

## **HL7 Healthcare Devices/IEEE 11073 Working Group Meetings**

**2016.09.19 – 2016.09.22 – Baltimore, MD, USA**

See meeting documents posted @ <http://www.hl7.org/Special/committees/healthcaredevices/docs.cfm?>

Details posted on Titan Pad: <https://titanpad.com/SWNf2rXeyF>

### **Beginning Sessions for 2016.09.19 – 2016.09.22**

#### **Welcome & Introductions**

- Local and remote participants are introduced.
- Agenda for the day is presented.

#### **Review of IP / Patent Policy Review**

- Participants are informed by the presiding WG Chair of the IEEE/HL7 code of conduct, Patent Policy, and IP Disclosure Policy.

### **Monday – Q3, 19 September 2016**

#### **Recurring Participants (4)**

- Stan Wiley (Dräger)
- John Rhoads (Philips)
- John Garguilo (NIST)
- David Gregorczyk (Dräger)

#### **Q3-Specific Participants (19)**

- Ken Fuchs (Center for Medical Interoperability)
- Masato Tanaka (Nihon Khoden)
- Koichiro Matsumoto (Nihon Khoden)
- Jan Wittenber (Independent Consultant)
- Paul Schluter (GE)
- Michael Faughn (Prometheus Computing)
- Malcom Clarke (Brunell University, BSI)
- Swampna Abhyankar (Regenstrief Institute)
- Björn Andersen (University of Lubeck)
- Kathryn Bennett (IEEE SA)
- Lisa Perry (IEEE SA)
- Masato Tanaka (Nihon Khoden)
- Qi Zhou (BCBS of MA)
- Shennon Lu (NIH, NLM)
- Raj Mehra (Cerner Corp.)
- Recurring participants

## Other Participants Pool (note – use for future Qs if present) (31)

- Adamu Haruna (Nokia Technologies Oy)
- Stefan Karl (Philips Healthcare)
- Simon Baumhof (University of Lubeck)
- Martin Kasparick (University of Rostock)
- Clem McDonald (National Library of Medicine)
- Ioana Singureanu (US Dept. of Veteran Affairs/Eversolve)
- Matthew Graham (Mayo Clinic)
- Beth Pumo (Kaiser Permanente)
- Alexander Mense (HL7 Austria)
- Ewout Kramer (Furore)
- Chris Courville (EPIC)
- Stefan Schlichting (Dräger)
- Christoph Fischer (Roche Diabetes Care)
- Behnaz Minaei (FDA)
- Jan Schlamelcher (University of Luebeck)
- Brian Natz (GEHC)
- Andrew McCafferty (NIST)
- Harry Rhoads (AHIMA)
- Gora Datta (Cal2Cal)
- Nathan Botts (Westat)
- David Tao (ICSA Labs)
- Thomas Welsh (Independent Consultant)
- Yvonne Cole (DoD VA)
- Igor Yyabov (CMOOP)
- Mlynda Owens (Cognosante)
- Brian Reinhold (LNI/PCHA)
- Joerg-Uwe Meyer (MT2IT)
- Todd Cooper (Breakthrough Solutions)
- John Donnelly (Interpro. Solutions)
- Ron Shapiro (Qvera)
- Patrick Loyd (ICODE)

## Minutes for Q3

- Session Summary
  - Agenda revision 0.5 was reviewed.
  - Minutes summary from May 2016 WG meeting was reviewed.
  - IEEE SA Update – K. Bennett
    - See posted presentation from K. Bennett
      - 3 PARs open
      - 12 PARS due to expire 12/31/2016
      - 32 active Standards
      - 3 standards pending ISO approval
      - 10101a FDIS to close 1/2/2017
      - SASB Approvals on 6/30/2015
      - PARs on NesCom Agenda 9/20/2016
      - RevCom Agenda approvals for 9/19/2016
      - ISO TC215 Liaison Report for 11073

- Collaborative Relationships
- Process Reminders (with respect to administer WG documents inside and outside of IEEE)
- 2016 Meetings/Conferences
- Database Standards
- eHealth Strategy

#### **Motions**

- To approve agenda revision 0.5, as amended – offered by Wiley, seconded by Garguilo – motion passed unanimously.
- To approve minutes from May 2016 Work Group meeting, as amended – offered by Rhoads, seconded by Gregorczyk – motion passed unanimously

#### **Action Items**

- Provide an aligned report to ISO TC215 – action: K. Fuchs and D. Zhong by 10 Oct. 2016
- Investigate informative letter for publication identifying 10101 license-free use of terminology on NIST RTMMS to IEEE SA website and 11073 reflector – action: K. Bennett – K. Fuchs to propose text content.

### **Monday – Q4, 19 September 2016**

#### **Q4-Specific Participants (19)**

- Recurring Participants from Monday
- Michael Faughn
- Swampna Abhyankar
- Malcolm Clarke
- Kathryn Bennett
- Lisa Perry
- Koichiro Matsumoto
- Masato Tanaka
- Joerg-Uwe Meyer
- Todd Cooper
- Björn Andersen
- Shennon Lu
- John Donnelly
- Ken Fuchs
- Paul Schluter
- Jan Wittenber

#### **Minutes for Q4**

- IEEE 11073 Policies and Procedures, and Prospective Elections - K. Fuchs
  - Call for nominations was issued for the positions of Chair, Vice-Chair, and Secretary of IEEE 11073 Standards Committee.
  - Interested parties should send nominations to S. Wiley by 29 Sep. 2016
  - Terms are for 2 years
  - PoCD WG will also announce its call for s call for nominations in October.

- IEEE 11073 PHD Update - J. Wittenber
  - See posted presentation from D. Zhong
  - Membership includes 341 members from 220 different entities
  - 27 standards have been completed
  - 13 projects are currently underway
  - Next F2F meeting is on 8 - 9 Dec. 2016 in Washington, DC
  
- ISTO ICE Alliance - K. Bennett
  - ISTO has ended its ICE Alliance program
  
- AAMI UL JC2800 - J. Wittenber
  - See posted presentation from J. Wittenber
  - General overview of standards concept and proposed standards matrix
  - Focus on initial standard, 2800-0 - individual standards clauses: time synchronization, component connectivity, usability, partitioning and access control, testing requirements, et. al.
  - Integration of individual standards clauses into one standard document as focus of F2F meeting in Nov. 2016 in Northbrook, Illinois
  
- Standards Maintenance - J. Wittenber
  - See posted presentation from J. Wittenber
  - NESCOM meeting on 20 Sep. 2016 to review PARs for revisions to 11073-10101, 11073-10201, and 11073-20101.
  - Target is to have ballots for these maintenance standards completed by 2018.
  - Seeking volunteers to help with the revision of these documents.
  - 11073-10201 will be generated automatically from the NIST tools. This will be a pilot to demonstrate how the tool can automatically generate the standard document from the model.
  
- Infusion Pump Discussion - T. Cooper
  - See posted presentation from T. Cooper
  - The IHE Infusion Pump group will meet on 10 Oct. 2016 at the next IHE PCD F2F meeting in Boca Raton, FL.
  - Agenda topics will include:
    - Pump-relevant updates that are being included in RTMMS
    - PIV for multi-step programs
    - IHE Devices on FHIR Initiative support for infusion pumps
    - MEM DMC Remote Device Control White Paper

**Motions**

- None

**Action Items**

- None

## Tuesday – Q1, 20 September 2016

### **Q1-Specific Participants (22)**

- Recurring Participants from Monday
- Kathryn Bennett
- Lisa Perry
- Malcolm Clarke
- Joerg-Uwe Meyer
- Todd Cooper
- Swampna Abhyankar
- Björn Andersen
- Beth Pumo
- Christoph Fischer
- Clem McDonald
- Brian Reinhold
- Michael Faughn
- Koichiro Matsumoto
- Masato Tanaka
- Ken Fuchs
- Brian Reinhold
- Paul Schluter
- Jan Wittenber

### **Minutes for Q1**

#### Welcome & Introductions

- Participants are introduced.
- Today's agenda is reviewed.

#### IP / Patent Policy Review

- Content is reviewed with participants.

#### Web site

- See presentation from M. Clarke
- 11073.org, 11073.com, 11073.net
- Purpose of web-site
- Online demonstration of PHD section and its expandability

#### NIST Tooling:

- DIM Tooling Update and Demo
  - See presentation from M. Faughn
  - DIM UML Development and supporting models (10101, 20101, 20601)
  - DIM Classes 9~350)
  - UML to Artifacts: Challenges
  - New editions
    - PHD in DIM
    - PHD Classes
  - Simplified Workflow
  - Device Profile Editor – Existing Capabilities (Review)
  - Recent Features

- New Features
- Pulse Ox Numeric PHD profile exemplar
- Near-Term Goals
  - Application Redesign
  - GUI improvements
- Next Steps

#### PHD Device Security approach

- See presentation from C. Fischer
- Background on need for security for PHD devices
- What is to be achieved and definition of PHD cybersecurity? Process part and product capability part
  - Process part addresses risk analysis
  - Product capability part is defined in ISO IEC 27000:2016 – information security
- What do we want to solve?
  - 11 use scenarios in white paper
  - Scalability of information security toolbox
- How do we attack PHD cybersecurity?
  - PHD Cybersecurity Team – mission
  - PHD Community
  - PHD Cybersecurity Road Map
  - Scope of Scalable Information Security Toolbox

#### Motions

- None

#### Action Items

- Investigate incorporating IEEE 11073 urls into Wikipedia entries for IEEE 11073 PoCD WG – S. Wiley

### Tuesday – Q2, 20 September 2016

#### Q2-Specific Participants (24)

- Recurring Participants from Monday
- Kathryn Bennett
- Lisa Perry
- Malcolm Clarke
- Joerg-Uwe Meyer
- Todd Cooper
- Swampna Abhyankar
- Dan Vreeman
- Björn Andersen
- Beth Pumo
- Christoph Fischer
- Clem McDonald
- Brian Reinhold
- Simon Baumhof
- Behnaz Minaei
- Michael Faughn

- Koichiro Matsumoto
- Masato Tanaka
- Ken Fuchs
- Jan Wittenber
- Paul Schluter

## Minutes for Q2

### Terminology Update – P. Schluter

- 11073-10101a and NIST RTMMS update
  - See presentation from P. Schluter
  - RTMMS updated with 10101a nomenclature and has been used for limited testing at IHE NA Connectathon
  - 880 harmonized terms
  - 1733 non-harmonized terms
  - Co-constraints for 10101a have been uploaded to RTMMS
  - hRTM2
  - Co-constraints for PHD devices
- 11073-10101b Status
  - PAR approved
  - New content
    - Infusion Pumps
    - Ventilator mode
    - NMT
    - WCM
    - IHE PCD DMC
    - IHE PCD RTLS
    - General Signal Quality Index
    - Dialysis
    - Surgical and OR devices (by OR.NET)
    - Additional observation identifiers and settings
- PAR for 11073-10101c
  - PAR approval in progress
  - Extending support for existing identifiers to support IHE PCD Rosetta for events and alerts
  - Will cover physiologic alerts and essential technical events and alerts
- IDCO (11073-10103a)
  - PAR approved
- Participants from Heart Rhythm Society
- NIST RTTMS – accelerate numeric code assignments
  - Prescriptive process proposal
- PHD Terminology: Approach and RTMMS Inclusion – M. Clarke
  - See last slide of Terminology Update

### Terminology Mapping

- LOINC – S. Abhyankar
  - 880 hRTM – 511 in a mapping file on LOINC web-site – sending file update to J. Garguilo for posting on RTMMS
  - 170 new terms ready in Dec. 2016 release
  - 130 ventilator terms in process
  - Remaining 70 terms awaiting infusion pump and events input
  - Getting LOINC codes for home devices

#### **Motions**

- None

#### **Action Items**

- None

### **Tuesday – Q3, 20 September 2016**

#### **Q3-Specific Participants (20)**

- Recurring Participants from Monday
- Kathryn Bennett
- Lisa Perry
- Malcolm Clarke
- Joerg-Uwe Meyer
- Todd Cooper
- Björn Andersen
- Beth Pumo
- Brian Reinhold
- Simon Baumhof
- Jan Schlamelcher
- Michael Faughn
- Koichiro Matsumoto
- Masato Tanaka
- Ken Fuchs
- Jan Wittenber
- Paul Schluter
- Martin Kasparick

#### **Minutes from Q3**

11073-SDC - D. Gregorczyk

- Status Overview
  - See presentation from D. Gregorczyk
- Ballot Results: 20702 (MDPWS)
  - 80% Response Rate
  - Reconciled 230 comments
  - 40 balloters
  - 96% approval rate
  - 6% abstain rate



- 2 recirculation ballots
- Ballot passed
- RevCom authorized delivery to Standards Board for its final approval on 22 Sep. 2016.
- Editorial review after SASB approval.
- Ballot Plan Discussion: 10207 (BICEPS)
  - Form ballot group by mid Oct. 2016
  - Conduct initial balloting in Nov. 2016
  - Re-circulations are expected to take place in Dec./Jan. 2017
- Device Specializations – Bjorn Andersen
  - Require with generic and exchangeable devices (e.g. endoscopic device, high frequency surgical devices, et. al. – similar to PHD approach)
  - Work is in its infancy. One academic paper has been published on this topic.
- Access to DICOM devices via BICEPs – Jan Schlamelcher
  - Integrating existing DICOM devices to a network and using BICEPS for configuration settings
  - Extension to BICEPS
- BICEPS Primer
  - General Outline of the SDC Series
  - Overview of BICEPS
    - Participant Model
    - Communication Model
- Agenda for Next Week's Educational Session

#### **Motions**

- None

#### **Action Items**

- None

#### **Tuesday – Q4, 20 September 2016**

##### **Q4-Specific Participants (22)**

- Recurring Participants from Monday
- Kathryn Bennett
- Lisa Perry
- Malcolm Clarke
- Joerg-Uwe Meyer
- Todd Cooper
- Björn Andersen
- Beth Pumo
- Brian Reinhold
- Michael Faughn
- Koichiro Matsumoto

- Masato Tanaka
- Ken Fuchs
- Jan Wittenber
- Paul Schluter
- Stefan Karl
- Stefan Schlichting
- Martin Kasparick
- Adamu Haruna

## **Minutes from Q4**

### **SDC Update Continued – D. Gregorczyk**

- BICEPS Overview
  - Service Control Object
  - Metrics
  - Alert Systems
  - Communication Model
  - Discovery Model
  - Non-Functional Requirements
  - Participant model (28 Sep)
  - Communication model (29 Sep)

### **ONC Roadmap – K. Fuchs**

- From M. Kirwan, excerpts from 2017 ONC Advisory
- Discussion on how best to respond to the request for comment from ONC on its proposed interoperability roadmap and on specific interoperability standards it is choosing to recognize.

### **PHD/HL7 UDI approach – M. Clarke**

- Background
- FDA UDI
- Electronic submission method in HL7 SPL
- IEEE 11073 Production Spec.: need to expand spec to cover gap with FDA documentation
- Representation in HL7 V2.8
- Actions to be taken in 11073-20601 to enable PHD devices to electronically communicate UDI information.

## **Motions**

- None

## **Action Items**

- None

## **Wednesday – Q1, 21 September 2016**

### **Q1-Specific Participants (16)**

- Recurring Participants from Monday

- Kathryn Bennett
- Malcolm Clarke
- Joerg-Uwe Meyer
- Todd Cooper
- Björn Andersen
- Brian Reinhold
- Michael Faughn
- Koichiro Matsumoto
- Masato Tanaka
- Ken Fuchs
- Jan Wittenber
- Paul Schluter

## Minutes from Q1

### Summary:

#### MDAP (-20101) Revision Drafting Topics

- 20101 will expire by end of 2018; standard needs to be revised and approved for release.
- Focus of IHE PCD DPI WG
  - Pre-associations (discovery) has been added. Leveraged similar content from PHD. Contributors included S. Karl (Philips).
  - Document has been re-structured and includes references to PHD and SDC.
  - A request has been submitted to RevCom to extend the current PAR expiration date for 2 years to 2018.
  - A semi-monthly web-conference is currently being held to work on this content.

#### UDI and Security

- Expect to follow lead of PHD and fold results from Cybersecurity Tiger team into MDAP spec.

#### Optimized Associations

- Establishing medical device encoding rules and leveraging PHD content in this area.

#### Dialysis System/Support Update (IEEE P11073-10316)

- See slide deck from J. Wittenber.
- History of project with representatives from the Dialysis Industry Consortium.
- Ad-hoc group has been collaborating with the Consortium to perform modeling of the proposed interoperability - ~150 new parameters have been identified.
- Defining VMD, common name, nomenclature descriptions, units of measure, data types, etc. an entering this content into the NIST profiling tool.
- First version will be a device containment tree of nomenclature. Have several terms similar to those that were defined PHD – now vetting them and targeting to integrate into P11073-10101b.
- Goal for the Consortium is to complete this modeling and nomenclature alignment by Q2 2017.
- Semi-monthly web-conferences are held with Fresenius, DaVita, et. al. on Mondays.

#### Overflow Topics (M. Clarke)

- ISO Comments received on IEEE 11073-10417
  - See posted slide deck from M. Clarke.

- Background on IEEE 11073- ISO TC215 standardization process and the “Vienna Agreement”
- Comments received on disclaimer clauses included in 10417 (also included in other 11073 standards now)
- Need to have IEEE SA to provide clarification of these disclaimer clauses or re-write them so as to make clear the safety-related coverage these standards provide. ISO TC215 is responsible for responding to all comments received on balloted international standards within its charter.
- Expect this topic to be discussed in ISO TC215 JWG2 meeting in Nov. 2016.
- 11073 Scoping Topics:
  - Follow-up on scoping questions from last WG meeting (“Equipment”, “App”, and “software” as potentially new objects for inclusion in the DIM) – awaiting specific DIM proposal inputs from T. Rausch (DocBox). This topic will be re-scheduled until the January 2017 WG meeting. Continuing discussion in the IHE PCD DPI web-conference.
- 11073 Roadmap Planning
  - See table posting from J. Wittenber
  - Projections for 2018 for 101xx, 102xx, and 2xxxx.

#### **Motions**

- To formally adjourn the IEEE 11073 PoCD WG, provided by J. Wittenber, seconded by T. Cooper: passed unanimously

#### **Action Items**

- Provide alternative text for current disclaimers in recent IEEE 11073 standards and provide to K. Bennett: K. Fuchs
- Escalate to IEEE SA Leadership the recently discussed issue of disclaimers in IEEE 11073 standards as well as proposed alternative text to reach a corrective action for public clarification and for ISO TC215’s response to related comments in recent 11073 standards ballots – K. Bennett

#### **Wednesday – Q2, 21 September 2016**

##### **Q2-Specific Participants (16)**

- Recurring Participants from Monday
- Kathryn Bennett
- Malcolm Clarke
- Joerg-Uwe Meyer
- Todd Cooper
- Björn Andersen
- Brian Reinhold
- Michael Faughn
- Koichiro Matsumoto
- Masato Tanaka
- Ken Fuchs

- Jan Wittenber
- Paul Schluter

## Minutes from Q2

### Welcome & Introductions

- Participants are introduced.
- Today's agenda is reviewed.

### IP / Patent Policy Review

- Content is reviewed with participants.

### Work Group Overview – John Rhoads

- Relationship to HL7 - modeling
- Relationship to IHE PCD – use of HL7 V2 with specific profiling stipulations
- Relationship to NIST

### IHE PCD Update – John Garguilo

- Medical Device Communication Test presentation from J. Garguilo
- The Team
- Work Area & Status Updates
  - HL7 V2 IHE-PCD Validation Tools
    - IHE-US Connectathon in Jan. 2016 – next one in Jan. 2017
    - IHE Europe in Apr. 2016
    - IHE Korea in Aug. 2016
    - IHE Japan in Sep. 2016
  - Rosetta Terminology Mapping Management System (RTMMS)
    - RTMMS Deployment Update and service status
    - 240 new terms added; 358 LOINC mappings to MDC terms
  - IGAMT – Implementation Guide Authoring Management Tool + TCAMT – Test Case Authoring Management Tool
    - Will have demonstration in January WG meeting
- Meetings and Activities
  - HIMSS 17 Orland (Feb. 2017)
  - IHE PCD F2F Boca Raton (Oct. 2016)
- HL7 V2 IHE-PCD Tooling Status & Updates
  - 3 adopted Change Proposals (125, 126, 128)
  - Validating EUI-64 or DNS
- DIM Editor work updates, tool review

### Update on Object Hierarchy Containment Tree (OBX4) – M. Clarke (see posted slide deck)

- Introduction to architecture
  - Introduction to PHD architecture
- PCD01 messaging
- Object Hierarchy Containment Tree
  - OBX-4 Observation Sub-ID
- Classification of PCD01

- Arrived at no decision – topic to be followed-up in IHE PCD F2F meeting.

### **Motions**

- None

### **Action Items**

- None

## **Wednesday – Q3, 21 September 2016**

### **Q3-Specific Participants (18)**

- Recurring Participants from Monday
- Kathryn Bennett
- Malcolm Clarke
- Masato Tanaka
- Ken Fuchs
- Joerg-Uwe Meyer
- Todd Cooper
- Björn. Andersen
- Brian Reinhold
- Michael Faughn
- Chris Courville
- Stefan Schlichting
- Stefan Karl
- Brian Natz
- Andrew McCafferty

### **Minutes from Q3**

Updates from “Devices on FHIR” Ad-Hoc Team – T. Cooper (see posted presentation)

- PSS Updated
  - Created PSS #1277; deprecated #1103
  - Simple title: FHIR for Device Data Reporting
  - Targets:
    - Data reporting
    - Advance FHIR Maturity Model (FMM) for resources
    - Consider device-related profiles
    - Implementation Guide – for consistent implementation
    - White papers for topics like alerting or control
  - Co-Sponsors: O&O; mHealth; HIS;
  - Schedule: Target May, 2017
  - Project Team
    - T. Cooper
    - C. Gessner

- et. al.
- FMM Status Update
  - DoF Webinar on 17 Oct 2016
  - IHE PCD @ FHIR
- FHIR Connectathon Report
  - DoF Participants
    - S. Schlichting
    - C. Courville
    - B. Reinhold
    - J. Rhoads
  - Pre-2016.09: limited participation
  - 2016.09 FHIR Connectathon
    - CDS Collaborative engagement
    - Pre-Connectathon testing @ Cognitive Platform
    - Major operational challenges
    - Post-2016.09 PHIR Connectathon – will use HSPC-based sandbox
    - Future F2F Connectathon events
    - HL7+Continua+IHE collaboration
- General DoF Issues with DEV-FHIR
  - Review PSS and Roadmap
  - FHIR: Schedule & Input to HCD & DOF
  - IG Production
  - Mapping: Formalized in STU3
  - Terminology Bindings (esp. 11073 & LOINC)
  - 11073 BITS-to-FHIR Approach
  - Security Considerations
  - Mapping 11073 to FHIR Resources/Profiles
  - DeviceComponent: last SystemChange
  - Regulatory Status Indicator
  - Terminology Bindings (incl. 11073 & LOINC)
  - PCIM – ‘Procedure’ use (Ioana’s proposal)

#### **Motions**

- None

#### **Action Items**

- Coordinate DoF PSS with C. Gessner: J. Rhoads

#### **Wednesday – Q4, 21 September 2016**

#### **Q4-Specific Participants (24)**

- Recurring Participants from Monday

- Brian Reinhold
- Malcolm Clarke
- Koichiro Matsumoto
- Masato Tanaka
- Koichiro Matsumoto
- Matthew Graham
- Beth Pumo
- Ioana Singureanu
- Joerg-Uwe Meyer
- Todd Cooper
- Harry Rhoads
- Brian Natz
- Gora Datta
- Nathan Botts
- David Tao
- Thomas Welsh
- Adamu Haruna
- Yvonne Cole
- Igor Yyabov
- Mlynda Owens

## **Minutes from Q4**

### Hosting Mobile Health

- Introductions – See presentation from Matthew Graham
- Mobile Health Sessions today
- Mobile Health Efforts
  - Emerging Standards
  - Projects
- mFHast Emerging Standard – Nathan Botts: ballot for comment in 2017
  - Goals
  - Importance
  - Concept
  - Use Cases
  - Needs
  - mFHASt.org – Evidence database
  - Preliminary Findings
  - Preliminary mFHASt Implications
  - Development of Comment-Only Ballot
  - mFHASt Contextual Requirements
  - mFHASt Message Requirements
  - mFHASt Implementation
  - Promotion & Dissemination via Social Media
- CMHAFF Emerging Standard – David Tao and Nathan Botts
  - Consumer Mobile Health Application
  - Needs – mobile health apps on mobile telephones
  - Scope and Goals



- cMHAFF Exemplar Use Cases
  - Mobile App Lifecycle
  - CMHAFF Topics
  - Ballot results from Jan. 2016
  - Addressing National Gaps
  - cMHAFF and API Task Force Scope
  - Value proposition for adoption of this proposed standard
  - Privacy, security, data access, data integrity are within scope; clinical validity of health software is not within scope
- MH Application Interoperability Environmental Scan – Christopher Doss
  - Pictorial Representations In Mobile Health – G. Datta/Mlynda Owens
    - Concepts are being represented pictorially.
    - The need.
    - Standards for Symbols (none from TC215!) – gap is that Mobile Health can drive these symbol efforts.
    - Initial potential applications
    - Next steps

#### Review of New Project Scope Statements – I. Singureanu

- Background – Detailed clinical models for medical devices
- Take the Domain Analysis Model and to revise and update in Q2 2017; also look at FHIR profiles to assess gaps with the DAM. Guidance document for implementation of HL7 V2 and FHIR.
- Sponsor: PC; Co-Sponsors: HCD, Structured Documents, FHIR, Conformance
- Scope: EHR systems, Device Models – similarity to PCD DEC or FHIR to EHR
- Out-of-Scope: medical device to medical device communications
- Appears to be relevance on DoF work, need time to evaluate proposal further

#### Motions

- None

#### Action Items:

- None

#### **Thursday – Q1, 22 September 2016**

#### **Q1-Specific Participants (xx)**

- Recurring Participants from Monday
- Masato Tanaka
- Koichiro Matsumoto
- Joerg-Uwe Meyer
- Todd Cooper
- Paul Schluter
- Jan Wittenber
- Brian Reinhold

- Chris Courville
- Stefan Schlichting
- Björn Andersen
- Joerg-Uwe Meyer
- Matthew Graham
- Ewot Kramer
- Brian Natz
- Adamu Haruna
- Ron Shapiro
- Patrick Loyd
- Behnaz Minaa
- Ioana Singureanu

## Minutes from Q1

- Summary

Hosting FHIR (#1103 FHIR Resources Project) – See presentation from T. Cooper

- Devices on FHIR Update
  - See DoF Launched after 2016 May WGM
  - Weekly web meetings
  - Updated DEV FHIR PSS (#1277); retired #1103
  - Coordination with CDS Collaborative
  - Coordination with Continua and IHE PCD
- New PSS
  - Narrower scope (omitted alerting and control; focus on device reporting)
  - Deliverables in Jan 2017, May 2017
  - Leveraging 4 FHIR resources
  - Creating a new Implementation Guide
  - Creating potential whitepapers
  - Co-Sponsors: O&O, mHealth, HIS
- DoF Testing
  - 2016.09 FHIR Connectathon
    - CDS Collaborative engaged as consumer
    - Pre-Connectathon testing @ Cognitive Platform
  - Next Steps
  - Next F2F Connectathon events
  - Clarification of FHIR Maturity Model (FMM) Level 2 goals
  - HL7 FHIR Developer Days in Amsterdam, 16 – 18 Nov 2016
- FHIR TSC Update – E. Kramer
  - Ballot results (STU3)
    - 737 FHIR core comments
  - Triaging of Defects
  - Reconciliation Timelines
    - Change proposal cut-off: Oct. 9
    - Substantive Core change deadline: Nov. 27
    - Final content deadline: Dec. 4
    - Publish by beginning of Jan. 2017

- Resolution considerations
- Reconciliation reminders
  - Release 4: Next release of FHIR in 2018 will have normative content (either Sep 2017 or Jan 2018) – publish by mid-2018
- Resource maturity – must have maturity scale of level 4 for resources to be normative.
- Combining Device and Device Component – need to review with O&O (scale from simple devices to more complex devices with devices)
- Key Topics
  - IG Production: separated IG tooling from specification tooling; Furore has fee-based consulting resources to assist with this. Training session from Graham was held on Sunday (9/17).
  - Semantic Mapping: Formalized in STU3: 11073->V2->FHIR; need to provide both narrative and an algorithm for doing conversion; See “Structure Map” to formally do mapping with an executables.
  - ASN.1 – In IEEE devices, a way to record measurement is a 16bit integer – how to represent in FHIR? See proposal slide from B. Reinhold.
- Motions
  - None
- Action Items:
  - None

**Thursday – Q2, 22 September 2016**

**Q2-Specific Attendees (12)**

- Recurring Participants from Monday
- Masato Tanaka
- Koichiro Matsumoto
- Joerg-Uwe Meyer
- Todd Cooper
- Paul Schluter
- Jan Wittenber
- Brian Reinhold
- Behnaz Minaa

**Minutes from Q2**

- Summary
  - Updates from HL7 Co-chair meeting – presentation posted by J. Rhoads
    - ITHSDO is working on a free sub-set with ~7000 terms. Continua started an IEEE to SNOMED mapping.
    - HCD WG received high marks for operational efficiency (received a “gold” star).
    - Essentialism
    - Work Group participations on PSS
    - TSC Organizational Structure

- FHIR TSC update
- HL7/HCD Status Report
  - DEV Projects Review
    - Anesthesia WG – joint work items are hold pending completion of the anesthesia domain analysis model.
    - Ioana's PSS – propose Patient Care WG to lead.
    - FHIR – already addressed in Q1 today.
  - Connectathons
    - See content from Q1
  - Dev Wiki alignment with TSC requirements
    - In process – J. Rhoads
  - Other Standards Updates
  - FDA UDI
    - Use of UDI and eui-64 incorporation in HL7 V2.8.2 for the PRT-segment implementation of UDI
    - See UDI PSS on HCD section of HL7 web-site
    - See presentation on 12 Oct. 2015 (E. Moll)
  - Time Sync - Closed from prior WG meetings
- Motions
  - None
- Action Items
  - Convene web-conference on Ioana's PSS proposal for WG discussion – J. Rhoads

**Thursday – Q3, 22 September 2016**

**Q3-Specific Attendees (6)**

- Recurring Participants from Monday
- Koichiro Matsumoto
- Brian Reinhold

**Minutes from Q3**

- Summary
  - Attendees collaborated on the preparation of response to the ONC Interoperability Roadmap proposal.
- Motions
  - To formally adjourn the HL7 HCD Work Group meeting, offered by S. Wiley, seconded by B. Reinhold - passed unanimously
- Action Items
  - None

**Adjourn Meeting**