

An HL7 v2 Platform for Standards Development and Testing

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Agenda

- ❑ Overview of NIST
- ❑ NIST Activities in HIT
- ❑ What are we trying to solve?
 - ❑ Foundation for Interoperability
 - ❑ An End-to-End Strategy
- ❑ NIST HL7 v2 Platform Overview
 - ❑ IGAMT
 - ❑ TCAMT
 - ❑ Testing Infrastructure & Framework
- ❑ NIST HL7 v2 Tooling Portfolio

National Institute for Standards and Technology (NIST)

- ❑ Part of the Department of Commerce
- ❑ Founded in 1901 as National Bureau of Standards
- ❑ The mission of NIST is to promote **U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology** in ways that enhance economic security and improve our quality of life.
- ❑ Laboratories and Centers
 - ❑ Communications Technology Laboratory
 - ❑ Engineering Laboratory
 - ❑ **Information Technology Laboratory**
 - ❑ Material Measurement Laboratory
 - ❑ Physical Measurement Laboratory
 - ❑ Center for Nanoscale Science and Technology
 - ❑ Center for Neutron Research
- ❑ Campuses in Gaithersburg, MD and Boulder, CO, ~3000 employees

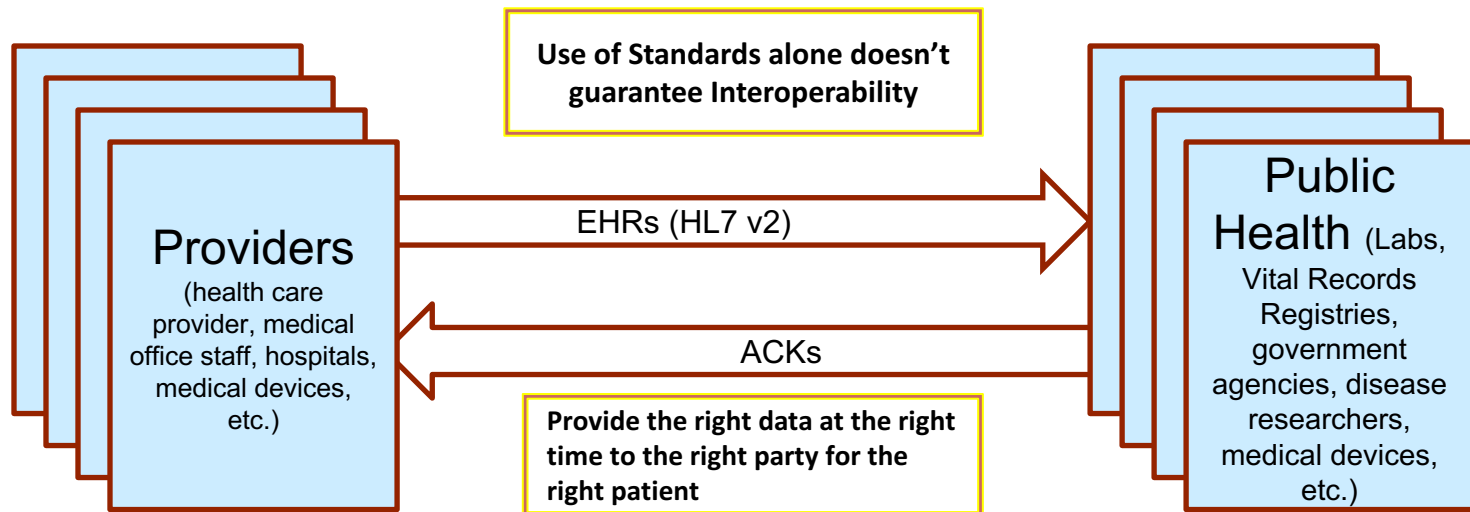


NIST Activities in HIT

- ❑ Under HITECH ACT, developing a **health IT standards testing infrastructure** to support current and future testing needs within the healthcare domain
 - ❑ Developed the conformance test method (test procedures, test data, and test tools) to measure HIT compliance with the ONC 2011, 2014, and 2015 Edition certification criteria that named interoperability standards
 - ❑ Developed conformance test tools to assure that the standards are implemented correctly and consistently (HL7, IHE, ONC, CDC, AIRA, ...)
 - ❑ Supports Standard Development Organizations (SDOs) via guidance; and assessment and certification programs via tools, but does not perform certification

What is the problem we are trying to solve?

Correct data exchange is critical for ensuring reliable healthcare systems. Standards based systems are the foundation for achieving this goal. **However, standards alone are not enough to ensure this promise; conformance and interoperability testing are essential.**

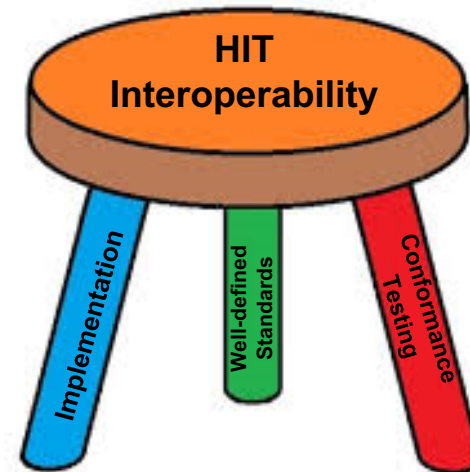
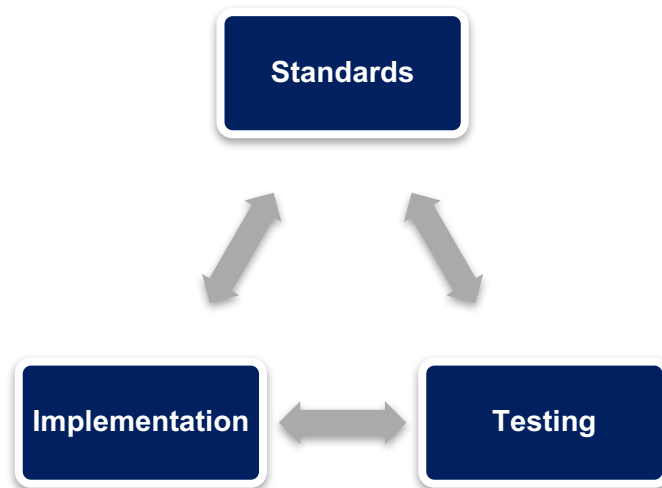


Challenges:


- Standards are not well-defined
- Difficult to decipher requirements
- Many mistakes
- Many requirements left to interpretation
- Gaps in requirements
- Lack of reference and pilot implementations
- Lack of testing

Foundation for Interoperability

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

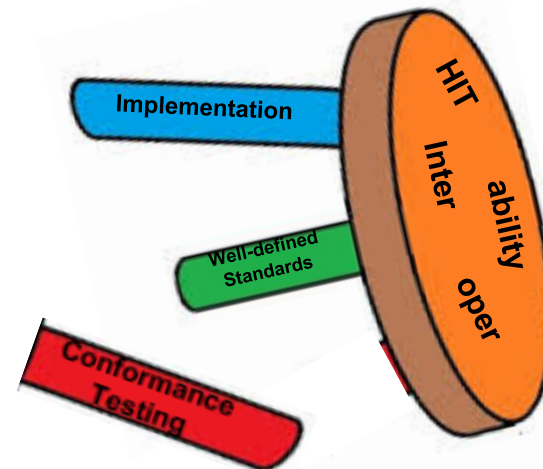
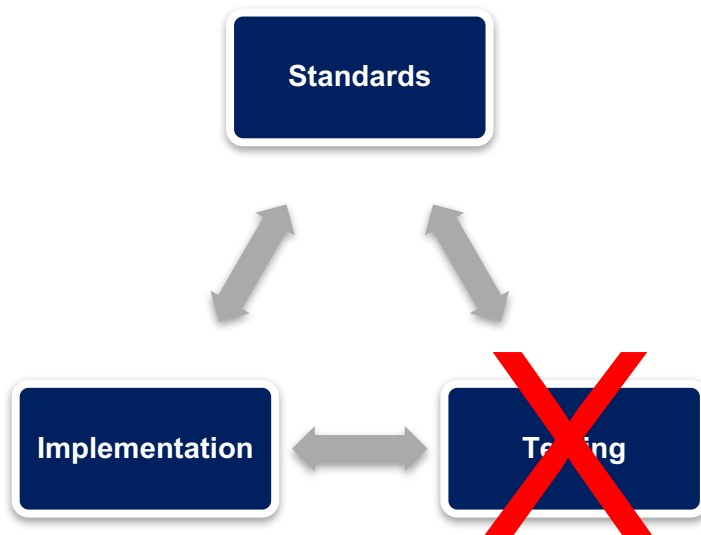


Success depends on:

- ❑ Well-defined Standards – precise and complete requirement specification 
- ❑ 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:

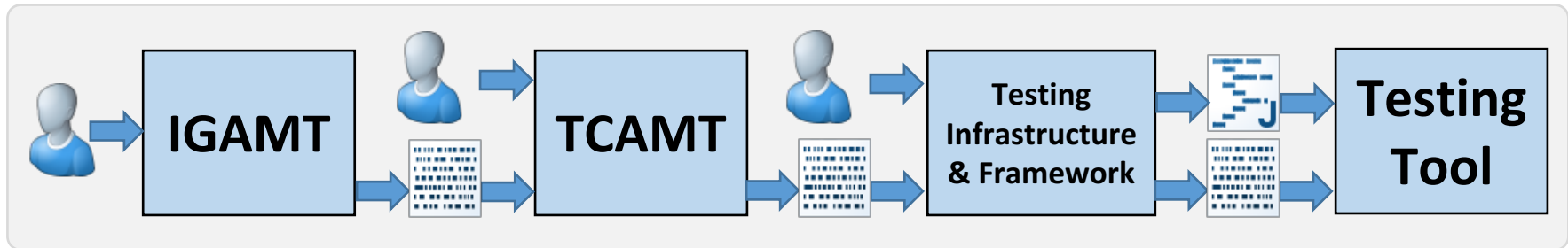
- ❑ One or more components are omitted or are not sufficient



An End-to-End Strategy

- ❑ Specification of Requirements
 - ❑ Development of Specifications
 - ❑ Development of Test Cases
 - ❑ Testing Infrastructure
 - ❑ Platform to build and manage tools
-
- ❑ NIST builds the platform—let domain experts create and maintain guides, test cases, and tool instances via productivity tools

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

Implementation Guide Authoring and Management Tool (IGAMT)

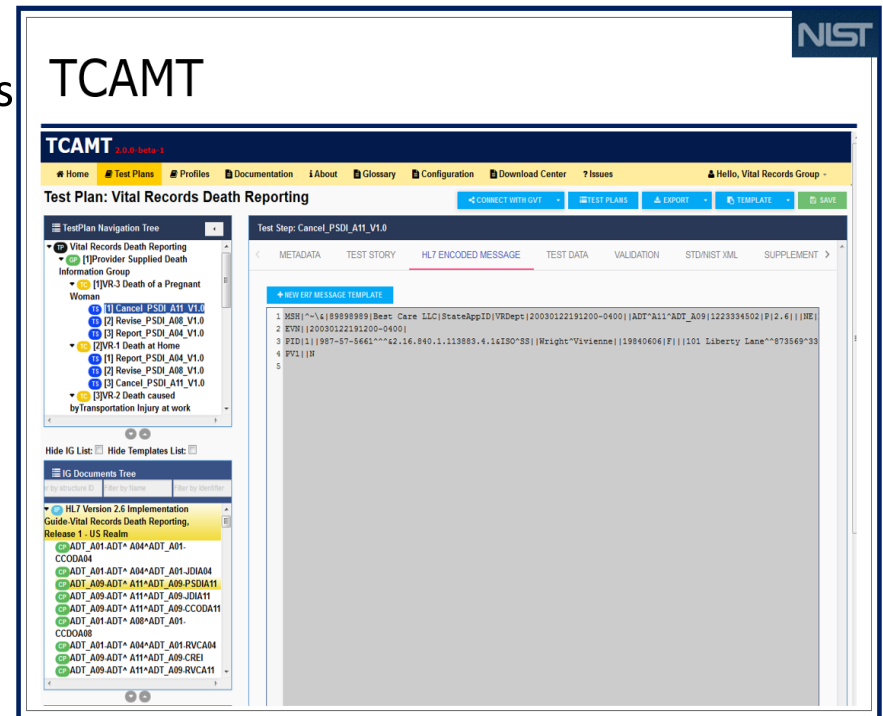
- ❑ Tool to create standards (i.e. HL7 v2 implementation guides)
- ❑ Narrative + Message Definition
- ❑ **Built-in template**
- ❑ Supports current conformance constructs
- ❑ **Enforces conformance rules**
- ❑ **Promotes consistency in requirements**
- ❑ XML export is gateway to other services
- ❑ **Single source of truth**
- ❑ **Constraints for basic testing (context-free)**

The screenshot displays the IGAMT interface. On the left is a 'Table of Contents' pane listing various HL7 segments and their versions. On the right, the 'Edit Area' shows the 'Segment: RXA_IJ_01' definition. Below the segment name are tabs for 'Segment Main Data', 'Segment Definition', 'Segment Data', and 'Segment Cross References'. The 'Segment Definition' tab is active, showing a table with columns: Name, Usage, Cardinality, Length, Conformance, Data Type, Value Set, Predicate, Conformance Statement, Definition Text, and Comments. The table lists several data elements for the RXA_IJ_01 segment, including sub-ID counter, administration sub-ID counter, date/time start and end of administration, administered code, administered amount, administered units, administered dosage form, and administration notes.

Name	Usage	Cardinality	Length	Conformance	Data Type	Value Set	Predicate	Conformance Statement	Definition Text	Comments
1 Sub-ID Counter	R	1	1	D	NAI_01			[3-05]		
2 Administration Sub-ID Counter	R	1	1	D	NAI_01			[3-05]		
3 Date/Time Start of Administration	R	1	1	D	DTM_02					
4 Date/Time End of Administration	R	1	1	D	DTM_02			[3-05]		
5 Administered Code	R	1	1		CHE_01	CHE_01				
6 Administered Amount	R	1	1	D	NAI_01			[3-48]		
7 Administered Units	OR(X)	0	1		CHE_01	UCHE_01	If the value of CHE_01 is not '999'			
8 Administered Dosage Form	O	0	1		CHE_01					
9 Administration Notes	OR(O)	0			CHE_01	NPI01_01	If the value of CHE_01 is not '999'	[3-01]		

Test Case Authoring and Management Tool TCAMT

- ❑ Tool Test Plans and Test Cases
- ❑ **Import XML profiles in IGAMT format**
- ❑ XML profiles provides underlying model
- ❑ Expands testing capabilities
- ❑ Example/test messages
- ❑ XML export is gateway to other services



Context-free Validation

NIST Vital Records 2016

Version 1.0.1

NIST VR Validation tool

[Home](#)
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[Profiles](#)
[Help](#)

- ☒ CCOD_A04
- ☒ CCOD_A08
- ☒ CCOD_A11
- ☒ CREI_A08
- ☒ CREI_A11
- ☒ CREI_A04
- ☒ JDI_A04
- ☒ JDI_A08
- ☒ JDI_A11
- ☒ PSDL_A04
- ☒ PSDL_A08
- ☒ PSDL_A11
- ☒ RVC_A11
- ☒ RVC_A04

Profile: PSDL_A04

[Validation](#)
[Report](#)
[Profile Viewer](#)
[ValueSets](#)

Message Tree

- MSH[1] Message Header R[1,1]
- EVN[1] Event Type R[1,1]
- PID[1] Patient Identification R[1,1]
- PV[1] Patient Visit R[1,1]
- OBX[1] Observation/Result R[1,1]
- OBX[2] Observation/Result R[1,1]
- OBX[3] Observation/Result R[1,1]
- OBX[4] Observation/Result R[1,1]
- OBX[5] Observation/Result R[1,1]
- OBX[6] Observation/Result R[1,1]
- OBX[7] Observation/Result R[1,1]
- OBX[8] Observation/Result R[1,1]
- OBX[9] Observation/Result R[1,1]
- OBX[10] Observation/Result R[1,1]
- OBX[11] Observation/Result R[1,1]
- OBX[12] Observation/Result R[1,1]
- OBX[13] Observation/Result R[1,1]
- OBX[14] Observation/Result R[1,1]
- OBX[15] Observation/Result R[1,1]
- OBX[16] Observation/Result R[1,1]
- OBX[17] Observation/Result R[1,1]
- OBX[18] Observation/Result R[1,1]
- OBX[19] Observation/Result R[1,1]
- PDA[1] Patient Death and Autopsy R[1,1]

Message Content

[Validate](#)
[Load Example](#)
[Browse](#)
[Download](#)
[Clear](#)

```

1>|20101102133312-0400||ADT^A04^ADT_A01|1223334499|P|2.6|||AL|NE|US|||PSDIA04_V1.0^PHIN VS
2
3S||Smith^Madelyn^NMI||19350312|Y||5590 Lockwood Drive^^1086974^39^44709^US|||20101102140000-0500|Y
4
5Z^Yes^HL70136|||||
6mbolism|||||F
7^LN|12 hours|||||F
8|||||F
9arcombosis|||||F
10^LN|2|Aproximately 8 days|||||F
11|||||F
12F
13^LN|3|40 years|||||F
14|||||F
15# Number^LN|2|2344509|||||F
16J-0500|||||F
17|2121 Main St^^2403120^37^12345^|||||F
18# Death^LN|3|73067005^No^SCT|||||F
19involve injury of any kind^LN|N^No^HL70136|||||F
20Natural Death^SCT|||||F
21|201011021400-0400|||||F
22# indicated^F Mrs. Smith had 40 yr hx of lupus. Recent overseas travel. \T\ Good health prior to her husband findi
23curred if not facility^LN|5590 Lockwood Drive^^1086974^39^20621^|||||F
24

```

[Message Validation Result](#)
[Help](#)
[Remove Duplicates](#)
[Report](#)

2 Errors
111 Warnings
7 Alerts

2 All
1 Value Set
1 R-Usage

☐ Highlight All

Path	Description	Line #
PID[1]-8[1]	The value "Y" at location Field PID-8 (Administrative Sex) is not member of the value set PHVS_Sex_MFU	3

Context-based Validation

NIST Vital Records 2016 Version 1.0.1

NIST VR Validation tool

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[Test Selection](#)
[Test Execution](#)

Test Cases

- ▼ Vital Records Death Reporting
 - ▼ Provider Supplied Death Information
 - ▼ VR-1 Death at Home
 - ☒ 1.Report_PSDI_A04_V1.0
 - ☒ 2.Revise_PSDI_A08_V1.0
 - ☒ 3.Cancel_PSDI_A11_V1.0
 - ▶ VR-2 Death caused byTransportat
 - ▶ VR-3 Death of a Pregnant Woman
 - ▶ Jurisdictional Death Information Group

TestStep: Report_PSDI_A04_V1.0

[Load Test Step](#)

[Test Story](#)
[Message Content](#)
[Example Message](#)

[Download PDF](#)

FULL

Description

Comments

Pre Condition

Post Condition

Test Objectives

Evaluation Criteria

Notes for Testers

Description

On November 2, 2010, upon arriving at his home, John Smith found his wife, Madelyn Smith, lying on the couch unconscious and not breathing. He quickly called 9-1-1 and started cardiopulmonary resuscitation (CPR). Within ten minutes, the paramedics arrived at the scene. They transported Madelyn to the Emergency Room at the Llewellyn Hospital in Rosemont, NC where Dr. Tom Delaney examined Madelyn and pronounced her dead on arrival at 1400. He spoke to Madelyn's husband John and learned that the couple had just returned from a trip overseas and that Madelyn had a 40 year history of lupus. Dr. Delaney started an electronic health record for Madelyn and populated the patient death indicator with a "Y" to confirm her death, along with his full name and his NPI number. Meanwhile, a nurse collected and entered basic identifying information, including patient name, birth date, sex, address, zip code, and social security. The case was referred to the medical examiner's office for an autopsy and Dr. Delaney noted Madelyn's history of lupus and recent overseas travel in his referral note.

The Medical Examiner (ME), Dr. Revel, assigned a case ID and conducted the autopsy. After speaking to Madelyn's husband, Dr. Revel consulted the referral notes and he immediately suspected that a blood clot might have formed in one of Madelyn's legs during her recent overseas flight. He notes Madelyn's 40 year history of lupus, which is a risk factor for developing deep vein thrombosis. The autopsy results revealed that Madelyn's immediate cause of death was a pulmonary embolism which resulted from deep vein thrombosis. He entered the estimated date and time of death, the immediate cause of death as well contributing conditions, and the underlying cause. He also entered the code which indicated that the autopsy results were available for the decedent and entered all information required to identify the death certifier. Finally, the ME signed Madelyn Smith's death certificate which completed the data entry for this decedent and the all information related to filing the death certificate is transmitted via an ADT^A04 message from the EHR to the jurisdictional vital records office.

Comments

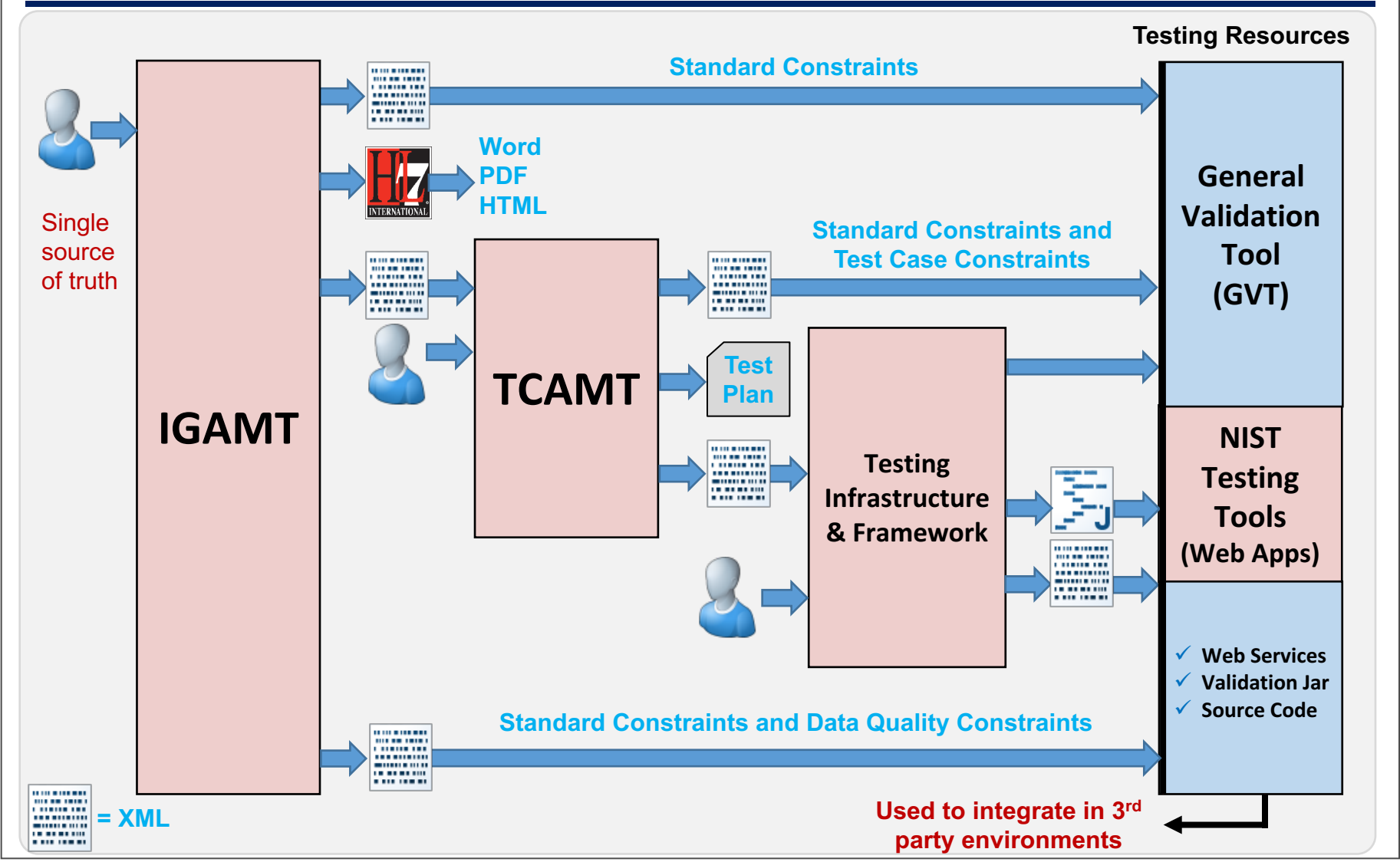
No Comments

Pre Condition

Testing Infrastructure & Framework

- ❑ Provides core services
 - ❑ E.g., Validation Engine
- ❑ Building Blocks
- ❑ XML profiles provides underlying model
- ❑ NIST-built constraint mechanism
- ❑ Expands testing capabilities
- ❑ Builds test/example messages
- ❑ XML export is gateway to other services
- ❑ Single source of truth

NIST Testing Platform



NIST HL7 v2 Tool Portfolio

❏ <https://hl7v2tools.nist.gov>

Standard	Owner	Testing Program	Links
Immunization R1.4*	CDC	✓ ONC 2014 Ed. Certification	http://hl7v2-iz-testing.nist.gov
Immunization R1.5*	CDC	✓ ONC 2015 Ed. Certification ✓ AIRA IIS Assessment ✓ HIMSS/CDC EHR Certification	http://hl7v2-iz-r1.5-testing.nist.gov http://iztool-cdc.hit.icsl.net:8080/iztool
Syndromic Surveillance R1.1*	CDC/ISDS	✓ ONC 2014 Ed. Certification	http://hl7v2-ss-testing.nist.gov
Syndromic Surveillance R2.0*	CDC/ISDS	✓ ONC 2015 Ed. Certification	http://hl7v2-ss-r2-testing.nist.gov
ELR (Reportable Labs) R1.0*	HL7	✓ ONC 2014/2015 Ed. Certification	http://hl7v2-elr-testing.nist.gov
LOI R1 DSTU R2	HL7/ONC	✓ ONC Pilot Testing	http://hl7v2-loi-r1-testing.nist.gov
LRI R1 DSTU R2	HL7/ONC	✓ ONC Pilot Testing	http://hl7v2-lab-r2-testing.nist.gov
eDOS R2 DSTU R2	HL7/ONC	✓ ONC Pilot Testing	http://hl7v2-edos-r1-testing.nist.gov
Vital Records DR R1	CDC/HL7/IHE	✓ CDC ✓ IHE Connect-a-thon	http://hl7v2-vr-r2-testing.nist.gov
Height and Weight	CDC/IHE	✓ CDC ✓ IHE Connect-a-thon	http://hl7v2-cf-validator.nist.gov
Patient Care Devices (PCD)	IHE	✓ IHE Pre-connect-a-thon ✓ IHE Connect-a-thon	http://ihe-pcd-precon.nist.gov http://ihe-pcd-con.nist.gov
PIX and PDQ	IHE	✓ IHE Pre-connect-a-thon ✓ IHE Connect-a-thon	http://pixpdqtests.nist.gov http://hl7.connectathon-pixpdq.nist.gov/

*State Registries use for on-boarding

✓ Unknown number of local installations

NIST Productivity Tool – IGAMT

IGAMT – Implementation Guide Authoring and Management Tool			
Standard	Developer	Use	HL7 Version
Immunization HL7 R1	CDC	✓ May 2017 HL7 Ballot	HL7 v2.8.2
Immunization R1.5	NIST	✓ NIST Internal for ONC 2015 Ed. Certification	HL7 v2.5.1
Syndromic Surveillance R2.?	CDC/ISDS	✓ In Progress	HL7 v2.5.1
Syndromic Surveillance R2.0	NIST	✓ NIST Internal for ONC 2015 Ed. Certification	HL7 v2.5.1
Vital Records Death Reporting	NIST	✓ NIST Internal for 2017 Connectathon Testing	HL7 v2.6
Vital Records Birth Reporting	CDC	✓ May 2017 HL7 Ballot	HL7 V2.6
LOI R1 DSTU R2	NIST	✓ NIST Internal-In Progress	HL7 v2.5.1
LRI R1 DSTU R2	NIST	✓ NIST Internal-In Progress	HL7 v2.5.1
eDOS R2 DSTU R2	NIST	✓ NIST Internal-In Progress	HL7 v2.5.1
Patient Care Devices (PCD)	NIST	✓ NIST Internal-In Progress for IHE	HL7 v2.6
Electronic Case Reporting	CDC	✓ In Progress	HL7 v2.5.1
Local Use	Vendors/States	✓ Unknown	Unknown

✓ = 30+ registrations

IGAMT-generated implementation guides balloted by HL7

NIST Productivity Tool – TCAMT

TCAMT – Test Case Authoring and Management Tool

Standard	Developer	Use
Immunization R1.5	CDC/CNI/HIMSS	✓ HIMSS Certification
Immunization R1.5	CDC/NIST	✓ ONC 2015 Ed. Certification
Immunization R1.5	AIRA	✓ AIRA IIS Assessment Program
Syndromic Surveillance R2.0	ISDS/NIST	✓ ONC 2015 Ed. Certification
Vital Records Death Reporting	CDC/NIST	✓ IHE Pre-connect-a-thon/Connect-a-thon, CDC
Vital Records Birth Reporting	CDC/NIST	✓ IHE Pre-connect-a-thon/Connect-a-thon, CDC – In Planning
LOI R1 DSTU R2	NIST	✓ NIST Internal-In Progress
LRI R1 DSTU R2	NIST	✓ NIST Internal-In Progress
eDOS R2 DSTU R2	NIST	✓ NIST Internal-In Progress
Patient Care Devices (PCD)	NIST	✓ NIST Internal-In Progress for IHE
ePrescribing	NIST/NCPDP	✓ Tool in development (Adapted)

- ❑ TCAMT allows domain experts to develop test scenarios and test cases, with example messages—set in the foundation of the XML Profile created in IGAMT.
- ❑ Scenarios can be created to test capabilities, workflow, functional requirements, and robustness via “negative” testing.

NIST Testing Tools & Resources – HL7 v2 Portal

Menu

All Tools
Technical Support
Interoperability Testbed
Tools By Standard
HL7 v2
HL7 v3
CDA/CCDA
ISO/IEEE 11073
XD* (Profiles)
NCPDP
Tools By Functional Domain
Document Sharing
Medical Devices
ePrescribing
Lab
Public Health
Patient Identification
Tools By Operational Domain
Meaningful Use
IHE
NwHIN (Healthway)

HL7v2 Immunization Test Suite (2015 Edition)	HL7v2 Syndromic Surveillance Test Suite (2015 Edition)	Electronic Lab Reporting (2014 and 2015 Edition)	Immunization (2014 Edition)	Syndromic Surveillance (2014 Edition)	Laboratory Results Interface (2014 Edition)
IHE PCD Pre-Connectathon	IHE PCD Connectathon	IHE PIX and PDQ Pre-Connectathon	IHE PIX and PDQ Connectathon	HL7v2 Context-free (Vital Records Death and Height and Weight)	HL7 Web Services
HL7v2 Lab Compendium (eDOS)	HL7v2 Lab Results Interface (LRI) Release 2 (2015)	Test Case Authoring and Management Tool (TCAMT)	Implementation Guide Authoring Tool (IGAMT)	NIST Vital Records (2016)	

Tools to Build Tools

<http://hl7v2tools.nist.gov/portal/#/tools>

In Summary

- ❑ NIST research provides an end-to-end methodology and platform for developing standards, test plans, and testing tools in the HL7 v2 technology space.

- ❑ The platform addresses the three foundational components of HIT Interoperability:
 - ❑ a tool to create implementation guides and conformance profiles and promote well defined standard
 - ❑ a tool to author and manage test cases
 - ❑ a testing infrastructure and test framework to build testing tools.

- ❑ Our goal is to operationalize the platform
 - ❑ Could be part of HL7 v2 ballot process

Thank You

Questions

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