HL7 Healthcare Devices/IEEE 11073 Working Group Meetings

2015.10.05 - 2015.10.08 - Atlanta, GA

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

Details posted on Titan Pad: Titan Pad: https://titanpad.com/P4eYa3TSfC

Beginning Sessions for 2015.10.05 – 2015.10.08

Welcome & Introductions Review of IP / Patent Policy Review

Monday - Q3 Oct. 05, 2015

Recurring Participants (4)

- Stan Wiley (Dräger)
- Jan Wittenber (Center for Medical Interoperability)
- Paul Schluter (GE)
- Alpo Varri (Tampere University of Technology, Finland)

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Q3-Specific Participants (17)

- Ken Fuchs (Center for Medical Interoperability)
- Todd Cooper (Center for Medical Interoperability)
- Joerg-Uwe Meyer (MT2IT)
- Kathryn Bennett (IEEE-SA)
- Anasthasie Sainvilus (IEEE-SA)
- Leslie Sistla (Microsoft)
- John Rhoads (Philips)
- John Garguilo (NIST)
- Stefan Schlichting (Dräger)
- Stephan Poehlsen (Dräger)
- Koichiro Matsumoto (Nihon Khoden)
- Masato Tanaka (Nihon Khoden)
- Chris Courville (Epic)
- Recurring participants

Other Participants Pool (note – use for future Qs if present) (30)

- Ewout Kramer (Furore)
- Ron Shapiro (Quera)
- Elizabeth Newton (Kaiser Permanente)
- Michael Faughn (Prometheus Computing)
- Leslie Stem (FDA)
- Terrie Reed (FDA)

- MaryKay McDaniel (Cognosanti)
- Toni Skokovic (Interfaceware)
- Clem McDonald (NLM)
- Norman Shaw (IEEE SA)
- Lisa Perry (IEEE SA)
- Matthew Graham (Mayo Clinic)
- Dan Vreeman (Regenstrief Institute)
- Mark Palmaffy (Center for Medical Interoperability)
- Paul Spadafora (Center for Medical Interoperability)
- Harry Rhodes (AHIMA)
- Gora Datta (Cal2Cal)
- Martin Rosner (Philips)
- Stefan Karl (Philips)
- Dmytro Rud (Roche Diagnostics International)
- Brian Reinhold (LNI/PCHA)
- Frank Ploeg (HL7 Netherlands0
- Mohd Anwar (NC A&T University)
- Masaaki Hirai (Nihon Khoden)
- Bruce Bray (University of Utah)
- David Hay (HL7 FMG)
- Mahesh Krishnan (DaVita)
- Matt Brzanschweig (DaVita/HCP)
- Barry Miller (DaVita/HQ)
- Teri Neal (Fresenius Medical Care)
- David Tap (ICSA Labs)

Minutes for Q3

- Session Summary
 - o Patent policy and Anti-Trust statements of IEEE were presented and reviewed.
 - o Attendee introductions were made.
 - o Agenda revision <u>0.5</u> was reviewed.
 - o Minutes from May 2015 WG meeting was reviewed.
 - The draft Policies and Procedures (document P&P) from the IEEE 11073 PoCD WG was reviewed.
- Motions
 - o Approval of meeting agenda revision 0.5 Passed: motion by Wiley seconded by Cooper
 - o Approval of meeting minutes from May 2015 Passed: motion by Fuchs seconded by Wittenber
- Action Items
 - o None

Monday - Q4 Oct. 05, 2015

Q4-Specific Participants (18)

- Recurring Participants from Q3 on Monday
- John Garguilo
- Ken Fuchs
- John Rhoads
- Chris Courville
- Stefan Schlichting
- Stephan Poehlsen
- Koichiro Matsumoto
- Todd Cooper
- Joerg-Uwe Meyer
- Kathryn Bennett
- Anasthasie Sainvilus
- Leslie Sistla
- Elizabeth Newton
- Masato Tanaka

Minutes for Q4

- Session Summary
 - o Overview of IHE PCD Pump Model RTMMS Content and DIM Profiling Tools
 - o Content based on device specialization infusion pump 2.0
 - Next steps preparing terms for inclusion in 10101b.
- Motions
 - o None
- Action Items
 - o None

Tuesday - Q1 Oct. 06, 2015

Q1-Specific Participants (19)

- Recurring Participants from Q3 on Monday
- John Garguilo
- Michael Faughn
- Ken Fuchs
- John Rhoads
- Chris Courville
- Stefan Schlichting
- Stephan Poehlsen
- Koichiro Matsumoto
- Kathryn Bennett
- Anasthasie Sainvilus
- Masato Tanaka
- Leslie Stem
- Terrie Reed
- MaryKay McDaniel
- Toni Skokovic

Minutes for Q1

- Summary
 - o Patent policy and Code of Conduct statements of IEEE were presented and reviewed.
 - o Attendee introductions were made.
 - o Results from HL7 Co-Chairs Meeting (J. Garguilo)
 - Review of results from HL7 Co-Chairs Meeting
 - US Realm meets every Tuesday.
 - PSS submission date end of next week (October 16).
 - Status of FHIR.
 - Corrective actions for DEV
 - Need to update 3 year plan
 - Need to post off-line Work Group meeting minutes to the HL7 website
 - Co-Chair nominations submit nominations by Oct. 23 (T. Cooper's position expires in Jan. 2016; C. Courville to advise on his status as Co-Chair)
 - o HL7 Status Report (J. Rhoads)
 - Review status of HL7 HCD Projects (reference:

http://www.hl7.org/Special/committees/healthcaredevices/projects.cfm)

- #850 active
- #595 closed
- #513 inactive proposing to close
- Others to be investigated
- Review of updates on other HL7 HCD related standard activities
 - Request for work on a spirometry report from ISO.....John Rhoads to drive and recruit additional contributing resources. Will present a draft PSS at the Jan. 2016 WG meeting.
 - IHE PCD V2.9 messaging standard will be launched with DEV as a co-sponsor.
 - IHE PCD ACM has constructs (adding trigger events) that are enabled in V2.9.
- o FDA UDI Update (T. Reed/Leslie Stem)
 - See posted presentation.
 - Update from FDA on UDI roll-out and desire for UDI support in standardized HL7 messages. Proposing transport of EUI-64 and UDI.
- Time Synchronization (P. Schluter/J. Wittenber)
 - No presentation available. Defer to B. Reinhold (Q4 on Wednesday)
- Motions
 - o None
- Action Items
 - o Provide updated status of all DEV projects J. Rhoads, T. Cooper, C. Courville, J. Garguilo
 - o Defer Time Synchronization discussion to Q4 on Wednesday Reinhold/Schluter
 - o Report on results of UDI discussions from O&O WG meeting Rhoads

Tuesday - Q2, Oct. 06, 2015

Q2-Specific Participants (17)

- Recurring Participants from Q3 on Monday
- John Garguilo
- Michael Faughn
- Ken Fuchs
- Chris Courville
- Stefan Schlichting
- Stephan Poehlsen
- Koichiro Matsumoto

- Masato Tanka
- Kathryn Bennett
- Anasthasie Sainvilus
- Norman Shaw
- Todd Cooper
- Joerg-Uwe Meyer

Minutes for Q2

- Summary
 - o IEEE Update (K. Bennett see posted presentations)
 - Licensing with IEEE SA
 - Basic information and requirements and use cases to facilitate clarity on copyright compliance
 - Proposals via process flow diagrams leading to closure discussion in Jan. 2016 WG meeting.
 - Review of current guidance statements on copyright
 - IDCO Example: Seeking spreadsheet of codes and terms for distribution to EHR customers? What is "compliant product development?
 - C4MI Example
 - NIST Example
 - Standards Maintenance
 - A number of standards that are in distribution which will require update.
 These documents would be modified, then be re-balloted.
 - At the end of 10 years, a standard must be revised or withdrawn from circulation. Some documents that already have revision PARS, if not approved by 12/31/2018, would move to an "INACTIVE" state.
 - List of 4 PoCD WG standards that are at the 10 year age limit. Implications for submissions of new PARs. Example: Seeking spreadsheet of codes and terms for distribution to EHR customers? What is "compliant product development?
 - IEEE SA Public Review
 - Overview of IEEE system that uses the public review process.
 - Public review has already been implemented as of July 1, 2015.
 - A separate IEEE-SA system permits non-SA members to purchase a
 draft standard and make comments via the public review system.
 Governance rules for dispositioning comments from the public
 reviewer are different from those comments provided by the Ballot
 group.
 - System addresses improvements in outreach transparency.
 - https://publicreview.standards.ieee.org/public-review-web/public-app

- Motions
 - o None
- Action Items
 - Send use cases for and examples of potential compliant product use to K. Bennett IEEE 11073
 PoCD WG members and HL7 DEV members.

Tuesday – Q3, Oct. 06, 2015

Q3-Specific Participants (16)

- Recurring Participants from Q3 on Monday
- John Garguilo
- Michael Faughn
- Ken Fuchs
- Chris Courville
- Stefan Schlichting
- Stephan Poehlsen
- Koichiro Matumoto
- Masato Tanaka
- Kathryn Bennett
- Anasthasie Sainvilus
- Michael Faughn
- Joerg-Uwe Meyer

- Summary
 - o IEEE SA Update K. Bennett (see posted presentation)
 - 29 PARs open
 - 27 PARS in development
 - 2 drafts in ballot
 - 31 active standards
 - 5 standards in ballot at ISO
 - 25 adopted standards by ISO
 - 0 PARs due to expire by 12/31/2015
 - Ballot Status
 - P10101a Nomenclature Amendment
 - P10422 in comment resolution since July 2013
 - SASB Actions and Status since May 2015
 - Working Group P&Ps
 - Collaborative Relationships
 - eHealth Strategy
 - ProCom Ad-hoc for data base standards
 - 2015 Meetings/Conferences
 - 2016 IEEE SA Meetings: http://standards.ieee.org/about/sasb/2016calendar.pdf
 - o IEEE SA Central Desktop J. Wittenber/K. Bennett
 - IEEE SA Tool to support WGs
 - See video for training:
 - https://www.youtube.com/watch?v=cT3ildpDMm4&feature=player_embedded
 - o IEEE 11073 PoCD WG Membership Affirmation J. Wittenber
 - Updated membership roster
 - Edited PoCD WG P&P content
 - o Review of discussions during DPI calls J. Wittenber
 - Focus on usability and update of the DIM
 - o IEEE 11073 PHD Update see posted presentation J. Wittenber
 - Meeting Nov. 12-13, 2015 with Continua, Washington DC

- o AAMI-UL JC2800 Update J. Wittenber
 - Focus on standards for safety and security of interoperable medical systems
 - Discussion of formal liaison relationship with IEEE 11073 PoCD WG to be placed on agenda for Dec. 2015 F2F meeting in Newport Beach, CA.
- Motions
 - None
- Action Items
 - o Defer IEEE 11073 PHD UDI update for IEEE 11073 overflow session on Thursday J. Wittenber

Tuesday – Q4, Oct. 06, 2015

Q4-Specific Participants (13)

- Recurring Participants from Q3 on Monday
- John Garguilo
- Michael Faughn
- Chris Courville
- Stefan Schlichting
- Stephan Poehlsen
- Koichiro Matsumoto
- Masato Tanaka
- Kathryn Bennett
- Joerg-Uwe Meyer

- Summary
 - 11073 PoCD WG Membership Recruitment J. Wittenber/K. Bennett
 - o IEEE-SA can support membership recruitment with a call for participation: e-blast prepare a request form to create the e-blast to IEEE-SA Marketing Dept.
 - 11073 SDC S. Schlichting/S. Poehlsen
 - Standards and Document Review
 - PAR Number corrected approved.
 - SDC Google Group/DKE Work Group (40 active participants) activities since May 2015
 - Content from the ticketing system
 - IEEE SA Central desktop upload ("Drafts")
 - Proposed "socialization" telcos on OpenSDC: IEEE 11073, IHE PCD, JC2800
 11/2015 call for participation
 - Overview of draft documentations
 - 20701 SDC binding document: content collection started; stable since May; Content ready by Q1 2016.
 - 20702 MDPWS: content completed; clearer information on safety content;
 3 remaining editorial tasks; Form ballot group and familiarize stakeholders.
 Assess ballot worthiness at the Jan. 2016 WG meeting

- 10207 BICEPS: content completed; improved the containment tree model; finalized all messages and services; 15 remaining editorial tasks; will implement 3 demonstrators to validate the model. A document of use cases is available. Form ballot group and familiarize stakeholders. Assess ballot worthiness at the Jan. 2016 WG meeting
- OpenSDC
 - o Reference implementation available by end of Oct. 2015.
 - o "SDC for Dummies" document Martin Kasparak to support
 - OR.Net will propose an IHE profile (IHE Germany) for OpenSDC
- Challenges and Ballot Discussion
 - Ballot group balance requirements
 - Proposed ballot order: 20702, 10207, 20701
 - Introduce topic of PCD01 to OpenSDC communications and vice versa. OpenSDC to FHIR.
- Motions
 - o None
- Action Items
 - Defer detailed discussion on 11073 PoCD WG Membership Recruitment to IEEE overflow session on Thursday - J. Wittenber
 - Initiate actions to introduce OpenSDC concepts to potential ballot group stakeholders S.
 Schlichting

Wednesday - Q1 Oct. 07, 2015

Q1-Specific Participants (18)

- Recurring Participants from Q3 on Monday
- John Garguilo
- Ken Fuchs
- John Rhoads
- Chris Courville
- Stefan Schlichting
- Stephan Poehlsen
- Todd Cooper
- Kathryn Bennett
- Lisa Perry
- Joerg-Uwe Meyer
- Masato Tanaka
- Toni Skokovic
- Michael Faughn
- Clem McDonald

- Summary
 - o Patent policy and Anti-Trust statements of IEEE were presented and reviewed.

- o Attendee introductions were made.
- o P. Schluter was recognized for his Medallion award presented by the IEEE SA.
- C. Courville announced a new job assignment outside of the US that will necessitate him to step down as an HL7 Co-Chair.
- o Terminology Update P. Schluter
 - 11073-10101a Status
 - See posted slide presentation
 - Joint effort between IEEE 11073 PoCD WG, IEEE 11073 PHD, ISO TC 121 SC4, HL7 GAS SIG, Regenstrief Institute
 - Adds 660 terms
 - Re-circulation ballot currently underway.
 - RevCom review scheduled for Dec. 2015,, with anticipated approval on Dec. 5, and earliest publication possibly Dec. 9.
 - Terminology code assignment quality assurance tooling has been validated in this process.
 - IEEE 11073 PHD is now using RTMMS for all future terminology code assignments
 - Term Co-Management Issues with PHD
 - Lessons Learned
 - Collaborations
 - Mapping to LOINC
 - 11073-10101b Content Planning
 - Infusion Pumps
 - NMT
 - Ventilator Modes
 - Ventilator Terms
 - Et. al.
 - 11073-10101c Content Planning
 - Alarms and alerts
 - IDCO (11073-10103)
 - PAR request being submitted
- Motions None
- Action Items None

Wednesday – Q2 Oct. 07, 2015

Q2-Specific Participants (16)

- Recurring Participants from Q3 on Monday
- John Garguilo
- Ken Fuchs
- John Rhoads
- Chris Courville
- Stefan Schlichting
- Stephan Poehlsen
- Kathryn Bennett
- Lisa Perry

- Joerg-Uwe Meyer
- Masato Tanaka
- Michael Faughn
- Daniel Vreeman

Minutes from Q2

• Summary

Terminology Mapping

- LOINC (Cooper/Schluter)
 - o Harmonized Rosetta terms have been mapped to LOINC.
 - o Proposal to use 10101b to make an amendment (concern regarding limit of 3 amendments that are permitted on a standard).
 - o There is no ANSI-accredited process in LOINC for balloting a mapping.
 - Proposal from Cooper for an immediate ballot of the mapping as a normative annex. Issue PAR application by Dec. 9.
 - o 11073-101014 mapping of 11073-10101 to LOINC; 11073-101015
- SNOMED-CT (Wittenber)
 - A few t-cons focusing on the scope and nature of the relationship between 11073 and IHTSDO.
 - o Concerns about resources and scope of project (several 1000 terms).
 - Identifying with alternatives 11073 mappings to LOINC and use this content to start the project.
 - IHTSDO seeking proposal from 11073. IHTSDO already has a MoU with Regenstrief.
 - SNOMED International is driven by its members, countries. It is less likely that
 device considerations will be a strong driver at SNOMED. LOINC does have
 internal terminologists who are already involved in terminology mapping projects
 with SNOMED International.

IEEE 11073-10101b (Schluter)

- Infusion pumps and infusion events (IHE PCD PIV and IPEC)
- Ventilator modes
- NMT
- WCM for ECG waveforms
- IHE PCD DMC
- IHE CD MEM LS
- Generalized Signal Quality Index
- Observation Identifiers and Settings

11073-10101c (Schluter)

• IHE PCD Rosetta identifiers for events, alerts, and alarms

Motions

- Create a new PAR 11073-10101.4 that maps 11073-10101 terms to LOINC terms, based on collaborative mapping work completed to-date and that a PAR be issue as soon as possible: offered by Cooper; seconded by Wiley. Passed unanimously.
- Create a new PAR on 11073-10101b, content consistent with presentation proposal. offered by Wittenber; seconded by Schluter. Passed unanimously.

- Action Items
 - o None

Wednesday - Q3 Oct. 07, 2015

Q3-Specific Participants (17)

- Recurring Participants from Q3 on Monday
- John Garguilo
- Ken Fuchs
- John Rhoads
- Chris Courville
- Stefan Schlichting
- Stephan Poehlsen
- Koichiro Matsumoto
- Kathryn Bennett
- Lisa Perry
- Joerg-Uwe Meyer
- Masato Tanaka
- Michael Faughn
- Mark Palmaffy

Minutes from Q3

Summary

NIST Tooling:

- IHE PCD v2 Tooling, RTMMS (Garguilo)
 - See posted presentation content
 - Introduction of RTMMS development team members
 - o Overview of Validation Tools
 - o IGAMT
 - o TCAMT
 - o DIM Editor
 - o IHE PCD Change Requests 109-121
 - o IHE Japan Connectathon Event 7-11 Sep. 2015
 - o Going from SQLDB to MongoDB
 - LOINC mapping views
- DIM Tooling Update (Faughn)
 - See posted presentation
 - o Background on DIM development
 - o Device Profile Editor
 - Recent Efforts
 - o FY 2016 Goals
- IEEE Publishing Tooling
- Discussion about tooling roadmap

- Motions
 - o None
- Action Items
 - o None

Wednesday - Q4 Oct. 07, 2015

Q4-Specific Participants (24)

- Recurring Participants from Q3 on Monday
- John Garguilo
- Ken Fuchs
- John Rhoads
- Chris Courville
- Koichiro Matsumoto
- Kathryn Bennett
- Lisa Perry
- Joerg-Uwe Meyer
- Masato Tanaka
- Toni Skokovic
- Mark Palmaffy
- Harry Rhodes
- Matthew Graham
- Gora Datta
- Martin Rosner
- Michael Faughn
- Dmytro Rud
- Brian Reinhold
- Frank Ploeg
- Mohd Anwar

Minutes from Q4

• Summary

Hosting Mobile Health (Datta/Graham)

- mFHAST
 - o Provide standards for communicating health information with "short messages"
 - o Low-cost, low infrastructure, low learning-curve
 - o Use Cases: diabetes, smoking cessation, weight management, et. al.
 - Immunization use case
 - o Barrier for adoption
- Consumer Mobile Health Functional Framework cMH2F
 - O Define security, privacy, and data control standards for secure mobile health apps
 - o How to interact with PHR and HER systems
 - White paper that will go to ballot in Jan. 2016

- Limited set of use cases
- o Request liaising with IEEE 11073

• FHIRframe

- o Development of mobile APIs
- Working with Continua
- o Request liaising with IEEE 11073
- o Mobile Health Weekly Friday calls 11:00 EDT
- o 100,000 Health Apps already for IOS platform
- \circ $\,$ Tom Ericsson (BT SIG) and mobileHealth SoU HL7 HQ has prepared a SOU with the BT SIG.
- o 21st Century outlook:

Continua Alliance Update (Reinhold)

- Remote Patient Monitoring
 - See posted presentation
 - o Maps Continua end-to-end architecture
 - o Health devices use IEEE 11073-20601 and BT low energy profiles
 - o PCHA data in IHE
- Motions
 - o None
- Action Items
 - o None

Thursday - Q1 Oct. 08, 2015

Q1-Specific Participants (23)

- Recurring Participants from Q3 on Monday
- Ken Fuchs
- John Rhoads
- Chris Courville
- Joerg-Uwe Meyer
- Mark Palmaffy
- Michael Faughn
- Brian Reinhold
- Stefan Schlichting
- Stephan Poehlsen
- Masato Tanaka
- Masaaki Hirai
- Ewout Kramer
- Stefan Karl
- Ron Shapiro
- Dmytro Rud
- Todd Cooper
- Matthew Graham
- Bruce Bray
- David Hay

- Summary
 - Patent policy and Anti-Trust statements of IEEE were presented and reviewed.
 - o Attendee introductions were made.
 - T. Cooper was re-elected as a HL7 Co-Chair.
 - Hosting FHIR WG (HL7 HCD Project #1103)
 - Review DSTU2 Resources (Kramer)
 - Not all parts of the specification are equally mature in DSTU 2.0.
 - Expect DSTU 2.1 to be released that focuses on workflow topics. To be determined by May 2016 HL7 WG meeting. New resources can be included in 2.1.
 - Some DSTU2.1 Resources are being frozen:
 - Final list @ http://wiki.hl7.org/index.php?title=FHIR_Ballot_Prep
 - This URL also includes a timeline for 2.1
 - NOTE: The group reviewed these and saw no issue for the device-related work.
 - "frozen" indicates that there will be no changes of these DSTU2 resources before DSTU3, unless there are major issues identified.
 - Note, OBSERVATION, VALUESET, and others have been "frozen"
 - Introduced concept of maturity metric for each resource ("0"=draft; "5"= nearly normative; etc.); to get to level "2", artifact has to be tested by 3 independent parties at a Connectathon...see TitanPad links.
 - T.Cooper provided a general review / overview of device-related FHIR resources and profiles. The following Links chart the group's discussion:
 - https://www.hl7.org/fhir/resourcelist.html
 - https://www.hl7.org/fhir/devicemetricobservation.html
 - https://www.hl7.org/fhir/resource.html#maturity
 - http://wiki.hl7.org/index.php?title=DSTU 2 QA guidelines
 - https://docs.google.com/spreadsheets/d/18HfXF7mUCUV7jACCG00ejFp6D-ibtvbmcgywNhn76lw/edit#gid=0
 - http://wiki.hl7.org/index.php?title=FHIR Connectathon 10
 - Discuss mACM effort in IHE ITI (Courville/Cooper)
 - Using FHIR to communicate alerts to the clinician
 - Trial use in IHE ITI (published in August 2015)
 - Roadmap for FHIR
 - Now working on DSTU 3.0, expected to be published for end of 2017
 - Primary expansion will be in the area of workflow support resources + care continuity
 - 2016 January Connectathon (Cooper)
 - Process for participating: FHIR management group determines the tracks for the Connectation (David Hay coordinates). See as an example, "HL7 FHIR 10" on the web.
 - Use cases...combination of Continua devices and PoCD devices (vital signs monitor, infusion pump, and ventilator).

- Todd to drive a kick-off web-conference to coordinate the preparation by HCD participants in the Connectathon.
- Draeger has 2 interns working on OpenSDC-to-FHIR converter. Also convert OpenSDC-to-PCD01 (DOC).
- Sign-up for Connectation has had more than 100 participants January participants are strongly requested to sign-up NOW.
 - o Interested parties included Continua, C4MI, OpenSDC / Draeger, QVera (Don), Dr. Meyer
 - FMG will meet in next 2-4 weeks to consider the scenarios
- Review of FHIR-DEV PSS (Cooper)
 - Proposing using current PSS to create a new PSS follow-on project to add maturity and alerts.

Motions

 To authorize closing of current FHIR DSTU Project #1103 and to open a new PSS, targeting work for DSTU3 that will incorporate the work the current in #1103 and add work for FHIR quality/maturity of the current resources and profile. Motion offered by Cooper and seconded by Courville. Passed unanimously.

• Action Items:

- Oconvene web-conference to coordinate work plan for January 2016 FHIR Connectation by HCD participants T. Cooper / C. Courville
- Supplemental Comments -
 - Alpo's comments: Here in Tampere University of Technology we'll have a course called Health Information Systems Laboratory during the 2016 spring term. We plan to set up a local FHIR server to which our student groups connect with their software... like a poor man's connecthatcon.

Thursday - Q2 Oct. 08, 2015

Q2-Specific Attendees (22)

- Recurring Participants from Q3 on Monday
- Ken Fuchs
- John Rhoads
- Chris Courville
- Joerg-Uwe Meyer
- Masato Tanaka
- Mark Palmaffy
- Michael Faughn
- Stefan Schlichting
- Stephan Poehlsen
- Todd Cooper
- Masaaki Hirai
- Koichiro Matsumoto
- Barry Miller
- Matthew Brzanschweig
- Mahesh Krishnan
- Kathryn Bennett
- Teri Neal
- David Tao

Minutes from Q2

Summary

Dialysis Support Update

- See posted presentation
- Background
 - No dialysis machine interoperability yet
 - o Various proprietary machine data communication protocols
 - o Interested in "teledialysis" remote monitoring of dialysis
 - Driven by an international shortage of nephrologists
 - Only 10% of U.S. based dialysis is at home today
- Key use cases
 - o Telemedicine and in-center monitoring
 - Monitoring clinical data
 - Direct lab feeds
 - Device/patient interface
 - Dialysis EMR
 - Remote monitoring: eICU example in Bogota, Columbia South America; in home remote monitoring
 - Monitoring of biomed data for maintenance
 - Monitoring of actions taken by user
- Key stakeholders
 - Most dialysis device vendors
 - O US dialysis plus international providers (about 80-90% represented by group)
 - o Government CMS ESRD program
 - o DaVita, Tufts Medical Center, Todd Cooper, Teri Neal (FMC), et. al.
- Standardization
 - Support the definition of an IEEE-compliant interface for machine interactions of dialysis devices
 - Options
 - IEEE 11073-10101 Amendment to the standard for terminology (possibly 10101b amendment)
 - IEEE 11073-103xx Specializations (leveraging -10316 from 2006)
 - HL7 Implementation guide
 - IHE Profile
 - As well as OpenICE and OpenSDC
 - Actions in process
 - Use Case Development (including biomedical maintenance and remote control)
 - Message Definition Development
 - Value set Development
 - Current Status
 - Devices are not part of the communications link tablets and other computing devices provide this access.
 - Home therapies are usually performed by the patient. A base assumption is that the device and the user interface are facilitated by Wi-Fi access.
 - Have today 181 attributes, but expected to grow by 50%.
 - "genmymodel.com"
 - Questions for today
 - Prioritization (human dialysis)

- Should this work be done in IHE PCD v IEEE 11073 vs. HL7?
- Strong desire to use HL7 FHIR and make cloud based
- Motions
 - o None
- Action Items
 - Jan W. volunteered to support the dialysis team as they formalize their work from this year into UML models and 11073 terminology definitions

Thursday - Q3 Oct. 08, 2015

Q3-Specific Attendees (18)

- Recurring Participants from Q3 on Monday
- Ken Fuchs
- John Rhoads
- Chris Courville
- Mark Palmaffy
- Joerg-Uwe Meyer
- Michael Faughn
- · Stefan Schlichting
- Stephan Poehlsen
- Koichiro Matsumoto
- Masato Tanaka
- Kathryn Bennett
- · Barry Reinhold
- Stefan Karl
- Paul Spadafora

- Summary
 - C4MI Update
 - Overview
 - See posted presentation
 - Vision
 - Mission
 - 501 © (3) public charity
 - Driven by healthcare system CEOs
 - Vendor outreach and request for collaboration
 - Use purchasing power of members to influence adoption of open interoperability standards
 - Plug and Play Interoperability Platform
 - Bedside Data Broker
 - Enterprise Data Broker
 - Multi-Enterprise Router
 - Interoperability Maturity Model
 - Protocol Interoperability Manager (Paul transitions to Marc)
 - Built on 10101, 10201, IHE PCD, Open ICE with DDS, OpenSDC

- Request for Collaboration (RFC)
- Collaboration Overview
- MDI Security
 - o Revision to the 11073 classic profiles
 - See Jan's posted Cybersecurity White Paper
 - Survey of healthcare domain standards and their treatment of communications security issues
 - Include ISO 27999 and JC2800 WG03 TG02 to bibliographies
 - Additional inputs:
 - Stan: Additional bibliography content collected by AAMI-UL JC2800 WG03 TG02
 - Stan: Reference work from ASTM E31.25 Committee
 - Alpo: Add ISO DIS 27799: https://www.iso.org/obp/ui/#iso:std:iso:27799:dis:ed-2:v1:en
 - Alpo: The ISO&IEC project team revising 62304 Software Life Cycle Processes standard wants to address cybersecurity better than now but the issue is open. Therefore inputs are welcome to us.
- Motions
 - o None.
- Action Items
 - o None.

Thursday - Q4 Oct. 08, 2015

Q4-Specific Attendees (17)

- Recurring Participants from Q3 on Monday
- Ken Fuchs
- John Rhoads
- Chris Courville
- Mark Palmaffy
- Joerg-Uwe Meyer
- Michael Faughn
- Stefan Schlichting
- Stephan Poehlsen
- Koichiro Matsumoto
- Kathryn Bennett
- Barry Reinhold
- Stefan Karl
- Paul Spadafora

- Summary
 - New Standards Planning:
 - Optimized Association
 - o Impacts to 10201: PHD, SDC (10207 BICEPS);
 - o Impacts to 10101:
 - o Impacts to 20101:
 - Point to Point over multiple Physical Layers

- CNS convergence
 - We are trying to be transport agnostic. How are clients discovered if one is transport agnostic?
- Specializations
 - o Dialysis et. al.
 - o 20 PHD standards
 - o 10301 Infusion
 - o 10302 Physiological patient monitors
 - o 10303 ventilator
- Remote Control
 - Have a PAR already defined. Closely tied with Security.
- Others?
 - o Private Terms (Schluter)
 - Code in the upper 4K that uniquely identified the term as a vendor private term.
 - High frequency ventilator terms
- UDI Summary from O&O WG Meeting
 - Should O&O provide a way to include the parsed-out components in the UDI separately or only include some form of the entire code decision: provide for a way to include the parsed-out components.
 - Should, in including the whole content, it will be in the form of a typical scanner output ("AIDC") or should it be "human readable form" (HRF)? Decision: "human readable form".
- Standards Roadmap Planning:
 - o HL7 HCD 3 Year Plan
 - GAS, FHIR, mHealth, Dialysis
 - o IEEE 11073 Plan
 - See posted content from Jan.
- Motions
 - To delegate the decision on Private terms designation methods to the IHE PCD F2F meeting offered by Schluter and seconded by Courville. Motion passed unanimously (10101b).
- Action Items
 - None

Adjourn Meeting

O Motion to adjourn – offered by Cooper seconded by Wittenber. Motion passed unanimously.