HEALTH IT
STANDARDS TESTING INFRASTRUCTURE

# NIST
# Medical Device Communication Testing

## Semantic interoperability of Medical Devices

*Test Tool Update*
*Joint IEEE / HL7 May WG Meeting @ New Orleans, LA*

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National Institute of Standards and Technology

# *NIST* MDC Testing Staff

- John J. Garguilo
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- Nicolas Crouzier(Contractor-Dakota)
  - RTMMS – 11073-10101 MDC Nomenclature
  - HL7 V2 Tools (IGAMT + TCAMT support)
- Michael Faughn, (Contractor - *Prometheus Computing, LLC w/* Art Griesser)
  - 11073-10201 MDC Domain Information Model
  - DIM Modeling + “DIM Editor/Medical Device Profiler”

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

# Key Discussion Topics

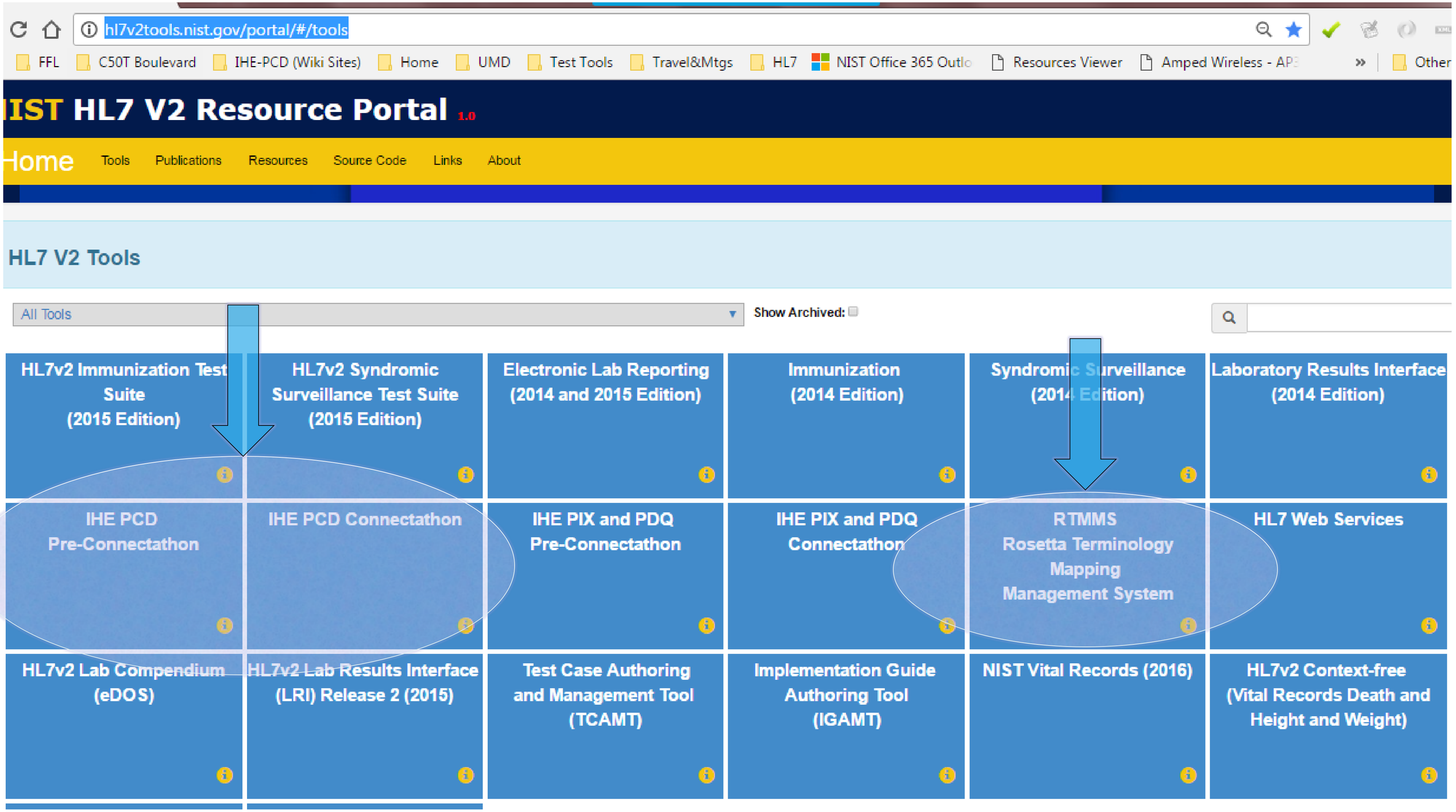
- Work Area & Status Updates
- HL7 V2 IHE-PCD Tooling Status & Updates
  – NA Connectathon 2018 (Cleveland, Ohio)
- DIM Editor work updates, tool review, discussion topics (see also Michael Faughn's slide set)

## *Conformance Tooling Suite*

- *HL7 V2 (2.6) IHE-PCD Validation Tools*
  - IHE-PCD Pre-Connectathon: http://ihe-pcd-precon.nist.gov/
  - IHE-PCD Connectathon, http://ihe-pcd-con.nist.gov/
- 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
  - TCAMT – Test Case Authoring Management Tool

# Work Areas & Status Updates

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



# Work Areas & Status Updates
## *HL7 V2 (2.6) IHE-PCD Validation Tools*

- IHE-PCD Pre-Connectathon, “Isolated Environment” http://ihe-pcd-precon.nist.gov/
- IHE-PCD Connectathon, “Instance Environment” http://ihe-pcd-con.nist.gov/
- Enhancements to Pre-Connectathon, Connectathon Tools support IHE-PCD Cycle 12; mainly CPs
- *Key test events*
  - Supported IHE-Europe Connectathon (May 2017)
  - Supported IHE-Korea Connectathon (Aug 2017)
  - Supported: IHE-Japan Connectathon (Sept 2017)
  - Supported : IHE-North America Connectathon (Jan 2018)
  - ~~(New) IHE Australia – targeted August 2017~~ (NO PCD - cancelled)
- IHE-PCD Cycle 12 ending at HIMSS – Connectathon completed CPs updated 2017-18 (mainly from IHE-PCD; 1 April 2017 – 31 March 2018)

# 2018 IHE-PCD Pre-Connectathon Tool: Cycle 12 Status

- 161 existing User Accounts (as of 29 January 2018)
  - Contributing Orgs, SDO (leads/Co-chairs), Reviewers
  - In total since tool made publically available (2011)

Recorded or stored by NIST tool registered user

- Cycle 12: 16 Users Testing, 135 Tests Executed/Stored
  - 15 Unique Companies
- Cycle 11: 14 Users Testing, 95 Tests Executed/Stored
- Cycle 10: 17 Users, 124 Tests Executed/Stored
- Cycle 9: 17 Users, 106 Tests Executed/Stored
  - Recorded or stored by NIST tool registered user
- Cycle 8: 22 Users, 115 Tests Executed/Stored
- Cycle 1-7: 42 Users, 99 Tests Executed/Stored*

**Cycles 1-7 not all test were stored in tool – 99 tests are primarily from cycle 7*

# Example of New V2 Validation Tool: Used at 2018 IHE NA Connectathon (by Test Monitors)

**NIST PCD Test Suite** 1.0.0-SuperBeta

Home | Context-free | Context-based | Documentation | About | Hello Guest

Test Execution

Profile Group Type: Public  Profile Groups: DEC profiles

Profiles Help

- DEC profiles
  - ORU^R01^ORU^R01
  - ACK^R01^ACK

Profile: ORU^R01^ORU^R01

Validation | Report | Profile Viewer | ValueSets

Message Tree

- MSH[1]:Message Header R[1,1]
- PID[1]:Patient Identification R[1,1]
- PV1[1]:Patient Visit R[1,1]
- OBR[1]:Observation Request 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]

Message Content  4s  Validate | Load Example | Browse | Download | Clear

```
1  MSH|^~\&|Bernoulli One|Bernoulli|Hill-Rom GW|Hill-Rom|20180115211358+0000||ORU^R40^ORU_R40|3441e31a-c703-4a04-b57b-3c32063
2  PID|||HO2009001^^^BERNOULLI MRN^MR||Hon^Albert^^^^^L|||||||||||||||||||||||||||
3  PV1||I|HO Surgery^OR^1|||||||||||||||||||||||||||||||||||||||||||||||||||||||
4  OBR|1|3C1A5720180115211358^Bernoulli One|3C1A5720180115211358^Bernoulli One|196616^MDC_EVT_ALARM^MDC|||20180115211358+0000
5  OBX|1||69965^MDC_DEV_MON_PHYSIO_MULTI_PARAM_MDS^MDC|1.0.0.0|||||X|||||||||
6  OBX|2||69642^MDC_DEV_ANALY_SAT_02_VMD^MDC|1.22.0.0|||||X|||||||
7  OBX|3||149530^MDC_PULS_OXIM_PULS_RATE^MDC|1.22.1.0|||||X|||||||
8  OBX|4|ST|196648^MDC_EVT_HI|1.22.1.1.1|High Pulse Rate|||||R||20180115211358+0000||||||
9  OBX|5|NM|149530^MDC_PULS_OXIM_PULS_RATE^MDC|1.22.1.1.2|70|||||R|||20180115211358+0000|||||
10 OBX|6|ST|68481^MDC_ATTR_EVENT_PHASE^MDC|1.22.1.1.3|start|||||R|||||||
11 OBX|7|ST|68482^MDC_ATTR_ALARM_STATE^MDC|1.22.1.1.4|active|||||R|||||||
```

Message Validation Result Help  Remove Duplicates | Report

3 Errors | 161 Warnings | 78 Alerts

3 All | 3 Constraint Failure

Highlight All

| Path | Description | Line # |
|---|---|---|
| MSH[1]-9[1].2 | MSH_PCD_PCD-01_9 - The value of MSH-9 (Message Type) is 'ORU^R01^ORU_R01'. | 1 |
| MSH[1]-21[1].3 | MSH_PCD_PCD-01_21 - [[The value of MSH-21[*].3 (Universal ID) is '1.3.6.1.4.1.19376.1.6.4.1'.] OR [The value of MSH-21[*].3 (Universal ID) is '1.3.6.1.4.1.19376.1.6.1.1.1'.]] AND [The value of MSH-21[*].4 (Universal ID Type) is 'ISO'.] | 1 |
| OBX[2] | OBX_3_MDC_Check - ERROR CODE #1: NIST custom plugin to check for MDC validity. | 6 |

# IHE North American 2018 'Connectathon' By the numbers

## Overall Connectathon

- 63 organizations
- 70 Integration Profiles
- 90 Systems
- 1735 actors (1100+ passed CN)
- 2374 tests run (2248 verified)
- 44 monitors
- Nearly 500 health IT engineers and other stakeholders participated

## Patient Care Device

- 27 organizations
- 6 Integration Profiles
- 36 Systems
- 138 actors (126 passed)
- 406 Test Instances verified (55 Aborted)
- 7 PCD monitors

# January 2018 IHE 'Connectathon' Notes…

- Connectathon findings
  - New validator (GVT generated from IGAMT + TCAMT)
  - New tooling should be supported by more precise requirements (i.e., conformance constructs)
    - E.g., OBXs in sequential order, status, MDC terms, Rosetta Containment (MDS→VMD→Channel→Metric/numeric
- From IHE International news (Feb 2018)
- **IHE NA Connectathon 2018 Hits High Notes**
- This year marks the 19th anniversary of the IHE NA Connectathon. Sixty-three organizations took part in testing, and 90 systems were tested at the event, resulting in 2,374 interoperability tests being verified by a team of over 40 Connectathon monitors. In all, nearly 500 health IT engineers and other stakeholders participated. The Connectathon also featured three Plugathon tracks, as well as a number of events designed for networking and education in the interoperability space. Read a full account of the highlights. (http://www.iheusa.org/news)

# 2018 IHE 'Connectathon' news... http://www.iheusa.org/news


## Highlights from the IHE NA Connectathon 2018

2 weeks ago

The IHE NA Connectathon hit its 19th anniversary this year and the IHE profile development and testing process continued to advance the adoption of interoperable health IT system.

**Check out the recap videos from day 1 and day 3 of the event.**

This year the IHE NA Connectathon served as an intersecting point for legacy health IT systems and new and emerging technology in both the Connectathon and IHE Plug-a-thon. IHE's thought leadership was also showcased at The Road to Interoperability Workshop with stories from implementers of IHE Profiles – The Sequoia Project's eHealth Exchange and Strategic Health Information Exchange Collaborative (SHIEC) Patient-Centered Data Home.

Through the week, IHE's process was acknowledged as a key player in advancing interoperability by leveraging mHealth, Blockchain, Internet of things and HL7 FHIR®. The IHE NA Plug-a-thon brought together several technical implementers spanning healthcare solutions leveraging HL7 FHIR® for devices, mHealth apps, Internet of Things - Medical, and Blockchain - Healthcare. As these are emerging technologies, attendees had the opportunity to learn from leading experts in these areas as well as identify potential use cases, challenges and opportunities associated with these technologies in healthcare, and agree on next steps as these areas gain increased awareness and utilization.

If you weren't able to attend or want an easy breakdown of what the IHE Connectathon is and its benefits, check out this recent blog post explaining why the event matters.

The breadth of programs and educational opportunities at the IHE NA Connectathon continued to grow in 2018. Below is a full list of all the events and testing options on-site this year:

### Testing Programs:

- IHE NA Connectathon of IHE Profiles and Consolidated CDA
- Three IHE Plug-a-thon tracks including mHealth, Internet of Things- Medical, Blockchain – Healthcare and Devices on FHIR®

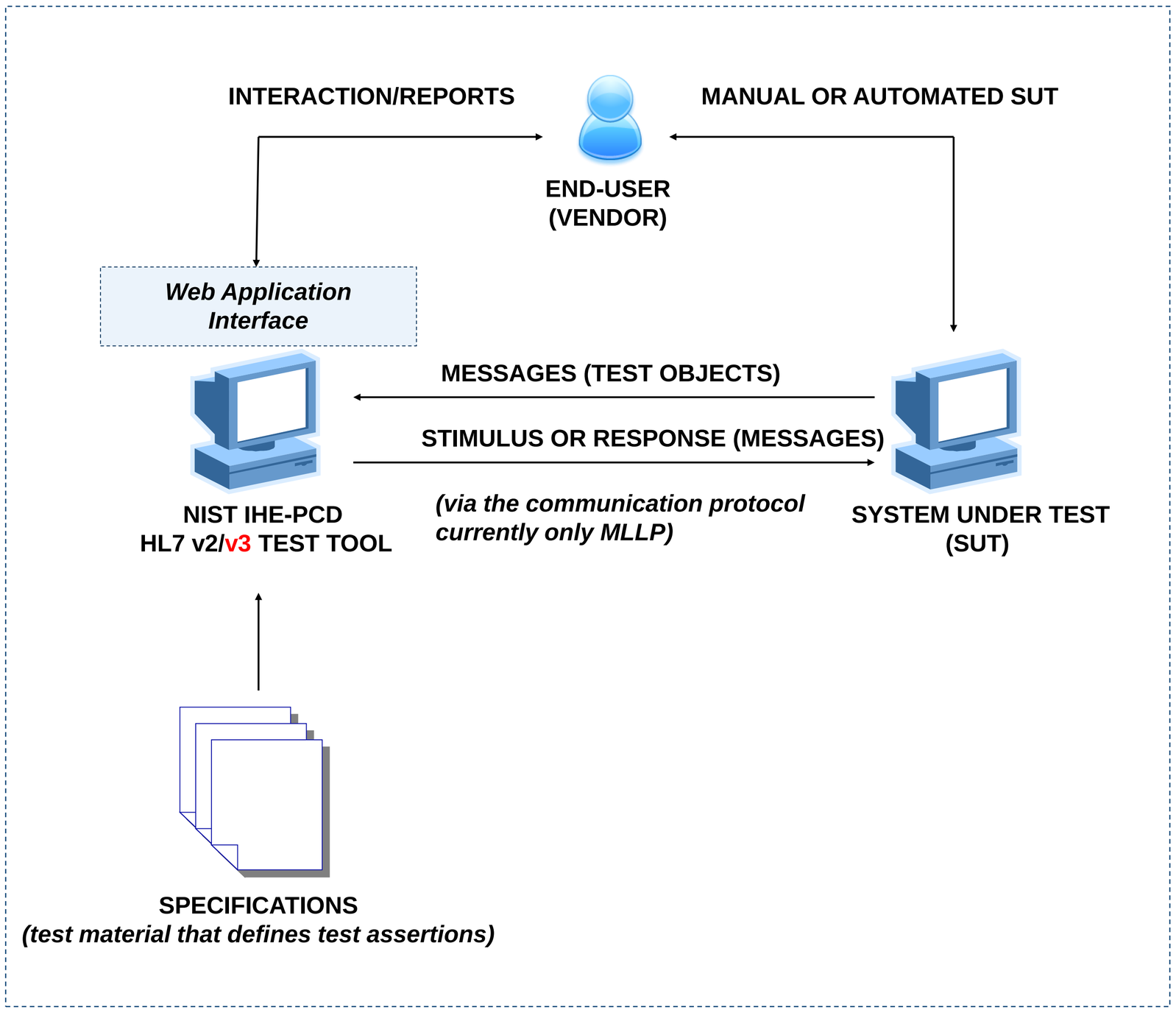
### Events:

- IHE NA Connectathon Social Event at Dante's Inferno
- HIMSS informational breakfast featuring testing programs including ConCert by HIMSS and the Immunization Integration Program
- The Road to Interoperability Workshop – Educational event for health IT executives focused on adoption and implementation of IHE Profiles
- Disruptive Health IT Fireside Chat and Networking Session
- IHE NA Plug-a-thon Educational Session

### IHE NA Connectathon 2018 Highlights:

- 63 participating organizations
- 90 discrete individual systems being tested
- 2,374 tests verified by monitors
- 100+ IHE Profiles available for testing
- Nearly 500 engineers working collaboratively to test interoperability
- 41 monitors carrying out and independently judging the tests
- $2.8 million of test effort (500 x 8 hrs/day x 5 days x $140/hr) - not including a very sizeable amount of prep and setup time!)

# NIST V2 HL7 IHE-PCD Test Tool: Operational Process




**V3 – Future Work**

# Work Areas & Status Updates
# 2017-18 IHE-PCD Pre+Connectathon Tool: Cycle 12 Status

- 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’)

# 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): 590 LOINC mappings to MDC terms!
  - -10101b Work underway, 10101c (future TBD)
  - NIST-IEEE Royalty Free Agreement makes available the “Works” (5 key nomenclature attributes) – *perpetual agreement*
  - Latest numbers…

- Many thanks to lead Paul Schluter, retired Principal Engineer, now working with CMI! ☺

- https://rtmms.nist.gov

# RTMMS by the numbers; 29 January 2018 (@NOLA WG Mtgs)

| | Oct 2015 | Jan 2016 | May 2016 | Sept 2016 | Jan 2017 | May 2017 | Sept 2017 | Jan 2018 |
|---|---|---|---|---|---|---|---|---|
| **11073-10101** | | 10685 | 10685 | 10685 | 10685 | 10685 | 10713 | 10725 |
| **Rosetta Terms** | 1642 | 1648 | 1731 | 1733 | 1763 | 1764 | 1765 | 1807 |
| **hRTM (Harmonized)** | 693 | 804 | 879 | 880 | 911 | 911 | 911 | 953 |
| **Groups** | 226 | 317 | 323 | 323 | 337 | 337 | 337 | 338 |
| **Unit Groups** | 8 | 8 | 12 | 12 | 12 | 12 | 12 | 15 |
| **-Units (MDC)** | 515 | 524 | 547 | 551 | 552 | 552 | 552 | 562 |
| **-Units (UCUM)** | 520 | 526 | 540 | 545 | 548 | 548 | 548 | 559 |
| **Enumeration Groups** | 39 | 43 | 43 | 43 | 43 | 43 | 43 | 45 |
| **-Enumerations** | 317 | 317 | 403 | 403 | 436 | 436 | 436 | 459 |
| **Organizations Registered** | 61 | 65 | 70 | 71 | 78 | 91 | 91 | 94 |
| **Users** | | | | | | | 148 | 157 |

# Term Approval in RTMMS
# As of 29 January 2018

## Terms being or to-be vetted
("Term Approval" tab for 'SDO' user)

- "Proposed Terms": 187
- "Ready Terms Table":121
- "Mapped Terms": 78
- "Proposed Units": 187
- "Proposed Enumerations": 187

# Work Areas & Status Updates, DIM Editor/Profiler

- ISO/IEEE 11073 '*Domain Information Model Editor*' -> "DIM Editor"
  - Progress/Update/Status (Michael Faughn)
  - UML Defined 11073-10201 DIM basis for tooling
  - Issues list (actively/weekly addressing and resolving)
    - » Tool continues to improve performance and usability
  - ❖ DIM Editor tool – Medical Device subject matter experts wanted!
  - Auto producing ISO/IEEE documentation (to meet SDO's templates)
    - No major hurdles – from IEEE and w/ document generation
    - Michael provided a sample – Kathryn B. circulated w/in IEEE and accepted
  - Continue weekly TCons (Thursdays @ 2 pm Eastern) – all welcome!

# Work Areas & Status Updates
# Implemention Guide and Test Case Tools

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

- IGAMT – Implementation Guide Authoring Management Tool
- TCAMT – Test Case Authoring Management Tool
- Underlying 'Framework': HL7 profile→IGAMT→TCAMT→Tool
  - Tool to create Implementation Guides and conformance profiles
  - Tool to create test plans, test cases, and associated test data
  - Testing Infrastructure and test framework to build testing tools
- Rethink "normal" approach
  - Requirements are captured with tools that internalize the requirements as computable artifacts
    (*not as typically done* – using natural language and subsequently interpreting the requirements to create test plans and test assertions)…
- Approach is entry in tools (IGAMT + TCAMT) from a 'Quality' perspective by SME

# Work Areas & Status Updates
# Implemention Guide and Test Case Tools

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

- IGAMT + TCAMT
  - *Currently being used for MU/ONC + CDC domains (e.g., within Lab, Immunization, Syndromic Surveillance, eRX)…*
  - *Development work underway on IHE-PCD HL7 V2 Messages:*
    - *PCD-01 (ORU^R01) + PCD-03 (RGV^R015)…*
  - *Initial Goal: Develop first version of IG for IHE-PCD Int. Profiles (TF Vol. II)*
    - *Focus on IHE-PCD TF Vol. II/III (+ IHE-PCD test cases in TCAMT)*
    - *Base device profiles*
  - *(?? On hold; pending next release) Contributing to CAsC 'Virtual Machine' (conformity Assessment ISO 17025)*
    - *TCAMT focus on relatively small number of CAsC Identified Test Cases (presently from IHE-PCD, from cycles 11+12)*
  - *Begin producing IGs for device baseline **profiles/specializations***

# NIST Tool Framework Work…

- Underlying ‘Framework’ (continued):
  HL7 profile→IGAMT→TCAMT→Tool
  - “**Resource Bundle**” generated to automatically produce (and update) tool instance
  - *Concept investigated by developing initial version of IHE PCD transactions – e.g., PCD-01 (ORU^R01, ACK^R01) and PCD-03 (RGV^O15, ACK^O15)… + additional constructs (e.g., support of “conditionals” such as OBX-2 [Value Type] and OBX-5 [Observation Value ] in development)*
  - *Existing IHE-PCD V2 tools in process of being upgraded to new NIST framework – accomplished via IGAMT + TCAMT*
  - *Initial Goal: Develop first version of IG for PCD-01 through 15 (TF Vol. II)*
    - *Focus on IHE-PCD TF Vol. II/III*
    - *Continue to grow IGs for Volume IIIs (Device Specializations) in conjunction with the 11073-10201 DIM tooling work*

# Meetings + Activities: past, on-going and future

- Weekly “DPI” Meetings on Thursdays @ 2pm (w/ Jan Wittenber)
- Joint HL7 HCD / IEEE 11073 WG Mtgs., NOLA (Jan. 2018)
- ✓ IHE NA Connectathon (15-19 January 2018*)
- ✓ Joint HL7 HCD / IEEE 11073 WG Mtgs., San Diego, CA (Sept. 2017)
- ✓ Joint HL7 HCD / IEEE 11073 WG Mtgs., San Antonio, TX (Jan 2017)
- ✓ Joint HL7 HCD / IEEE 11073 WG Mtgs., Madrid, Spain (May 2017)
- ✓ IHE-PCD F2F:
  - Upcoming Spring F2F, Irvine, CA (Apr 2018)
  - Past Fall F2F, Boca Raton (Oct 2017)
  - Past Spring F2F, San Diego @ Qualcomm (Apr 2017)
- ✓ HIMSS’17 – Orlando (Feb.2017)
- ✓ IHE North American Connectathon, Cleveland (23-27 Jan 2017)
  - NIST Connectathon Tool used for static validation
  - *John G., Nicolas C., and Sandra Martinez serve as test monitors
  - John G. to participated (“Staff”) in IHE’s education series (“Connectathon 101”)
    - presented session on how PCD tests…
  - NIST’s IHE-PCD V2 Tool Tutorial (recorded fall 2015 for cycle 10 – on IHE wiki)

# 2018 Work Plans

- IHE-PCD Cycle 13 (2018-19), complete Cycle 12 (2017-18)
  - New HL7 V2 Tooling framework (same functionality and execution)
    - Generate tooling from resource bundle (files output from IGAMT and TCAMT)
  - Test Cases/demographics review – used as basis for tooling 2017-1
    - Also for IHE-Japan, Korea
  - CPs as introduced + requirements added into tooling (see PCD wiki: http://wiki.ihe.net/index.php?title=PCD_CP_grid)
  - Consider ACM WCTP validation service (from TF Vol 2)
  - Continue to support IHE (Inter-)National Test Events
    - N. America, Europe, Korea, Japan, Australia(tbd)
  - Roadmap of activities updated… see PCD wiki

http://wiki.ihe.net/index.php?title=Patient_Care_Devices

# 2018 Work Plans

Terminology Additions Continuing…

- 10101a (~240 terms) + co-constraints; 10101b near completion…

Informational Update

- MDC / LOINC mappings view (i.e., tab in interface)
  - 590…add about 60 more (nearly completely reviewed)
  - Thanks to Dr. Swapna Abhyankar (Regenstrief)

RTMMS Technology Update
(On hold - coming soon (??) – mid ’18 (??))

- Updating tool (interface and dBase)
- ‘AngularJS’ for the front end (user interface).
- ‘Node.js’ for the backend and MongoDB for the NoSQL database.

# 2018 Work Plans

- DIM Editor/Profiler 11073-10201 *(see Michael Faughn's slides)*
  - ➢ Generate camera ready IEEE standard (in MS Word 11073:10201© 2018)
  - ➢ Redesign application for reusable profiles
  - ➢ Resolve critical issues on "Revisions & Comments"
  - → Finished implementation of r/w permissions in web application
  - → Improved integration with RTMMS
  - → Comprehensive audit of updated DIM model / application with respect to 11073:10201© 2004
  - → Easier access to metadata and information from the DIM standard for device profile users
  - → Deploy to NIST server (from Prometheus Computing)
  - → Release Device Profiling app for general use
  - → Conformance statements from the profile editor
  - → Work with Open SDC (11073 Web Services) on similar tool

*Key Goal:*

- → Build library/repository of template 'Device Specializations'
- ❖ *See Michael Faughn's slides*

# 2018 Work Plans

- Devices on FHIR
  - –Weekly Tcons – Weds. @ 9:30 AM (EST)
- DoF Validation Service
  - – Evaluating and researching FHIR validation services
  - – Key goal: develop framework (similar to HL7 V2)
- Use RTMMS as nomenclature/mapping repository
  - – Continue to build alliance around RTMMS being medical device terminology “single source of truth”…
  - – Continue work with PoCD + PHD – PCHA/Continua – IHE-PCD/IEEE Upper Layers WG

# NIST Tool URLs/Websites

## *Conformance Tooling Suite*

- *HL7 V2 (2.6) IHE-PCD Validation Tools*
  - IHE-PCD Pre-Connectathon: http://ihe-pcd-precon.nist.gov/
  - IHE-PCD Connectathon, http://ihe-pcd-con.nist.gov/
- Rosetta Terminology Mapping Management System (*RTMMS*) https://rtmms.nist.gov
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  - Development Tool: dim.prometheuscomputing.com
- NIST HL7 V2 Portal: http://hl7v2tools.nist.gov/portal/#/tools
  - IGAMT – Implementation Guide Authoring Management Tool
  - TCAMT – Test Case Authoring Management Tool

Coming Soon:

- New V2 (with IEEE MDC semantics) validation tool instance and test cases

# Thank You or your attention ☺

- Questions
- Discussion