HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST
Medical Device Communication Testing

Semantic interoperability of Medical Devices

IEEE-SA, Critical Connections Series, On-line

John J. Garguilo
National Institute of Standards and Technology

3 April 2020, On-line Presentation/Recording

Contact: john.garguilo@nist.gov, 301-975-5248; nicolas.crouzier@nist.gov

NIST
National Institute of Standards and Technology

- ***John J. Garguilo,*** Computer Scientist
  301-975-5248 john.garguilo@nist.gov
- NIST Information Technology Laboratory (ITL) Systems Interoperability Group (SIG) Leader
- Manage Semantic Interoperability of Medical Devices (SIMD) Project
- Health Level Seven (HL7) Health Care Device Co-Chair
- IEEE 11073 Point-of-Care Device (PoCD) WG, Secretary
- Previously IHE-Patient Care Device Domain Technical Committee Co-Chair; On-going IHE-PCD Test Project Lead

❖ Note: As part of US Federal Government, all NIST work products are freely and publically available

Topic Overview

- Introduction to NIST and Background
- Landscape & Work Areas – Healthcare – Standards & Testing
- An end-to-end Testing Strategy and Framework
- NIST HL7 v2 Tooling Platform Overview
- Medical Device Profile and Testing

Topic Overview, cont.

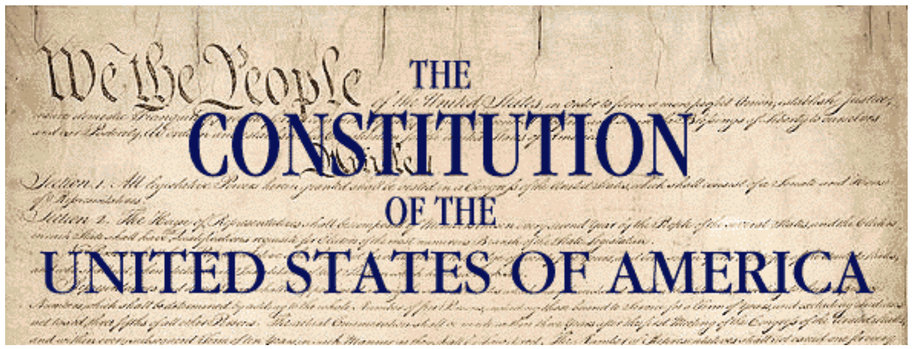
- *Integrating the Healthcare Enterprise (IHE)*
  - Focus:
    - *Integrating the Healthcare Enterprise – Patient Care Device (IHE-PCD)* Domain
    - *IEEE 11073 Medical Device Communication family of Stds*
    - *Health Level Seven (HL7) Heathcare Devices WG*
- IHE-PCD "Integration Profiles" – use cases addressed to date…
- Device Enterprise Communication

❖ Note: As part of US Federal Government, all NIST work products are freely and publically available

NIST & The Importance of Standards

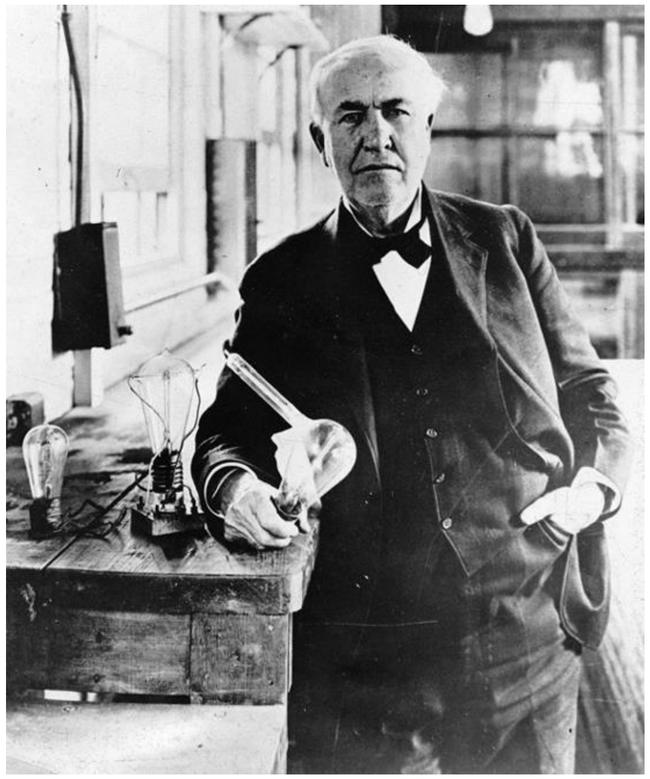
National Institute of Standards and Technology
U.S. Department of Commerce

Measurements, testing, and standards are the basis for developing and deploying technology.



Article I, Section 8: The Congress shall have the power to…*fix the standard of weights and measures*

- National Bureau of Standards established by Congress in 1901
- Eight different "authoritative" values for the gallon
- Electrical industry needed standards
- American instruments sent abroad for calibration
- Consumer products and construction materials uneven in quality and unreliable



National Archives

Estimated that 80% of global merchandise trade is influenced by testing and other measurement-related requirements of regulations and standards

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

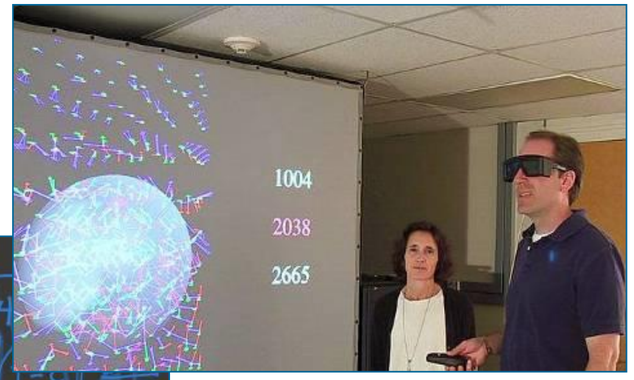
Information Technology Laboratory Mission

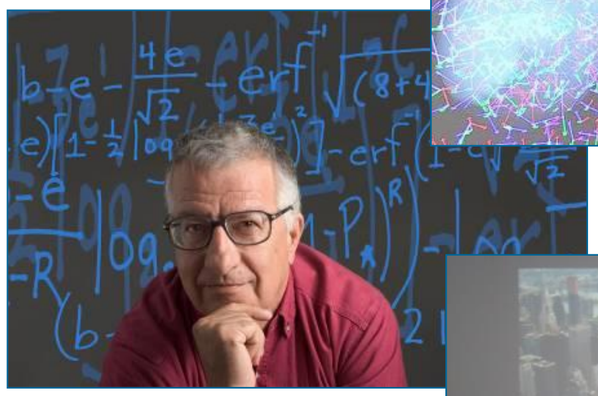
To promote U.S. innovation and industrial competitiveness by advancing

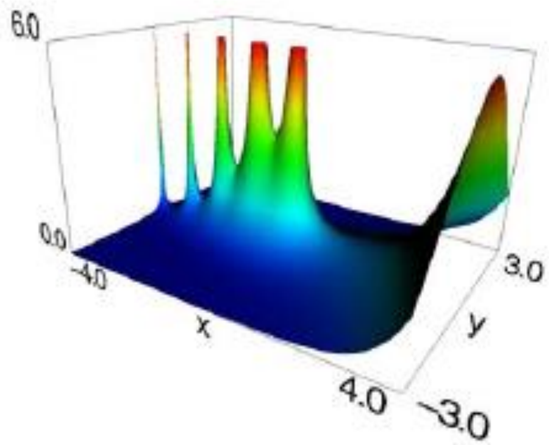
measurement science, standards, and technology

through research and development in

information technology, mathematics, and statistics.







National Institute of Standards and Technology (NIST)

- Research Bureau within U.S. Department of Commerce
- Non-Regulatory
- Laboratories: Communications Technology, Engineering, ***Information Technology (ITL)***, Material Measurement, and Physical Measurement
- Work described from the ***Systems Interoperability Group*** of the ***Software and Systems Division*** of ITL.

- Developed the conformance test method (test procedures, test data, and test tools) for NIH's ONC Meaningful Use 2011, 2014, and 2015 Edition certification
- Develop/ed conformance test tools for CDC, IHE, HL7, ONC, AIRA, ISDS, HIMSS, …
- Support Standards Development Organizations (SDOs) via guidance; and assessment and certification programs via tools, but does not perform certification

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Setting the stage… a few key ingredients

Premise that **standards** are important, if not essential, to achieve medical device integration and interoperability

Perspective from capturing and communicating (bi-directional) device data:

- Between devices
  - E.g., Respirator reporting/communicating to Patient Monitor
- Between devices (device gateways) and Enterprise
  - E.g., Medical Device reporting/communicating information to Electronic Medical Record or Electronic Health Record systems)
  - E.g., Communicating device alarm to nurse call station (or personal device on nurse)

Premise that rigorous testing is critical to achieve conformance, integration, and enable medical device **Interoperability**

- Enabling people to manage their own health independently as well as to supporting the clinician decision to manage the patient (in both acute and personal settings) in a safe, timely, and effective manner

What's Needed for Interoperability (of medical devices)? Standards perspective

Standards are Necessary! Why?

- Value of Standards
  - Common and repeatable use
  - Consensus established by recognized body - Common definition, meaning, and attributes
  - Provide use, rules, guidelines for activities or their results
  - Aimed at the achievement of the optimum degree of order in a given context

- Great, but aren't standards intentionally open ended? Often Vague?
- How do we enable semantic interoperability? (i.e., convey consistent meaning)
- How do Standards help with (/address) medical device integration and interoperability?

- …Standards alone are not the answer

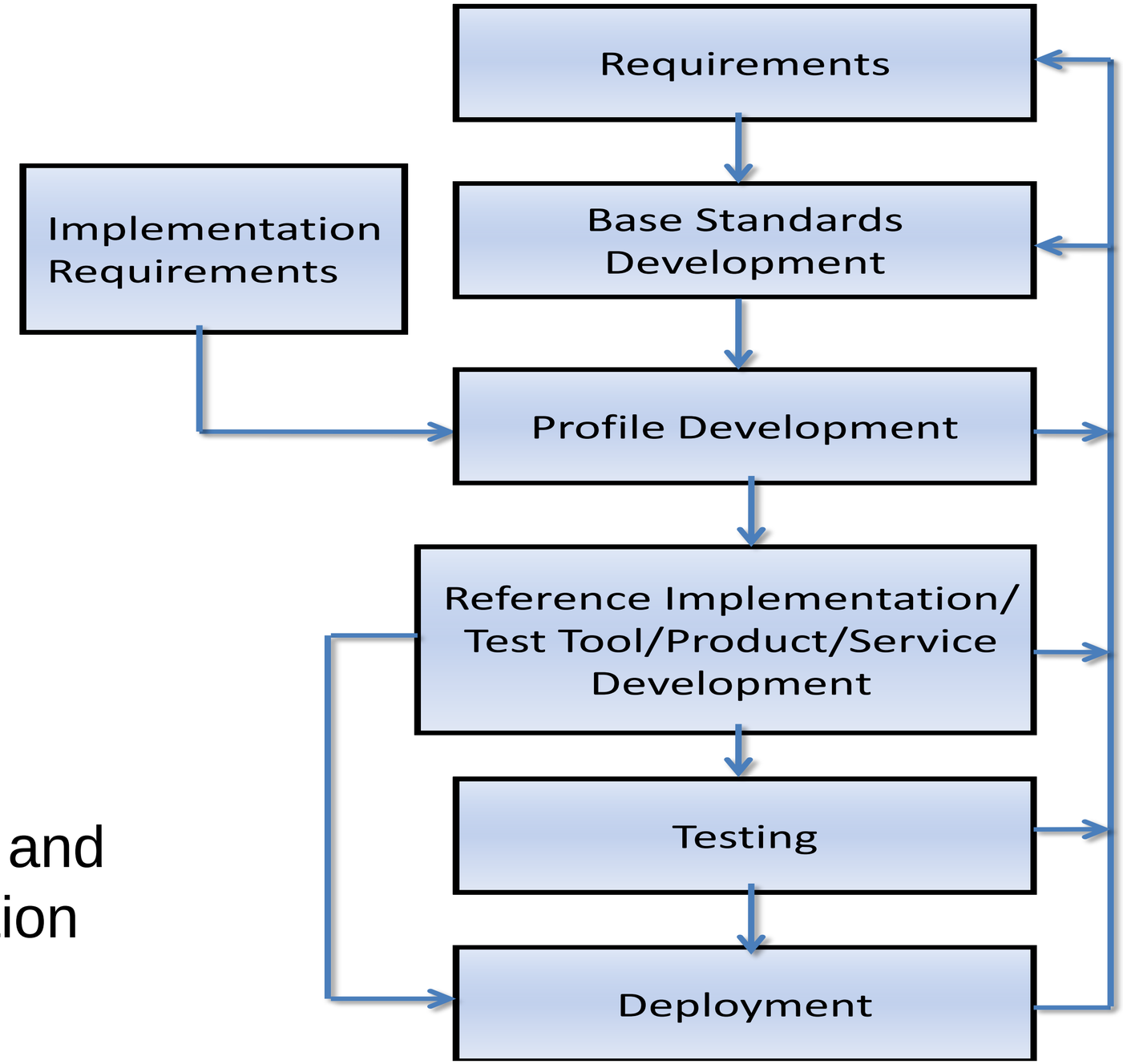
What's Needed to test for Interoperability (of medical devices)? Standards perspective

- So, How might one narrow this 'open-endedness' to achieve appropriate constraints?
- Constraining Medical Device Communication Standards
  - Need to constrain the scope to be realistic, 'usable', 'implementable', 'testable' and therefore "Conformant"

- One way is by *Profiling* – Constraints placed on Standards
  - Integration Profiles (realistic use cases of business/clinical process being addressed)
  - Implementation Profiles (requirements that device manufacturers build to…)
  - Conformance Profiles (ideally traceable to Standards, no optionality, able to be rigorously tested)

ICT Standards Life Cycle

NIST Special Publication 500-291



ICT: Information and Communication Technology

Work Areas & Status Updates

http://healthcare.nist.gov

https://www.nist.gov/itl/products-and-services/healthcare-standards-testing

nist.gov/itl/products-and-services/healthcare-standards-testing

Apps Office 365

An official website of the United States government Info

NIST

Search NIST Menu

Information Technology Laboratory / Software and Systems Division

SYSTEMS INTEROPERABILITY GROUP

Share

- Healthcare - Standards & Testing
- Health IT Testing Infrastructure +
- ONC Certification - Test Methods for Health Information Technology +
- Tools Portal
- Health IT Standards Reports
- Healthcare IT Contacts

Healthcare - Standards & Testing

Helping the Health IT Industry Connect

Welcome to the NIST Health IT Standards and Testing web site. This site provides information about the key health IT testing initiatives underway. It provides an overview of the Health IT Standards Testing Infrastructure as well as educational material on conformance testing, access to Meaningful Use specific information, tools and test methods, direct access to all NIST hosted testing tools and information on Health IT Standards.

Health IT Testing Infrastructure	ONC Certification
NIST is responsible for leading the development of the core health IT testing infrastructure that will provide	NIST is developing the conformance test methods (test procedures, test data, and test tools) to ensure compliance

Conformance Tooling Resource Portal:

https://hl7v2tools.nist.gov/portal/#/

Home Tools Publications Resources Source Code Links About

Welcome to the NIST HL7 V2 Resource Portal!

NIST provides a number of tools and utilities in support of the HL7 v2.x messaging standard. Conformance testing tools include web applications and web services for validating HL7 v2.x message instances based on message profiles. The foundation of the tool kit is a set of Java APIs that supports testing activities such as automated message generation and message validation. The APIs are organized as a testing framework which can be used to build tools such as web services and web applications. NIST provides the testing tools via these portal or the utilities can be incorporated into 3rd party applications and testing environments. Additionally, NIST is in the process of developing productivity tools to support the creation of HL7 v2 implementation guides (including the message profiles) and to develop test plans (i.e., creating test cases based on message profiles). This site provides access to the NIST HL7 v2 Toolkit.

TOOLS

Explore NIST HL7 V2 Tools here:

- Testing Tools
- Profile Generation
- Test Case Generation
- Web Services

PUBLICATIONS

Explore NIST HL7 V2 Publications here:

- Papers
- Presentations and Talks
- Tutorials

RESOURCES

Explore NIST HL7 V2 Resources here:

- Profiles
- Profile Schemas
- Value Set Libraries
- Value Set Schemas

SOURCE CODE

Access NIST HL7 V2 Source Code here:

- Testing Framework
- Validation Tools
- Productivity Tools
- APIs

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

Application Information
Date: 11/14/2019
Application Version: 1.0

Supported Browsers
Firefox, Chrome, Safari, IE 9 and 10

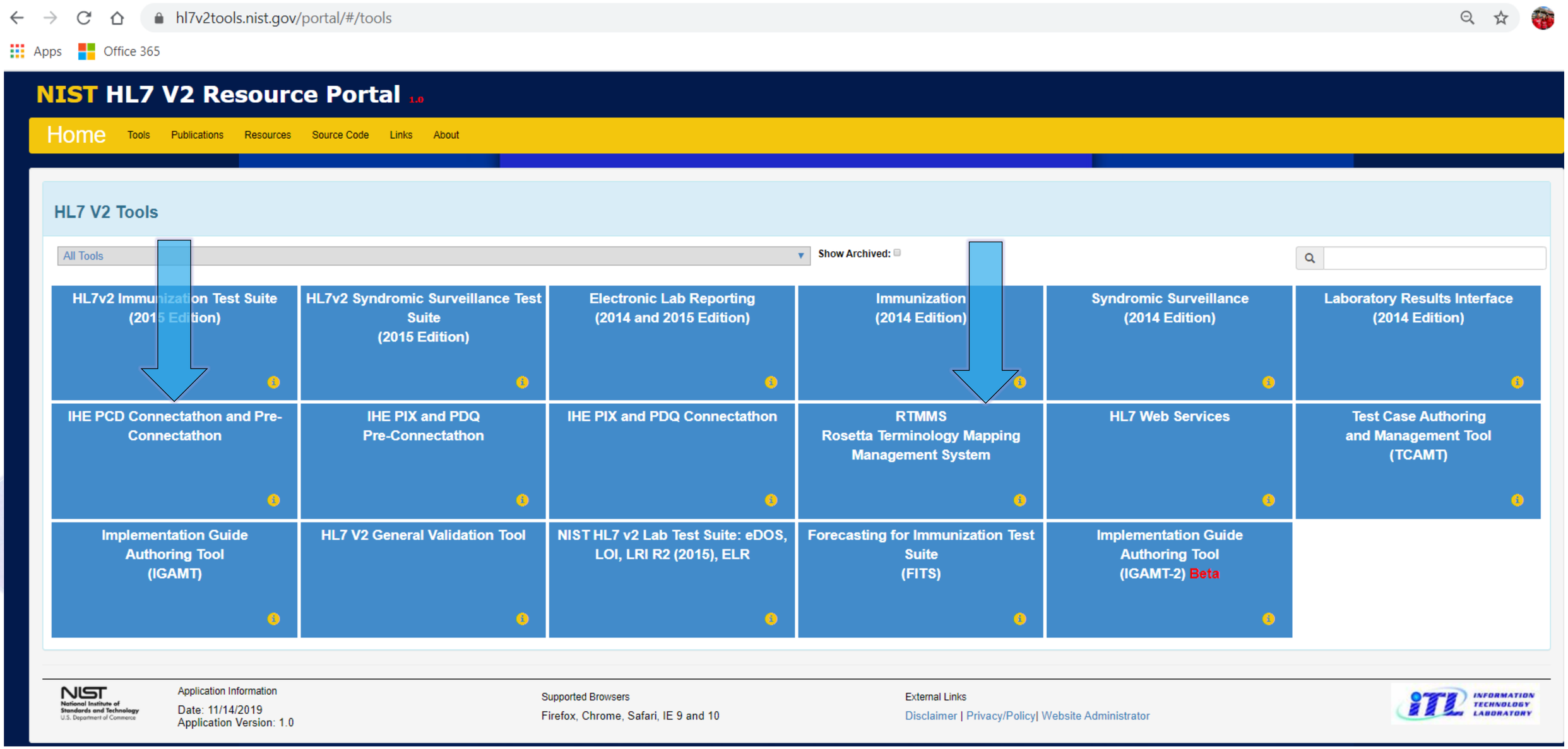
External Links
Disclaimer | Privacy/Policy| Website Administrator

iTL INFORMATION TECHNOLOGY LABORATORY

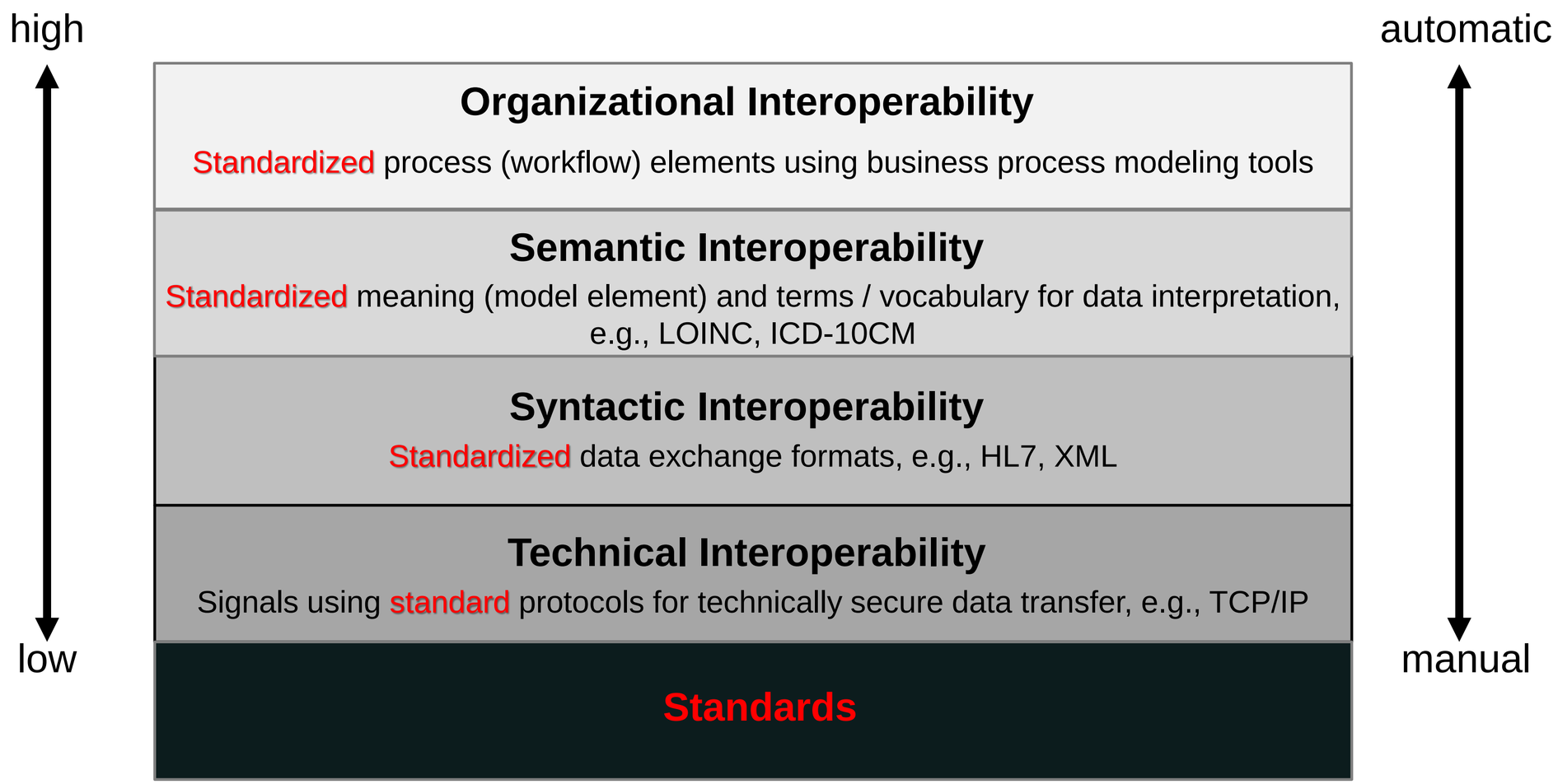
Work Areas & Status Updates

http://healthcare.nist.gov

Conformance Tooling Portal: https://hl7v2tools.nist.gov/portal/#/tools



Four Levels of HIT Interoperability



Based on
Oemig F, Snelick R, Healthcare Interoperability Standards Compliance Handbook. Springer International Publishing Switzerland. 2016. Page 13, Figure 1.3.

Interoperability Model - Turnitsa

Turnitsa proposes a 7 level Interoperability Model:

- Level 0 – No Interoperability
  - The situation in which two systems have no need to, or cannot, interoperate.
- Level 1 - Technical interoperability
  - Achieved when two systems have the means to communicate, but neither has a shared understanding of the structure or meaning of the data communicated.
  - For example a receiving system simply records what is received, not understanding structure or meaning.
- Level 2 – Syntactic Interoperability
  - Occurs when information is communicated with structure but without any meaning.
- Level 3 – Semantic Interoperability
  - Achieved when the data have meaning, but a full understanding of the relationships between elements of data and the context of the data is missing.

http://cyrusxp.com/?page_id=18

Interoperability Model – Turnitsa Continued

- Level 4 – Pragmatic Interoperability
  - Encompasses a shared understanding of data, the relationships between elements of the data, and the context of the data; however, pragmatic interoperability cannot accommodate changing relationships or context.
- Level 5 – Dynamic Interoperability
  - Allows for changing contexts and relationships over time or within the scope of specific transactions.
- Level 6 – Conceptual Interoperability
  - Complex concepts are exchanged and understood.

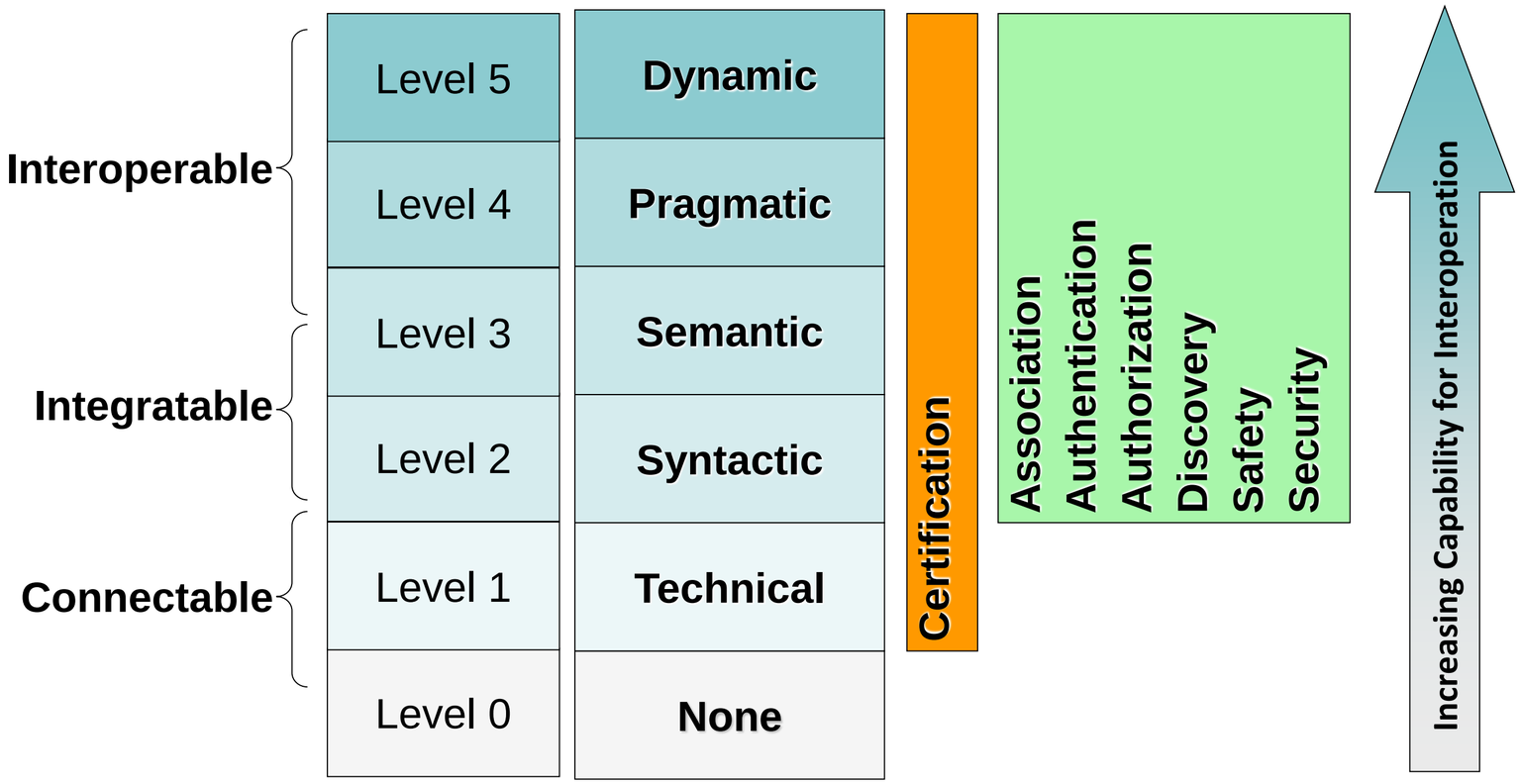
http://cyrusxp.com/?page_id=18

Turnitsa's Model

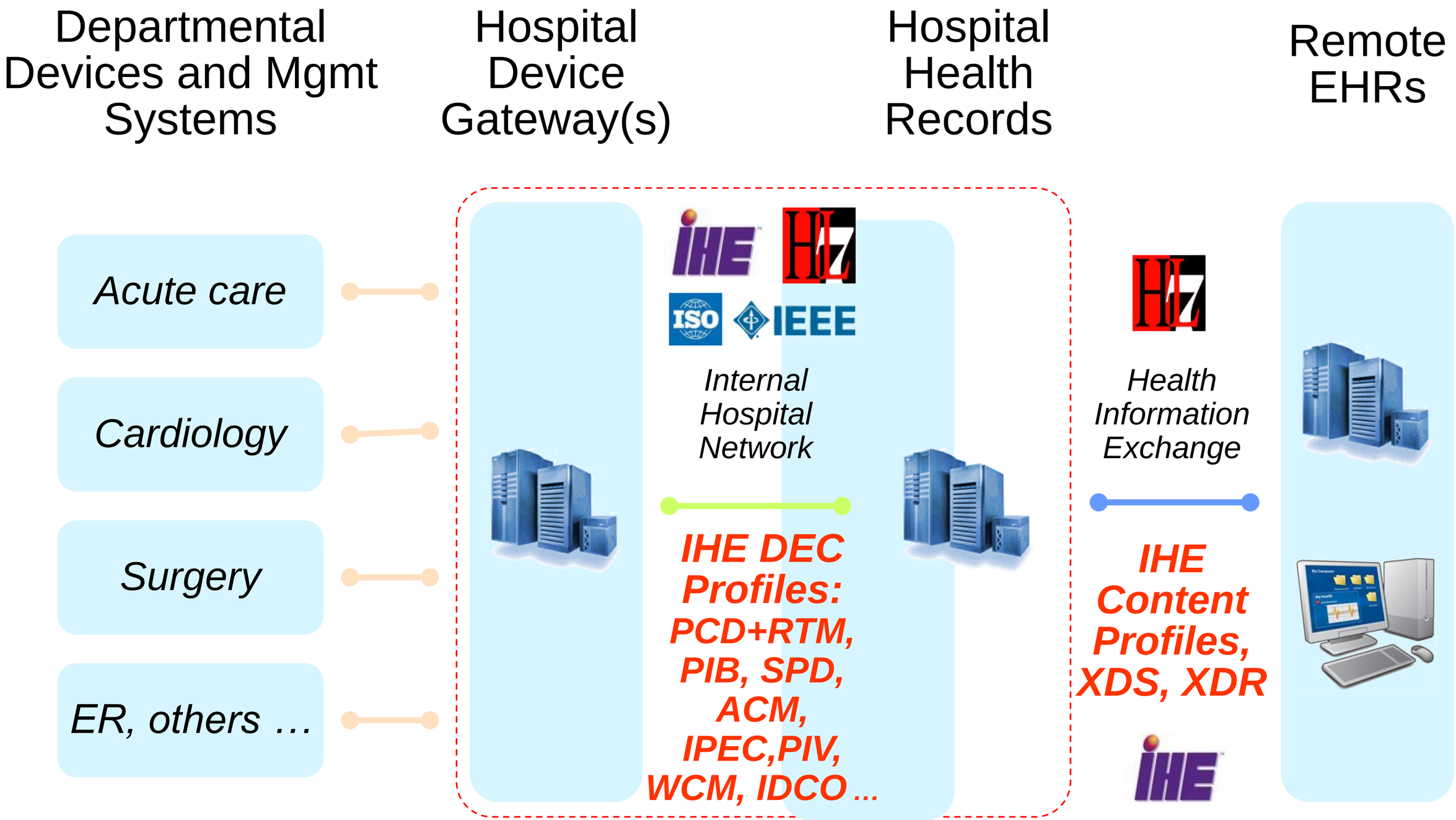
Interoperable	Level 5	**Dynamic**	Dynamic Context understood
	Level 4	**Pragmatic**	Context understood
Integratable	Level 3	**Semantic**	Meaning understood
	Level 2	**Syntactic**	Common Format
Connectable	Level 1	**Technical**	Common Physical and Transport Layers
	Level 0	**None**	Stand-alone

Increasing Capability for Interoperation

Turnitsa's Model – Adapted
Additional Requirements



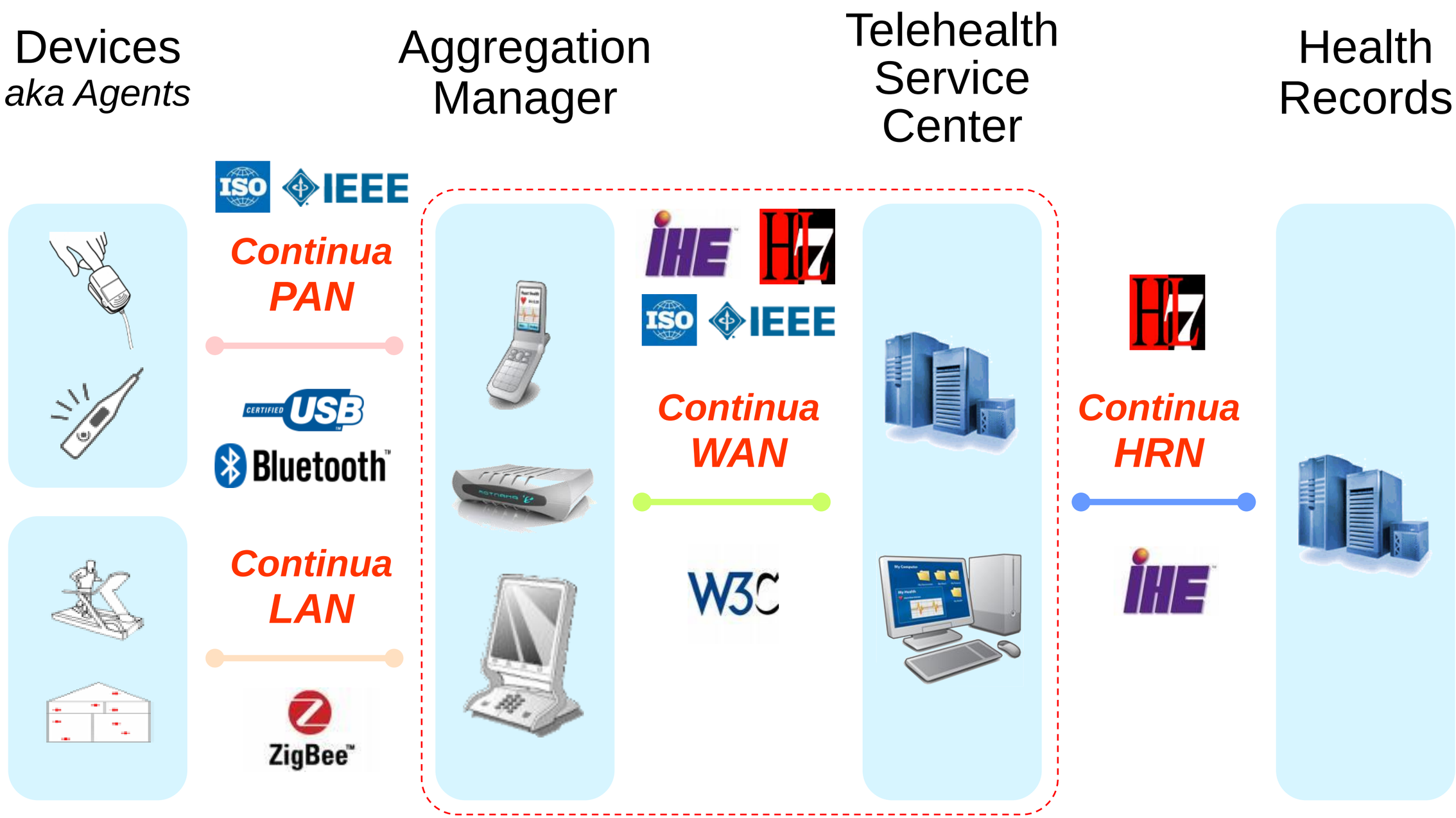
Clinical Device Connectivity



Note: *IHE Profiles shown above are being demonstrated at HIMSS as trial implementations;* ***IHE DEC PCD-01*** *Technical Framework "Final Text" became available in Q3 2011.*

Slide developed and provided by Paul Schluter, GE Healthcare

Personal Health Device Connectivity



Note: *Continua Guidelines available today. The Continua WAN interface uses the* ***IHE DEC PCD-01*** *transaction over Web Services.*

Slide developed and provided by Paul Schluter, GE Healthcare

Medical Device Testing Work Areas & Tool Site Links

*Conformance Tooling Suite – **Semantic Interop of Medical Devices***

- *HL7 V2 (2.6) IHE-PCD Validation Tools*
  (Newest version: https://ihe-pcd.nist.gov/pcdtool/#/home)
  - IHE-PCD Pre-Connectathon Context Sensitive
  - IHE-PCD Connectathon, Context Free
- Rosetta Terminology Mapping Management System (*RTMMS*) https://rtmms.nist.gov
- DIM Work - 'DIM Editor/Profiler' and ISO/IEEE 11073 UML Model
  - Development Tool: dim.prometheuscomputing.com

- NIST HL7 V2 Portal: http://hl7v2tools.nist.gov/portal/#/tools
  - IGAMT – Implementation Guide Authoring Management Tool
    - » https://ihe-pcd.nist.gov/pcdtool/#/home
  - TCAMT – Test Case Authoring Management Tool
    - » https://tcamt.nist.gov/tcamt/#/

NIST Tools publicly available 24 (hours) x 7 (days) x 365 (days/year)

Medical Device Testing Work Areas & Status Updates

HL7 V2 (2.6) IHE-PCD Validation Tools

- On-going Enhancements to Pre-Connectathon, Connectathon Tools
  (supported IHE-PCD Cycle14; mainly CPs)
- Support/ed IHE-North America, -European and -Japan Connectathons
  Key test event support:
  - Supported : IHE-North America Connectathon (Jan 2018, 2019, 2020)
  - Supported/ing: IHE-Japan Connectathon (Oct 2019, upcoming Oct ‘20)
  - Supported Center for Medical Interoperability Test Events (April, July 2019)
  - Supported IHE-Europe Connectathon (April 2018, 2019, upcoming fall of ’20)
  - Supported IHE-Korea Connectathon (August 2018)
  - (*New??*) IHE Australia – *targeted in 20xx??*
- IHE-PCD Cycle 14 ended (at HIMSS20) in March 2020
- NA Connectathon completed (Jan 20-24, 2020)
-

End-to-End Test Strategy

- Specification of Requirements
- Development of Specifications
- Development of Test Cases
- Testing Infrastructure
- Platform to build and manage tools

- NIST Computer Scientists build the platform—let domain experts create and maintain guides, test cases, and tool instances via productivity tools

XDS: Cross Document Sharing and Exchange Toolkit:

https://ihexds.nist.gov/

NIST Document Sharing Test Facility

XDS Toolkit

Introduction

Download

Wiki

Tool Listing

Hosting Requirements

Installation instructions

Internet Service

GoTo

Codes Configuration (link at top)

Endpoint Configuration

Open Source

GitHub Project

This site supports the IHE effort in Document Sharing as part of the IT Infrastructure Domain with testing, tools, and technical expertise.

Introduction

This server is operated by the National Institute of Standards and Technology (NIST) in support of Cross-Enterprise Document Sharing (XDS) and related profiles published by Integrating the Healthcare Environment (IHE). This family of profiles is now referred to as Document Sharing.

This test facility is based on the IHE IT Infrastructure Technical Framework.

All testing done against this facility is considered conformance testing: testing against a reference. The primary goal of IHE is interoperability testing where implementations are tested against other implementations. Conformance testing always preceeds interoperability testing. Interoperability testing in IHE takes place at IHE Connectathons.

Public Registry Server

The Public Registry Server has been removed from this site and is no longer supported. XDS Toolkit replaces it.

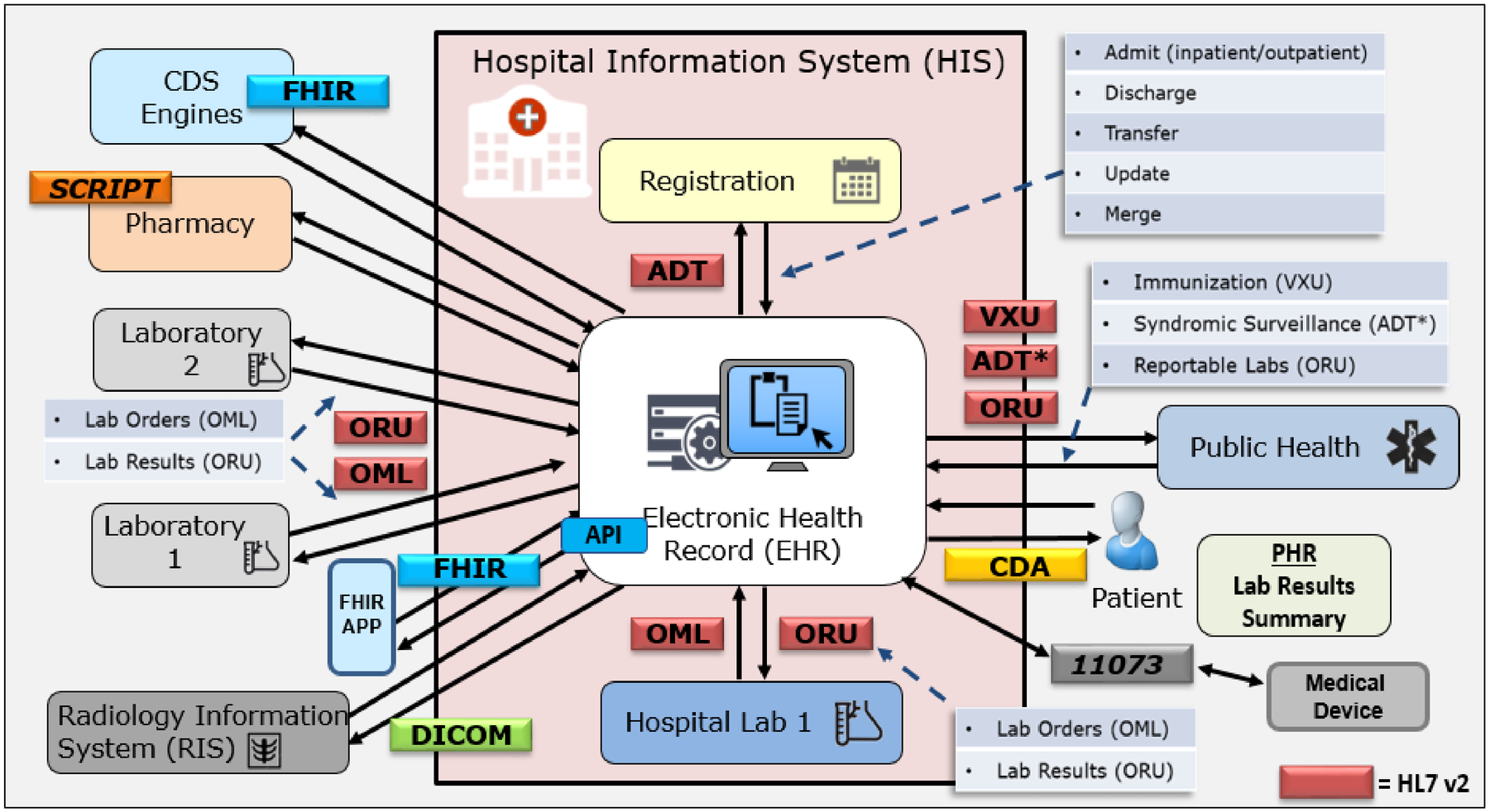
XDS Toolkit Download

XDS Toolkit is the tool platform where we host Document Sharing related tools. It is available online and as a download. Most of our users download Toolkit and run it on their own machine so they can use it to test within their own development environment without messing with firewalls.

While most of our users download XDS Toolkit and run it on their own machine we do maintain an Internet copy as a service configured somewhat like the old Public Registry.

XDS Toolkit Service

Standards Landscape



Variety and volume of data exchange is daunting

100s of million of exchanges performed in single a organization per year

- Provide a *common language* and set of expectations that enable interoperability
- Fundamental building blocks for developing and deploying technology products
- Establish consistent protocols that can be universally understood and adopted
- Allow for systems to be verified—thus offering credibility
- Give customers a choice, thus enabling competition

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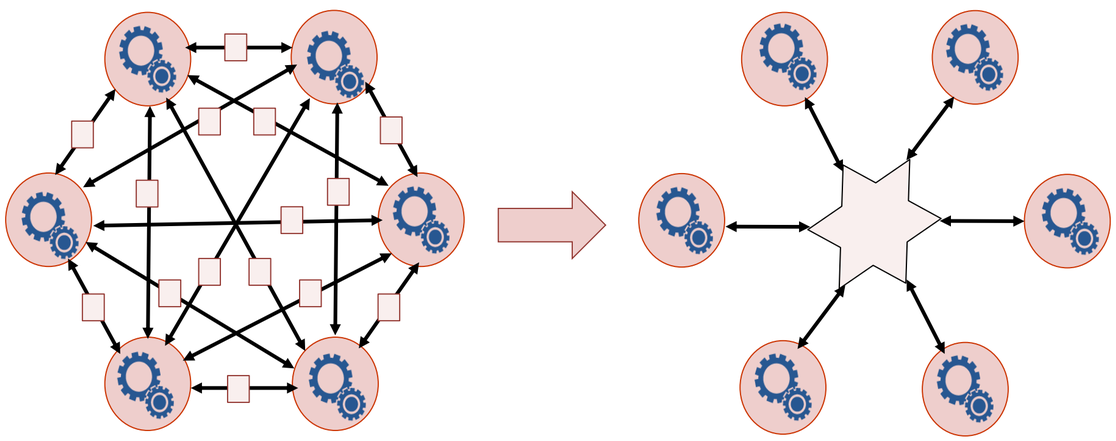
Why do we need Standards?



Multiple point-to-point non-standard solution

Single standard solution

Combinatorial explosion of the number of interfaces needed

The more interconnected systems, the greater the benefit of using standards

- But can we really get a “one-size” fits all standard?
- In most cases, NO, but we can significantly reduce the number of translations needed and site-specific details
- If standards are underspecified or not specific, there can be multiple interpretations of the standard—which pushes us back to where we started
- Conformance, profiling, and precise documentation puts us back on track

Diagram Source: Numerous HL7 publications (adapted)

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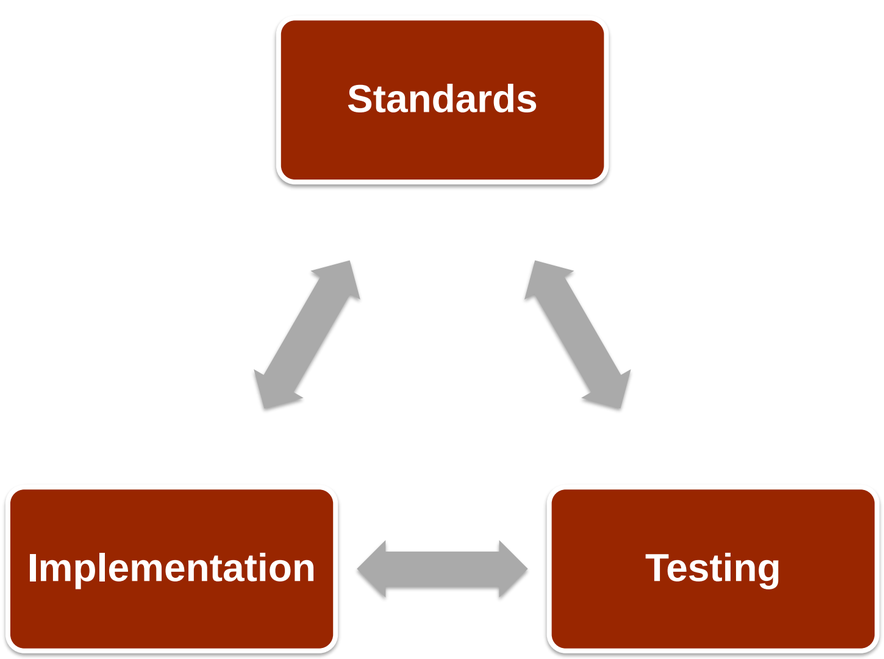
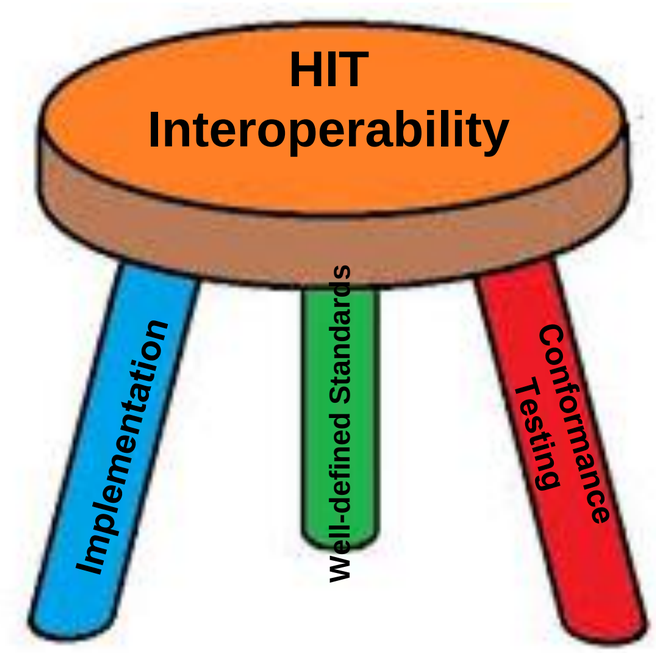
Foundation for Interoperability

- Well-defined Standards
- Testing
- Implementation
- Standards Development Lifecycle





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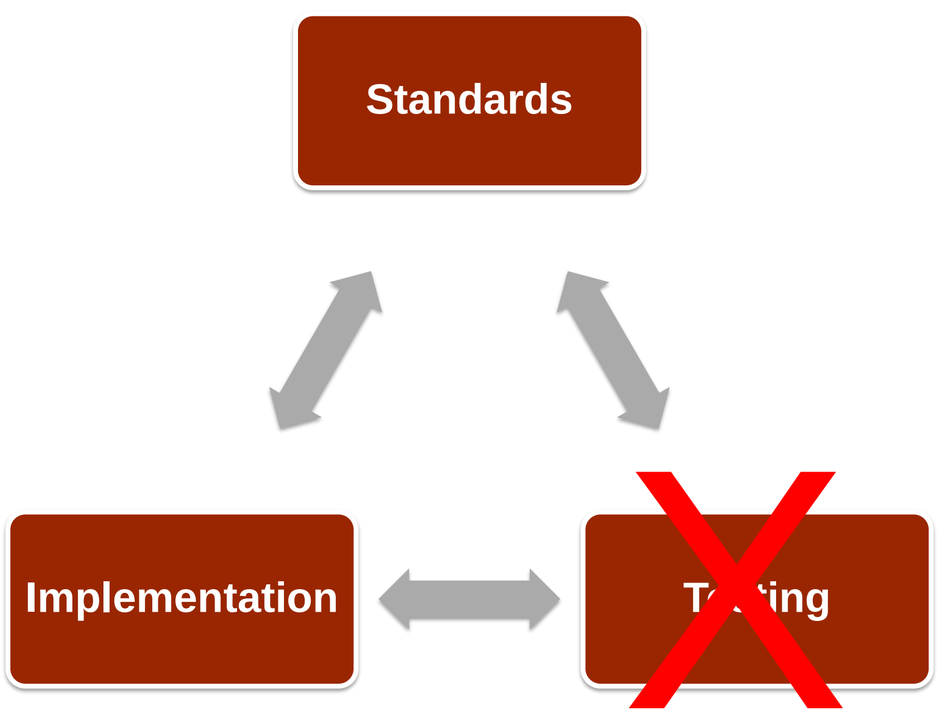
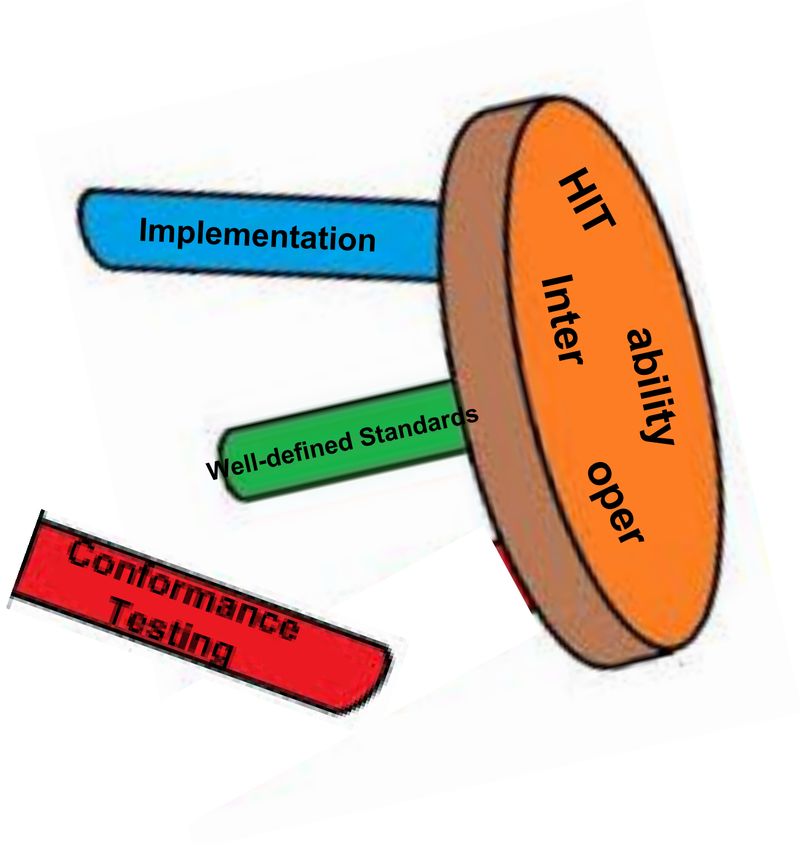
Failure happens when:

- One or more components are omitted or are not sufficient





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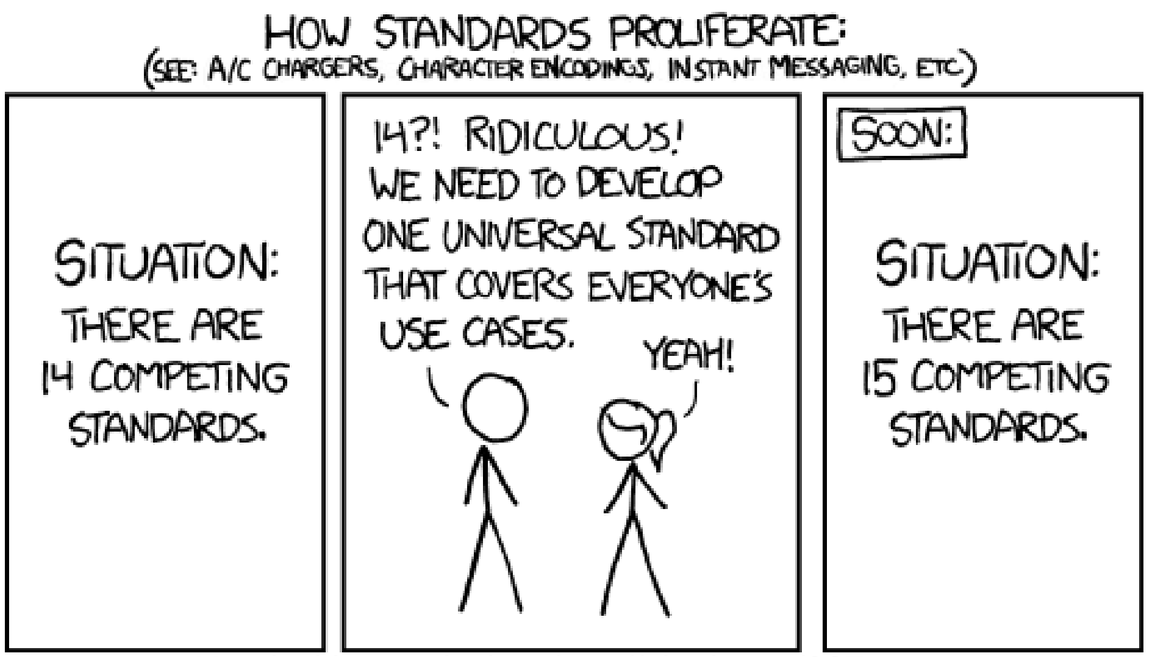
Lessons Learned: Standards

- Ambiguous
- Inadequate investment

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



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

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HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST's HL7 V2.6 Validation Tooling
IHE-PCD Pre-Connectathon Cycle 14

Semantic interoperability of Medical Devices

Test Tool Example – HL7 V2 + IEEE Nomenclature, DIM
NIST + IHE-PCD Working Group

April 1, 2020
National Institute of Standards and Technology
Contact: john.garguilo@nist.gov, 301-975-5248

NIST
National Institute of Standards and Technology

Topic Overview

- *Integrating the Healthcare Entrprise (IHE)*
  - Focus: *Integrating the Healthcare Enterprise – Patient Care Device (IHE-PCD)* Domain
- IHE-PCD "Integration Profiles" Addressed to date…
- Integration Profiles based on 'Device Enterprise Communication'

❖ Note: As part of US Federal Government, all NIST work products are freely and publically available

What is IHE?

IHE Domains

- Cardiology
- Dental
- Eye Care
- IT Infrastructure
- Pathology and Laboratory Medicine
- Patient Care Coordination
- Patient Care Devices
- Pharmacy
- Quality, Research and Public Health
- Radiation Oncology
- Radiology

➢ IHE home page: www.ihe.net

What Are IHE PCD Standards, and Why Do They Matter?

IHE Patient Care Devices (PCD) Domain

- Created in 2005 to "address the integration of medical devices into the healthcare enterprise, from the point-of-care to the EHR, potentially resulting in significant improvements in patient safety and quality of care" ("IHE Patient Care Device" Retrieved October 27, 2015, from http://www.ihe.net/Patient_Care_Devices)

Sponsored by the *American College of Clinical Engineering* (ACCE), *Health Information Management Systems Society* (HIMSS) and the *Association for the Advancement of Medical Instrumentation* (AAMI)

Patient Care Device (PCD) Domain

Mission – enable “Out of the Box”, Reliable, “Functionally Interoperable” solutions

Using IHE & PCD open Processes and open Standards

Technical Underpinnings:

- **HL7** version 2.6 baseline, with some profile specific drawing upon 2.7, 2.8, & 2.8.2
- **IEEE 11073** Medical Device Communication Standards
- Part -**10101 Standardized Nomenclature**,
  Part -**10201 – Standardized Domain Information Model**
- Wireless Communication Transfer Protocol (**WCTP**) version 1.3
- IHE ITI domain **Consistent Time (CT) profile** – **Network Time Protocol** (NTP)

What Are IHE Actors?

IHE Actors

- Every profile is executed through a number of distinct actors (defined in Technical Framework Vol. II)

- Actors are "responsible for producing, managing and/or acting on information in the context of an IHE Profile."
  ("Actors" Retrieved October 27, 2015, from http://wiki.ihe.net/index.php?title=Actors)

- An actor can be used within multiple profiles

What Are IHE PCD Standards, and Why Do They Matter?

IHE PCD Profiles

- Alert Communication Management (ACM)
- ***Device Enterprise Communication* (DEC) ← Foundational**
- Device Enterprise Communication – Subscribe to Patient Data (DEC-SPD)
- Implantable Device Cardiac Observation (IDCO)
- Infusion Pump Event Communication (IPEC) <- Patient Saftey
- MEM-LS (Medical Equipment Management - Location Services)
- MEM-DMC (Medical Equipment Management - Device Management Configuration)
- Point-of-care Infusion Verification (PIV)
- Pulse Oximetry Integration (POI)
- Retrospective Data Query (RDQ)
- Rosetta Terminology Mapping (RTM)
- Waveform Content Module (WCM)

IHE Development Process

IHE Profiles Drafted & Revised

IHE Technical Framework Developed

Published For Public Comment

Trial

Trial Implementation Posted

6-13 mos.

Test at IHE Connectathons

14-18 mos.

Publish in IHE's Product Registry

Demonstrate at a HIMSS INTEROPERABILITY SHOWCASE

Install Interoperable products in Clinical Settings worldwide

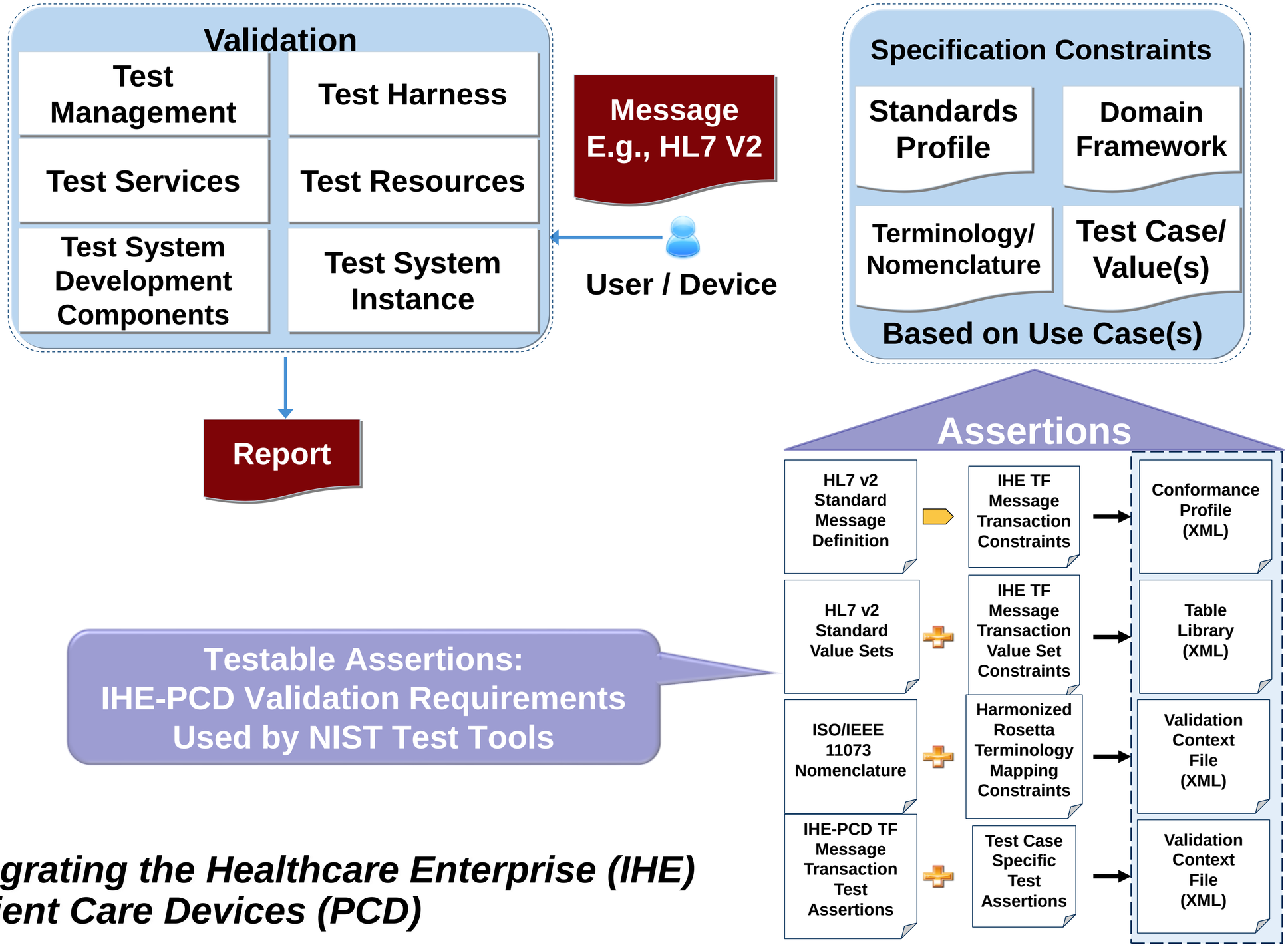
Profile Selection by Committees

IHE Call for Proposals Opens

1-5 mos.

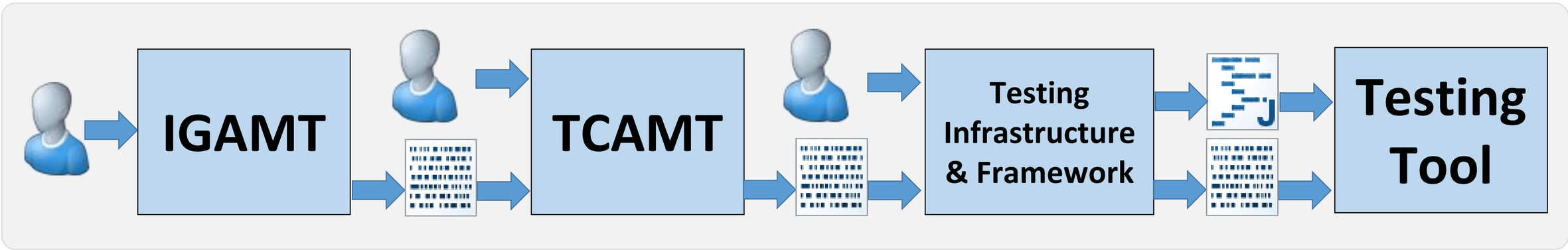
IHE Improves, Safety, Quality and Efficiency in Clinical Settings.

Medical Device Interoperability
Using 'Profiles' To Advance Rigorous Testing



Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PCD)

NIST HL7 v2 Platform Overview



- IGAMT – Implementation Guide Authoring and Management Tool
- TCAMT – Test Case Authoring and Management Tool
- Testing Infrastructure and Framework
- Testing Tool

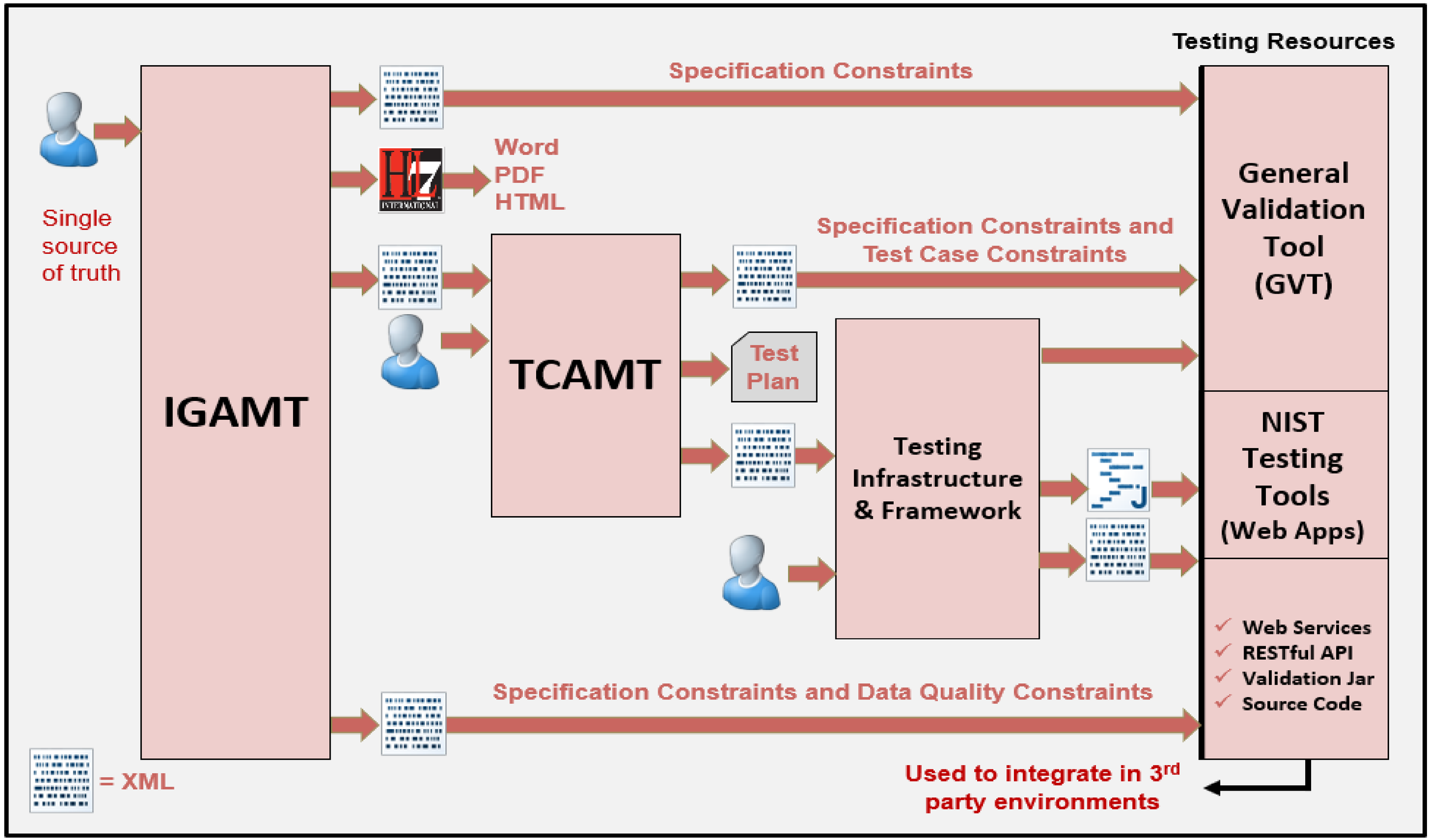
IGAMT - Implementation Guide Authoring and Management Tool

- Tool to create standards
- Narrative + Message Definition
- Built-in template
- Supports current conformance constructs
- Enforces conformance rules
- Promotes consistency in requirements
- Single source of truth
- New profile schema (for XML profile instances)
- XML export is gateway to other services
- Constraints for context-free testing

TCAMT - Test Case Authoring and Management Tool

- Tool Test Plans and Test Cases
- Narrative + Test Case Definitions
- Import XML profiles in IGAMT format
- XML profiles provide underlying model
- NIST-built constraint mechanism
- Expands testing capabilities
- Example/test messages ← Powerful notion
- Single source of truth
- XML export is gateway to other services
- Constraints for context-based testing

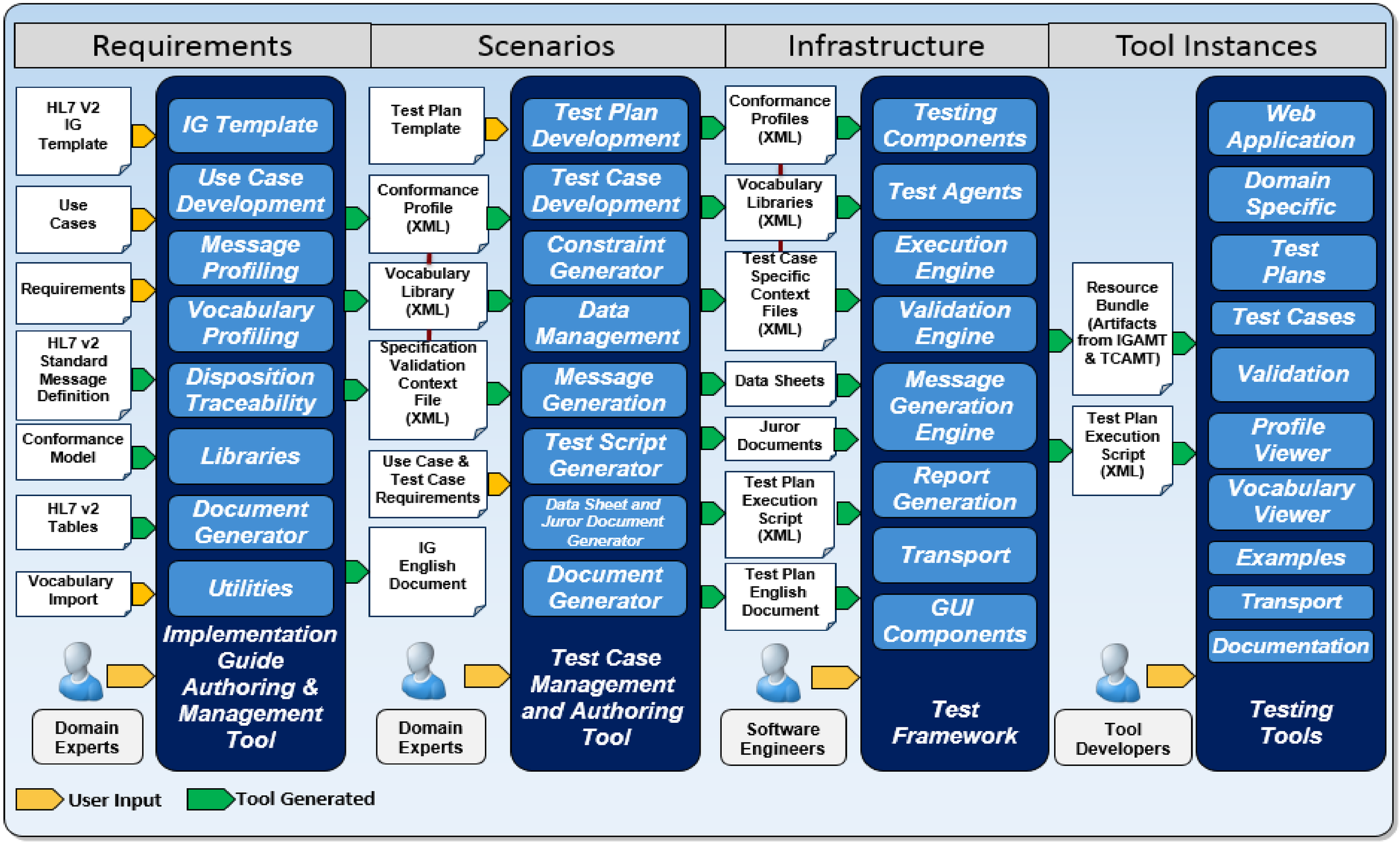
NIST HL7 v2 Platform



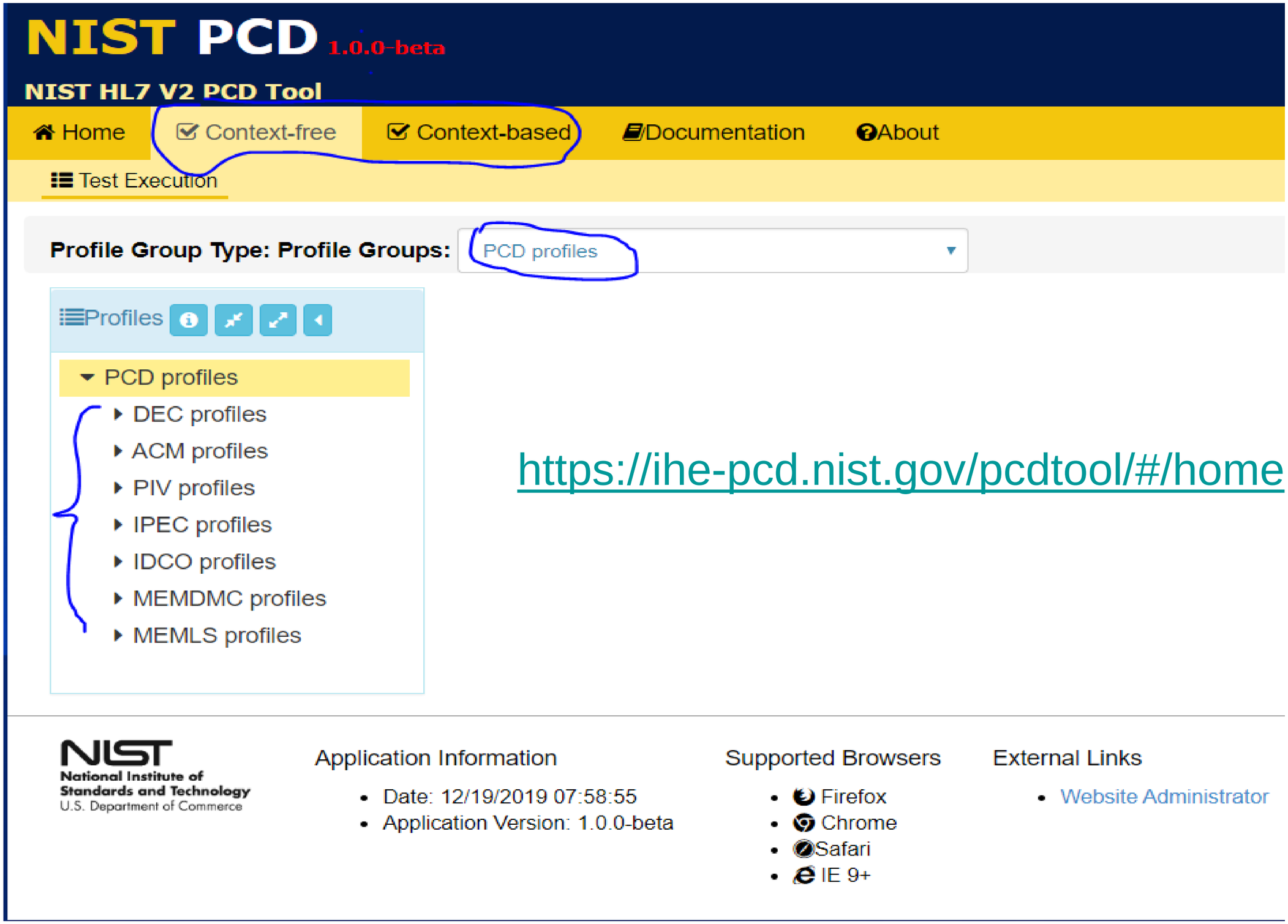
NIST HL7 v2 Platform

- Platform to build and manage tools
- Transfers tooling to standard developers
- SMEs create targeted test cases
- Low barrier to entry for non-techies
- Single source for modifications
- Changes are propagated through the platform—less error prone
- Reduces costs
- Reduces maintenance effort (quick updates)
- Promotes tool sustainability (tool longevity)
  - Other tools start all over again for updates

NIST HL7v2 End-to-End Platform



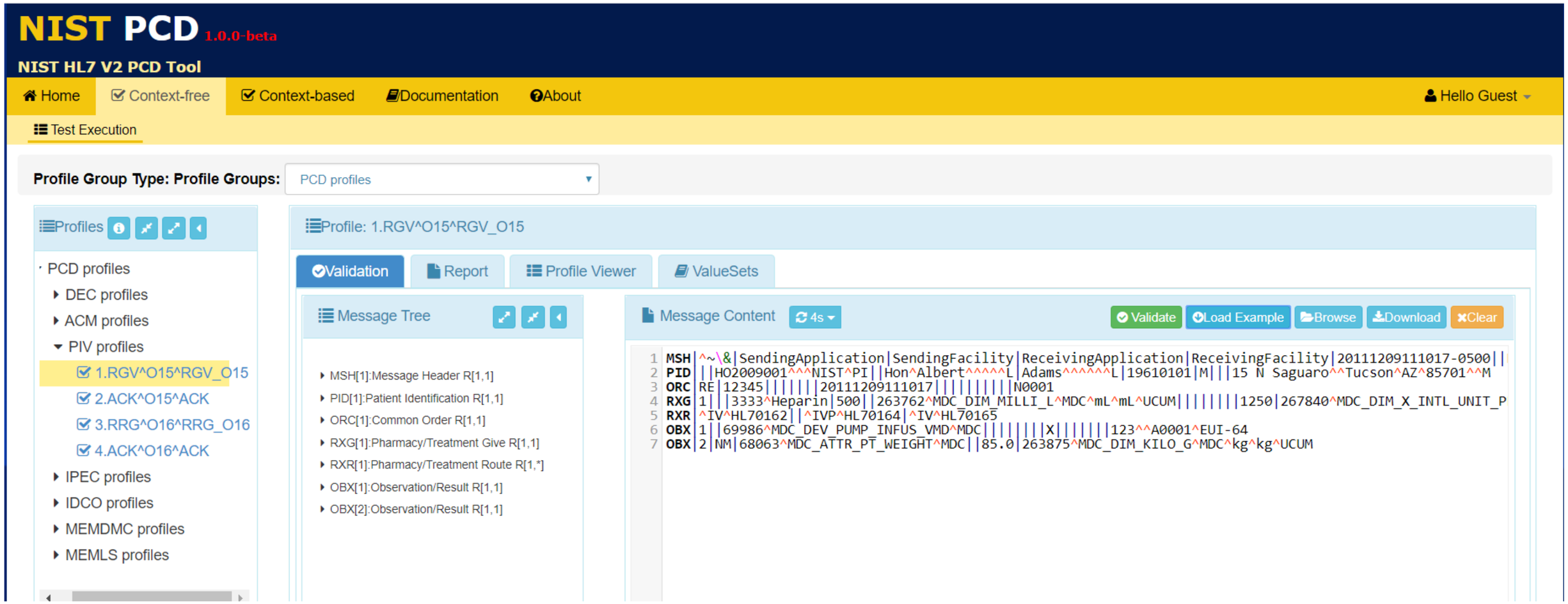
Example of IHE-PCD V2 Validation Tool: Used at 2020 NA Connectathon (January 2020)



https://ihe-pcd.nist.gov/pcdtool/#/home

Example of V2 Validation Tool (derived from Framework): Used at January's 2020 NA Connectathon & Going Forward

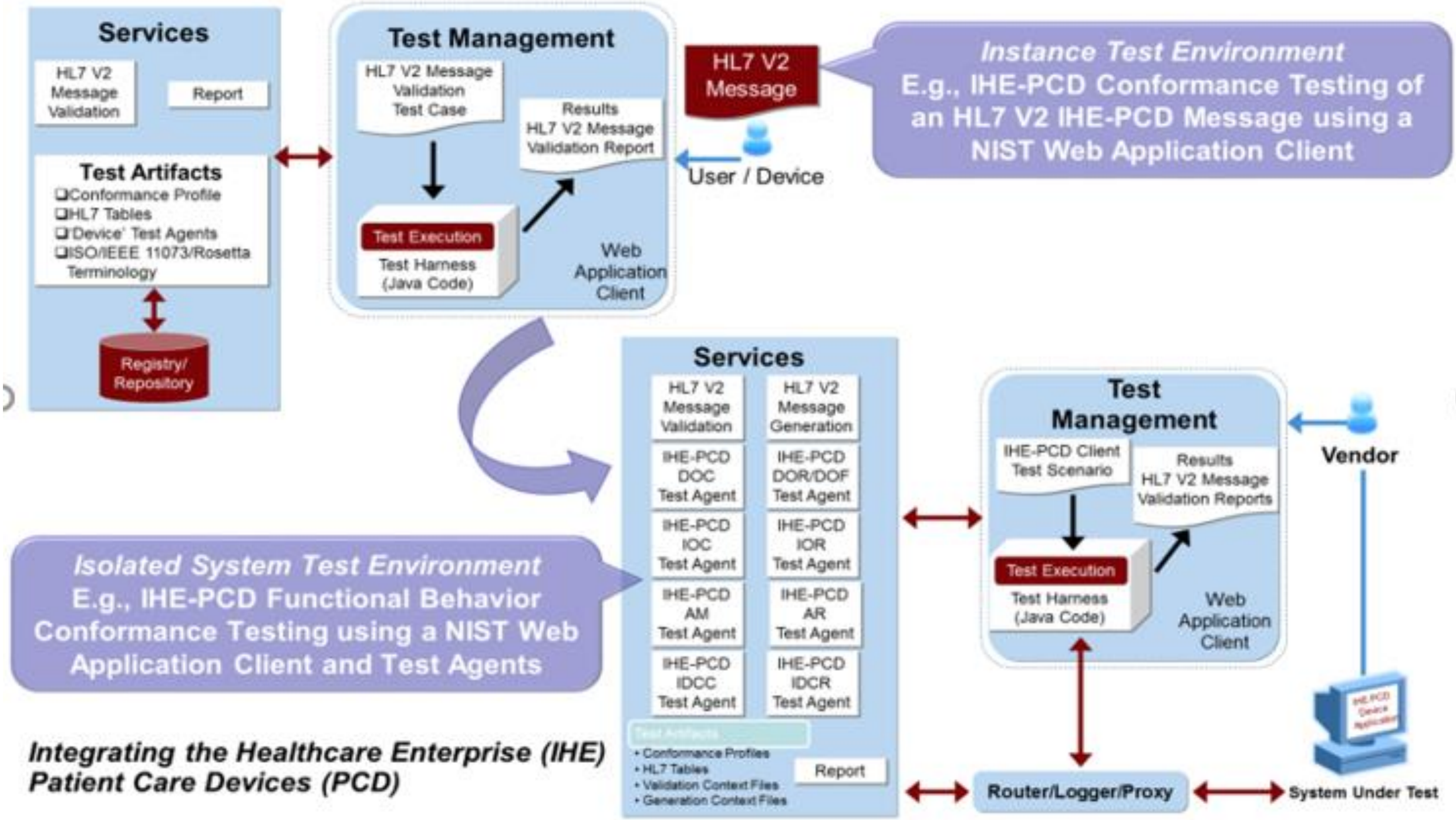
- IHE-PCD Profiles - PIV Profiles
  - *RGV^O15_RGV_O15* HL7 V2 Message Type
  - *"PCD-03"*



Test Cases
2019-20 IHE-PCD Pre+Connectathon Tool: Cycle 14

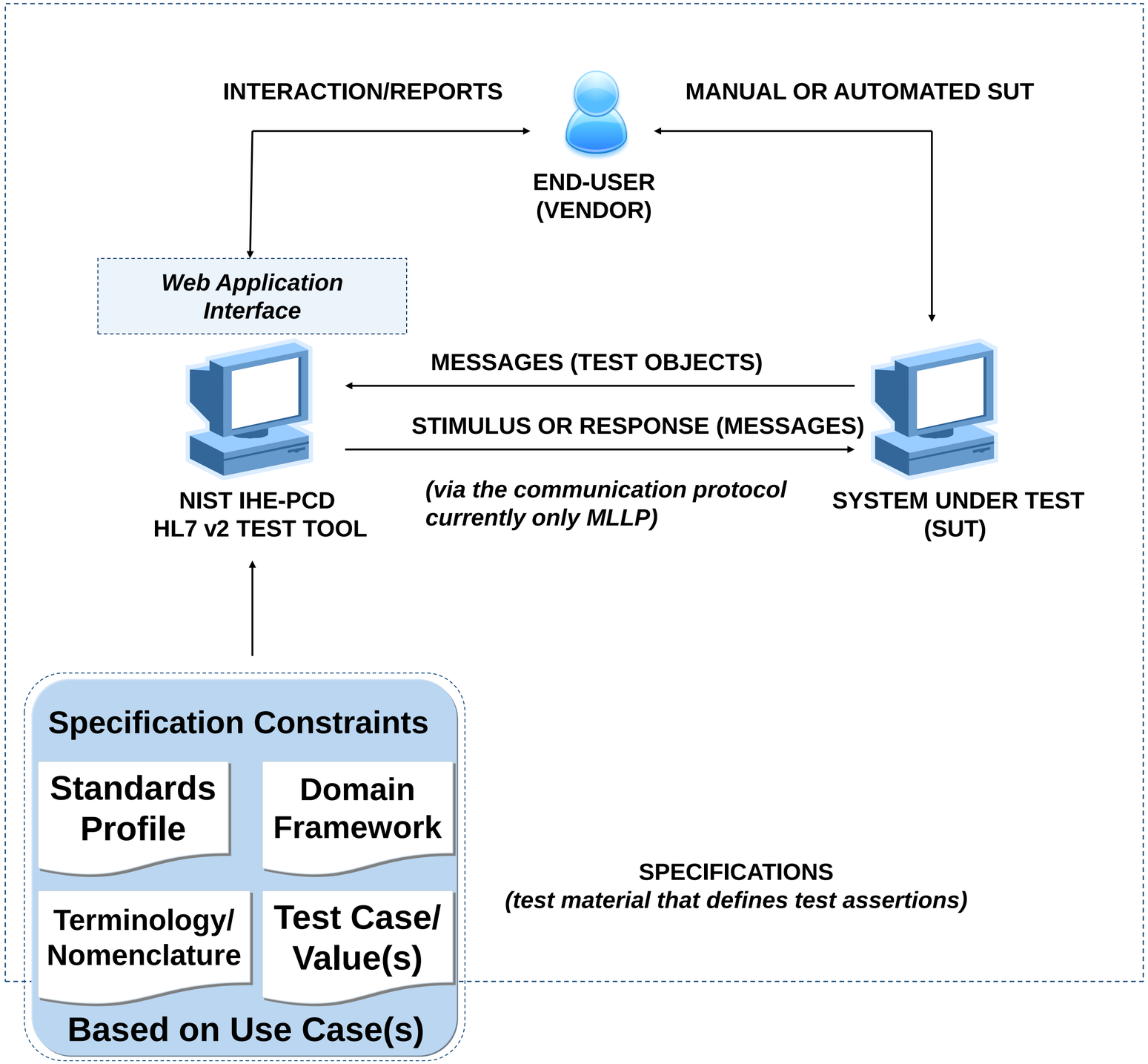
- IHE-PCD: NIST "Isolated Environment" Test Tools
  - HL7 V2.6
  - Supports 8 Integration Profiles (*number of test cases, some duplicated amongst actors*)
    - DEC – Device Enterprise Communication (10)
      - SPD – Filter (4)
      - POI – Pulse Ox (3)
    - PIV – Patient Infusion Verification (9)
    - IPEC – Infusion Pump Event Communication (6)
    - IDCO – Implantable Device Cardiac Observation (4)
    - ACM – Alert Communication Management (2), (*WTCP validation not supported*)
    - RDQ – Retrospective Data Query (1)
    - MEMDMC – Device Management Communication (1)
    - MEMLS – Location Services (1)
    - *OMS, RTLS/CMS, Security white papers/WGs*
- 64 Test Cases {31 Unique} (across all 'Actors')

Medical Device Interoperability
NIST Test Environments and Services



Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PCD)

NIST V2 HL7 IHE-PCD Test Tool: Operational Process



What are IHE PCD Standards?

IHE PCD "Integration Profiles" Overview:

- Consuming data from medical devices and reporting that data to EHRs:
  - ✓ *Device Enterprise Communication* (DEC)
  - ✓ (Option) Device Observation Filter (DOF)

IHE PCD page:
www.http://ihe.net/Patient_Care_Devices/

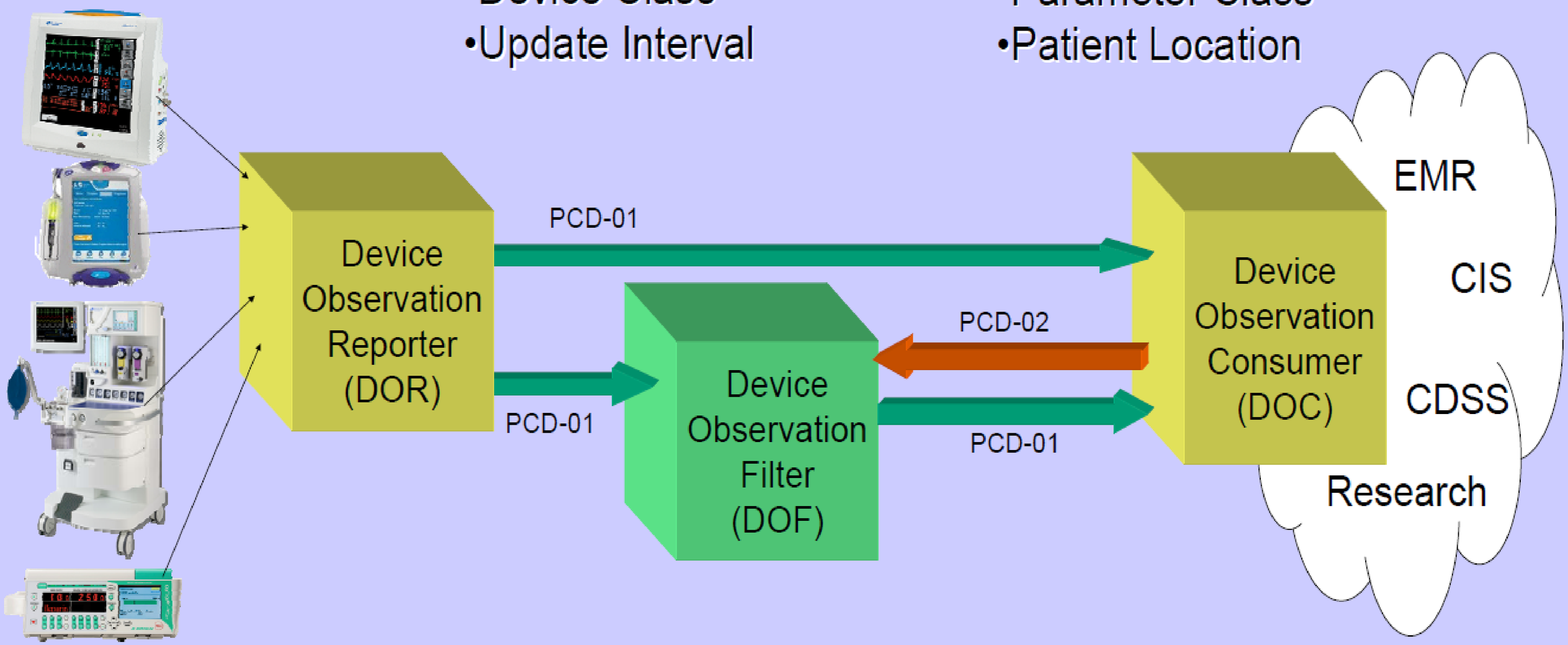
IHE Integrating the Healthcare Enterprise

Device to Enterprise Communication (DEC)

The DEC profile allows a consuming system (DOC) to receive patient clinical information including vitals, demographics, settings, and location from a reporting device/system (DOR).

The Subscribe to Patient Data (SPD) option allows the consumer to filter the data by:

- Medical Record #
- Device Class
- Update Interval
- Start & End Times
- Parameter Class
- Patient Location



PCD-01 Message Example, HL7 V2

IEEE EUI-64

Unsolicited Observation Message Type

Unified Code for Units

Regenstrief Institute

OBX-4

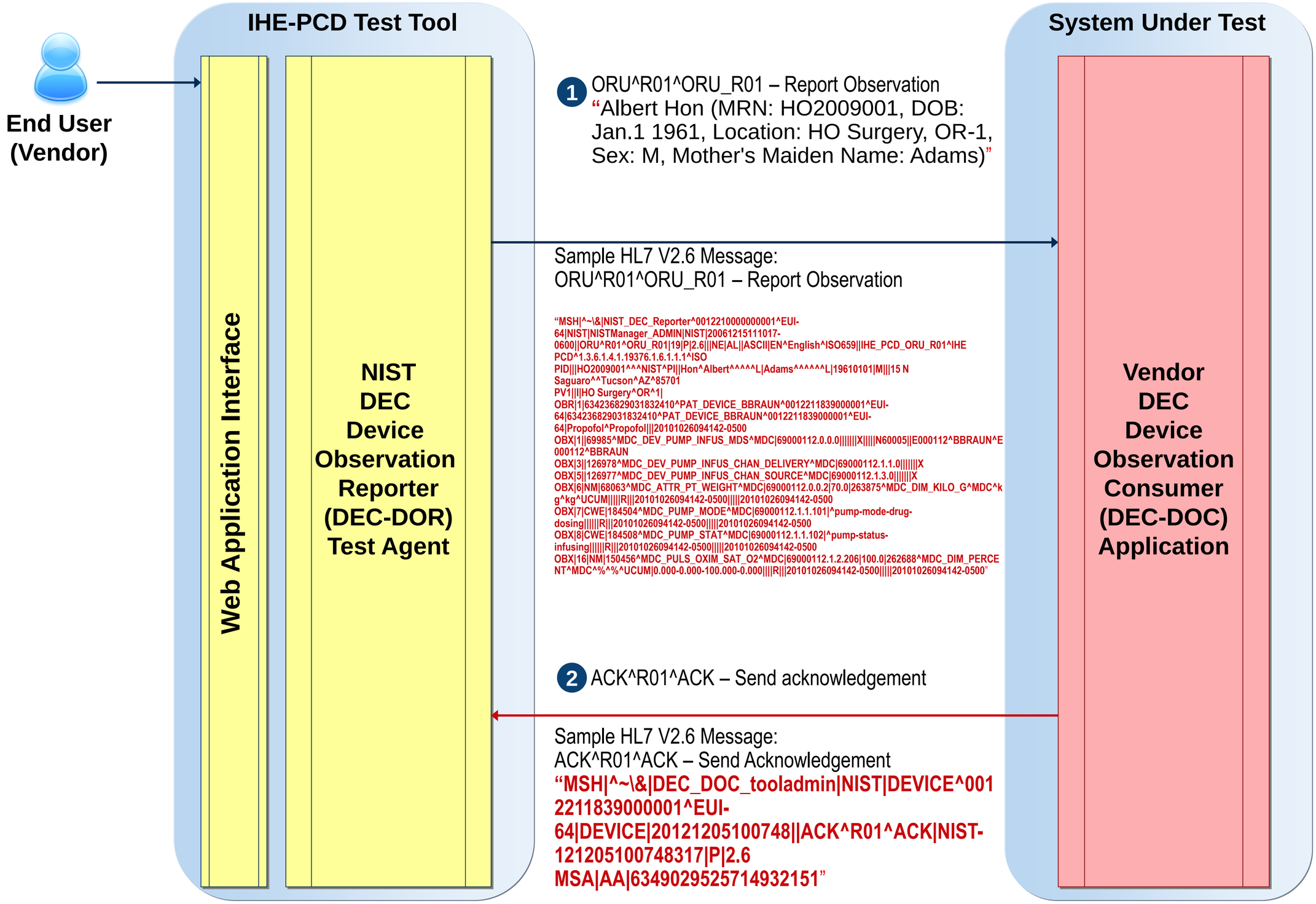
‘Heart Rate’

Value= 80 BPM

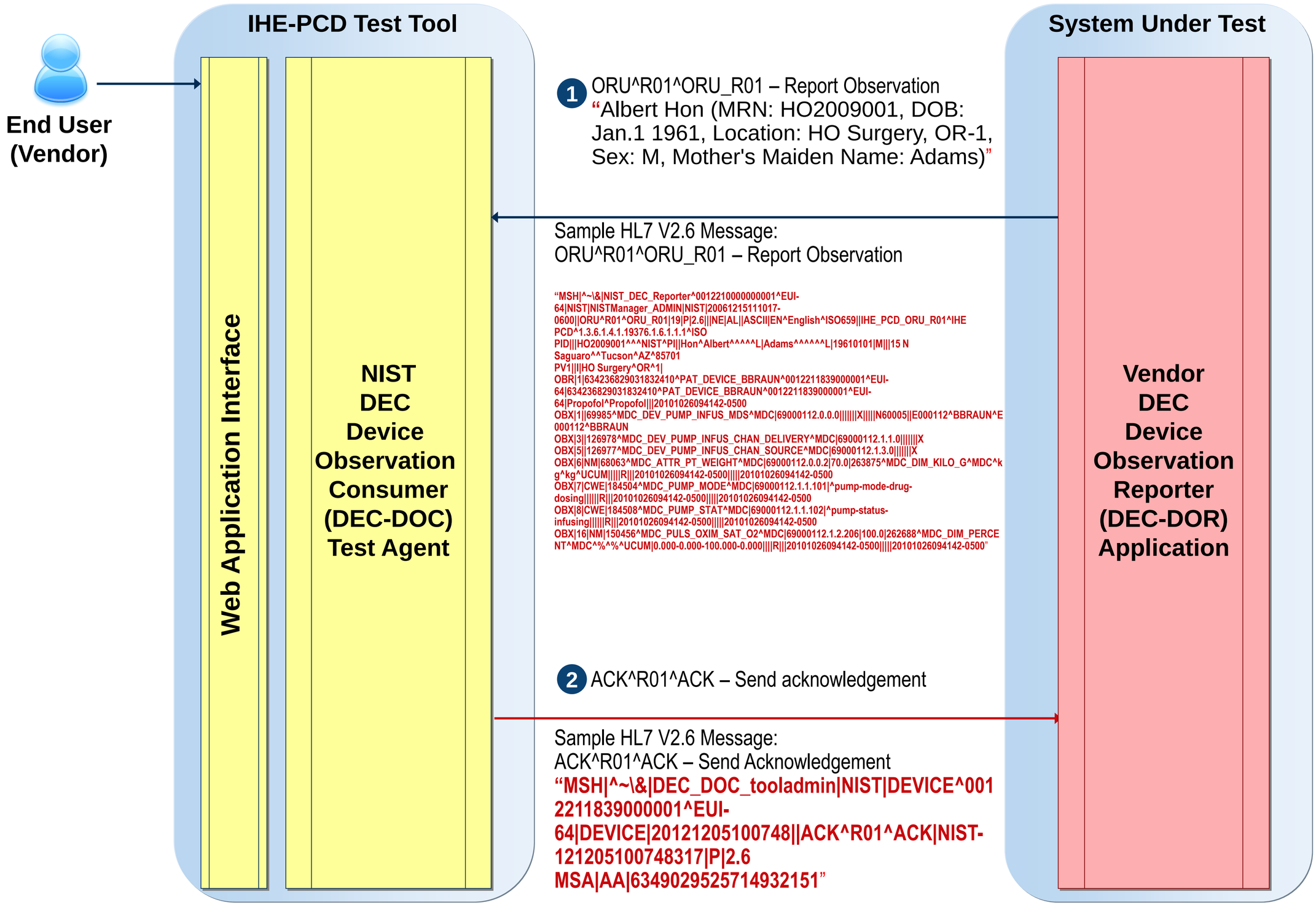
‘/min’ MDC UOM

```
MSH|^~\&|HL7^080019FFFF4F6AC0^EUI-64|MMS|||20070118133700||ORU^R01|a4e2e3:11036b5cdbb:-
|P|2.6|20070118133700||NE|AL||8859/1
PID|||GE101^^^DefaultDomai||JACKSON^IRWIN^^^^^L
PV1||E|3WICU^305^305
OBR|1|080019FFFF4F6AFE200701|080019FFFF4F6AC0200701|126.3.3.1^2000^MDC|||20070118133700
OBX|1|NM|147842^MDC_ECG_HEART_RATE^MDC|1.6.1.1|80|/min^MDC/min^UCUM|||||R
OBX|2|NM|148065^MDC_ECG_V_P_C_CNT^MDC|1.6.1.2|0|/min^/min^UCUM|||||R
OBX|3|NM|150035^MDC_PRESS_BLD_ART_MEAN^MDC|1.3.1.1|96|{mm[Hg]}^{mm[Hg]}^UCUM|||||R
OBX|4|NM|150036^MDC_PRESS_BLD_ART_SYS^MDC|1.3.1.2|120|{mm[Hg]}^{mm[Hg]}^UCUM|||||R
OBX|5|NM|150037^MDC_PRESS_BLD_ART_DIA^MDC|1.3.1.3|80|{mm[Hg]}^{mm[Hg]}^UCUM|||||R
OBX|6|NM|149522^MDC_BLD_PULSE_RATE_NON_INV^MDC|1.8.1.1|80|/min^/min^UCUM|||||R
OBX|7|NM|150047^MDC_PRESS_BLD_ART_PULM^MDC|1.4.2.1|[illegible]{mm[Hg]}^UCUM|||||R
OBX|8|NM|150045^MDC_PRESS_BLD_ART_PULM_SYS^MDC|1.4.2.2|[illegible]{mm[Hg]}^UCUM|||||R
OBX|9|NM|150046^MDC_PRESS_BLD_ART_PULM_DIA^MDC|1.4.2.3|10|{mm[Hg]}^{mm[Hg]}^UCUM|||||R
OBX|10|NM|150344^MDC_TEMP^MDC|1.10.1.1|26.4|cel^cel^UCUM|||||R
OBX|11|NM|150344^MDC_TEMP^MDC|1.10.1.2|37.4|cel^cel^UCUM|||||R
OBX|12|NM|151610^MDC_VENT_CO2_RESP_RATE^MDC|1.5.1.1|12|{{breath}/min}^{{breath}/min}UCUM|||||R
OBX|13|NM|151804^MDC_PRESS_AWAY_END_EXP_POS^MDC|1.5.1.2|4|{cm[H20]}^{cm[H20]}^UCUM|||||R
OBX|14|NM|152008^MDC_VENT_VOL_MINUTE_AWAY^MDC|1.5.1.3|0.0|l/min^l/min^UCUM|||||R
OBX|15|NM|151920^MDC_VENT_CONC_AWAY_O2_INSP^MDC|1.5.1.4|21|%^%^UCUM|||||R
OBX|16|NM|151980^MDC_VENT_VOL_TIDAL^MDC|1.5.1.5|920|ml^ml^UCUM|||||R
OBX|17|NM|151957^MDC_VENT_PRESS_MAX^MDC|1.5.1.6|17|{cm[H20]}^{cm[H20]}^UCUM|||||R
OBX|18|NM|151784^MDC_PRESS_RESP_PLAT^MDC|1.5.1.7|31|{cm[H20]}^{cm[H20]}^UCUM|||||R
OBX|19|NM|151792^MDC_PRESS_AWAY^MDC|1.5.1.8|36|{cm[H20]}^{cm[H20]}^UCUM|||||R
OBX|20|NM|151808^MDC_PRESS_AWAY_END_EXP_POS_INTRINSIC^MDC|1.5.1.9|1|{cm[H20]}^{cm[H20]}^U
CUM|||||R
```

Test Case : Device Enterprise Communication: Consumer



Test Case : Device Enterprise Communication: Reporter



What are IHE PCD Standards?

IHE PCD "Integration Profiles" Overview:

- Improving infusion order safety:
  - ✓ *Point of care Infusion Verification* (PIV)
  - ✓ Infusion Pump *Event Communication* (IPEC)

IHE PCD page:
www.http://ihe.net/Patient_Care_Devices/

Integrating the Healthcare Enterprise

Point of care Infusion Verification (PIV)

Physician's Order

Nurse Review

Pharmacist Review

BCMA to Pump (PCD-03)

Pump may provide data to EMR (PCD-01) and / or BCMA (PCD-03)

Medication Administered

Nurse confirms 6 Rights:
- Right Patient
- Right Medication
- Right Dose
- Right Time
- Right Route
- Right Device

Infusion Pumps

Barcoded Medication Administration (**BCMA**) is an inventory control system that uses barcodes to prevent human errors in the distribution of prescription medications at hospitals.

Infusion Pump Event Communication (IPEC)

Infusion Pump Event Communication enables reporting of clinical and operational events from an infusion pump to a Bedside Computer-assisted Medication Administration (BCMA) system or EMR. Clinicians can then view and validate this information for infusion documentation.

BCMA/EMR

Prior to medication administration, nurse confirms the 6 Rights of administration using BCMA/EMR:

- Right Patient
- Right Medication
- Right Dose
- Right Time
- Right Route
- Right Device

Infusion-related events are displayed, validated, and/or recorded by the clinician using the BCMA/EMR

Infusion order sent from BCMA/EMR to Pump (PCD-03)

Pump provides information on infusion-related events to BCMA/EMR (PCD-10) such as:

- Delivery Start
- Delivery Stop
- Delivery Complete

What are IHE PCD Standards?

IHE PCD "Integration Profiles" Overview:

- Getting alerts to staff on mobile and desktop devices:
  - ✓ Alert Communication Management (ACM)

IHE PCD page:
www.http://ihe.net/Patient_Care_Devices/

IHE Integrating the Healthcare Enterprise

Alert Communication Management (ACM)

HL7 Messages per ACM and WCM profiles ▶ Parameters, waveforms, etc. as evidentiary data items ▶ Device Specific graphics ▶

Alert Source

Alert Reporter AR — Report Alert PCD-04 → / ← PCD-05 Report Alert Status — **Alert Manager AM** — Disseminate Alert PCD-06 → / ← PCD-07 Disseminate Alert Status — **Alert Communicator AC**

Alert Information

Source, Phase, State, Priority
Patient
Location
Instance
Alert text
Callback
Timestamp
Evidentiary data

Dissemination Status

Instance
Accepted by AC
Undeliverable
Delivered
Read
Accepted
Rejected
Cancelled
Callback start/stop

What are IHE PCD Standards?

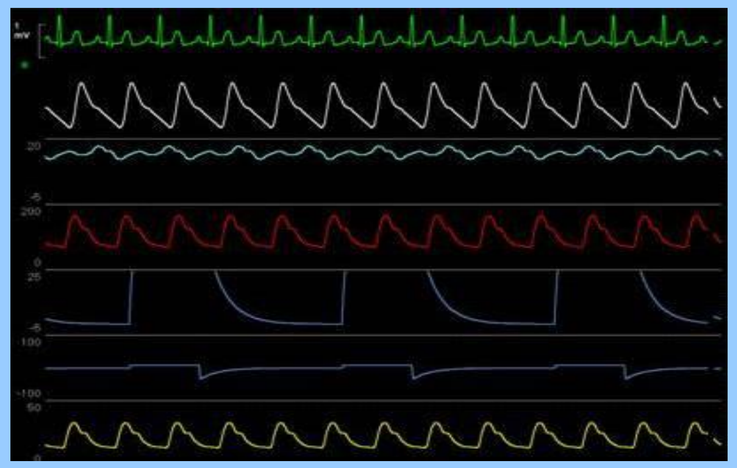
IHE PCD "Integration Profiles" Overview:

- Waveform support:
  - ✓ Waveform Content Module (WCM)

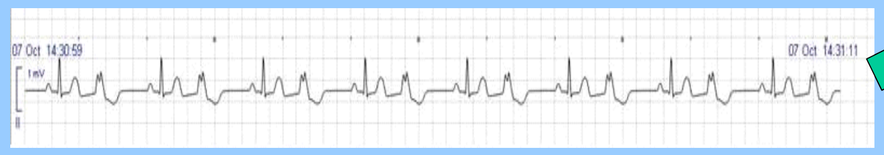
IHE PCD page:
http://ihe.net/Patient_Care_Devices/

IHE Integrating the Healthcare Enterprise

Waveform Content Module (WCM)



Continuous Waveform Data

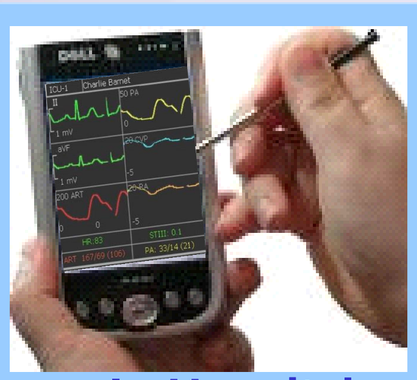


Alarm Evidentiary Data

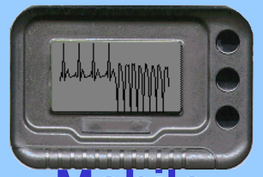
PCD-01

PCD-04

WCM encoded waveform

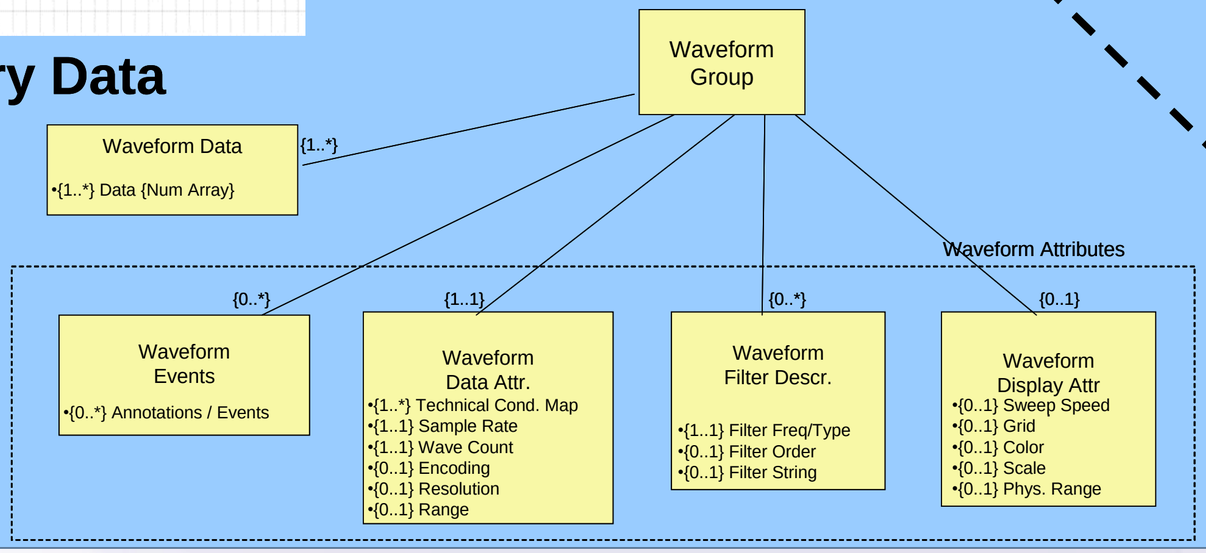


In-Hospital Access



Mobile Access

Remote Access



What are IHE PCD Standards?

IHE PCD "Integration Profiles" Overview:

- Medical Equipment Management:
  - ✓ Device Management Communication (MEMDMC)
  - ✓ Location Services (MEMLS)

IHE PCD page:
http://ihe.net/Patient_Care_Devices/

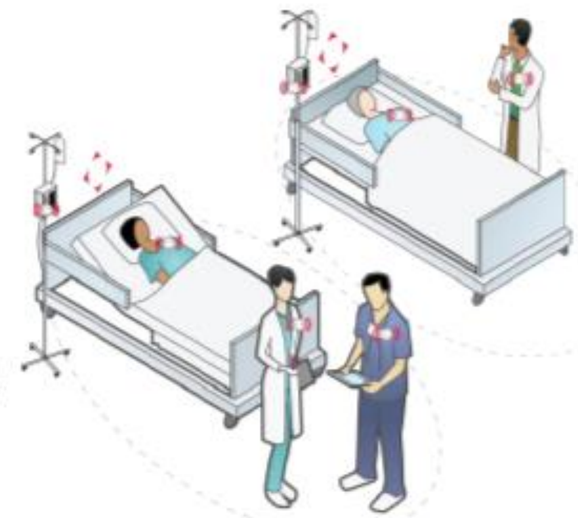
Device Management (MEMDMC) & Location Services (MEMLS)

Profile based messages relay IV pump status including:

- Infusing
- Stopped

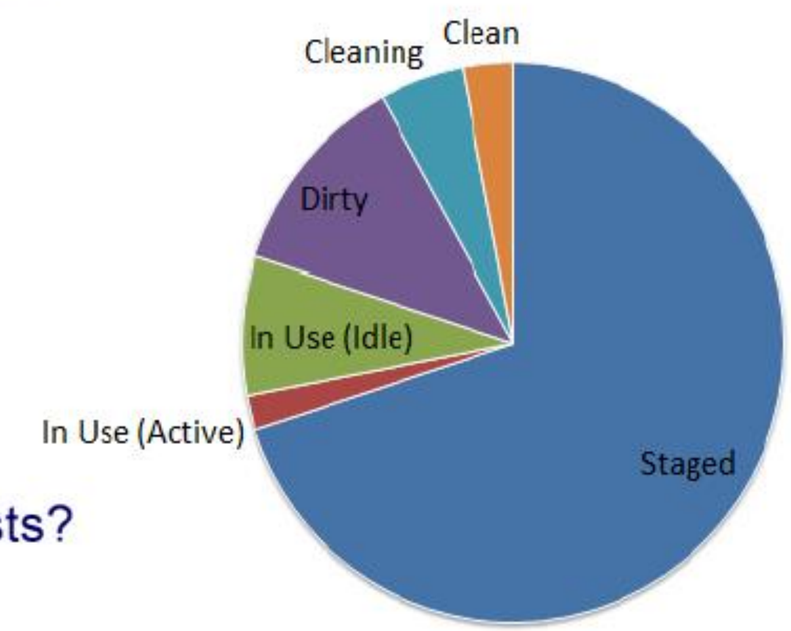
RTLS uses location to interpret asset status:

- Biomed (PM / Repair)
- CS (Cleaning)
- Clean Utility
- Patient Room (In Use)
- Dirty Utility



Combined data generates asset state:

- Available
- In Active Use
- Unavailable but Idle
- Unavailable (PM / Technical Assessment): *Future* based on CMMS Data



Drives workflow and analytics:

- Where can I find idle pumps to return to circulation and meet requests?
- How often are pumps sitting idle in patient rooms?
- What is my true utilization?
- Is the pump leaving the building running (with a patient) or idle (possible theft)?
- Do I have more inventory than I need? (And what is related maintenance cost? Replacement cost?)

What are IHE PCD Standards?

IHE PCD "Integration Profiles" Overview:

- <u>Implantable Devices</u>
  - ✓ Implantable Devices Cardiac Observation (IDCO)
  - ✓ specifies the creation, transmission, and processing of discrete data elements and report attachments associated with cardiac device interrogations (observations) or messages.

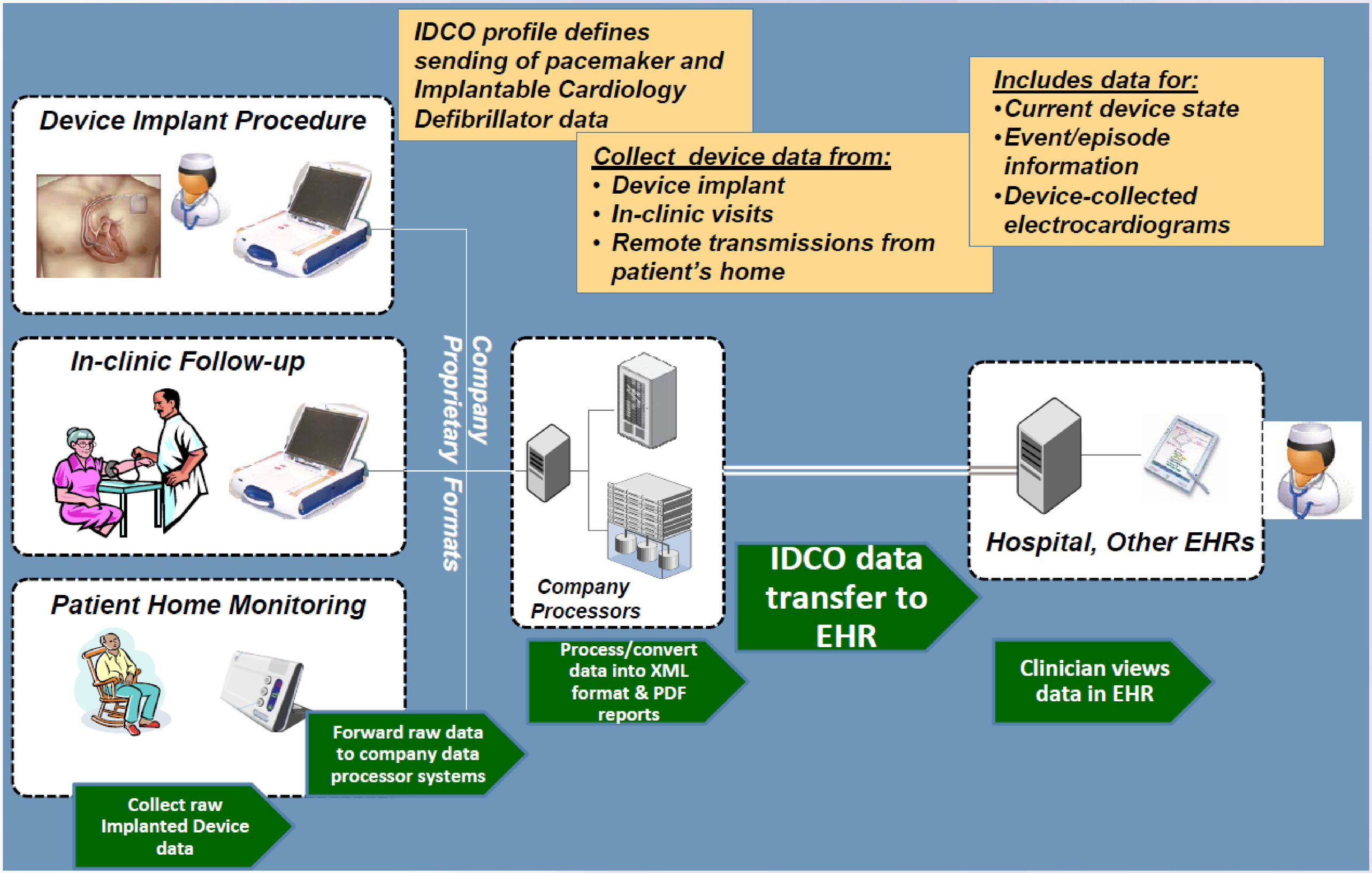
IHE PCD page:
http://ihe.net/Patient_Care_Devices/

Implantable Device – Cardiac Observation (IDCO)

IDCO profile defines sending of pacemaker and Implantable Cardiology Defibrillator data

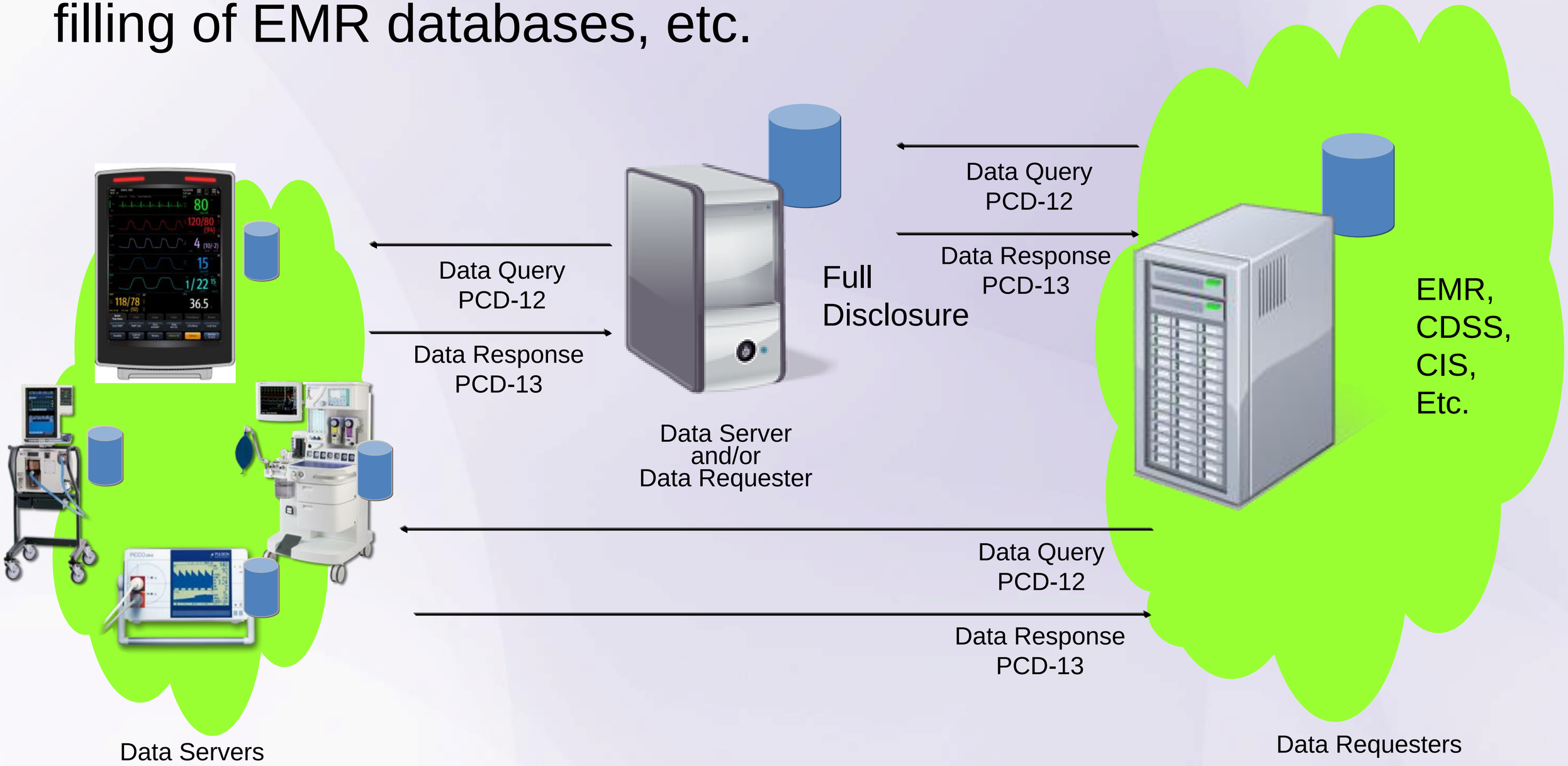
Collect device data from:
- *Device implant*
- *In-clinic visits*
- *Remote transmissions from patient's home*

Includes data for:
- *Current device state*
- *Event/episode information*
- *Device-collected electrocardiograms*



Retrospective Data Query (RDQ)

Supports retrospective query of PCD data from databases. Supports Use Cases such as Clinical Decision Support, back-filling of EMR databases, etc.



How Are the IHE Integration Statements Accessed And Interpreted?

IHE Integration Statements

- Integration statements: product-registry.ihe.net/PR/home.seam
- Search available for a specific organization or product, or for all systems within a given IHE domain and/or profile
- Each integration statement pertains to a specific vendor product
- Integration statement may also provide a link to the product vendor's website

How Does the Annual IHE Connectathon Testing Event Work?

You May Be Expecting This…

How Does the Annual IHE Connectathon Testing Event Work?

…But Connectathon Is Actually This…

How Does the Annual IHE Connectathon Testing Event Work?

…And This…

How Does the Annual IHE Connectathon Testing Event Work?

…And This.

HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

Rosetta Terminology Mapping Management System - RTMMS

Semantic interoperability of Medical Devices

Test Tool Update
IEEE-SA

National Institute of Standards and Technology

April 3, 2020, On-line

Contact: john.garguilo@nist.gov, 301-975-5248

National Institute of Standards and Technology

Rosetta Terminology Mapping

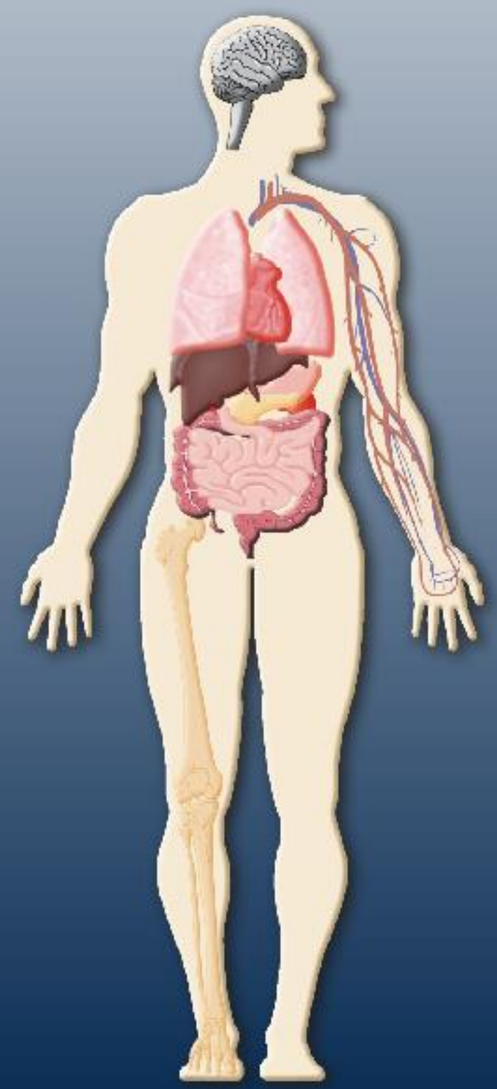
PCD Rosetta Project

Named after the Rosetta Stone, the PCD Rosetta Project maps existing and proprietary vendor parameters and units-of-measure for virtually all physiological measurements to the ISO/IEEE 11073-10101 vital signs nomenclature and related standards such as UCUM.

This will facilitate real-time interoperability between devices and systems, including EHR systems using the IHE PCD-01 Technical Framework.

This level of collaboration for the common good is open to all vendors in the IHE PCD.

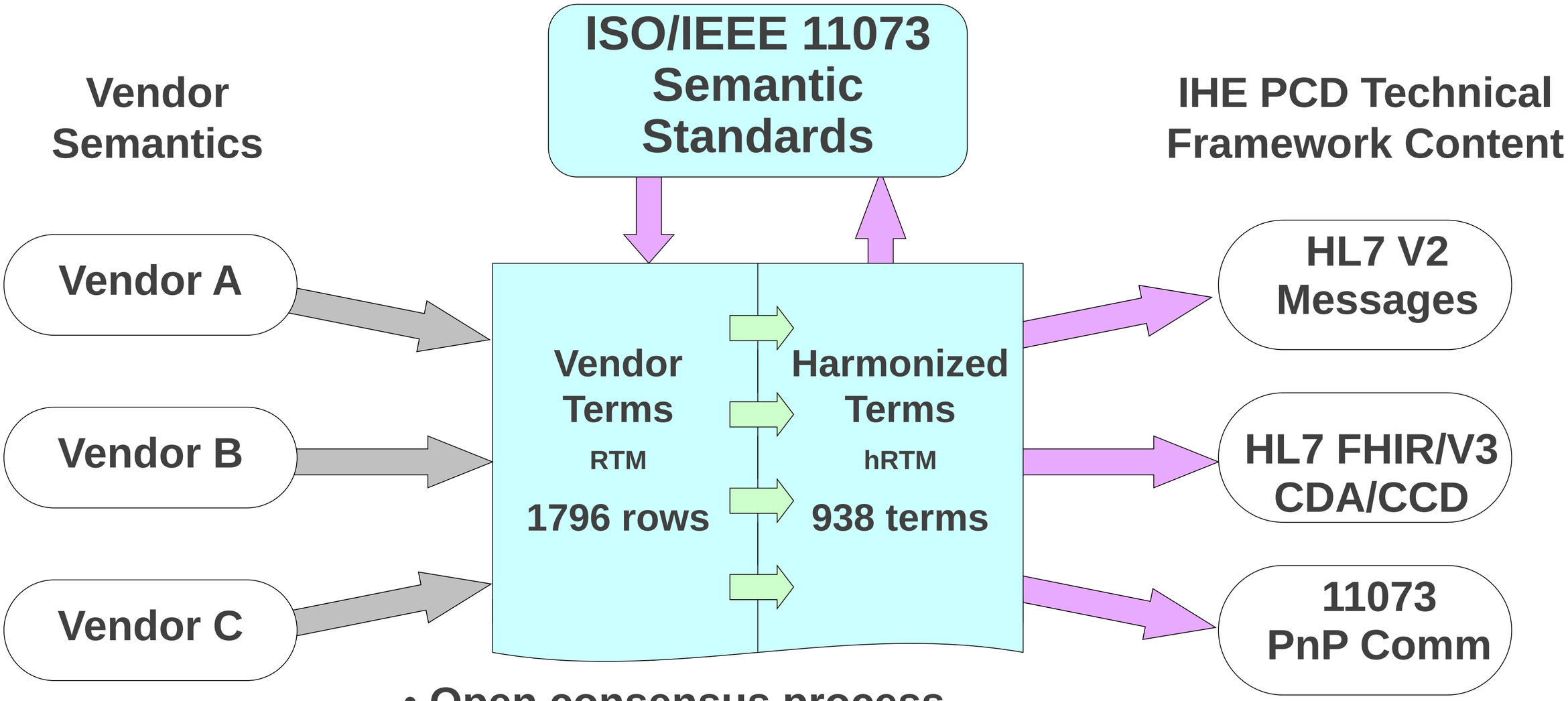
IHE *changing the way healthcare connects*



PCD Rosetta Project

Creating common terminology for device connectivity

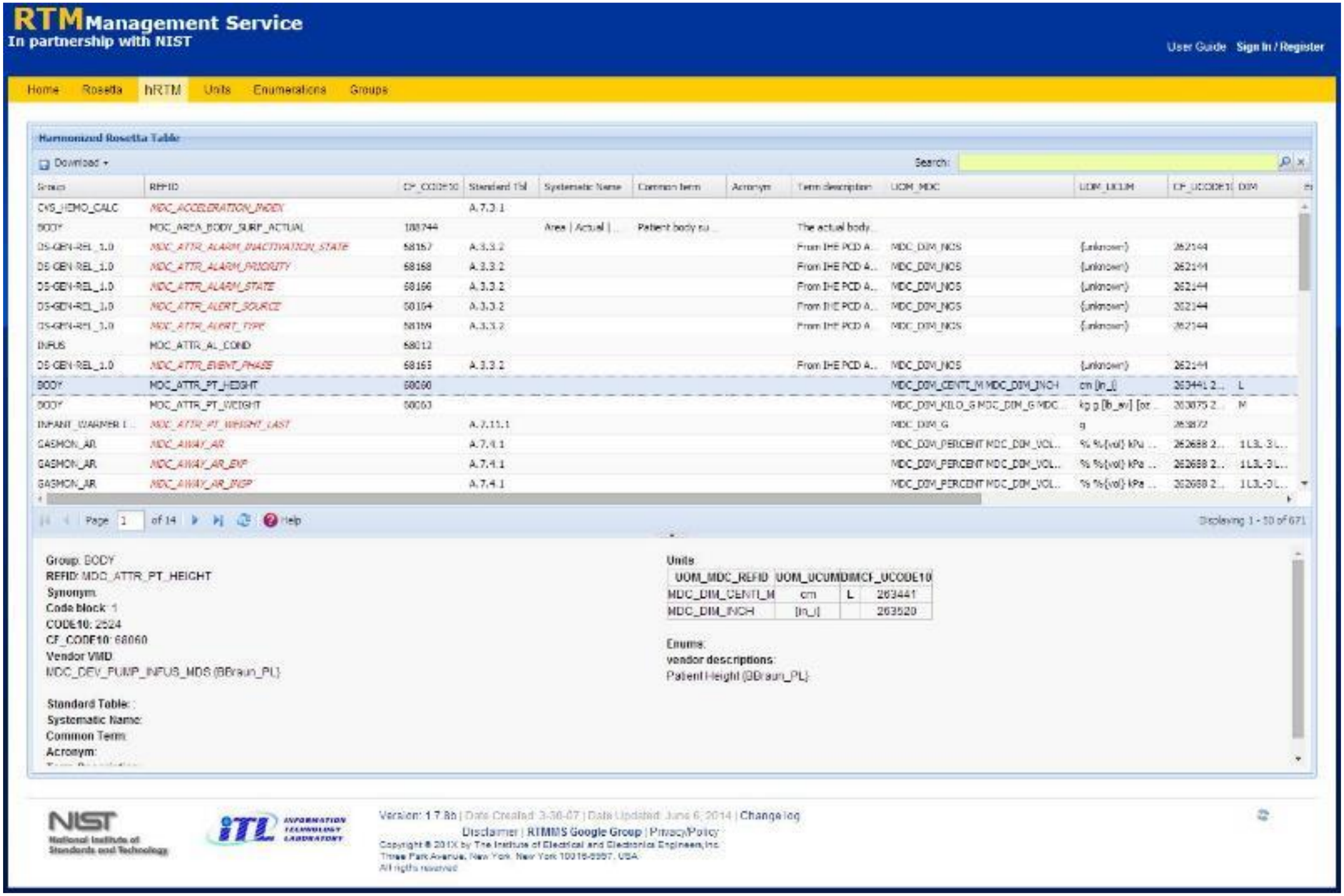
IHE-PCD Rosetta Terminology Mapping



- Open consensus process
- Observation identifiers *and* co-constraints
- New terms incorporated into standards
- hRTM used for conformance testing
- IEEE MDC codes → LOINC mappings (631)
- Total NIST Database contains 10,473 Terms

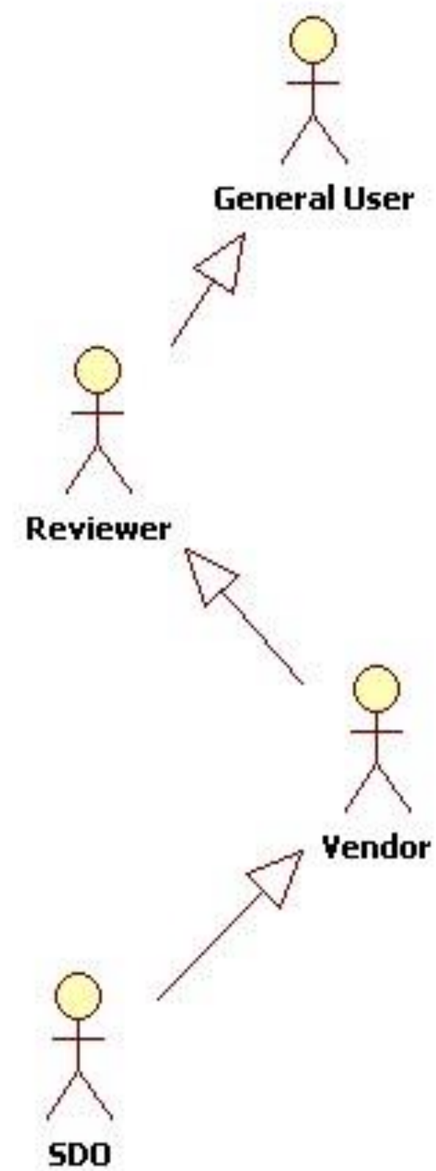
Slide developed and provided with permission by Paul Schluter, GE Healthcare

Rosetta Terminology Mapping Management System (RTMMS.nist.gov)



Rosetta Terminology Mapping Management System (RTMMS.nist.gov)

- Web application that allows access to Rosetta Tables over the internet
- Developed by and currently hosted at NIST
- Provides capability of saving data in XML format
- Identifies missing terms
- Automatic generation of the “Harmonized Rosetta Table”
- Provides latest up-to-date view of hRTM table
- Facilitates the proposal of New Terms to IEEE 11073 standard
- Enables Semantic Checking by Conformance Tooling
- Message verification and conformance (syntax and semantics)
- Integrated with NIST’s “DIM-Editor” Tool (ISO/IEEE 11073-10201)



Rosetta Terminology Mapping Management System (*RTMMS*)
ISO/IEEE 11073-10101

- RTMMS Deployment Update and service status
  - -10101a added + harmonized co-constraints (e.g., units, enums, body sites):
    631 LOINC mappings to MDC terms!
  - -10101R Work nearing completion, 10101 (future iterations TBD)
  - NIST-IEEE Royalty Free Agreement makes available the "Works" (5 key nomenclature attributes) – *perpetual agreement*
- Many thanks to lead Paul Schluter, retired Principal Engineer, GE Healthcare! ☺
  & Dr. Swapna Abhyankar (for LOINC mappings from Regenstrief and Dr. Clem McDonald from NLM) ☺

RTMMS by the numbers; Last HL7 WG Mtgs)

	Oct 2015	Jan 2016	May 2016	Sept 2016	Jan 2017	May 2017	Sept 2017	Jan 2018	May 2018	Oct 2018	May 2019	Sept 2019	Jan 2020
11073-10101		10685	10685	10685	10685	10685	10713	10725	10725	10473	10473	10473	10473
Rosetta Terms	1642	1648	1731	1733	1763	1764	1765	1807	1810	1834	1819	1796	1796
hRTM (Harmonized)	693	804	879	880	911	911	911	953	953	955	955	938	938
Groups	226	317	323	323	337	337	337	338	338	338	339	339	339
Unit Groups	8	8	12	12	12	12	12	15	15	15	15	15	15
-Units (MDC)	515	524	547	551	552	552	552	562	562	562	562	562	562
-Units (UCUM)	520	526	540	545	548	548	548	559	559	559	559	559	559
Enumeration Groups	39	43	43	43	43	43	43	45	45	45	36	36	36
-Enumerations	317	317	403	403	436	436	436	459	459	459	459	459	459
Organizations Registered	61	65	70	71	78	91	91	94	96	98	101	103	109
Users								151	157	158	174	177	183
LOINC Mappings											631	631	631

RTMMS Terminology Access and Views

✓ Agreement finalized between IEEE and NIST (Dec 2012, Sep. 2014)

- Allows users free and public access of terminology attributes that were formally 'pay-for' via the NIST tool
- The "Works"

Definition of the "Works" [from IEEE/NIST Agreement]

The following data items within the approved standards , existing and future versions, currently designated as:

1 – IEEE 11073-10xxx

2 – IEEE 11073-20xxx

Limited to the following data items within, currently designated as:

1 – Ref ID

2 – Code

3 – Description

4 – Systematic Name

5 – Common Term – added to agreement in Sept. 2014 (worked w/ Kathryn Bennett/IEEE to amend)

- Banner page updated on tool

RTMMS Primary Updates – Signed Agreement 12/20/12

PDF documents to Word or Excel.

For IEEE:
Konstantinos Karachalios
Managing Director, IEEE-SA
The Institute of Electrical and
Electronic Engineers, Inc.
445 Hoes Lane, Piscataway, NJ 08854

For NIST:
Ram Sriram
Chief – Systems and Software Division
Information Technology Laboratory
National Institute of Standards & Technology
100 Bureau Drive, Gaithersburg, MD 20899

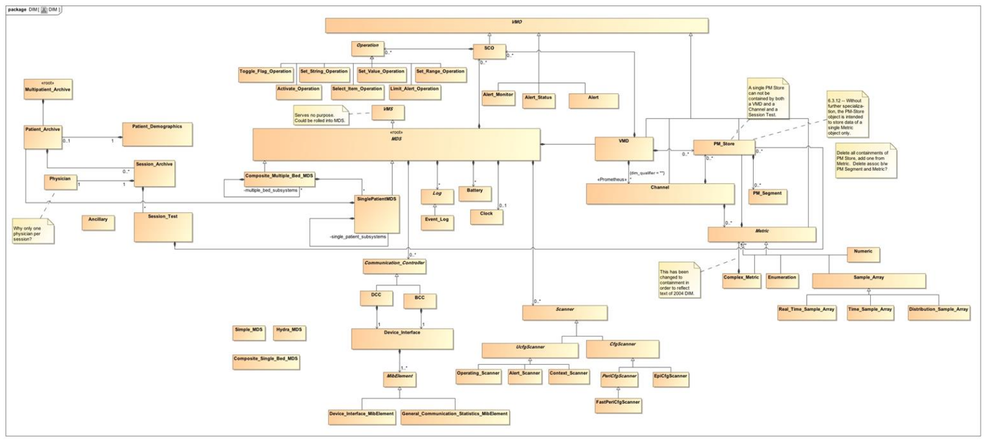
WHEREFOR, the signatories below, having signed this License Agreement, attest as to having the authority to enter into this Agreement and, agree to comply with all of the terms and conditions, covenants and obligations contained herein.

Licensor	Licensee
Signature	Signature
Konstantinos Karachalios	Ram D. Sriram
Name	Name
Managing Director IEEE-SA	Division Chief
Title	Title
20 Dec 2012	12-20-12
Date	Date

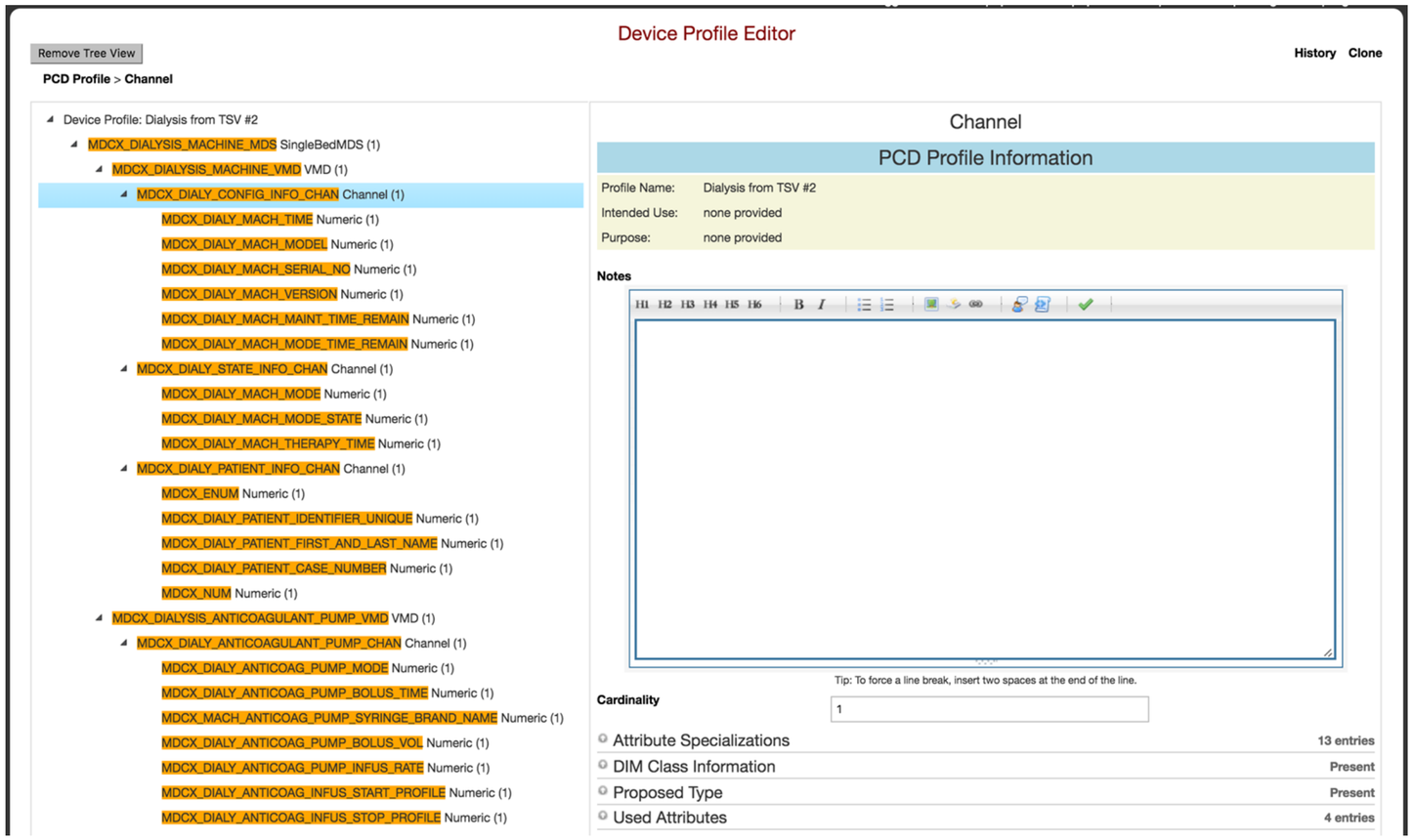
Medical Device Communication (MDC): Domain Information Model (DIM) – Editor/Profile Builder

- UML model programmatically derived from ISO/IEEE 11073-10201:2004
- *Model updated and successfully balloted producing : ISO/IEEE 11073-10201:2019*

- The Model **is** the Standard, Why?
- UML is Computable
- Artifacts programmatically derived from a common source help to ensure harmonization.
  - Software tools (Device Profiling, Validation, Integrated with MDC Nomenclature...)
  - Printed Standard
  - XML Schema
  - Conformance Statements



DIM Classes



HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

NIST
Medical Device Communication Testing

Semantic interoperability of Medical Devices

HL7 Health Care Device Working Group
FHIR-related activities overview

John J. Garguilo
National Institute of Standards and Technology

3 April 2020, IEEE-SA, On-line

Contact: john.garguilo@nist.gov, 301-975-5248; nicolas.crouzier@nist.gov

NIST
National Institute of Standards and Technology

HL7 Health Care Devices (DEV) Working Group

- Seeks to coordinate and facilitate the integration of health care devices to ensure interoperability and harmonization of data within healthcare entities

- Enabling more efficient and accurate processing of device-related data and ultimately resulting in improved patient safety and quality of care.

HL7 Health Care Devices (DEV) Working Group

The working group is actively engaged in...

- Establishing standardized version 2.x, version 3, and FHIR messaging profiles to support health care device interoperability at the enterprise level
- Harmonizing device data models between HL7 and other organizations including ISO/IEEE 11073
- Harmonizing and coordinating device terminology usage within HL7 components
- General coordination and harmonization between HL7 and other national and international organizations involved in health care device informatics and interoperability

HL7 Health Care Devices (DEV) Working Group

Link to join listserv:

- http://www.hl7.org/myhl7/managelistservs.cfm

Mission and Charter

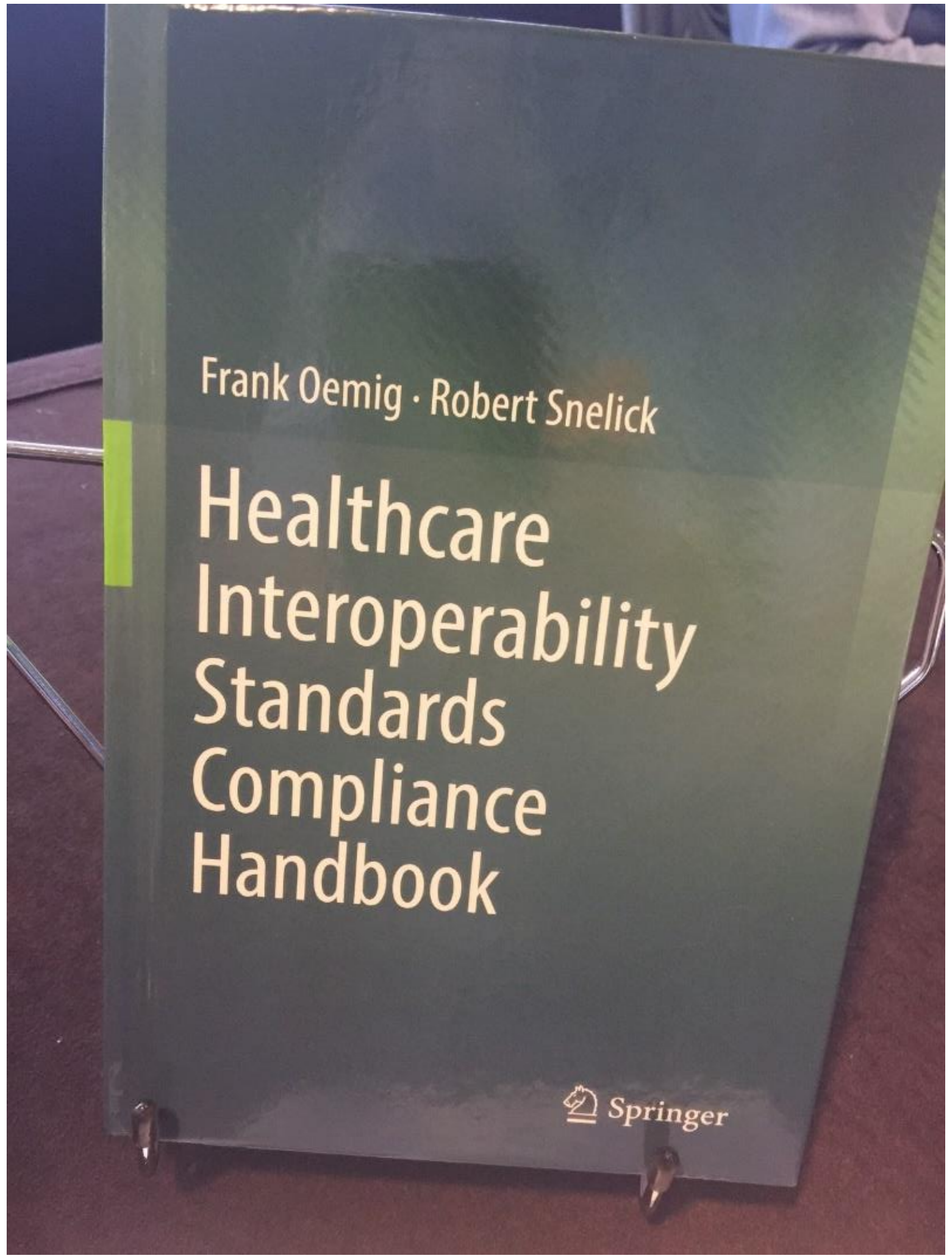
- http://www.hl7.org/Special/committees/healthcaredevices/overview.cfm

Health Care Device WG Main page on www.hl7.org

- http://www.hl7.org/Special/committees/healthcaredevices/index.cfm

Conformance

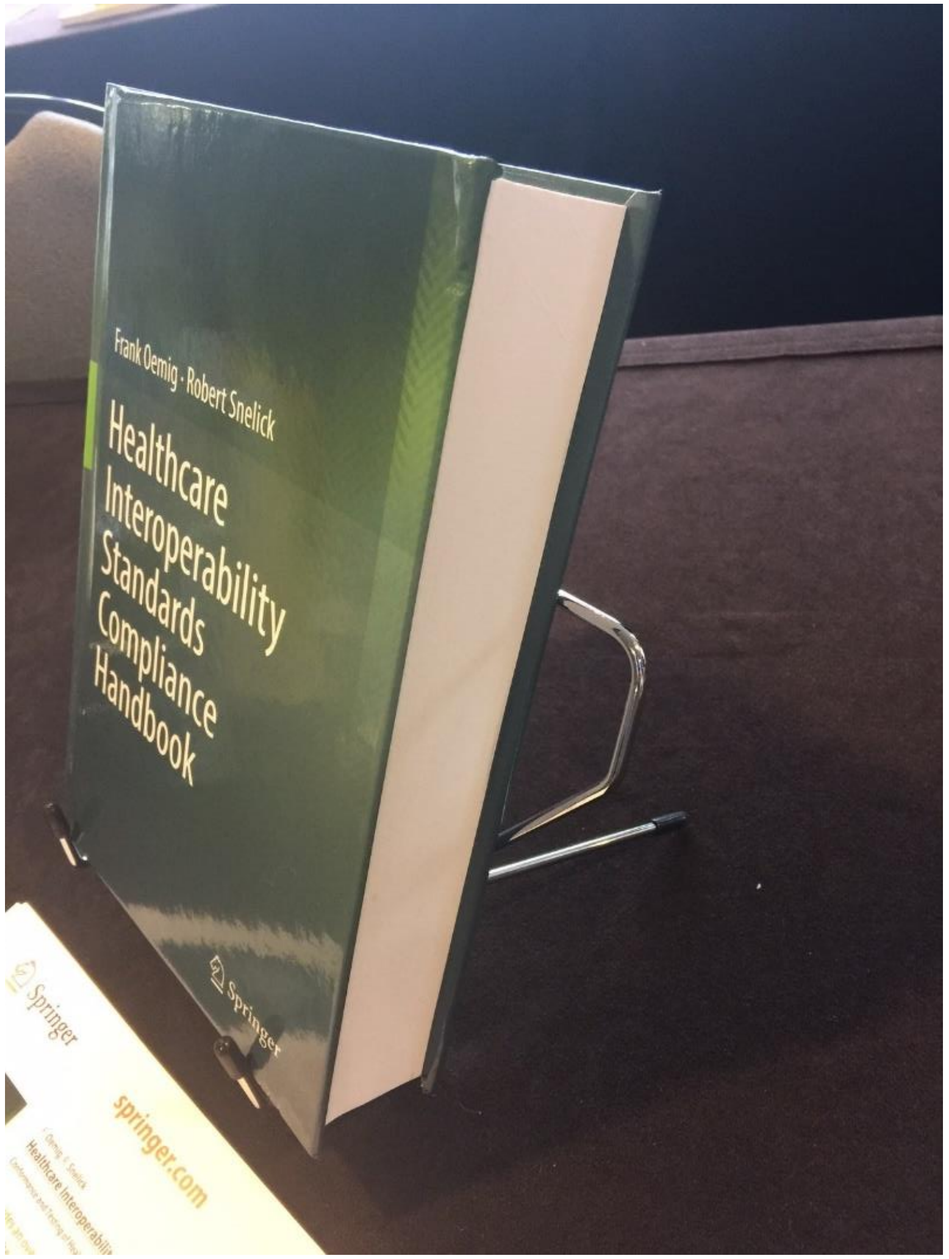
- Conformance Book released (Jan ‘17) by Springer publisher
- Authors:
  - Rob Snelick (NIST)
  - Frank Oemig (HL7 – Germany)
  - HL7 Conformance WG co-chairs
- Available through Springer (order form at HL7.org or at Springer Web Site)



Yes!

Conformance ***IS Hard Work***

- ***700+ pages***
- ***~3 inches thick***
- ***Good educational source***
- ***HL7 (v2) focus***



Questions? Discussion?

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

Thank you for your attention!