Welcome to the Confluence pages of the HL7 Devices Work Group

Mission

The HL7 Devices WG was established to coordinate and facilitate the integration of health care devices to ensure interoperability and harmonization of data within healthcare entities by:

- Establishing standardized version 2.x and version 3 content to support health care device interoperability at the enterprise level
- Harmonizing device data models between HL7 and other organizations including ISO/IEEE 11073
- Harmonizing and coordinating device terminology usage within HL7 components
- Harmonizing and coordinating device data messaging and interchange syntax
- Working with the FHIR project to create device related resources consistently with existing device standards, domain information models, and domain use cases and context.
- Support revision and harmonization of the Clinical and Laboratory Standards Institute (CLSI ) Point of Care Test (POCT) and laboratory automation standards
- General coordination and harmonization between HL7 and other national and international organizations involved in health care device informatics and interoperability
- Engaging the device informatics ecosystem to participate in standards development efforts including medical device manufacturers, information integrators, and data consumers.

Complete Mission and Charter

Relationships

- Clinical and Laboratory Standards Institute (CLSI) POCT Consensus Committee and Laboratory Automation and Informatics Consensus Committee
- World Health Organization eHealth Standardization Coordination Group (WHO eHSCG)
- Integrating the Healthcare Enterprise Device Domain (IHE DEV)
  - Personal Connected Health Program (PCH)
  - Device Point of Care Integration Program (DPI)
  - Patient Care Device Program (PCD)
- Global Consortium for eHealth Interoperability (joint HIMSS-HL7-IHE initiative)
- Health Information and Management Systems Society (HIMSS)
  - Personal Connected Health Alliance (formerly Coninua Alliance)
- FDA Center for Devices and Radiological Health
  - CDRH
  - Digital Health
- ISO TC 215 Health Informatics – Systems and Device Interoperability
  - WG2 Systems and Device Interoperability
  - WG11 Personalized Digital Health
- U.S. National Institute for Standards and Technology (NIST) Medical Device Communications Test Project
  - CEN TC 251 WG II - Technology and Applications
  - Association for the Advancement of Medical Instrumentation (AAMI)
  - AAMI/UL Joint Committee 2800
  - ISO/TC 121/SC4 Anaesthetic and Respiratory Equipment / Vocabulary and Semantics
  - Heart Rhythm Society (HRS)
  - OR.NET
  - Regenstrief Institute
  - MDPnP Medical Device “Plug-and-Play” Interoperability Program

Charter

Work Products and Contributions to HL7 Processes

The work products pursued by the WG, often in coordination with the HL7 internal and external groups identified, include the following:

- Support implementation and maintenance of the HL7 (v2.x) observation reporting
- HL7 (v3) observation reporting

Co-chairs

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John Walsh
Implantable Devices - Cardiac (IDC) messaging and support terminology
Response to any issues arising regarding v2.x Chapter 13 (Lab Automation)
Terminological and structural representation support for device data in the products of other HL7 working group products (e.g. Anesthesia)
Support revision of RCRIM Annotated-ECG related standard components
Support revision of POCT related standard components
Support FHIR device-related resource definitions

The Work Group will develop specifications using the principles and language of the Services Aware Interoperability Framework (SAIF) Canonical Definition (CD) and the restrictions and specializations of the HL7 SAIF Implementation Guide (IG) to ensure traceability from conceptual to logical to implementable specifications. When submitting artifacts or methodology to the HL7 SAIF IG the Work Group will develop this content in compliance with the principles and language of the SAIF CD.

Excluded from the scope are:

- Imaging-related data (e.g., from DICOM enabled systems) except insofar as DICOM, the Imaging Integration WG and this DEV WG jointly deem appropriate;
- Point-of-care device interoperability that is within the scope of the ISO /IEEE 11073 standards, except as jointly deemed appropriate by ISO TC215 WG2, IEEE EMBS 11073, CEN TC251 WGIV and this DEV WG
- Patient care (esp. vital signs) data not communicated from devices, except as the Patient Care WG and this DEV WG jointly deem appropriate
- Devices that do not have communications capability (or where that capability is limited only to self identification), e.g. orthopaedic implant, etc.
Agenda: 2022-May 9 thru 13 - IEEE 11073 and HL7 DEVICES Joint Working Group Meetings, Virtual

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