IHE profiles for personal device interoperability

A MedTech Europe Webinar
Wednesday, 13 January 2021, 15.00-16.30 CET
Welcome
Michael Strübin, Director Digital Health, MedTech Europe
Alexander Ihls, IHE International
## Practicalities

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## Agenda

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| 15:00  | Welcome                                                               | • Michael Strübin, *MedTech Europe*  
  • Alexander Ihls, *IHE International* |
| 15:10  | Interoperability: the bigger picture                                 | • Petra Wilson, *HIMSS*                                                   |
| 15:25  | The impact of the PCHAlliance/Continua collaboration with IHE and HIMSS | • Charles Parisot, *IHE Europe*                                          |
| 15:40  | Profiles for medical devices, testing and conformity assessment, new directions | • Thom Erickson, *HIMSS*                                                  |
| 16.10  | Q&A                                                                  |                                                                          |
| 16:30  | Closing & thank you                                                  |                                                                          |
About MedTech Europe

The European trade association for the medical technology industry including diagnostics, medical devices and digital health.

OUR MEMBERS

130+ multinational corporations*

50+ medical technology associations
The MedTech Industry in Europe

- **€ 115 billion market**
- **500,000+ Medical devices**
- **675,000+ employees**
- **5,000+ In vitro diagnostic tests**
- **500,000+ employees**
- **50,000+ Companies of which 95% are SMEs**
- **675,000+ employees**
- **#1 In filing patent applications 12% more than computer technology industries and double the pharmaceutical industry**
Interoperability and medtech

- Lack of interoperability seen as critical barrier for digital health deployment
- Growing momentum for buyers and authorities to recommend/adopt standards
- MTE founded Interoperability Working Group in 2018/19
- MTE published Interoperability position paper and call for action (July 2019)
- Current focus: stakeholder engagement, training and education
Definition: DiGA (digital health application)

- **Medical Device**
  - Classes I and IIa MDR (+ provisional rules MDR)

- **Intended use**
  - Centered on patients, possibly including treating doctors

- **Main function**
  - Relies on digital technologies

- **Functionalities**
  - Detection (monitoring), treatment, palliation / abatement of pain, compensation of diseases, injuries, disabilities

**General requirements**

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<thead>
<tr>
<th>Proof of</th>
<th>Consumer protection</th>
<th>Patient safety</th>
<th>Interoperability</th>
<th>Quality of medical content</th>
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<td>CE-Marking</td>
<td>Privacy &amp; Data-Security</td>
<td>Robustness</td>
<td>User friendliness (Patients &amp; Physicians)</td>
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**Application**

- for listing in DiGA-registry according to §139e SGB V
- compliances with general requirements
  - Safety, Functionality, Quality Privacy, Data-IT-Security
- positive care effects
  - Patient-related Structural and procedural effects and/or medical benefit

**BfArM**

- Consulting (Fees)
- Examine & decide (within 3 months)

**Standard Care**

- Listing: DiGA Registry
- Trial period: preliminary listing (12 months)

Follow us to stay up-to-date:
- health innovation hub (hih)
- @hih2025
- hih-2025.de - Newsletter
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Interoperability: the bigger picture

Petra Wilson, HIMSS
What is interoperability?

- The ability of different information systems, devices and applications to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally.

Definition of interoperability: [https://www.himss.org/resources/interoperability-healthcare](https://www.himss.org/resources/interoperability-healthcare)
Standards: a key driver of interoperability

Vocabulary/Terminology Standards
Content Standards
Transport Standards
Identifier Standards
Privacy and Security Standards

.... but not the only tool we need
The challenges of health data interoperability remain largely organisational.

Many practical questions about data remain in the health care environment

Location: where is the data?
Format: is the data digitised?
Structured: is it unstructured data?
Definition - subjective / source
Competing legal rules and frameworks
….and then we add personal health devices into the mix

Location : Data held by individuals
Format: multiple and changing
Structured: image, text, voice …
Definition : natural language / multiple languages
Consumer protection legislation
We have a little way to go yet, but IHE and HIMSS are taking big steps
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The impact of the PCHAlliance/Continua collaboration with IHE and HIMSS

Charles Parisot, IHE Europe
Who We Are

**IHE** is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information.

**HIMSS** is a global advisor and thought leader supporting the transformation of the health ecosystem through information and technology.

**Accelerate Health**: HIMSS initiative with innovation-focused content and connectivity platform from HIMSS that walks the cutting edge of healthcare.

**PCHAlliance**: an Accelerate Health Community to accelerate technical, business and social strategies necessary to advance personal connected health via connected health technologies.
Joint IHE / PCHAlliance Boards Proposal

• Establish a joint Exploration Committee to work out the vision for PCHA, HIMSS and IHE.

• ..with the goal to create a formalized cooperation agreement allowing the organizations to pursue common goals together.
High-Level Goals

1. Accelerate
   1. Reduce the confusion and consolidate scarce resources and support.
   2. Create a structure dedicated to pursuing data exchange standards (on platforms such as FHIR) and accelerate their adoption.
   3. Ensure that lessons learned and valuable work already done is not lost and is appropriately applied to new emerging paradigms for connected health.

2. Ensure that ongoing strategy adequately respects the differences in the *connected health market* versus *enterprise healthcare developers*.

3. Anchor this effort in an organization with sufficient scope and reach to adequately support the work.
PCHA & IHE Alignment
Discussion Topics

• Market Analysis
• Profile / Life Cycle Processes
• Product Development Support
• Profile / Domain Alignment
• Conformity Assessment Scheme
• Events (Connect-a-thons, Hack-a-thons, Educational Seminars)
• MARCOM Strategy
• Early Success Candidates

Addressing PCHA & IHE Pain Points

• Improving Market Awareness / Alignment / Recognition
• More with the same resources
• Shorten Development Cycles
• Simpler Solutions
• Coordinating with External Groups
• Reduce Mindshare Competition
• More robust Testing and Tooling
• Effective Marketing & Communications
Role in Ecosystem

- CDG a global standard through ITU
- Extend IHE profiles for personal connected health and participate in both IHE USA and Europe Connect-a-thons.
- Development of new standards within the IEEE PHD for acquiring medical-grade data.
- Integrating work group collaboration within both CTA and PCHAlliance.
- Joint initiative on SDO Global Health Informatics Standardization
- Driving IEC’s SyC AAL, Assisted Living Working Group
- Working to make medical-grade data available over BTLE
- First to profile HL7 FHIR for remote patient monitoring
- Advancing HL7 standards to support remote patient monitoring
- We enable standards-based solutions to be truly interoperable
Align & Accelerate

- CDG a global standard through ITU
- Accelerate standards development and adoption by consolidating resources and reducing confusion around implementing healthcare standards.
- Development of new standards within the IEEE PHD for acquiring medical-grade data.
- Integrating work group collaboration within both CTA and PCHAlliance
- Joint initiative on SDO Global Health Informatics Standardization
- We enable standards-based solutions to be truly interoperable
Mission Accomplished

- **Market Opportunity Analysis**
  - Determined plenty of opportunity already identified

- **Domain & Project Mapping**
  - Personal Health Devices Observation Upload profile TI released
  - New IHE Devices Domain operational

- **Test Process & Tooling**
  - Continua Test Tool Integrated with Gazelle Test Management Platform
  - IHE Global Conformity Assessment Scheme drafted

- **MARCOM**
  - Articulate compelling value of IHE solutions in stakeholder language
Marketing

- PCHA and IHE Establish Joint Task Force to Simplify Collection of Personal Health Data into Health Record Systems

- PCHA Makes Global Health IT Standards Development Personal

- New Continua Design Guidelines Support Health in the Home by Targeting Direct-to-Cloud Solutions

- Industry Collaboration Accelerating Mobile Health Data Standards
As hospitals deploy EMRs into their most critical care areas, the need to acquire data from Medical Devices is increasingly evident.

- **Accurate data**
  - Improved patient safety and care outcomes
  - Improved discharge decisions
  - Improved Case Management, Infection Prevention and QA

- **“Real time” data available to MD, clinicians and care managers**
  - More clinically sound diagnosis and orders
  - Earlier initiative of appropriate interventions and therapies
  - Prevention of undetected patient deterioration (“failure to rescue”)
  - More “proactive” patient management (↓LOS, ↑reimbursement)
  - Better outcomes

- **Automated Data Acquisition**
  - Increased MD productivity and satisfaction
  - Increased Nursing productivity and satisfaction
  - Outcomes data warehousing
Key IHE PCD – Profiles – Deployed Today in Hospitals

- Rosetta Terminology Management (RTM)
- Enterprise sharing of Patient Care Data (DEC)
- PCD Alarm Communication Management (ACM)
- Point-of-care Infusion Verification (PIV)
- Implantable Device – Cardiac Observation (IDCO)
- Waveform Content Module (WCM)


➤ Implemented and Tested

➤ Covers more than 500 types of hospital device measurements

➤ Open committee membership to any of the IHE Domains including the Device Domain. Simply requires an IHE Intl Membership with a low fee and the necessary Intellectual Property protection: https://www.ihe.net/about_ihe/governance/#Membership and https://www.ihe.net/participate/join_ihe/
IHE Patient Care Devices
Use Cases & Profiles - An example

● Use Case:
  • **Reporting of device data** (heart rate, infusion volume, airway pressure, etc.) to consuming systems such as EMRs

● Profile:
  • [DEC] Device to Enterprise Communications, based on HL7 V2 syntax and ISO/IEEE 11073 Device Model and Nomenclature.
  • Also adopted by Continua Guidelines for WAN reporting.
  • [DEC Profile in the IHE Device Technical Framework]
The DEC profile allows a consuming system (DOC) to receive patient clinical information including vitals, demographics, settings, and location from a reporting device/system (DOR).

The Subscribe to Patient Data (SPD) option allows the consumer to filter the data by:

- Medical Record #
- Device Class
- Update Interval
- Start & End Times
- Parameter Class
- Patient Location
Rosetta Terminology Mapping [RTM]

To access RTM:
- **NIST Terminology Browser**: [https://rtmms.nist.gov/rtmms/index.htm](https://rtmms.nist.gov/rtmms/index.htm)
Measurements within a 4-level structure with coded units
### DEC Profile: PCD-01 Transaction Example

Measurements within a 4-level structure with coded units

- Device Level (MDS)
- Virtual Device Level (VMD)
- Channel Level (CHAN)
- Measurement Level

#### Device Level (MDS)
- MDC_DEV_MON_PHYSIO_MULTI_PARAM_MDS

#### Virtual Device Level (VMD)
- MDC_DEV_MON_PHYSIO_MULTI_PARAM_MDS

#### Channel Level (CHAN)
- MDC_DEV_MON_PHYSIO_MULTI_PARAM_MDS

#### Measurement Level
- MDC_DEV_MON_PHYSIO_MULTI_PARAM_MDS
NIST Testing Tools & IHE Conformity Assessment

IHE Gazelle Testing Platform

Validation
- Test Management
- Test Services
- Test System Development Components
  - Test Harness
  - Test Resources
  - Test System Instance

Specification Constraints
- Standards Profile
- Domain Framework
  - Terminology/Nomenclature
  - Test Case/Value(s)

Based on Use Case(s)

User/Device

Report

Testable Assertions: IHE-PCD Validation Requirements Used by NIST Test Tools

- HL7 Message Definitions
- Value Set Constraints
- IEEE / Rosetta Nomenclature
- Test Case Specific Assertions
- Etc.

https://ihe-pcd.nist.gov/
https://www.ihe-europe.net/testing-IHE/gazelle
Access to Testing IHE PCD Profiles

➔ NIST Testing Tool covers the following IHE PCD profiles:

- DEC profile
- ACM profile
- PIV profile
- IPEC profile
- IDCO profile
- MEMDMC profile
- MEMLS profile

➔ Access the test tool at: https://ihe-pcd.nist.gov/

➔ IHE Conformity Assessment available for 4 PCD Profiles:

- Enterprise sharing of Patient Care Data (DEC) with Rosetta Terminology Management (RTM)
- Point-of-care Infusion Verification (PIV)

➔ Request Conformity Assessment for your product: mailto:casc-secretary@ihe.net
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Profiles for medical devices, testing and conformity assessment, new directions

Thom Erickson, HIMSS
Remote Patient Monitoring

- Pandemics can move swiftly
- Reduce patient anxiety, increase staff safety
- “Entertainment Grade” data
- Lack of Interoperability
Connectivity vs. Interoperability

- Many vendors provide *connectivity*.

- Need to quickly produce billions of sensors and platforms that can automatically communicate wherever they are deployed.

- This is where *interoperability* is essential.
Your Health, Your Data, Your Device, Your Choice

- We can exchange messages with trusted individuals using applications such as text and email.

- Because open standards describe specific mechanisms to enable this exchange of information.

- Likewise, open standards allow you to manage your health collecting your data with your device and easily share it with your doctor.
Continua Implementation Framework

http://www.itu.int/rec/T-REC-H.810-201312-I
IHE Devices Domain Programs

- **Patient Care Devices (PCD)**
  - In-clinic patient-centric point-of-care medical devices or information system communication

- **Device Point of Care Interoperability (DPI)**
  - Device-to-device interoperability technology that is optimized for high-acuity environments

- **Personal Connected Health (PCH)**
  - Device-related harmonization required for seamless integration between the clinical and consumer environments.
First Aligned Profile - POU

- Framework for interoperable ecosystem of simple medical sensors. The end result being more choice and lower prices for patients.
- Brings consistency and clarity to data being reported to enterprise health systems.
- Maps observations to FHIR resources and delivers them to a FHIR server, reducing the domain specific knowledge required to work with health information.
Transcoding the PHD data into FHIR Resources

Medical Device System Object
Agent’s bureaucratic and device information

Metric object
Describes a measurement weight, blood pressure, ECG waveform
Generic Measurement, Examples, Mapping to FHIR

**Temperature**
- **Numeric Value:** 37.8
- **TYPE:** MDC_TEMP_ORAL
- **Units:** MDC_DIM_DEGC
- **Time Stamp:** t

**Weight**
- **Numeric Value:** 167.8
- **TYPE:** MDC_MASS_BODY_ACTUAL
- **Units:** MDC_DIM_LB
- **Time Stamp:** t

**Generic Numeric Measurement**
- **Simple numeric Value:** x
- **TYPE:** 11073 10101 Nomenclature code
- **Units:** 11073 10101 Nomenclature code
- **Time Stamp:** t

**Observation Resource**
- **code:** Nomenclature code
- **valueQuantity.value:** x
- **valueQuantity.code:** Nomenclature code
- **effectiveDateTime:** t
Upload the FHIR resources

PCHA Gateway
Generate FHIR resources

Get information about H&FS
Authenticate & get token
Upload package (FHIR resources)

Capability Exchange
oAuth Server
Health & Fitness FHIR server
Persisting data
Pass-through data
Every PHD whose data can be mapped to the 11073 Metrics

Can be mapped to one of the six FHIR measurement profiles

Now and in the future

http://build.fhir.org/ig/HL7/PHD/
Simplifying Adoption

- IEEE 11073-10206 Abstract Information Model
  - Create a stand alone simplified information model independent of transport.

- BT SIG Generic Health Sensor
  - Create generic health sensor service and profile to communicate a wide range of health-related observations.

- D2C Constrained Devices Implementation
  - Create implementation guidance for observation uploads to health & fitness server from a compute constrained sensor.
Implementing Remote Patient Monitoring

- Reduce Patient Anxiety
- Increase Staff Safety
- Conserve Clinical Resources
- Save Lives
- To Simplify & Accelerate
- One Open API for Global Scale
- Test Framework to Assure
- Implementation Software

Fundamentals of RPM: Rapid Implementation with Commercial Ready Software
Connect *Any* Device to *Any* Health Record System

- Simulates existing or future devices
- Links proprietary devices into standards-based ecosystem
- Rapid testing throughout the development process

- Standard software to simplify and accelerate adoption
- Resolves common Bluetooth interoperability issues
- Low cost test platform

- Improves staff workflows
- Streamlines regulatory approvals
- Open source software to engage community experts

CODE Product Description
Conformity Assessment

- CAS 1 – Requirements for IHE Authorized Test Labs
  - Uniform Processes
  - Technical Requirements
- CAS 2 – Requirements for Conformity Assessment
  - Resources
  - Uniform Test Methods
- Conformity Assessment Scheme by Continua
  - Uniform Assessment
  - Self-Declaration & 3rd Party Certification
Test & Tools

- Continua Test Tool / Gazelle Integration
  - Download configuration
  - Upload the test report
- POU Profile Test Cases Package
  - TSS&TP Documents
  - Test Cases Scripts
- Remote Test Capability
  - Web Application
  - Local Agent
Conformance and Interoperability Testing

Continua Test Tool

Compliant

Certified

IHE Europe Connectathon

IHE North American Connectathon
Value Proposition

- Reduce Anxiety at Home
- Increase Staff Safety at Clinic
- Conserve Resources
- Global Scale
- Enhanced Care
- Reduced Burden
- Sustainable Revenue
Additional Information

• Fundamentals of Remote Patient Monitoring Blog Series
  • Increasing staff safety and reducing patient anxiety
  • Your Health, Your Data, Your Device, Your Choice
  • Collecting Personal Health Data for Clinical Decisions and Advice for Product Managers
  • Sharing personal health monitoring data with clinic of choice and Guidance for Developers
  • Demonstrate your Remote Patient Monitoring product meets customer requirements
  • Rapid Implementation with Commercial Ready Software

• Remote Patient Monitoring Implementation
  • CODE Product Description
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