Agenda: 2022-September 19 thru 23 - IEEE 11073 and HL7 DEVICES Joint Working Group Meetings, In-Person (Plenary)

MEETING AGENDA
Dated 22 September 2022
Reference IEEE 11073 / HL7 DEVICES – Final Version 1.4

Joint meeting of HL7 Devices (DEV) WG + IEEE EMBS 11073 PoCD + PHD WGs, Plenary, In-Person
Monday 2022/09/19 – Friday 2022/09/23

HL7 DEV WG Leadership:
CO-CHAIR: TODD COOPER
CO-CHAIR: CHRIS COURVILLE
CO-CHAIR: JOHN GARGUILO
CO-CHAIR: JOHN RHOADS
CO-CHAIR: MARTIN HURRELL
CO-CHAIR: MARTIN ROSNER

IEEE 11073 SC Leadership:
CHAIR: KEN FUCHS
VICE-CHAIR: DAIDI ZHONG
SECRETARY: STEVEN DAIN
STANDARDS REP: TODD COOPER

emb-11073-Listserv: emb-11073-sc@LISTSERV.IEEE.ORG

IEEE 11073 PoCD WG Leadership:
CHAIR: STEFAN SCHLICTING
VICE-CHAIR: STEVEN DAIN
SECRETARY: KONSTANTINOS MAKRODIMITRIS

IEEE-SA Liaison to PoCD: TOM THOMPSON

11073 PoCD Google Group: ieee-11073-pocd@googlegroups.com

Location: Baltimore, Maryland + Virtual (WebEx)

HL7 Site (September 2022) Working Group Registration and Information:
September 2022 Plenary Working Group Meeting (In-Person Event)
DEV on-site Room: "Watertable B"

Whova App: DEV WG (Please note, DEV will NOT be using Whova for meetings, see WebEx link below)

Meetings are held in the U.S. Eastern Time Zone - see below for Daily Schedule in several time zones

1. Meetings are held in the U.S. Eastern Time Zone - see below for Daily Schedule in several time zones

2. TBD: There are joint meetings - O&O (on Thursday Q1 and Friday Q1) and Mobile Health will join us Q2/Thursday, FHIR-I (Q1 Friday).

In-Person + Hybrid (WebEx) Meetings Scheduled:
Monday (Q1-Q2) Plenary; (Q3-Q4) 1:45 PM ET Start, room "Watertable B"
Tuesday (Q1-Q4), 9 AM ET Start (IEEE 11073 Focus), room "Watertable B"
### Daily Schedule Overview

- We will be holding 3+ sessions per day (U.S. Eastern Daylight Time (EST) Time Zone)
- **IEEE-SA 11073 PoCD Working Group Meetings**
  - Tuesday is dedicated for the IEEE 11073 PoCD
  - **Note: 9 am ET Start Time**
- **HL7 DEV Working Group Meetings**
  - DEV WG Meetings in Room "Watertable B"
  - Monday Q3/Q4, Meeting Admin focused
  - Wednesday - Friday, HL7 DEV focus

### Host organization:

ANSI - HL7 international - please register in advance on the web site
(see [HL7 Registration (September 2022 Plenary Working Group Meeting)](http://www.hl7.org) for details).

ANSI Anti-Trust Policy:

Professional Associations, such as HL7, which bring together competing entities are subject to strict scrutiny under applicable antitrust laws. HL7 recognizes that the antitrust laws were enacted to promote fairness in competition and, as such, supports laws against monopoly and restraints of trade and their enforcement. Each individual participating in HL7 meetings and conferences, regardless of venue, is responsible for knowing the contents of and adhering to the HL7 Antitrust Policy as stated in §05.01 of the Governance and Operations Manual (GOM).
Thursday focused on Gemini SES and MDI work
• Note: 9 am ET Start Time each day

**Daily Schedule Overview** - Detailed daily agendas are below

**NOTE** that the Baltimore meetings occur in the United States **Eastern Time Zone**

<table>
<thead>
<tr>
<th></th>
<th>US Eastern</th>
<th>US Central</th>
<th>US West</th>
<th>Central European Time</th>
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<tbody>
<tr>
<td>Q1 9:00 AM</td>
<td>8:00 AM</td>
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<td>15:00 pm</td>
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<tr>
<td>Break 10:30-11 AM</td>
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<td>Q2 11:00 AM</td>
<td>10:00 AM</td>
<td>8:00 AM</td>
<td>17:00 pm</td>
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<td>Lunch 12:30-1:45 PM</td>
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<td>Q3 1:45 PM</td>
<td>12:45 PM</td>
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<td>19:45 pm</td>
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<tr>
<td>Break 3:00-3:30 PM</td>
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<td>Q4 3:30 PM</td>
<td>2:30 PM</td>
<td>12:30 PM</td>
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**Meeting Calendar:**

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<thead>
<tr>
<th></th>
<th>Monday 9/19</th>
<th>Tuesday 9/20</th>
<th>Wednesday 9/21</th>
<th>Thursday 9/22</th>
<th>Friday 9/23</th>
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<tbody>
<tr>
<td>Room</td>
<td>Watertable B</td>
<td>Watertable B</td>
<td>Watertable B</td>
<td>Pride of Baltimore</td>
<td>James</td>
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<tr>
<td>Q1 9:00 AM</td>
<td>HL7 Plenary</td>
<td>IEEE 11073</td>
<td>HL7 DEV</td>
<td>HL7 DEV Joint at O&amp;O</td>
<td>HL7 DEV Joint at O&amp;O</td>
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<td>Coffee Break (10:30 AM)</td>
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<tr>
<td>Q2 11:00 AM</td>
<td>HL7 Plenary</td>
<td>IEEE 11073</td>
<td>HL7 DEV</td>
<td>HL7 DEV</td>
<td>HL7 DEV (if needed)</td>
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<tr>
<td>Lunch Break (12:30 PM)</td>
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<tr>
<td>Q3 1:45 PM</td>
<td>HL7 DEV / IEEE Admin topics</td>
<td>IEEE 11073</td>
<td>HL7 DEV</td>
<td>HL7 DEV Joint with MHealth</td>
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<td>Cookie Break (3:00 PM)</td>
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<tr>
<td>Q4 3:30 PM</td>
<td>HL7 DEV / IEEE Admin topics</td>
<td>IEEE 11073</td>
<td>HL7 DEV</td>
<td>HL7 DEV</td>
<td>No meetings</td>
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**WebEx Information** (Monday Q3 - Friday Q2, September 19-23, 2022)

- **Meeting link:**
  https://ieeesa.webex.com/ieeesa/j.php?MTID=mb8f9c1692e7cf097593c3f60890e0e3a
- **Meeting number (access code):**
  2346 824 0592
- **Meeting password:**
  Ck3cxJjbg55
- from a mobile device (attendees only):
  • +1-646-992-2010,,23490935561## United States Toll (New York City)
  • +1-213-306-3065,,23490935561## United States Toll (Los Angeles)
- **Join by phone:**
  • +1-646-992-2010 United States Toll (New York City)
  • +1-213-306-3065 United States Toll (Los Angeles)
  • **Global call-in numbers**

**Room:** "*Watertable B*

**Recording Attendance:**

- Please Log September 2022 HL7 DEVICE and IEEE 11073 WG Attendance here
Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>RI</td>
<td>Requirements Interoperability</td>
</tr>
<tr>
<td>MC</td>
<td>Model-Centric (rather than document-centric)</td>
</tr>
<tr>
<td>RR</td>
<td>Regulatory (submission) - Ready</td>
</tr>
<tr>
<td>PoCD</td>
<td>Point-of-Care Device</td>
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<tr>
<td>PHD</td>
<td>Personal Health Device</td>
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<tr>
<td>SDPi</td>
<td>Service-oriented Device Point-of-Care Interoperability</td>
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<tr>
<td>MDI</td>
<td>Medical device interoperability</td>
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<tr>
<td>SES</td>
<td>Safety, Effectiveness &amp; Security</td>
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<td>EP</td>
<td>Ecosystem Pathway</td>
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Agenda:

HL7 Devices (DEV) WG Meeting

19 Sep 2022 Monday, ET

Q3 1:45 – 3:00 PM
Break 3:00 - 3:30 PM
Q4 3:30 PM - 5:00 PM

19 Sep 2022 Room "Watertable B"

Monday Q3, 1:45 - 3:00 PM (Eastern Time - ET U.S.)

- Welcome, Introductions, and Agenda Review (HL7 Officers)
  - ANSI Anti-Trust Policy:

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- Agenda review:
  - Add PSS-1980 Gemini SES+MDI Update - Need a whole quarter // added Wednesday Q3 (spillover to Q4 as needed)
  - Add PSS-2091 Physical Activity Implementation Guide (from project proposal PSS-2069) Project review - Confirmed Thursday Q3 joint with mHealth...
  - other topics for consideration?...
  - ...

- General updates / announcements
  - Note: HL7 International Education on Demand Site for members: https://www.pathlms.com/hl7
    - E.g., "How To" videos on Confluence and Jira
  - HL7 Co-Chair Updates (Co-Chairs)
    - Chief Standards Development Officer: Dan Vreeman, Deputy Chief: Diego Kaminker
    - Other new TSC members: Jean Duteau (TSC Vice-Chair), Gora Datta, Rich Geimer
  - Note: HL7 International Education on Demand Site for members: https://www.pathlms.com/hl7
    - E.g., "How To" videos on Confluence and Jira
  - DEV WG Health Metrics: Working Group Health Files (September ’22 Interim Reports)
  - General updates / announcements
  - Other announcements / updates / suggestions from attendees...
    - 2022SEP NIB site is now OPEN: Book mark to submit Notice of Intent to Ballot (NIBs):
  - May 2022 WG Meeting Minutes Review / Approval (Garguilo)
    - Assumes review has occurred by attendees and those interested
Monday Q4, 3:30 - 5:00 PM (Eastern Time - ET U.S.)

• Review of Mission, Charter, SWOT - see DEV Main Page
• Current Versions of WG documents, for discussion (To Do: John Rhoads please validate for latest versions...)
• Housekeeping: Current Versions of WG documents, for discussion (Rhoads)
  • Review of DEV WG required documents
  • HL7 DEV Confluence Page providing mission and relationships: https://confluence.hl7.org/display/HCD
  • Download HL7 Decision making practices (Default_HL7_WG_DMP_2019_V5.2_Clean)
  • Download 3 Year Plan (2021-->2024)
  • Download SWOT Analysis (2019-01-17 Document)
  • Download Mission and Charter (2019-01-17 Document)
  • HL7 DEV Working Group "Health Reports and the Project and Ballot Health Metrics: (Rhoads)
    • The final WG Health and PBS Metrics reports have been released for the 2022 May cycle: 2022 May Final Reports
    • New WG Health Metric:
      • A new metric has been added to Work Group Health measuring the number stale issues your WG has in JIRA across product families. Since this is new, it is purely informational at this time, but eventually anything in the red zone will result in an increment on your work group health. This metric will be recalculated before each report is released.
      • See links to current "HL7 WG Health" documents at end of this Agenda

Monday Q5, 5:30 - 7:30 PM (Eastern Time - ET U.S.): Co-Chairs Meeting and Dinner

IEEE EMB 11073 PoCD WG Meeting

<table>
<thead>
<tr>
<th>20 Sep 2022</th>
<th>Tuesday, ET</th>
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<tbody>
<tr>
<td>Q1, Q2</td>
<td>9:00 AM –12:30 PM</td>
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<tr>
<td>Breaks</td>
<td>10:30 - 11:00 AM</td>
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<tr>
<td>Q3, Q4</td>
<td>1:45 PM - 5:00 PM</td>
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20 Sep 2022  Room "Watertable B"

IEEE EMB 11073 PoCD WG Meeting

Tuesday Q1, Q2, Q3, Q4 (9:00 AM - 5:00 PM, ET)

Meeting link (details above): https://ieeesa.webex.com/ieeesa/j.php?MTID=mb8f9c1692e7cf097593c3f60890e0e3a

Recording Attendance:
Please Log September 2022 HL7 DEVICE and IEEE 11073 WG Attendance here
IEEE 11073 PoCD WG meeting (September 20, 2022) Hybrid/Draft agenda (9 AM to 5 PM US ET -Eastern Time))

9:00a | Welcome, Introductions, and Agenda Review [Stefan/Kosta]

9:10a | IEEE Disclosures [Stefan/Steve]
   Call for Potential Essential Patents Holders. Please contact IEEE WG co-chairs with just name and affiliation.
   IEEE-SA Copyright Policy - IEEE Copyright Policy
   IEEE Meeting Conduct – IEEE Code of Conduct
   IEEE Ethics Policy - IEEE Code of Ethics

11073 SC Update [Ken]

9:15-9:30 am | Agenda Review [Kosta] / Review Previous Minutes and New Members[Kosta]

9:30-10:15 am | Update regarding PARs & Standards (Tom Thompson, IEEE-SA Liaison)
   IEEE 11073 PARs, Projects, SDOs and Analytics
   IEEE reports, dates and stats

10:15-10:30 am | PHD Update (Daidi, Ray, Isabel)

=====
Break 10:30-11 am

=====

11:00-11:30 am | Update from SDC SG (Björn, Martin K. & David)
   Vote on 1070x PAR Scope Change Proposals (Ken)

Update from the IDCO SG (Paul Schluter)

11:30 am-12:00 pm | Update from the Nomenclature SG (Paul Schluter)
   IEEE 11073 Nomenclature

12:00-12:30 pm | 11073 Stories/Pilots and Conformity - FDA/CDRH ASCA presentation: Simon Choi, Scott Colburn (Anil, Kosta, Stefan, Sajjad)

12:30-1:45 pm | LUNCH

1:45-2:15pm | Nomenclature continued (Paul)

2:15-2:30pm | 11073 lifecycle from cases, development to recognition to adoption to value for patients (Kosta, Stefan, Sajjad, Todd, Ray, Isabel, Martin, All)

2:30-3:00pm | 11073 to FHIR/PHR/EHR: how to integrate, map, coordinate medical device data for high quality clinical data and analytics (Kosta, Isabel Tejero FDA, Greg Pappas FDA, Danica Marinac-Dabic FDA, all)

3:00-3:30 pm | Break

3:30-4:00 pm | Presentation on AAMI/UL 2800 (Geetha Rao)

4:00-4:30 pm | PoCD WG organization, meetings & wrap-up

Greg Zeller ISO TC 215/WG2 ADA update
**New Member from LG**

Logistics next WG meeting

4:30 pm Closing and Adjourn [Stefan/Kosta/Steve]

- **CHAIR:** STEFAN SCHLICHTING, PHD
- **VICE-CHAIR:** STEVEN DAIN, MD
- **SECRETARY:** KONSTANTINOS MAKRODIMITRIS, PHD

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**HL7 Devices (DEV) WG Meeting**

<table>
<thead>
<tr>
<th>21 Sep 2022</th>
<th>Wednesday, ET</th>
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<tr>
<td>Q1</td>
<td>9:00–10:30 AM</td>
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<td>Breaks</td>
<td>10:30 - 11:00 AM</td>
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<td>12:30 - 1:45 PM</td>
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<td>3:00 - 3:30 PM</td>
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<tr>
<td>Q2</td>
<td>11:00 AM - 12:30 PM</td>
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<tr>
<td>Q3</td>
<td>1:45 - 3:00 PM</td>
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<tr>
<td>Q4</td>
<td>3:30 - 5:00 PM</td>
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21 Sep 2022 Room "Watertable B"

**Wednesday Q1, 9 AM - 10:30 AM (Eastern Time - ET U.S.)**

Meeting link (details above): [https://ieeesa.webex.com/ieeesa/j.php?MTID=mb8f9c1692e7cf097593c3f60890e0e3a](https://ieeesa.webex.com/ieeesa/j.php?MTID=mb8f9c1692e7cf097593c3f60890e0e3a)

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- **Welcome, Introductions, and Agenda Review** (HL7 Officers)
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- **Review Monday Q3/4 proceedings (@Cochairs)**
- **Co-Chair Report Out (@ Cochairs)**
  1. Report-out by Co-Chairs of Monday Q5 meeting ...
  2. TSC 2022-09-19: WGM + Co-Chair+Dinner
- **PHD Status update/report out - (Martin Rosner)**
  - IEEE ACOM and BT Generic Health Sensor update (Erik Moll, Javier Espina)
- **DoF:** "Larger bundle of device data as an example" (Zulip thread) (Jacob Andersen)
- **DoF:** PoCD – Device Settings Reporting / Snapshot Reporting (Elliot Silver)
- **PoCD and PHD IG Publication topics/issues/other (John Rhoads, Martin Rosner)**
- **(move to Wed. Q2) - Report out on IHE-DEV North American (and European) "Connectathons" - held Sept 12 - 16 in Atlanta and Montreal (John Rhoads John J. Garguilo)**

**Break** from 10:30 AM - 11:00 AM ET
Wednesday Q2, 11:00 AM - 12:30 PM (ET U.S.) Room "Watertable B"

Recording Attendance:

Please Log September 2022 HL7 DEVICE and IEEE 11073 WG Attendance here

- (NIST) Tooling & Testing (Michael Faughn, John J. Garguilo)
  - RTMMS new version release update and progress
  - Tooling updates
  - Connectathon 2022 Test Report Out (Atlanta and Montreux)

Wednesday Q3 + Q4 Room "Watertable B"

- (John Rhoads / Todd Cooper) DeviceAlert project:
  1. Consider leveraging the "What is a 'Device'?" metamodel mentioned previously to explain what is unique about the alerting devices & DEVAL space but without having to include the whole topic (again, linkable article)
  2. DISCUSS: (John Donnelly) Alert Policy
     a. Should the DeviceAlert project also include something around a care provider's "alert policy"?
     b. By analogy, security experts who see "risk management" as 100% a security issue, always talk about managing security policies
     c. Medical device alerting includes similar policies; however, they are never formalized (via standards) and are definitely not computable
     d. This is a similar concern to the ISO/IEC JWG7 "SES" concern and is tied in with requirements from 60601-1-8, 11073-10702, and similar standards
     e. Alert management systems (DIS / DAS / cDAS etc.) all include support for configuring in accordance with implementation environment policies, e.g., around escalation BUT...
     f. Is there value in making this COMPUTABLE (as is the case with security infrastructure) and if so, how?

- (Todd Cooper) "What is a 'Device'?
  a. Reference Confluence page/site: "What is a Device"
  b. Review general "heads up" content proposed for the updated Device resource description
  c. Review the content being added to the SDPi 1.0 TF-1 front matter related to the scope of the IHE DEV TF (this will be the first version of the broadened IHE domain (vs. PCD only)
  d. Discuss whether and who and where to include and publish the broader question of "What is a 'Device'?" material
     i. Consider Martin's work around establishing a metamodel w/ attributes, looking for "clusters" and leveraging that to address some common uses of the term: device
     ii. Link in the previous material from Paper: What is a device? confleunce page
     iii. Determine the best place to publish this article - for example as an article in the FHIR space similar to workflow and other topics (and linkable from the device-related resources!)
     iv. A previous project proposal (pre PSS) was floated for this topic but never fully advanced .. should it be now?
     v. All in favor of Dr. Martin Hurrell being the Editor-in-Chief, raise your hand! (you cannot vote, Martin ...)
     vi. Is this a Gemini (joint IHE-HL7 article) and should fly under that flag? Or simply an HL7 internal paper? (it will be used / leveraged in the IHE DEV TF-1 discussion)

- (Todd Cooper) MDIRA Project Update (esp. relevance to SDPi + EP group discussions)

Wednesday Q4 Room "Watertable B"

- Gemini SES+MDI Update - (Cooper)
  - PSS-1980 Status Update
  - SDPi Version Roadmap
  - GitHub Repository Wiki Article Review
  - ASCII Doc tour...

- Adjourn IHE-DEV Wednesday

HL7 Devices (DEV) WG Meeting
22 Sep 2022 DEV Room "Watertable B"; Joint w/ O&O room "Pride of Baltimore"

Thursday Q1 (9:00 - 10:30 AM ET)

Meeting link (details above): https://ieeesa.webex.com/ieeesa/j.php?MTID=mb8f9c1692e7cf097593c3f60890e0e3a

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- Welcome and Introductions (new attendees)

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- NO MEETING - DEV at O&O
- Q1 Joint at Orders and Observation WG + BR&R (Device Scope Technical Paper); room "Pride of Baltimore"
  - Update on Device resource discussions (Marti Velezis)
  - Update on PSS-2005 DeviceAlert project (John Rhoads)
  - Update on PSS-1980 Gemini SES+MDI (Todd Cooper)
  - Update on "What is a device?" technical report (Todd Cooper)

From O&O Agenda:

- Device Scope Whitepaper
- Gemini Safe, Effective & Secure Medical Device Interoperability (SES+MDI)
- Resource topics:
  - Device
    - specialization.systemType and specialization.category bindings
    - Mappings - PHD, PoCD
    - Identify stable elements, those that have changed and need further testing
    - Examples (review/clean-up based on R5)
    - FMM 3 or 4?
  - Device Definition
    - Scope/Boundary
    - Mappings to EUDAMED, GUDID (Catalog)

Break from 10:30 AM - 11:00 AM ET

Thursday Q2 (11:00 AM - 12:30 PM ET) Room "Watertable B"
Recording Attendance:

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- Anesthesia WG Topic
  - Allocate: partial Quarter
  - Intra-procedural Anesthesia FHIR IG Work
- Nomenclature - RTM status update (Paul Schluter)
  - Paul Schluter to provide Nomenclature update - RTM + on 10101b progress (and milestone!)
  - Nomenclature work/report can spill over to Q3 if needed

Thursday Q3 (1:45 - 3:00 PM) Room "Watertable B"

- Joint with Mobile Health WG (Matt Graham/Gora Datta/Nathan Botts/Frank Ploeg - Mobile Health Co-Chairs)
  - Welcome & Introductions (Mobile Health WG Agenda)
  - General mHealth WG Updates w/report out and status of on-going projects (Graham/Datta)
  - PSS Updates (e.g., "Unique Mobile Health App Identifier") (Datta)
  - PSS-2091 Physical Activity Implementation Guide Update (Laurie Whitsel)
  - Others...

- 2:30 PM Meeting Session w/ Physical Activity Alliance and the American Heart Association - continuation as they jump into the HL7 FHIR standards development world
  - Laurie Whitsel (Laurie.Whitsel@heart.org) and Maria Isler (Maria.Isler@heart.org) are the project sponsors.
  - They will be coming to the September WGM and are hoping to meet with certain relevant work groups to talk about their project proposal for an IG defining standards for physical activity measurement and enhancement.
  - Russell Buchanan (russell.buchanan@accenture.com) will be supporting them at the WGM. Devices is one of the work groups that seems to have overlap/interest.
  - Laurie, Maria, and Russ to provide an ~10 minute overview/presentation of work and proposal
  - Specifically, the project is looking at being able to capture measures related to physical activity level. This may well involve leveraging real-time device information such as step counts or heart rate monitor information.
  - Currently looking for sponsors, co-sponsors and interested parties, so please think about if/how the HC Devices work group might like to be involved.
    - Also reaching out to PC, FM, OO, MH, CIC, and the Gravity project

Thursday Q4 (3:30 - 5:00 PM) Room "Watertable B"

- Open Discussion / Topics Arising from this week... (Co-Chairs)
  - IEEE POCD 11073 additional topics
  - Interoperability standards success stories/Pilots and Conformity updates around the globe
  - Joint Standards Workgroup (Konstantinos Makrodimitris) Meetings - Planning 2022-2023
    - considerations about a future 2022 Meeting (Virtual) hosted by FDA
  - Regulatory map/coordination on interoperability
  - HL7 DEV Topics?

- Action Items overview going forward from September 2022(HL7/IEEE/ISO) and coordination with other SDOs
  - Action Item Review
  - HL7 PSS "Action Plan"

- Planning January 16-20 '23 WGM (Co-Chairs)
  - HL7 announced it will likely be a live event in Las Vegas, Nevada
  - Feedback from these/September '22 meetings
  - Objectives / Core Topics for January '23 (incl. joint sessions)
    - NOTE: we have been offered a full Quarter with OO - what day/quarter works best for DEV?
  - HL7 Room Reservation for January 2023 Meetings (Garguilo)
    - John J. Garguilo ACTION: Garguilo will reserve rooms and schedule joint quarters - needs to be completed by next week.
      - To include full Q with O&O and DEV (OO hosting)

- Meeting Adjournment (Co-Chairs)
Friday Q1 (9:00 AM - 10:30 AM ET)

TBD if WebEx will be available in O&O Meeting Room

If available - Meeting link (details above): https://ieeesa.webex.com/ieeesa/j.php?MTID=mb8f9c1692e7cf097593c3f60890e0e3a

Recording Attendance:

Please Log September 2022 HL7 DEVICE and IEEE 11073 WG Attendance here

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<tr>
<th>23 Sep 2022</th>
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<tr>
<td>Q1 at O&amp;O</td>
<td>9:00 AM - 10:30 AM</td>
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<td>Break</td>
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23 Sep 2022 O&O Room: "James"

**Note:** Joint DEV at O&O (Joint) - Members welcomed to join Joint O&O and FHIR-I WG Sessions in Q1 (No official DEV Meeting - room is available for)

- Friday Q1 (OO, DEV) - O&O Agenda
  - NOTE: joint meeting with O&O and may include FHIR-I WG
  - Device Overflow from Thurs Q1 with DEV group
  - If WebEx is available, the same connection link will be used: https://ieeesa.webex.com/ieeesa/j.php?MTID=mb8f9c1692e7cf097593c3f60890e0e3a

Friday Q2 (11:00 AM - 1:00 PM ET)

Open - NO meetings scheduled

Recording Attendance:

Please Log September 2022 HL7 DEVICE and IEEE 11073 WG Attendance here

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<td>Q2</td>
<td>11:00 AM - 1:00 PM</td>
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<td>End of Meetings</td>
<td>1:00 PM</td>
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23 Sep 2022

Welcome and Daily Agenda Review (Cooper)

ANSI Anti-Trust Policy:

Professional Associations, such as HL7, which bring together competing entities are subject to strict scrutiny under applicable antitrust laws. HL7 recognizes that the antitrust laws were enacted to promote fairness in competition and, as such, supports laws against monopoly and restraints of trade and their enforcement. Each individual participating in HL7 meetings and conferences, regardless of venue, is responsible for knowing the contents of and adhering to the HL7 Antitrust Policy as stated in §05.01 of the Governance and Operations Manual (GOM).

Current Versions of WG documents, for discussion (To Do: John Rhoads please validate for latest versions...)

September 2022 IEEE-11073 Point of Care Device (PoCD) WG Topics for consideration:

1. Add new topic here (which will be added below to schedule by IEEE PoCD Co-chairs/Secretary)

Pre Sept Meeting items noted...

- **(Todd Cooper)**: "What is a 'Device'?"
  1. Review general “heads-up” content proposed for the updated Device resource description
  2. Review the content being added to the SDPI 1.0 TF-1 front matter related to the scope of the IHE DEV TF (this will be the first version of the broadened IME domain (vs. PCD only)
  3. Discuss whether and where to include and publish the broader question of “What is a ‘Device’?” material
     - Consider Martin’s work around establishing a metamodel w/ attributes, looking for “clusters” and leveraging that to address some common uses of the term ‘device’
     - Link to the previous material from Paper: What is a device? confluence page
     - Determine the best place to publish this article – for example as an article in the FHIR space similar to workflow and other topics (and linkable from the device-related resources!)
  4. A previous project proposal (pre PSS) was floated for this topic but never fully advanced... should it be new?
  5. All in favor of Dr. Martin Hurrell being the Editor-in-Chief, raise your hand! (you cannot vote, Martin...)
  6. Is this a Gemini (joint IHE-HL7 article) and should fly under that flag? Or simply an HL7 internal paper? (It will be used leveraged in the IHE DEV TF-1 discussion)

- **(Todd Cooper)**: DeviceAlert project:
  1. Consider leveraging the “What is a ‘Device’?” metamodel mentioned previously to explain what is unique about the alerting devices & DEVAL space but without having to include the whole topic again, linkable article
  2. Discuss: (John Donnelly) Alert Policy
     - Should the DeviceAlert project also include something around a care provider’s “alert policy”?
     - By analogy, security experts who see “risk management” as 100% a security issue, always talk about managing security policies.
     - Medical device alerting includes similar policies; however, they are never formalized (via standards) and are definitely not computable
     - This is a similar concern to the ISO/IEC JWG7 “SES” concern and is tied in with requirements from 60601-1-8, 11073-10702, and similar standards
     - Alert management systems (DIS / DAS / cDAS etc.) all include support for configuring in accordance with implementation environment policies, e.g., around escalation BUT...
     - Is there value in making this COMPUTABLE (as is the case with security infrastructure) and if so, how?

- **(Todd Cooper)**: MDIRA Project Update (esp. relevance to SDPI + EP group discussions)
  1. Note: (Confirmed with Marti V.) DEV can meet w/ OO on Friday Q1 as spillover from Thursday or if additional discussion needed around Device resource
  2. (Paul Schluter) Confirmed: Paul Schluter to provide Nomenclature update - RTM + on 10101b progress (and milestone?) – Paul indicated he can present Wed or Thursday.
  3. (Michael Faughn, John J. Garguilo) NIST Tooling (primarily Michael Faughn - RTMMS new version release update and progress), available to present Wed Q2 or Thurs Q3
  4. (Co-Chairs) Co-Chair Report Out
  5. Morning after Co-Chairs Monday Q5 meeting – perhaps Wednesday Q1 –
  8. (John Rhoads, Martin Rosner) PoCD and PHD Publication topics/issues/other – topic for Wed Q12
  9. Joint Working Group meetings
     a. (Matthew Graham, Gora Dutta) MHealth (Thursday Q2)
     b. (Marti Valenz) Confirmed joint at O&O Thursday Q1
  10. **(Todd Cooper)**: FHIR-I - do we/DEV need meeting with FHIR-I team outside joint at O&O?? (waiting on FHIR-I Agenda to be formulated...)