MedTech Europe
from diagnosis to cure

IHE profiles for personal device interoperability

A MedTech Europe Webinar
Wednesday, 13 January 2021, 15.00-16.30 CET

YouTube

Welcome

Michael Strübin, Director Digital Health, MedTech Europe
Alexander Ihls, IHE International

MedTech Europe
from diagnosis to cure

Practicalities

- All attendees are asked to mute themselves.
- To comment or ask questions during the presentations, please use the chat.
- Before and during Q&A please ask your questions using the chat or “raise your hand” feature.
- The session will be recorded.
- The recording and slide deck will be made available to you.

Agenda

Time	Topic	Speakers
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.

MedTech Europe
from diagnosis to cure

OUR MEMBERS

130+ multinational corporations*

50+ medical technology associations

The MedTech Industry in Europe

€ 115
billion market

675,000+
employees

50,000+
In vitro diagnostic tests

500,000+
Medical devices

27,000+
Companies of which
95% are SMEs

#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

SGB V

DiGA acc. § 33a SGB V

Main function

Relies on digital technologies

Functionalities

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

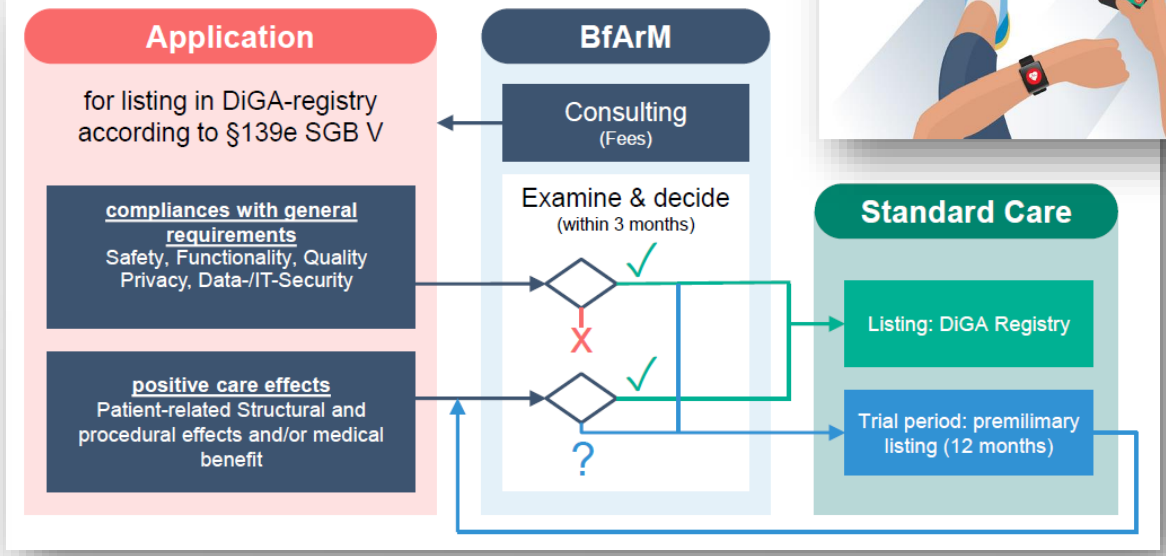
General requirements

Proof of

CE-Marking	Consumer protection
Privacy & Data-Security	Patient safety
Robustness	Interoperability
User friendliness (Patients & Physicians)	Quality of medical content

Digital Health Applications (DiGA)

DVG FastTrack



Follow us to stay up-to-date:

health innovation hub (hih)

@hih2025

hih-2025.de - Newsletter

Agenda

Time	Topic	Speakers
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**	

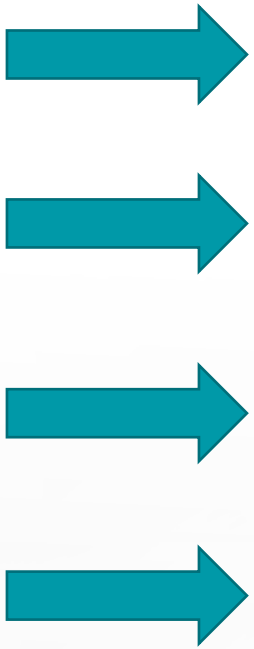
Interoperability : the bigger picture

Petra Wilson, HIMSS

MedTech Europe
from diagnosis to cure

What is interoperability?

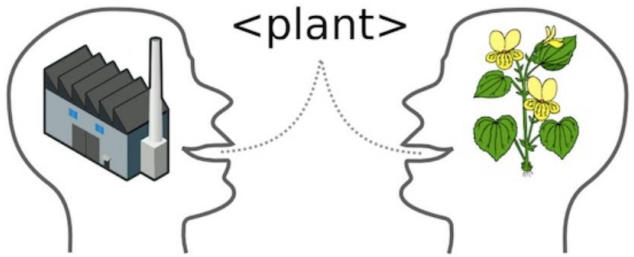
- The ability of different information systems, devices and applications to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health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



- Legal
- Organisational
- Semantic
- Technical

Definition of interoperability: https://www.himss.org/resources/interoperability-healthcare

Standards: a key driver of interoperability



Vocabulary/Terminology Standards

Content Standards

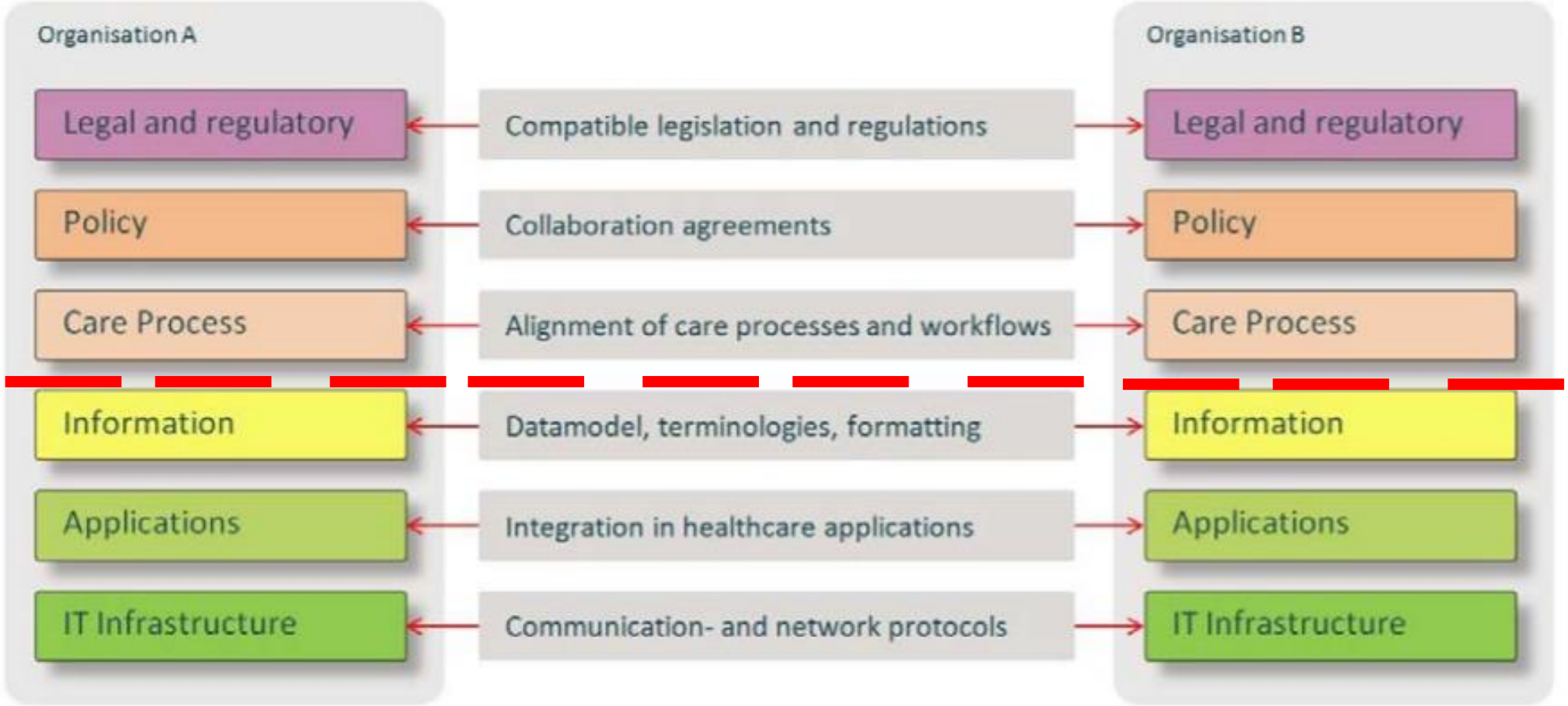
Transport Standards

Identifier Standards

Privacy and Security Standards

…. but not the only tool we need

The challenges of health data interoperability remain largely organisational



Graphic: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf

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

Agenda

Time	Topic	Speakers
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**	

The impact of the PCHAlliance/Continua collaboration with IHE and HIMSS

Charles Parisot, IHE Europe

MedTech Europe
from diagnosis to cure

Who We Are

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

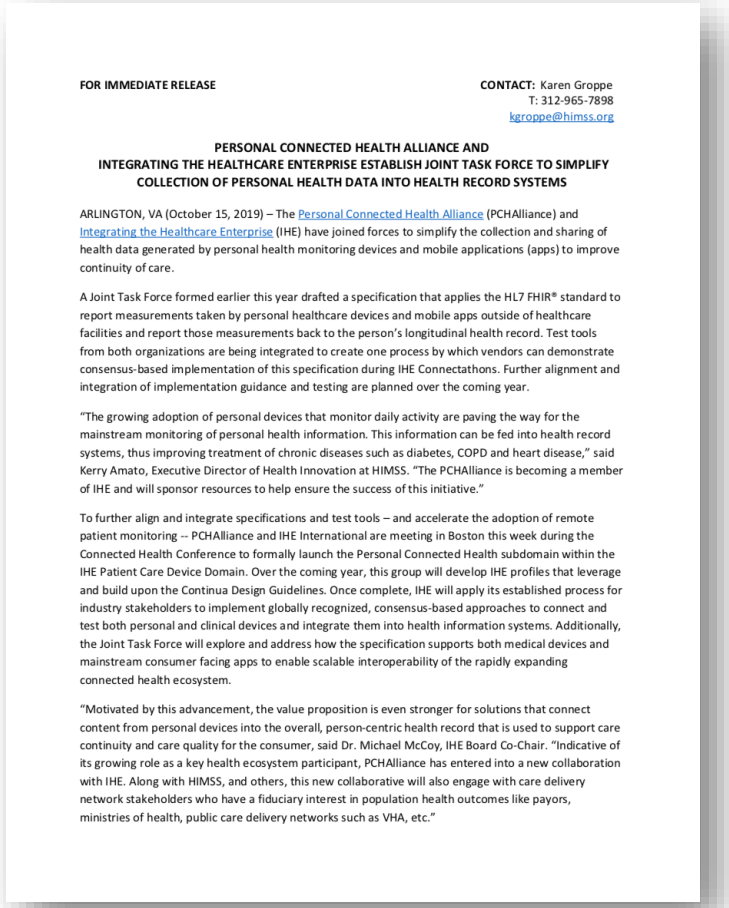
HIMSS is a global advisor and thought leader supporting the transformation of the health ecosystem through information and technology.

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.



FOR IMMEDIATE RELEASE

CONTACT: Karen Groppe
T: 312-965-7898
kgroppe@himss.org

PERSONAL CONNECTED HEALTH ALLIANCE AND INTEGRATING THE HEALTHCARE ENTERPRISE ESTABLISH JOINT TASK FORCE TO SIMPLIFY COLLECTION OF PERSONAL HEALTH DATA INTO HEALTH RECORD SYSTEMS

ARLINGTON, VA (October 15, 2019) – The Personal Connected Health Alliance (PCHAlliance) and Integrating the Healthcare Enterprise (IHE) have joined forces to simplify the collection and sharing of health data generated by personal health monitoring devices and mobile applications (apps) to improve continuity of care.

A Joint Task Force formed earlier this year drafted a specification that applies the HL7 FHIR® standard to report measurements taken by personal healthcare devices and mobile apps outside of healthcare facilities and report those measurements back to the person's longitudinal health record. Test tools from both organizations are being integrated to create one process by which vendors can demonstrate consensus-based implementation of this specification during IHE Connectathons. Further alignment and integration of implementation guidance and testing are planned over the coming year.

"The growing adoption of personal devices that monitor daily activity are paving the way for the mainstream monitoring of personal health information. This information can be fed into health record systems, thus improving treatment of chronic diseases such as diabetes, COPD and heart disease," said Kerry Amato, Executive Director of Health Innovation at HIMSS. "The PCHAlliance is becoming a member of IHE and will sponsor resources to help ensure the success of this initiative."

To further align and integrate specifications and test tools – and accelerate the adoption of remote patient monitoring -- PCHAlliance and IHE International are meeting in Boston this week during the Connected Health Conference to formally launch the Personal Connected Health subdomain within the IHE Patient Care Device Domain. Over the coming year, this group will develop IHE profiles that leverage and build upon the Continua Design Guidelines. Once complete, IHE will apply its established process for industry stakeholders to implement globally recognized, consensus-based approaches to connect and test both personal and clinical devices and integrate them into health information systems. Additionally, the Joint Task Force will explore and address how the specification supports both medical devices and mainstream consumer facing apps to enable scalable interoperability of the rapidly expanding connected health ecosystem.

"Motivated by this advancement, the value proposition is even stronger for solutions that connect content from personal devices into the overall, person-centric health record that is used to support care continuity and care quality for the consumer, said Dr. Michael McCoy, IHE Board Co-Chair. "Indicative of its growing role as a key health ecosystem participant, PCHAlliance has entered into a new collaboration with IHE. Along with HIMSS, and others, this new collaborative will also engage with care delivery network stakeholders who have a fiduciary interest in population health outcomes like payors, ministries of health, public care delivery networks such as VHA, etc."

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.

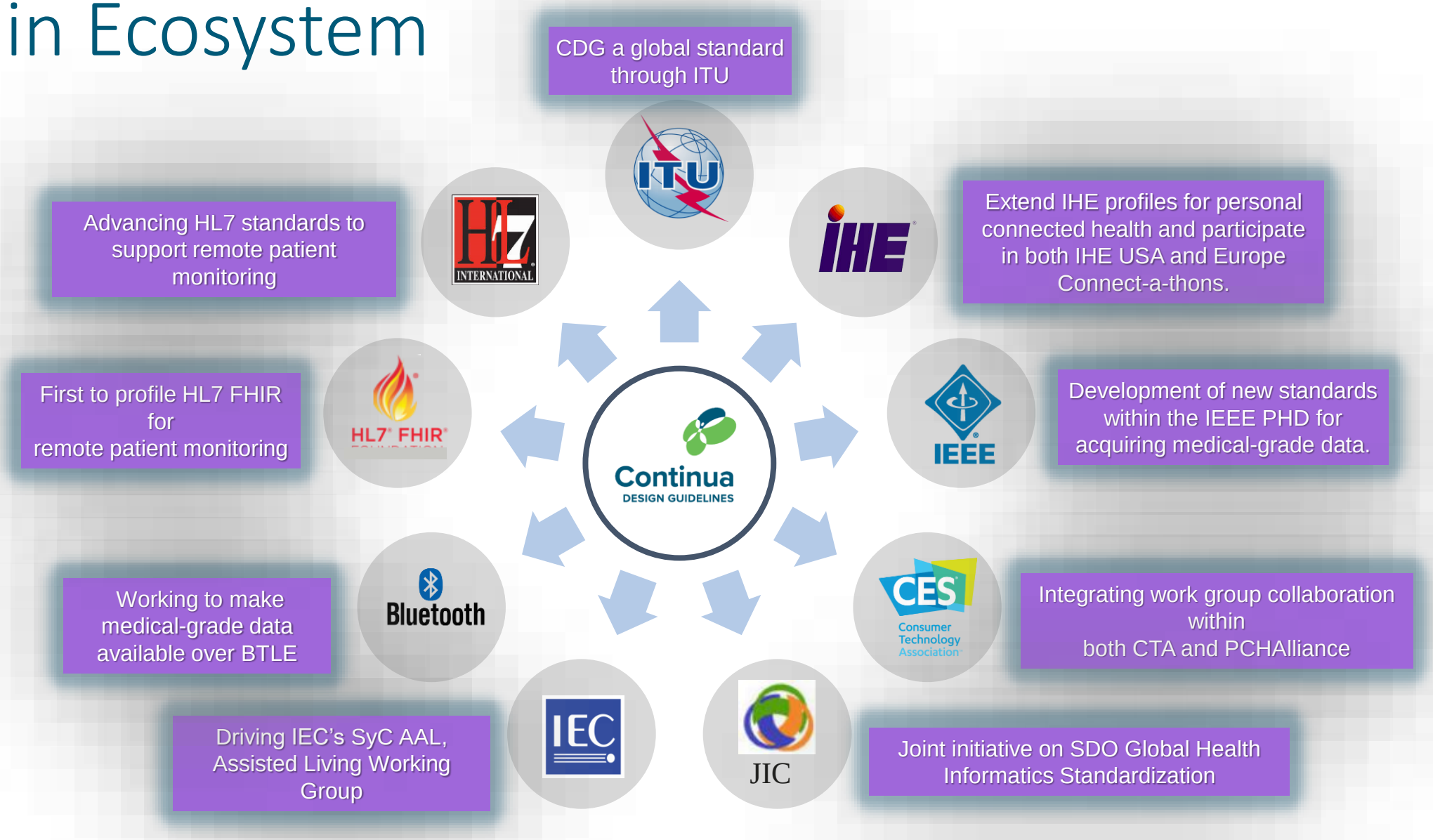
PCHA & IHE Alignment Discussion Topics

- 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

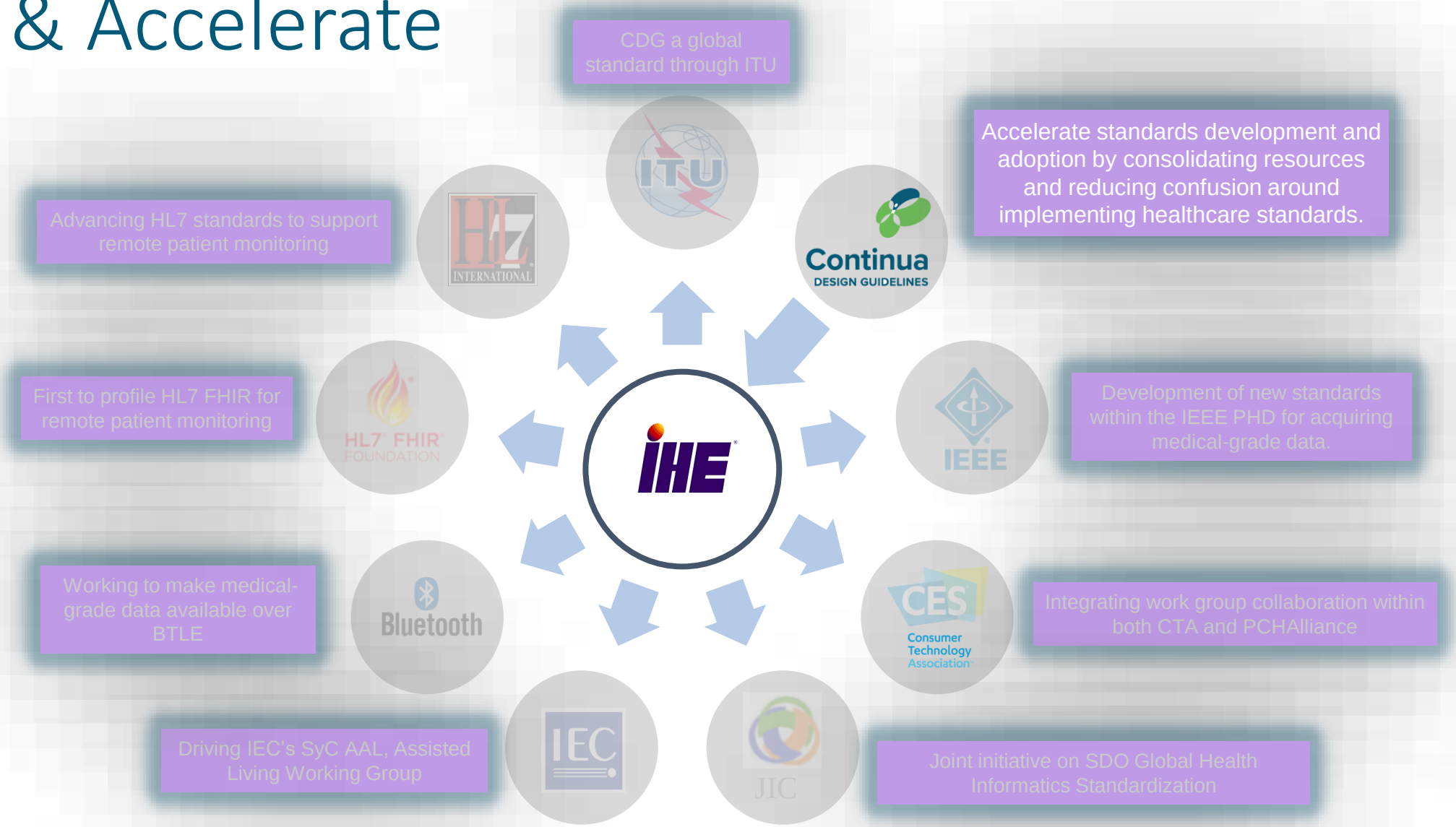
- Improving Market Awareness / Alignment / Recognition
- More with the same resources
- Shorten Development Cycles
- Simpler Solutions
- Coordinating with External Groups
- Reduce MindshareCompetition
- More robust Testing and Tooling
- Effective Marketing & Communications

Role in Ecosystem



We enable standards-based solutions to be truly interoperable

Align & Accelerate



We enable standards-based solutions to be truly interoperable

IHE Integrating the Healthcare Enterprise

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
  - https://www.pchalliance.org/news/pcha-and-ihe-establish-joint-task-force-simplify-collection-personal-health-data-health-record
- PCHA Makes Global Health IT Standards Development Personal
  - https://www.pchalliance.org/news/pcha-makes-global-health-it-standards-development-personal
- New Continua Design Guidelines Support Health in the Home by Targeting Direct-to-Cloud Solutions
  - https://www.pchalliance.org/news/new-continua-design-guidelines-support-health-home-targeting-direct-cloud-solutions
- Industry Collaboration Accelerating Mobile Health Data Standards
  - https://www.iheusa.org/story/industry-collaboration-accelerating-mobile-health-data-standards

IHE Patient Care Device Focus & Achievements

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)

➔ Openly available on in the IHE Patient Care Device Technical Framework: https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_TF_Vol1.pdf

➔ 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

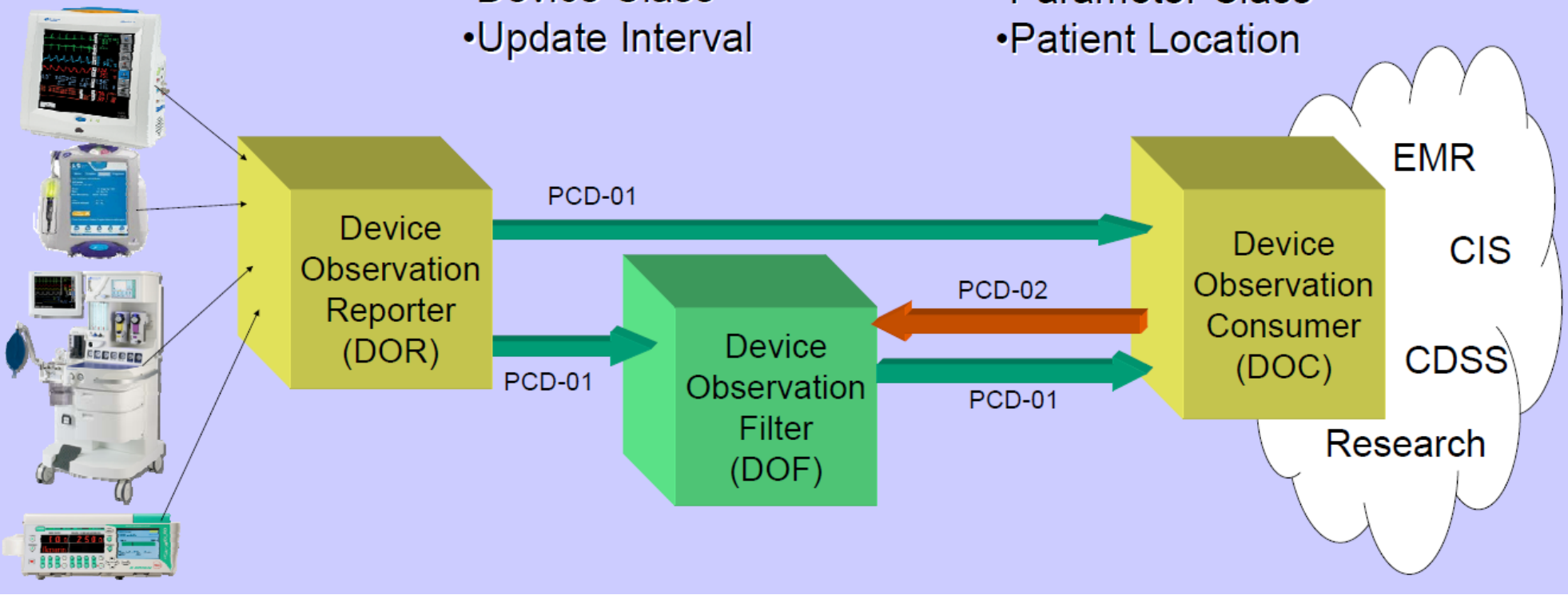
- Use Case:
  - **Reporting of device data** (heart rate, infusion volume, airway pressure, etc.) to consuming systems such as EMRs
- Profile:
  - [DEC] Device to Enterprise Communications, based on HL7 V2 syntax and ISO/IEEE 11073 Device Model and Nomenclature.
  - Also adopted by Continua Guidelines for WAN reporting.
  - DEC Profile in the IHE Device Technical Framework

Device to Enterprise Communication

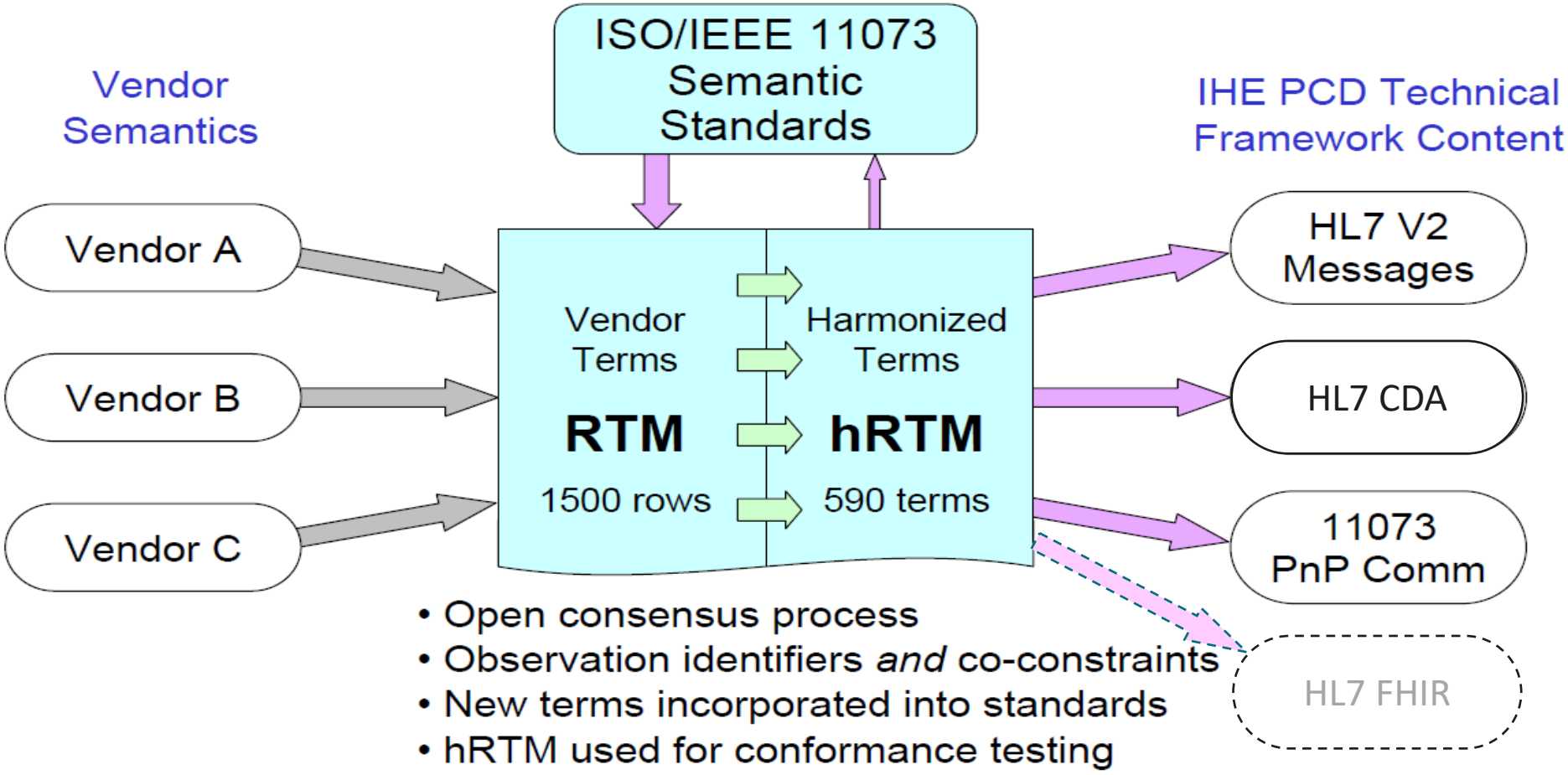
The DEC profile allows a consuming system (DOC) to receive patient clinical information including vitals, demographics, settings, and location from a reporting device/system (DOR).

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:

- ***IHE Wiki:*** https://wiki.ihe.net/index.php/PCD_Rosetta_Terminology_Mapping
- ***NIST Terminology Browser:*** https://rtmms.nist.gov/rtmms/index.htm

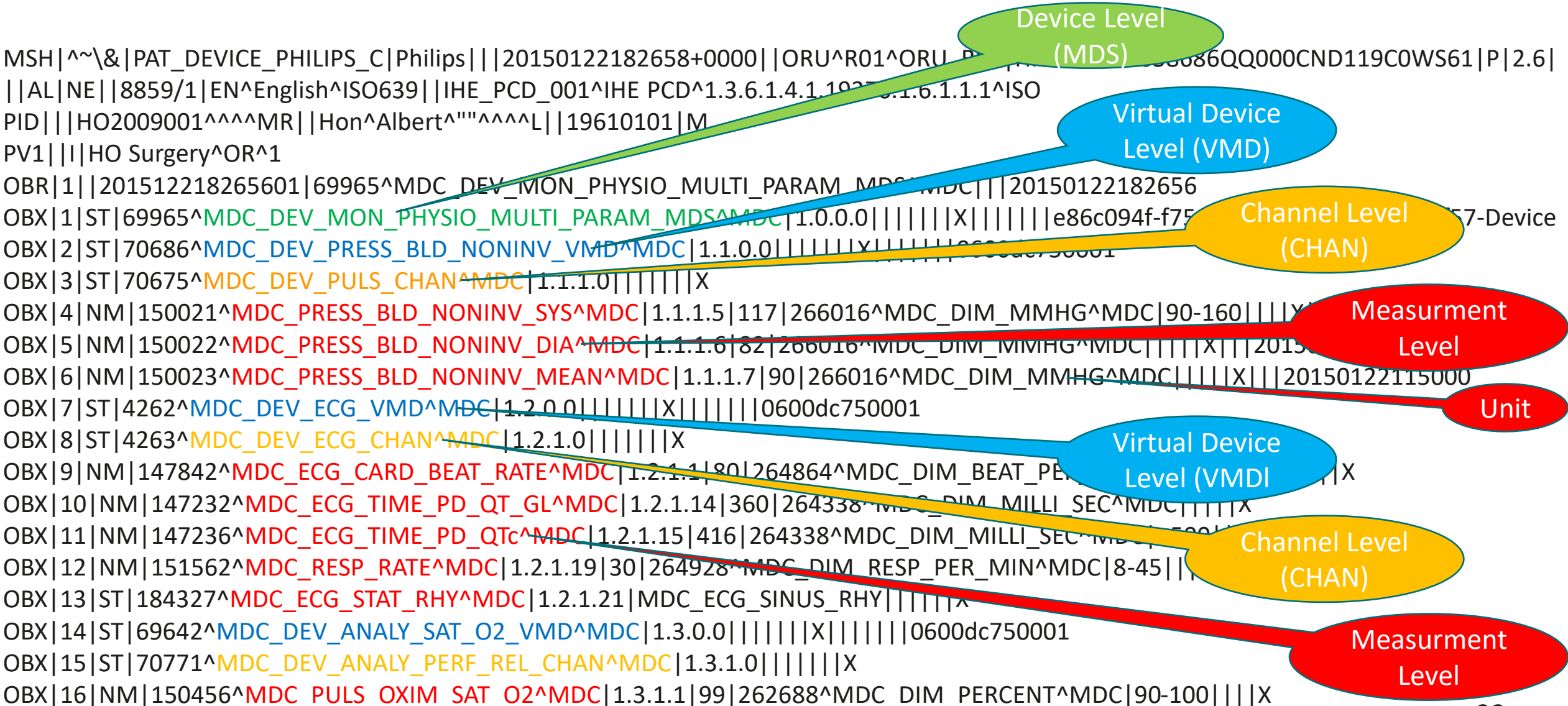
DEC Profile : PCD-01 Transaction Example

Measurements within a 4-level structure with coded units

```
MSH|^~\&|PAT_DEVICE_PHILIPS_C|Philips|||20150122182658+0000||ORU^R01^ORU_R01|HP0122182658686QQ000CND119C0WS61|P|2.6|
||AL|NE||8859/1|EN^English^ISO639||IHE_PCD_001^IHE PCD^1.3.6.1.4.1.19376.1.6.1.1.1^ISO
PID|||HO2009001^^^^MR||Hon^Albert^""^^^^L||19610101|M
PV1||I|HO Surgery^OR^1
OBR|1||201512218265601|69965^MDC_DEV_MON_PHYSIO_MULTI_PARAM_MDS^MDC|||20150122182656
OBX|1|ST|69965^MDC_DEV_MON_PHYSIO_MULTI_PARAM_MDS^MDC|1.0.0.0||||||X|||||||e86c094f-f751-4acf-92b2-38f11c1f6f57-Device
OBX|2|ST|70686^MDC_DEV_PRESS_BLD_NONINV_VMD^MDC|1.1.0.0||||||X|||||||0600dc750001
OBX|3|ST|70675^MDC_DEV_PULS_CHAN^MDC|1.1.1.0||||||X
OBX|4|NM|150021^MDC_PRESS_BLD_NONINV_SYS^MDC|1.1.1.5|117|266016^MDC_DIM_MMHG^MDC|90-160|||X|||20150122115000
OBX|5|NM|150022^MDC_PRESS_BLD_NONINV_DIA^MDC|1.1.1.6|82|266016^MDC_DIM_MMHG^MDC|||||X|||20150122115000
OBX|6|NM|150023^MDC_PRESS_BLD_NONINV_MEAN^MDC|1.1.1.7|90|266016^MDC_DIM_MMHG^MDC|||||X|||20150122115000
OBX|7|ST|4262^MDC_DEV_ECG_VMD^MDC|1.2.0.0||||||X|||||||0600dc750001
OBX|8|ST|4263^MDC_DEV_ECG_CHAN^MDC|1.2.1.0||||||X
OBX|9|NM|147842^MDC_ECG_CARD_BEAT_RATE^MDC|1.2.1.1|80|264864^MDC_DIM_BEAT_PER_MIN^MDC|50-120||||X
OBX|10|NM|147232^MDC_ECG_TIME_PD_QT_GL^MDC|1.2.1.14|360|264338^MDC_DIM_MILLI_SEC^MDC|||||X
OBX|11|NM|147236^MDC_ECG_TIME_PD_QTc^MDC|1.2.1.15|416|264338^MDC_DIM_MILLI_SEC^MDC|<500||||X
OBX|12|NM|151562^MDC_RESP_RATE^MDC|1.2.1.19|30|264928^MDC_DIM_RESP_PER_MIN^MDC|8-45||||X
OBX|13|ST|184327^MDC_ECG_STAT_RHY^MDC|1.2.1.21|MDC_ECG_SINUS_RHY|||||X
OBX|14|ST|69642^MDC_DEV_ANALY_SAT_O2_VMD^MDC|1.3.0.0||||||X|||||||0600dc750001
OBX|15|ST|70771^MDC_DEV_ANALY_PERF_REL_CHAN^MDC|1.3.1.0||||||X
OBX|16|NM|150456^MDC_PULS_OXIM_SAT_O2^MDC|1.3.1.1|99|262688^MDC_DIM_PERCENT^MDC|90-100||||X
OBX|17|NM|150448^MDC_PULS_OXIM_PERF_REL^MDC|1.3.1.3|3.9|262656^MDC_DIM_DIMLESS^MDC|||||X
```

DEC Profile : PCD-01 Transaction Example

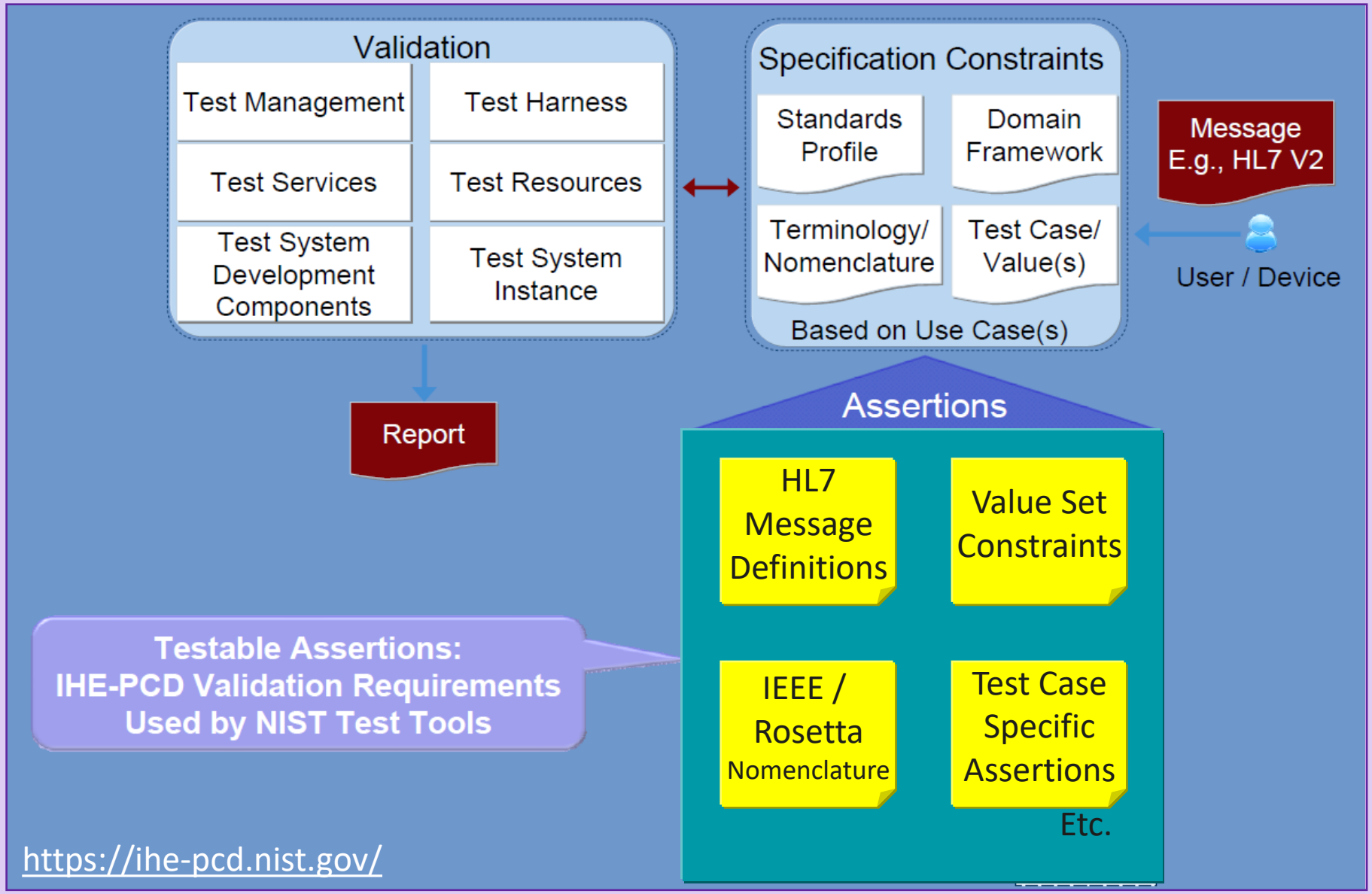
Measurements within a 4-level structure with coded units



MSH|^~\&|PAT_DEVICE_PHILIPS_C|Philips|||20150122182658+0000||ORU^R01^ORU_R[illegible]686QQ000CND119C0WS61|P|2.6|
||AL|NE||8859/1|EN^English^ISO639||IHE_PCD_001^IHE PCD^1.3.6.1.4.1.19[illegible].1.6.1.1.1^ISO
PID|||HO2009001^^^^MR||Hon^Albert^""^^^^L||19610101|M
PV1||I|HO Surgery^OR^1
OBR|1||201512218265601|69965^MDC_DEV_MON_PHYSIO_MULTI_PARAM_MDS[illegible]MDC|||20150122182656
OBX|1|ST|69965^MDC_DEV_MON_PHYSIO_MULTI_PARAM_MDS^MDC|1.0.0.0|||||||X|||||||e86c094f-f75[illegible]57-Device
OBX|2|ST|70686^MDC_DEV_PRESS_BLD_NONINV_VMD^MDC|1.1.0.0|||||||X|||||||[illegible]
OBX|3|ST|70675^MDC_DEV_PULS_CHAN^MDC|1.1.1.0|||||||X
OBX|4|NM|150021^MDC_PRESS_BLD_NONINV_SYS^MDC|1.1.1.5|117|266016^MDC_DIM_MMHG^MDC|90-160|||X
OBX|5|NM|150022^MDC_PRESS_BLD_NONINV_DIA^MDC|1.1.1.6|82|266016^MDC_DIM_MMHG^MDC|||||X|||201[illegible]
OBX|6|NM|150023^MDC_PRESS_BLD_NONINV_MEAN^MDC|1.1.1.7|90|266016^MDC_DIM_MMHG^MDC|||||X|||20150122115000
OBX|7|ST|4262^MDC_DEV_ECG_VMD^MDC|1.2.0.0|||||||X|||||||0600dc750001
OBX|8|ST|4263^MDC_DEV_ECG_CHAN^MDC|1.2.1.0|||||||X
OBX|9|NM|147842^MDC_ECG_CARD_BEAT_RATE^MDC|1.2.1.1|80|264864^MDC_DIM_BEAT_PE[illegible]|||X
OBX|10|NM|147232^MDC_ECG_TIME_PD_QT_GL^MDC|1.2.1.14|360|264338^MDC_DIM_MILLI_SEC^MDC|||||X
OBX|11|NM|147236^MDC_ECG_TIME_PD_QTc^MDC|1.2.1.15|416|264338^MDC_DIM_MILLI_SEC^MDC[illegible]
OBX|12|NM|151562^MDC_RESP_RATE^MDC|1.2.1.19|30|264928^MDC_DIM_RESP_PER_MIN^MDC|8-45|||
OBX|13|ST|184327^MDC_ECG_STAT_RHY^MDC|1.2.1.21|MDC_ECG_SINUS_RHY|||||||X
OBX|14|ST|69642^MDC_DEV_ANALY_SAT_O2_VMD^MDC|1.3.0.0|||||||X|||||||0600dc750001
OBX|15|ST|70771^MDC_DEV_ANALY_PERF_REL_CHAN^MDC|1.3.1.0|||||||X
OBX|16|NM|150456^MDC_PULS_OXIM_SAT_O2^MDC|1.3.1.1|99|262688^MDC_DIM_PERCENT^MDC|90-100|||X
OBX|17|NM|150448^MDC_PULS_OXIM_PERF_REL^MDC|1.3.1.3|3.9|262656^MDC_DIM_DIMLESS^MDC|||||X

NIST Testing Tools & IHE Conformity Assessment

IHE Gazelle Testing Platform



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

Agenda

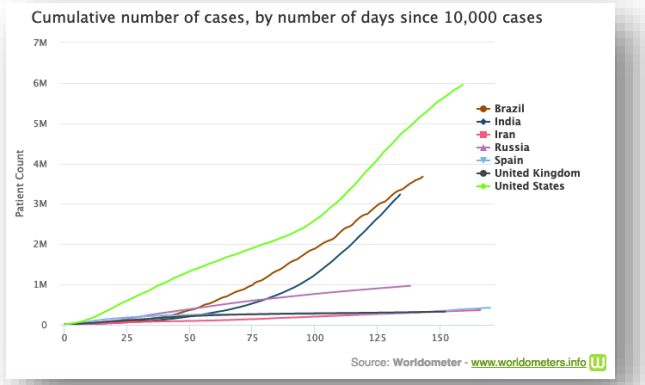
Time	Topic	Speakers
15:00	**Welcome**	• Michael Strübin, *MedTech Europe* • Alexander Ihls, *IHE International*
15:10	**Interoperability: the bigger picture**	• Petra Wilson, *HIMSS*
15:25	**The impact of the PCHAlliance/Continua collaboration with IHE and HIMSS**	• Charles Parisot, *IHE Europe*
15:40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

Profiles for medical devices, testing and conformity assessment, new directions

Thom Erickson, HIMSS

MedTech Europe
from diagnosis to cure

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 where ever they are deployed.
- This is where *interoperability* is essential.

Connectivity

Interoperability

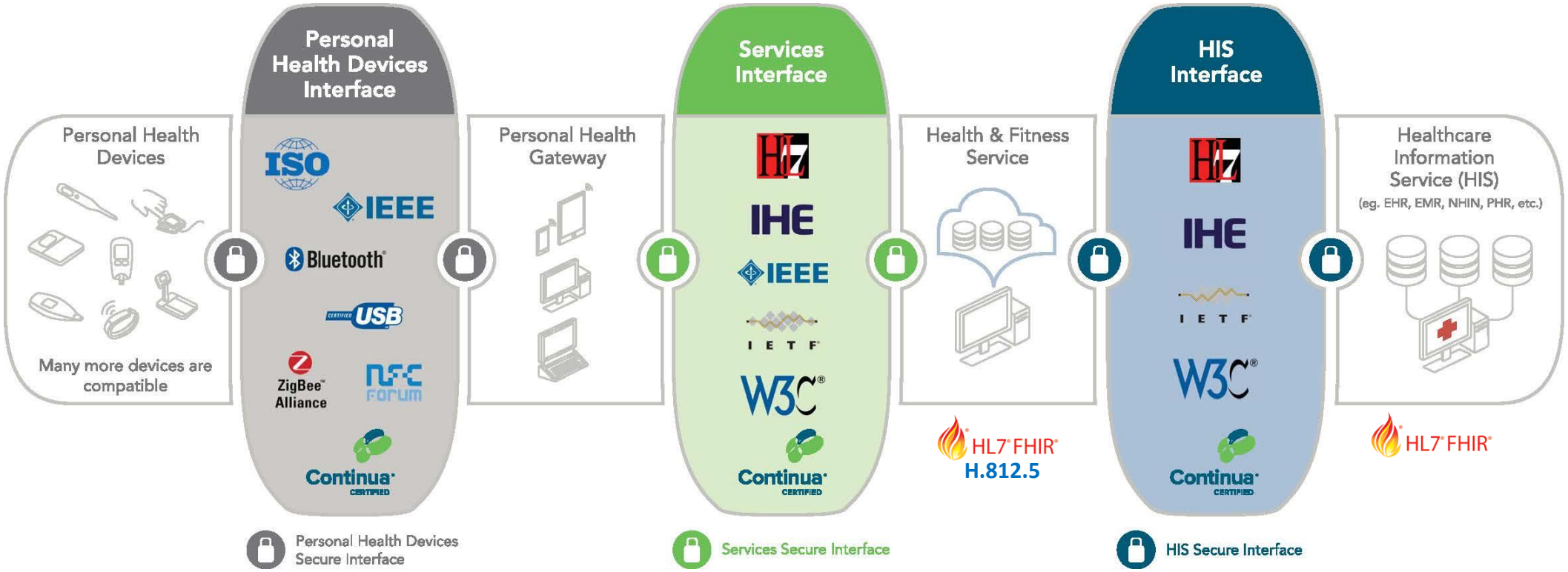
Your Health, Your Data, Your Device, Your Choice

- 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.

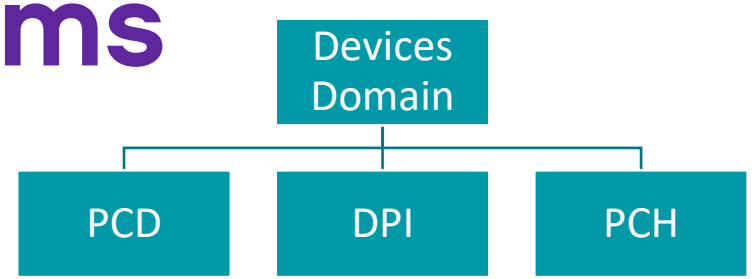
- Likewise, open standards allow you to manage *your* health collecting *your* data with *your device* and easily share it with *your* doctor.

Continua Implementation Framework



http://www.itu.int/rec/T-REC-H.810-201312-I

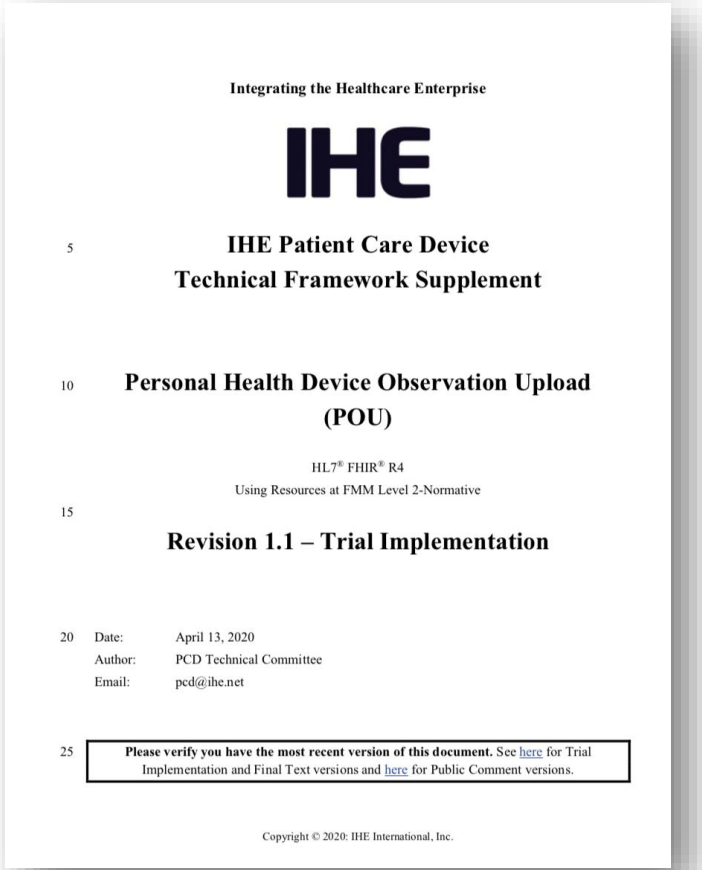
IHE Devices Domain Programs



- 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.



Integrating the Healthcare Enterprise

IHE

IHE Patient Care Device
Technical Framework Supplement

Personal Health Device Observation Upload
(POU)

HL7® FHIR® R4
Using Resources at FMM Level 2-Normative

Revision 1.1 – Trial Implementation

Date: April 13, 2020
Author: PCD Technical Committee
Email: pcd@ihe.net

Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

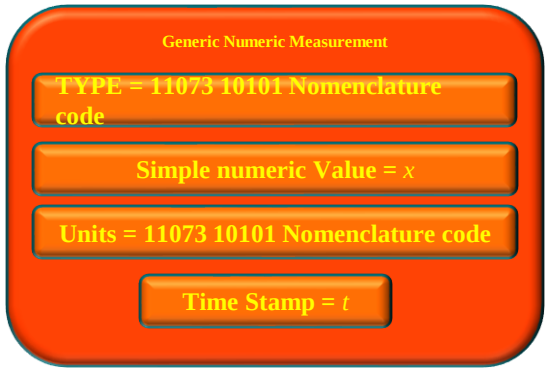
Personal Connected Device Observation Upload

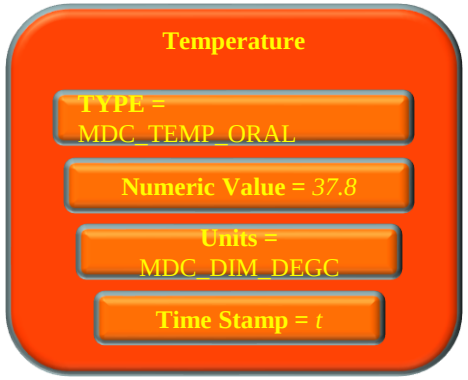
Transcoding the PHD data into FHIR Resources

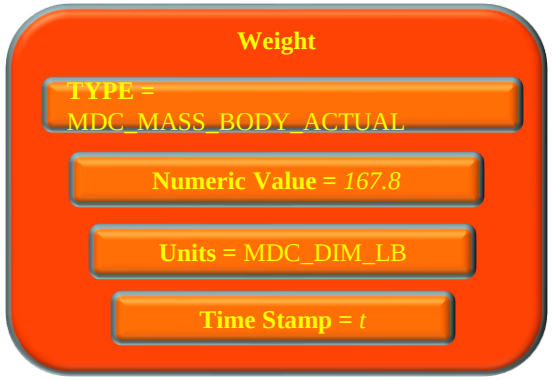
Medical Device System Object
Agent's bureaucratic and device information

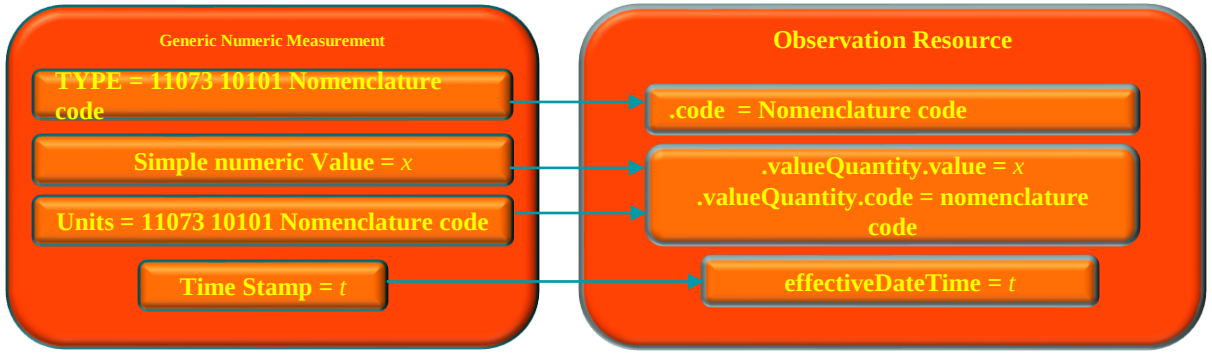
Metric object
Describes a measurement weight, blood pressure, ECG waveform

Generic Measurement, Examples, Mapping to FHIR

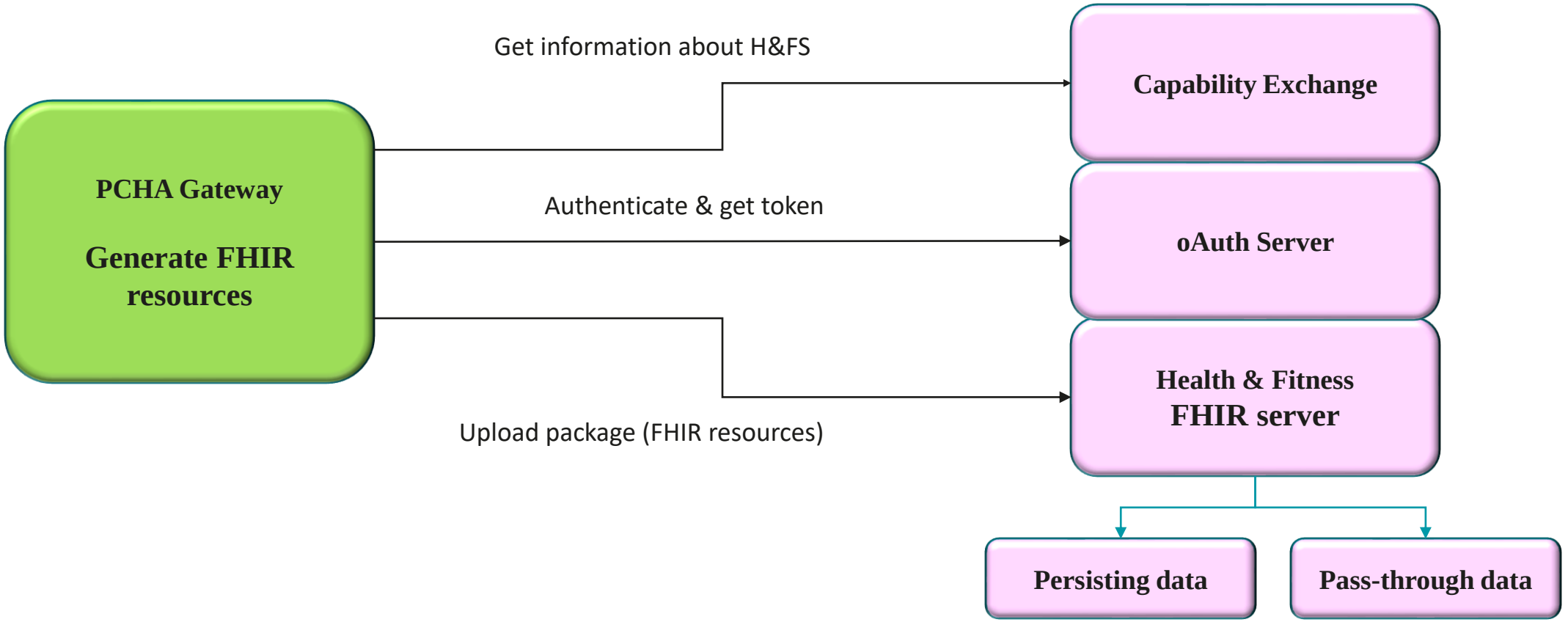








Upload the FHIR resources



IHE Integrating the Healthcare Enterprise

GENERIC!

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

Fundamentals of RPM: Rapid Implementation with Commercial Ready Software

- 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

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

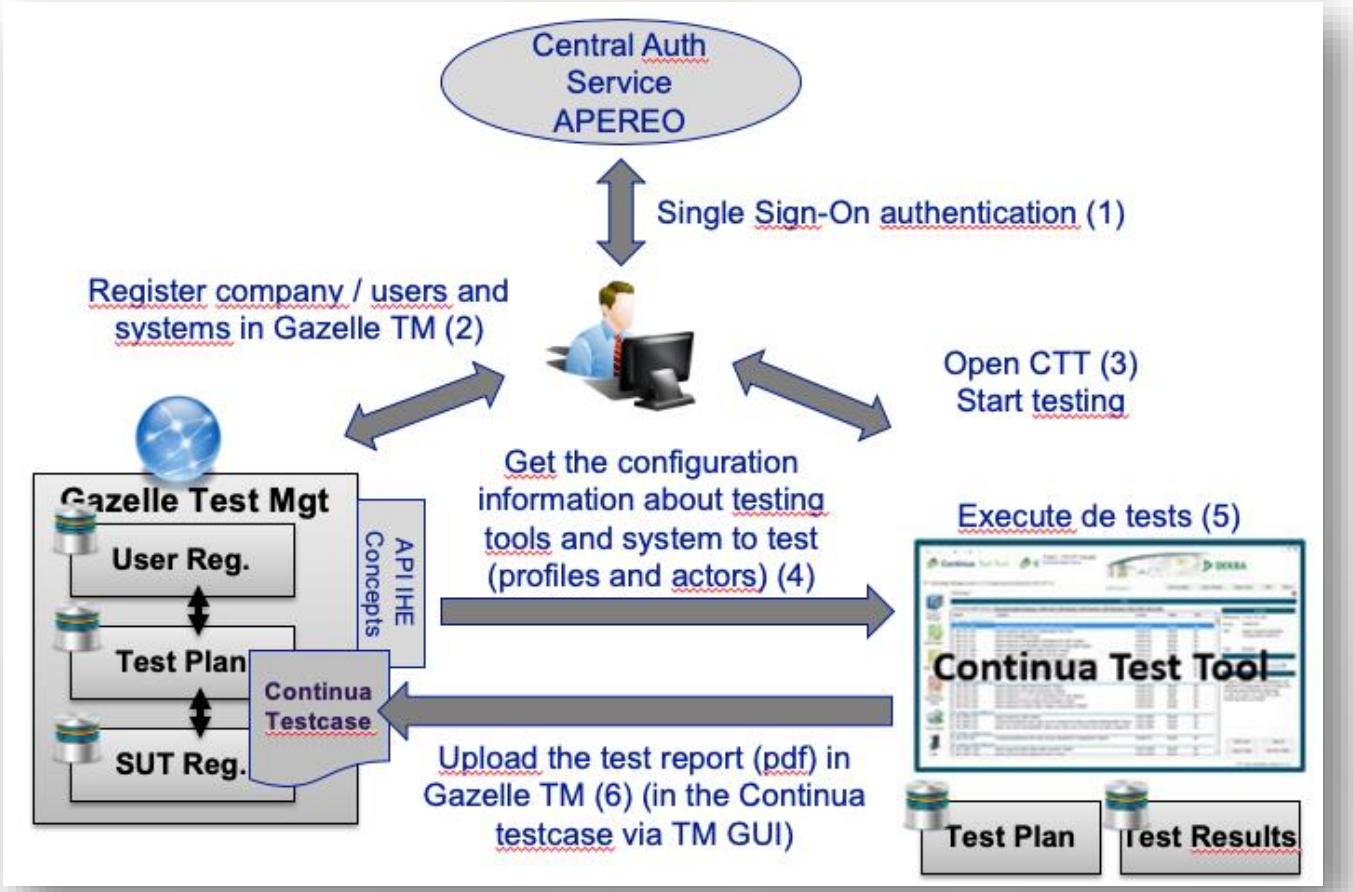
CODE Product Description

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

CTT
Continua Test Tool

Compliant

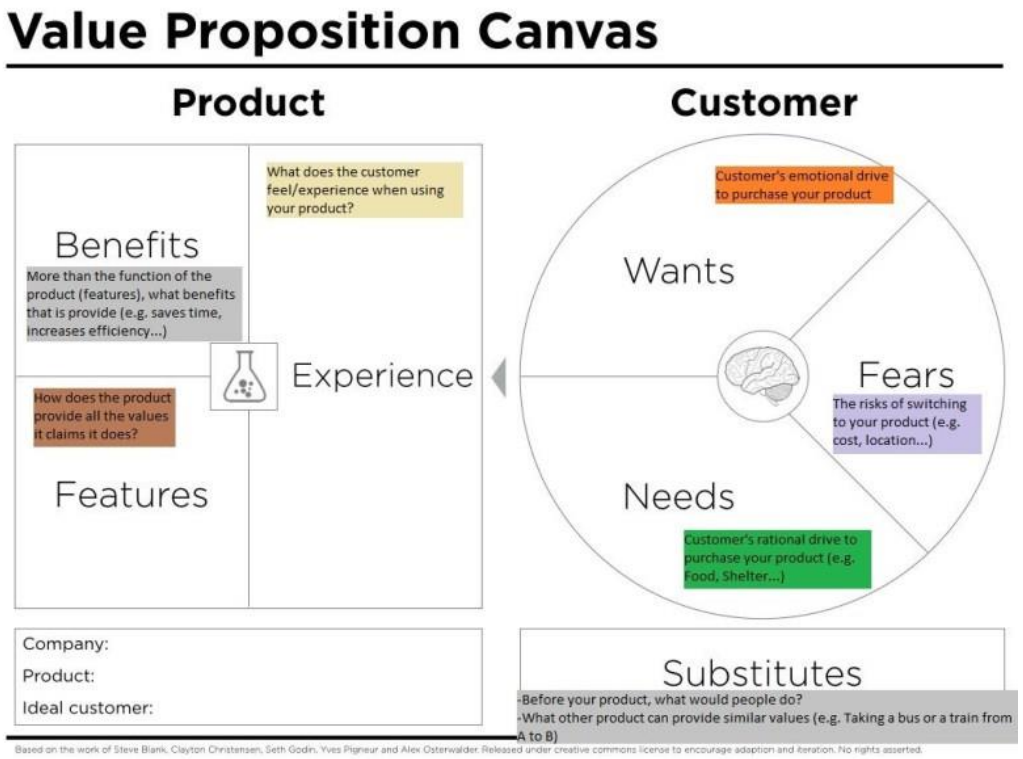
Certified

[Continua Test Tool]

[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

Agenda

Time	Topic	Speakers
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**	

MedTech Europe
from diagnosis to cure

Thank you!

For more questions please contact:

Charles Parisot, IHE Europe, Charles.Parisot@IHE-Europe.net
Thom Erickson, HIMSS, thom.erickson@himss.org
Michael Strübin, MedTech Europe, m.strubin@medtecheurope.org

www.medtecheurope.org

YouTube

MedTech Europe
from diagnosis to cure