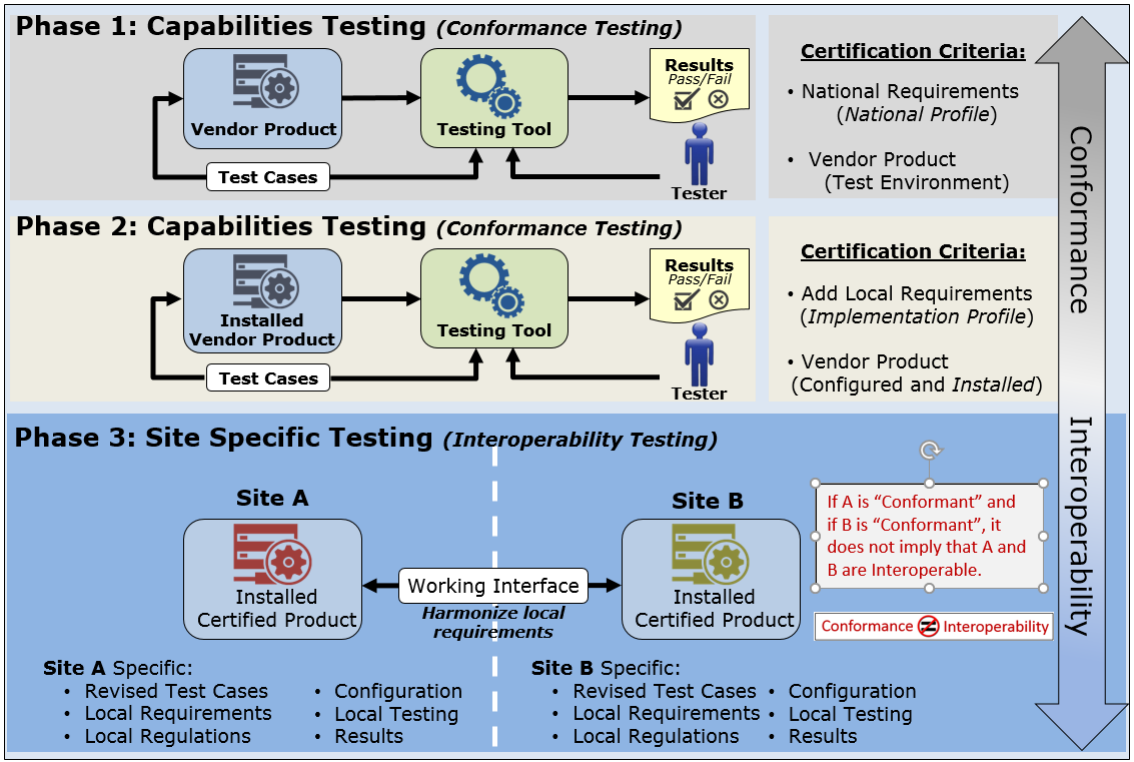
# Testing Overview

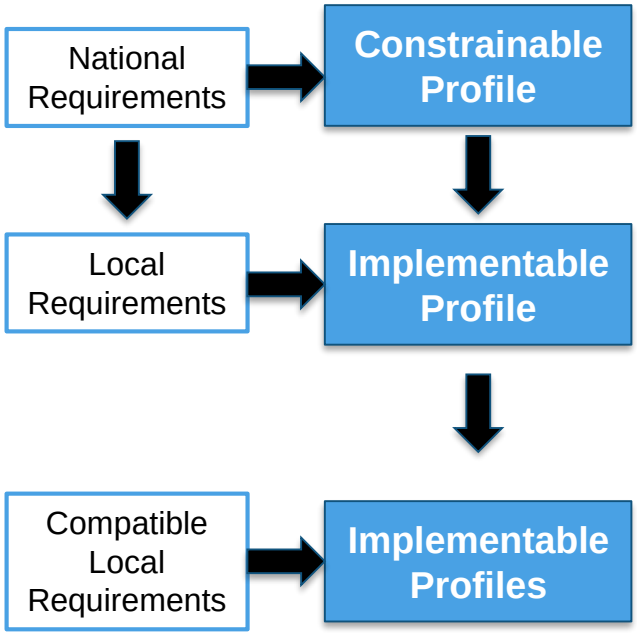
- Conformance Testing
  - Data Instance Testing
    - Object ↔ Requirements
  - Isolated System Testing
    - System ↔ Requirements
- Interoperability Testing
  - Peer-to-peer System Testing
    - System ↔ Requirements ↔ System



# Testing Progression



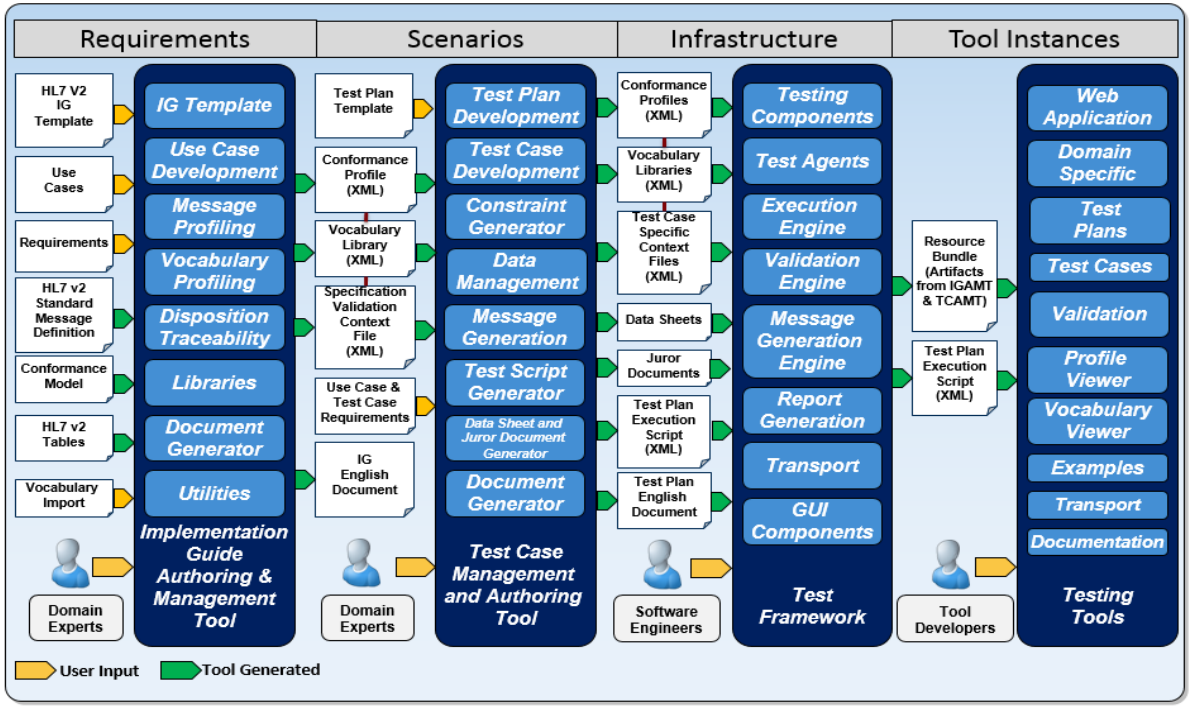



# Some Successes

- Awareness
  - Standards
  - Testing
- Resulting Actions
  - Directed efforts for standards improvement
  - Investments in tooling
  - Emphasis on real testing scenarios and data
- Outcomes
  - ONC Certification → Conformance (Capability) Testing
  - IHE Connect-a-thon Testing → Interoperability Testing

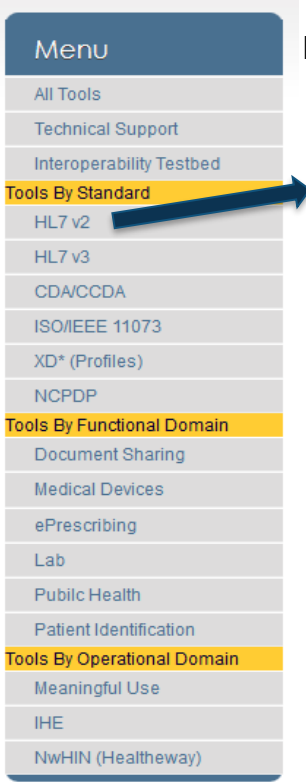
But we need much more!

# Strategy for Success

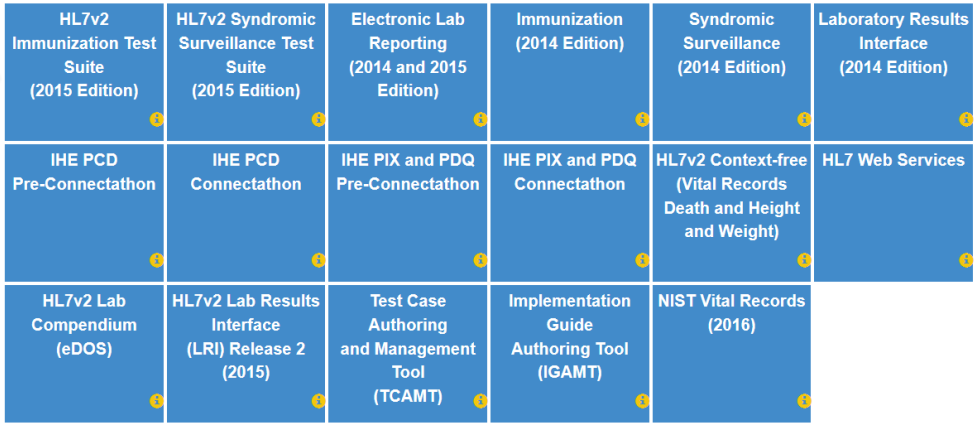



- Automated process
- Built-in expertise
- Computable standards and testing artifacts
- Single point of change
- Invest in testing infrastructures (services)
- Tools to build tools
- Give the power to the domain experts

# NIST Testing Tools & Resources




http://healthcare.nist.gov




http://hl7v2tools.nist.gov

- Deployment
  - Web Applications
  - Web Services
  - Source Code
- Uses
  - Certification
  - Self-attestation
  - On-boarding
  - Integrated

# A Summary of How Benefits Were Realized for the Value of Health IT

Health IT interoperability based on well-written data exchange standards has enabled value realization for

- T: Treatment/Clinical
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- E: Electronic Secure Data
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# Interoperability Testing and Certification

Session INT2, February 19, 2017

John T. Donnelly, President, IntePro Solutions Inc

IntePro SOLUTIONS

# Speaker Introduction

John T Donnelly, MBA, MS, CPHIMS

President, IntePro Solutions, Inc.

- *HIT architect and Interoperability SME for 20+ years*
- *Member of inaugural ONC HITSP team and repeated co-chair of ONC S&I committees*
- *3-term elected Board member of IHE International and elected Board member of NJ HIMSS chapter*
- *Technical project mgr of HIMSS Interoperability Showcase for 10 yrs; ongoing HIMSS strategic advisor*

# Conflict of Interest

John T Donnelly, MS, MBA

Has no real or apparent conflicts of interest to report.

# Learning Objectives

- Evaluate methodologies and approaches that the industry can adopt to excel certification processes and increase successful certification outcomes
- Describe lessons learned from certification activities to-date and how these lessons can improve certification processes in the future
- Identify the existing resources and tools available for interoperability testing in the areas of transport, privacy and security, and clinical content
- Discuss how various testing tools offered by non-profit and government entities improve consistent interpretation and implementation of interoperability standards (e.g. C-CDA) by all stakeholders

# Agenda

- HIT Testing Continuum
  - *Connectathons → Conformity Assessment*
- Public vs Private Sector Testing/Certification Initiatives
  - *Transference of Lessons Learned*
- How to Leverage Product Certifications
- Delivering HIT Standards Value in the new Healthcare Ecosystem

# Programs as Building Blocks

Structured Testing Events

Conformity Assessment

Certification Programs

- IHE NA Connectathon
- Continua Plugfest

- IHE International Conformity Assessment

- ONC HIT Certification
- ConCert by HIMSS™
- Continua Certification

# IHE and IHE ecosystem

IHE INTERNATIONAL Integrating the Healthcare Enterprise

- 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 Conformity Assessment program, under ISO/IEC 17025, has been launched in 2015 and is the next step in testing rigor, providing worldwide recognition of testing results.

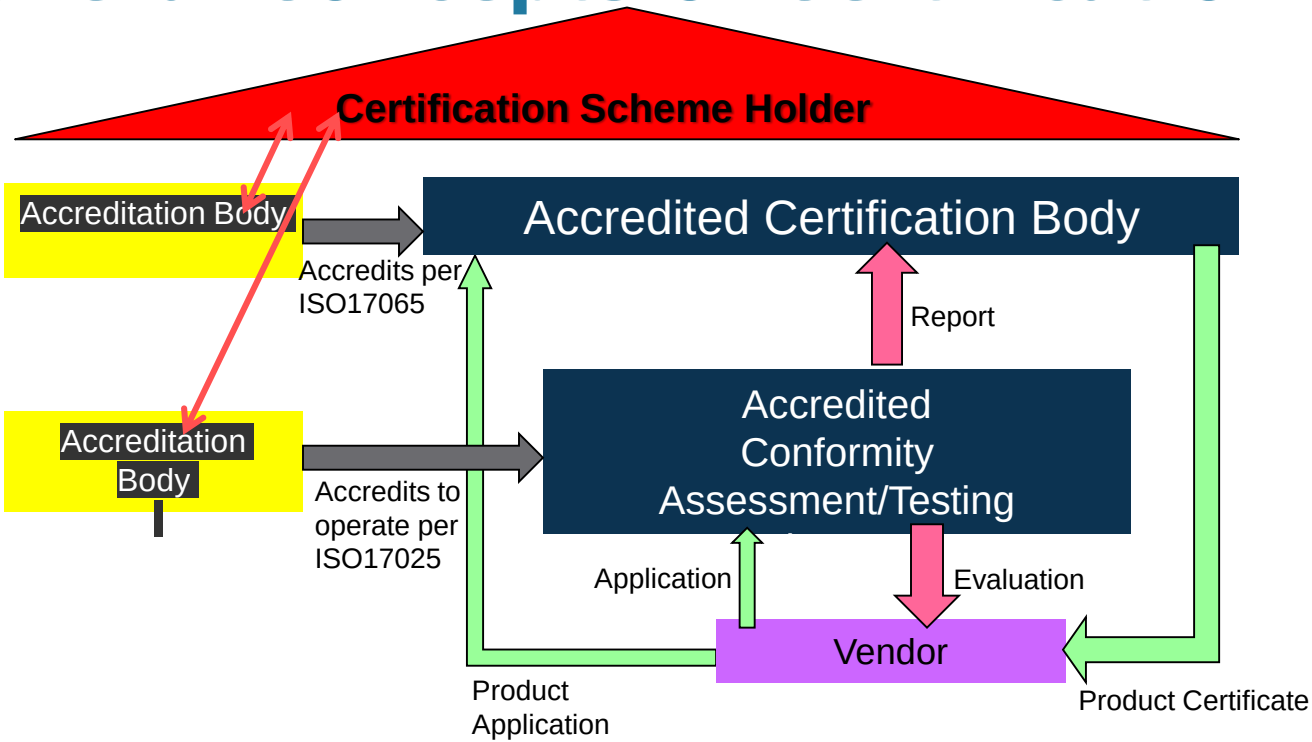
IHE CONFORMITY ASSESSMENT

- IHE continues to be successful in engaging hundreds of suppliers from every corner of the world to participate in IHE Connectathons
  - At IHE Connectathons, large and small companies dedicate a week working together to validate the interoperability capabilities of their systems against IHE Integration Profiles, under the supervision of an impartial team of "monitors"
  - Connectathons take place annually in North America, Europe, Australia, Japan, Korea, and China
  - Connectathon results publicly available at: http://www.ihe.net/Testing

# ISO/IEC Conformance Testing and Certification

- Organizational Elements
  - Scheme Owner
  - Test Tool Developers (e.g. NIST)
  - Authorized Testing Labs (ATLs)
  - Authorized Certification Bodies (ACBs)
- International Standards Organization (ISO) provides requirements for accrediting both testing labs and certification bodies (e.g ISO 17025, 17065, etc)
- Scheme Owners contract with Accreditation Organizations to accredit ATLs & ACBs

# General Concepts of Certification

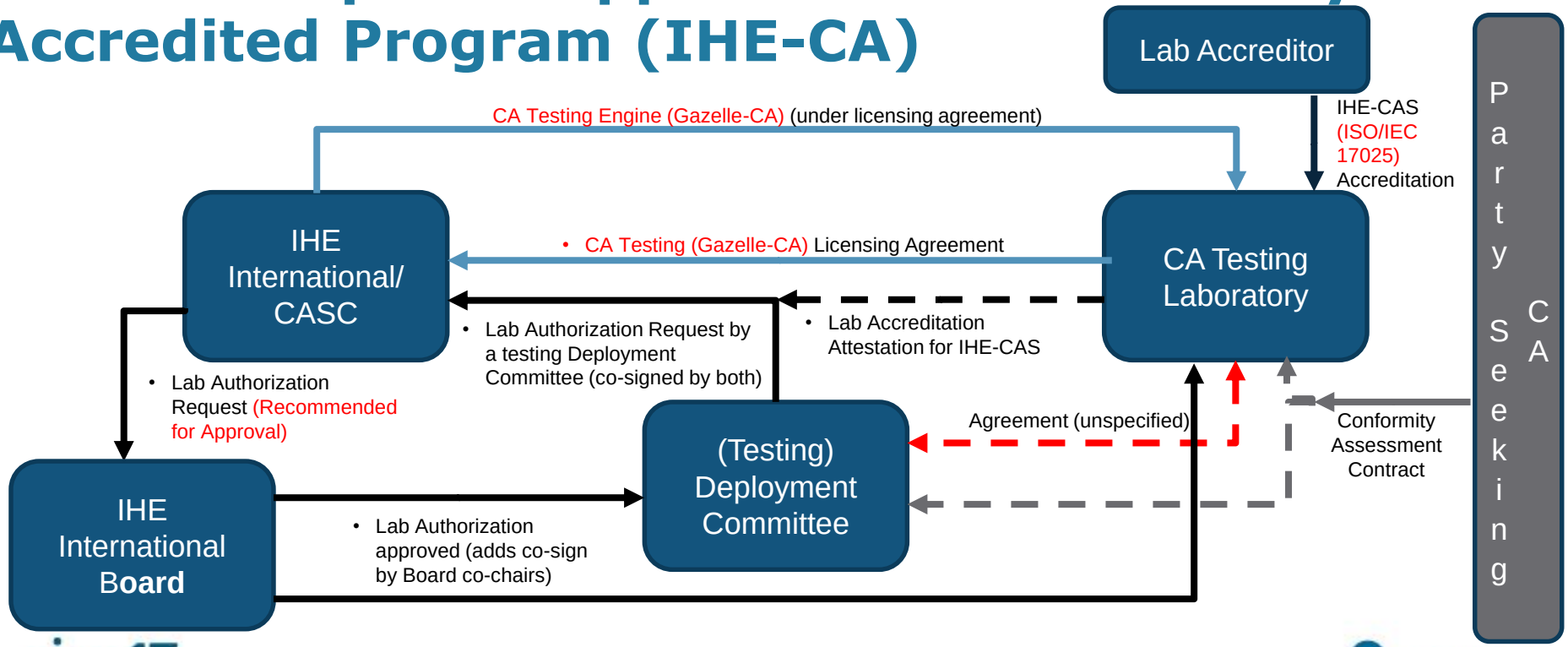



Elements shown above may be deployed in various ways and with different levels of formality

# Certification "stickiness" → SURVEILLANCE

| | |
|---|---|
| Use | • To enhance confidence in ongoing conformity<br>• The frequency and rigor should be balanced with the cost and confidence needs. (This is typically resource intensive.) |
| Activities | • May be performed through inspection<br>• May be performed through testing<br>• May be performed through audit<br>• May be performed pre-market or post-market<br>• These activities may be announced or unannouced<br>• These activities may be done in conjunction with each other |
| Who does it | • 3rd party |
| Relationship to other components of CA | This is a key part of a certification program or a registration system (e.g., ISO 9000 series). |
| Related Standards | Required in ISO/IEC 17011<br>Required in ISO/IEC 17065 (Guide 65) |

# Relationships to Support an Internationally Accredited Program (IHE-CA)



# Sample of ISO/IEC Accredited Programs

**ONC CEHRT Program**

- ATLs
  - Drummond Group
  - ICSA
  - Info Guard (UL)
  - National Tech Systems (NTS)
  - SLI Global
- ACBs
  - Drummond Group
  - ICSA
  - Info Guard (UL)

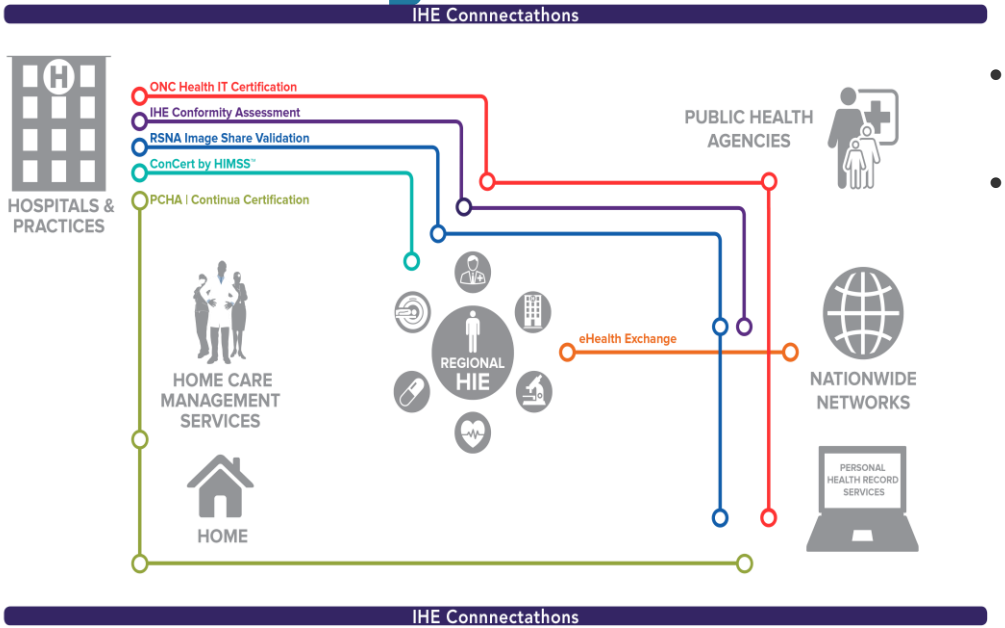
IHE Integrating the Healthcare Enterprise

- ATLs
  - Kereval
  - ICSA (2016)
- ACBs
  - Determined by Regional Deployment Committee

CONCERT BY HIMSS

- ATLs
  - ICSA
- ACBs
  - ICSA

# National 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**:

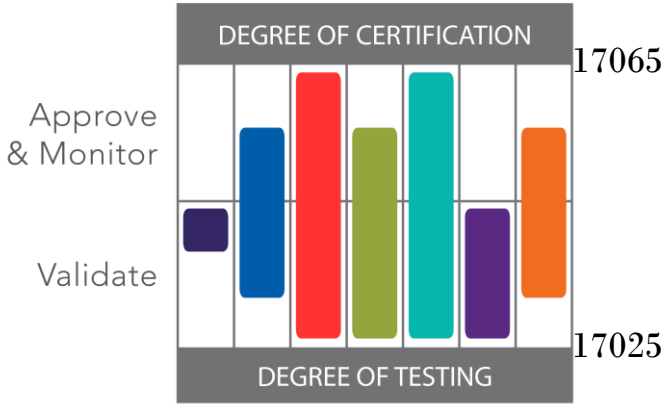
- Leverage recognized industry standards to optimize value, uptake, and efficiency

# Scope of Testing and Certification Activities

- Some programs based on ISO/IEC 17025 (for Testing) and/or ISO/IEC 17065 (for Certification)
  - Provides the highest rigor + international recognition
- Leverage **a testing and tools ecosystem** made operational via extensive tool set adopted (not developed) by the program

Legend

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




Comparison chart of rigor and testing

- Certification adds monitoring, aka surveillance, to verify conformity at point of installation
- Test results published for transparency & industry use

# Lessons Learned from ONC CEHRT Program

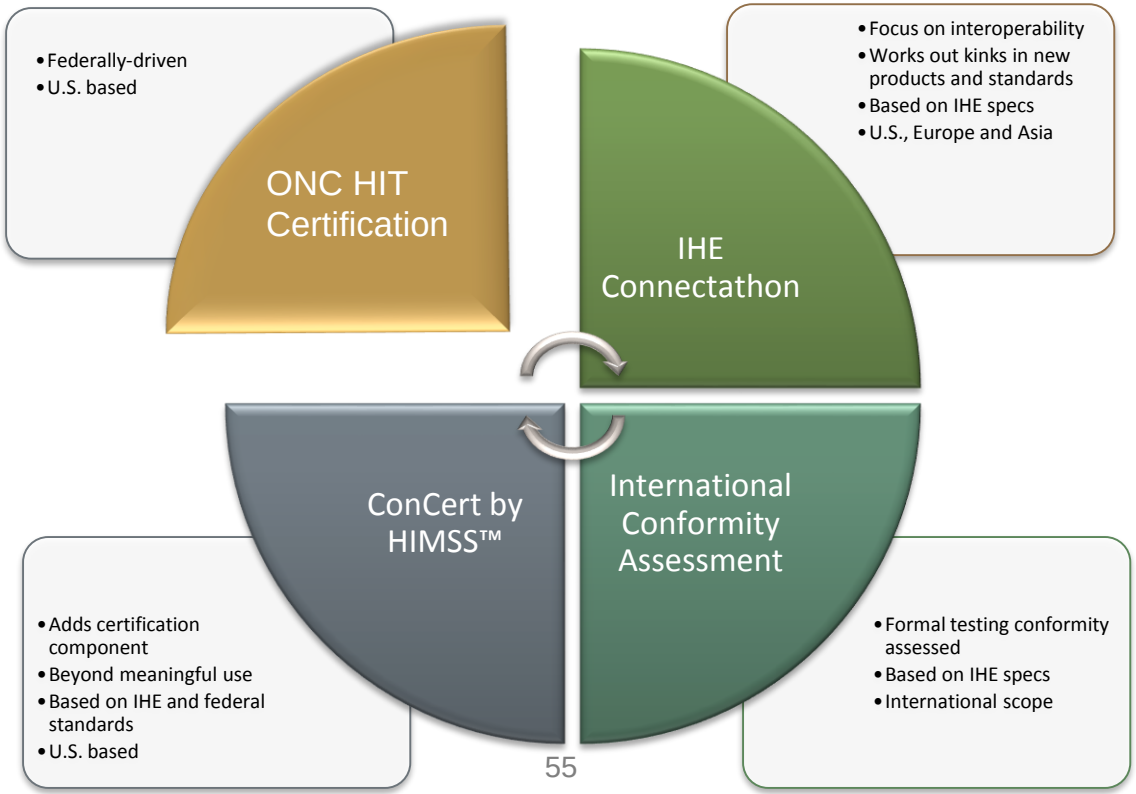
- **Connectivity vs Interoperability**
  - "IT" owned vs "Clinician" owned
  - Different IT "transports" for different use cases
    - Push, Pull, Subscription, Forms
  - Content used for routing/access control vs clinical decision making both important

- **Quality Measure Conformance Testing Dictates New Tools**
  - Validation of eMeasure computations puts heightened emphasis of test data sets
  - Multi-discipline and multi-organizational differences
  - Public-Private partnering for effective eMeasure development

# Lessons Learned from ONC CEHRT Program

- **Remember Who the Target Audience Is**
  - Simplify purchase decision process by leveraging 3rd party certification seal to reflect product capabilities
  - Offer a comprehensive certification for “bundles of functionality” that facilitate secure and reliable data exchange
  - Align functionality validation with other conformance / validation programs in healthcare (e.g. CMS, AHRQ, CDC, etc.)
- **The HIT Vendor Has a Formal Product Release Cadence**
  - Balance of industry requirements “pull” and product availability
  - HIT customers influence timing of product upgrades
  - Moving from routine connectivity to true interoperability increases the size of the stakeholder pool

# Interconnectivity of Programs



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- Grounded in real market demand (the EHR|HIE Interoperability Workgroup) combined with premier HIT industry leaders (HIMSS, ICSA, Stella Technology) to promote validated interoperable solutions.

# Interoperability Testing Tool (ITT)

- Designed from the outset for use by both a testing lab and a certification body organization
- Cloud-based, automated, self-service tool
- Individual test cases, or group-based testing
- Practice or Certification modes
- All necessary information at your fingertips (SUT, ITT, test cases, specifications, etc.)
- Test results – detail and summary
- Detailed troubleshooting help with references to underlying specifications

# ConCert by HIMSS™

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


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

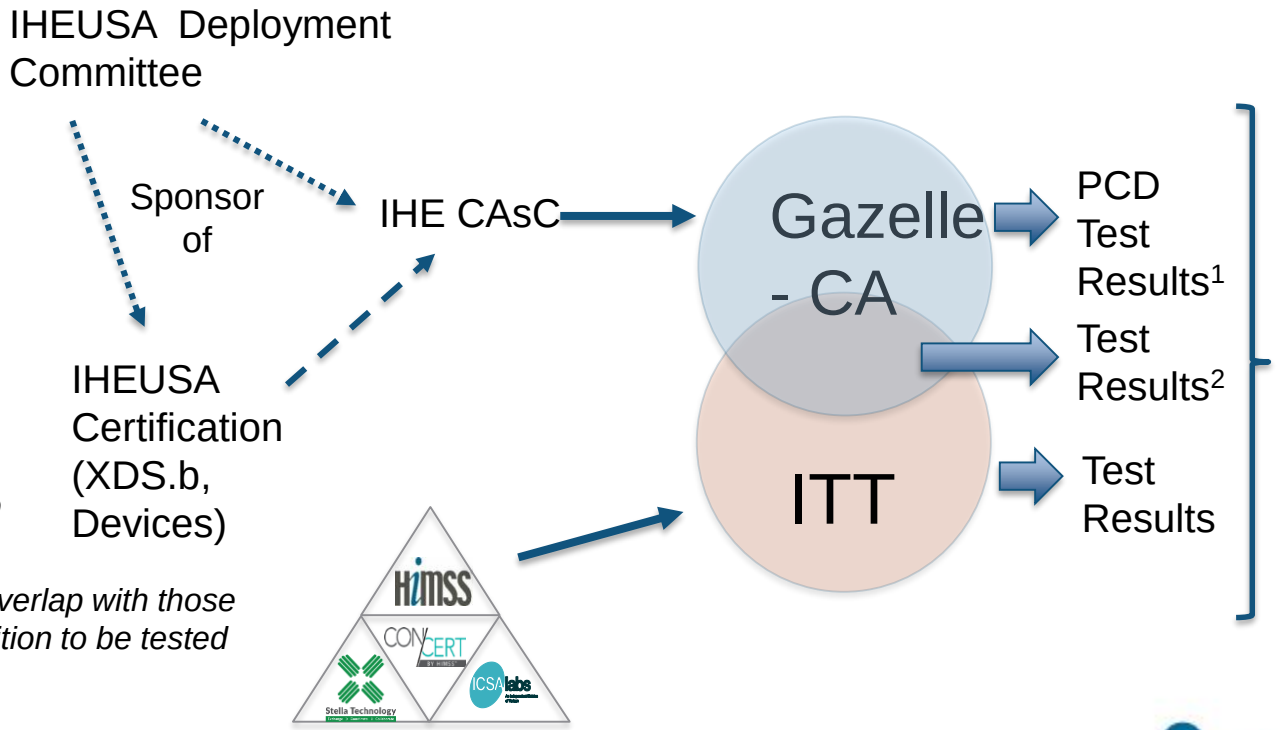

for Health Information Services Provider systems to send secure health information directly to trusted recipients, including patients

# Medical Device Certification Program (*New in 2017*)

*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

# ConCert - IHE CA Harmonization




*1 – Other Gazelle-CA Profiles to be included as approved*

*2 - IHE Profiles in the ITT that overlap with those in IHE CA program will transition to be tested in the Gazelle-CA*

# Opportunities for Private Sector Engagement

## Product Certification to Expedite HIE "Onboarding"

- Private-sector programs to compliment ONC activities
  - Joint program of IHE, HIMSS, EHR|HIE Interop Workgroup
  - More than DIRECT, and more than EHR
  - New program with CNI/Advantage for Immunization Reporting
  - New program for Medical Device certification
  - Diverse Advisory Committee to set future priorities

CONCERT BY HIMSS™

ISO

Continua® CERTIFIED

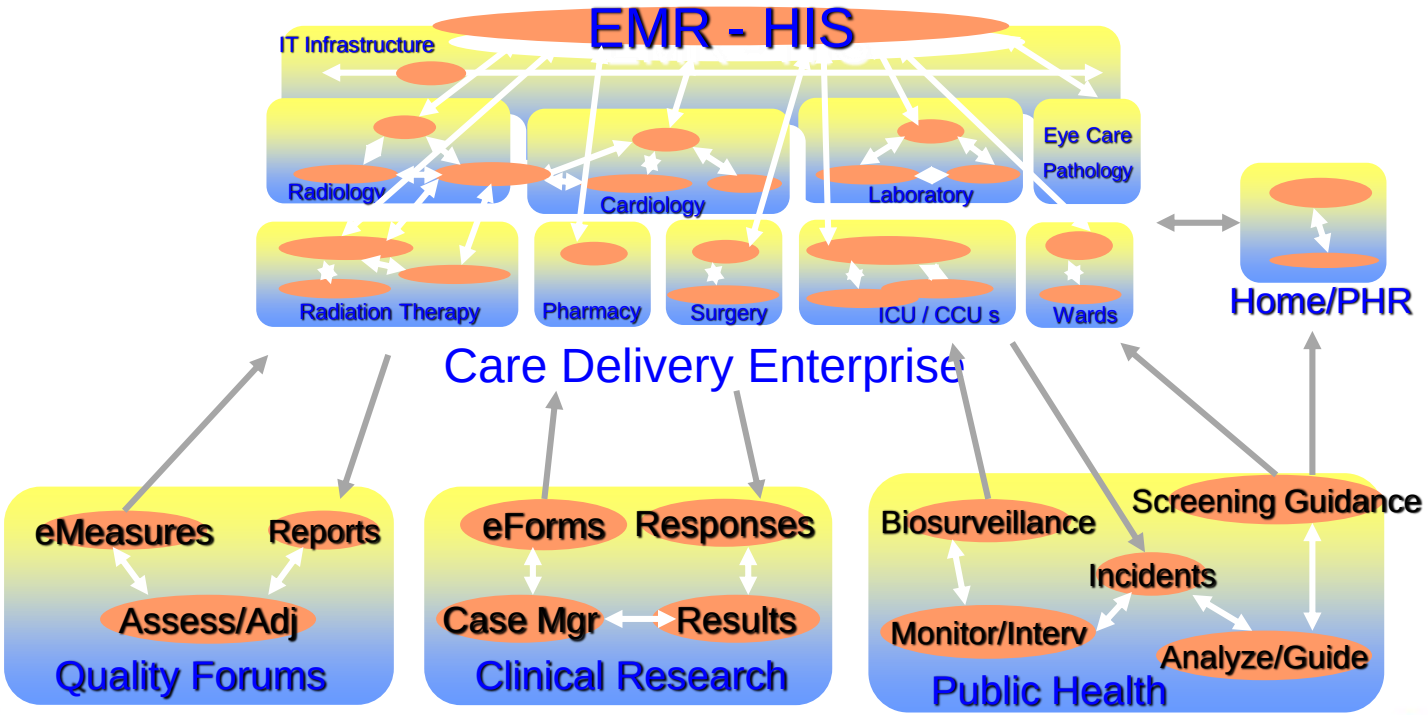
CONCERT APPROVEDEHR™ CONCERT APPROVEDHIE™ CONCERT APPROVEDHISP™

  - Personal Connected Health Alliance (PCHA)
  - Joint program of IEEE, IHE, HIMSS, Continua
  - Focus on medical device, home hubs; i.e. outside physician practice HIT …and their exchange with EHR's

# Opportunities for Private Sector Engagement

- **Direct Feedback to Shape Testing/Certification Tooling and Deliverables**
  - Pilot programs with HIT product vendors to validate test tools prior to production roll-out
  - Open forums to set success criteria and functionality priorities
  - Participation in Standards Development Organization(s) domains and workgroups
  - Engagement of care provider “user” community in process as early as possible , e.g. HL7 FHIR™ Community Forums

# HC Interoperability Landscape 2015-2020



# HIT Standards Evolution

- **HL7 C-CDA Release 2.n**
  - Included CDA document templates set for Referral Notes, Consultation Notes, and Care Plans
  - Data sections in Transfer Summary document for care transitions to Long-Term & Post-Acute Care (LTPAC) facilities
  - Included feedback from “real world” exchanges
- **Focus on Data for non-EHR Purposes**
  - ONC S&I and IHE collaborative work
    - Data Access Framework
    - Rx Drug Monitoring Programs (PDMP) interoperability
    - Structured Data Capture (SDC) for Clinical Trials/Research
- **Cross-enterprise Workflow Automation services**
  - IHE “roles” framework + clinical care delivery use case

# HIT Standards Evolution

- **De-coupling of Data from Clinical Documents**
  - Common data definitions for both messages and documents
  - Expand sources of data
    - Medical devices, wearables, PHRs
  - Fast Healthcare Interoperable Resources (FHIR®) standard in-development
    - RESTful Transport and OAuth for security
    - Argonaut Project, FHIR Foundation, IHE
    - API's for Patient and Provider data access
      - *Hackensack Univ Med Center pilot*

Personal Connected Health Alliance
A collaboration between Continua, mHealth Summit and HIMSS

HL7 TRANSITION

HL7® FHIR®
ARGONAUT PROJECT

HL7® version2 (2.x) is 30 years old.

HL7® CDA is over 10 years old.

# Drivers for New Standards

## Shift from off-line to on-line

- BYOD (clinician / nursing / patient apps)
- Mobile outside health care

## Shift towards data transparency

- Examples: MU, NHS GPSoC, VNA, ECM
- Access to data in distributed systems

## Growth of data and knowledge

- Big Data
- Limits on human capacity



Russell B Leftwich, MD
Intersystems

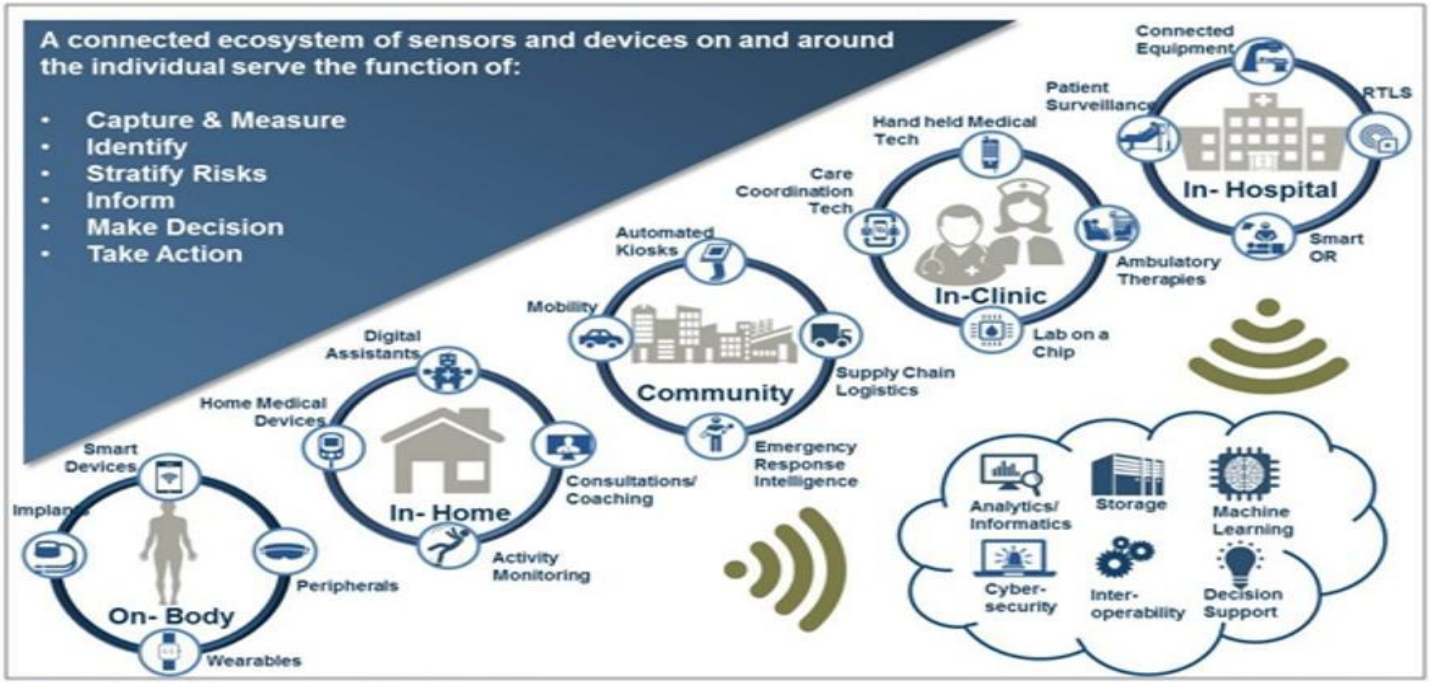



Figure 1: Healthcare World in 2025

*Source: Frost & Sullivan*

# Some Key Take-aways

- Standards are the Underpinning of an Effective Testing & Certification Program
  - ✓ *Multi-tiered Standards Profiles & Implementation Guides*
  - ✓ *They need time to mature*
- Public & Private Sector Testing/Certification Initiatives Need to Collaborate
  - ✓ *Program reciprocity*
  - ✓ *ISO/IEC enables international applicability*
- Testing & Certification Programs Need to Continually Adapt to Market Needs
  - ✓ *Value to both HIT customers and vendors is critical*

# Questions

- Speaker contact information

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- Remember to complete the online session evaluation