IEEE
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for Humanity

IHE | Integrating the Healthcare Enterprise

Medical Device Connectivity

Leveraging current approaches,
Developing New Capabilities –
IEEE 11073 SDC @ IHE PCD SDPi

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Executive Director, Trusted Solutions Foundry, Inc.

Trusted Solutions Foundry

SDC@IHE SDPi Workshop

Workshop Agenda

1000-1015 **Introductions & Overview**

1015-1200 **Session #1: SDC & SDPi Deep Dive**

1200-1230 Lunch

1230-1400 **Session #2: IHE SDPi White Paper – Review & Feedback**

1400-1415 Break

1415-1545 **Session #3: IHE SDPi Challenges/Opportunities in AU**

1545-1600 **Wrap-up & Planning**

Workshop Objectives

#1   *WORK*shop … *not Death-by-PowerPoint*!

Today's journey will include …

1. **Understanding of the challenges and current state of open standards-based medical device interoperability (MDI)**

2. **Detailed understanding of ISO/IEEE 11073 SDC interoperability**

3. **Review of the IHE SDPi Profile Proposal** (in comment period)

4. **Identify & Discuss Challenges with PnP MDI Realization**

5. **Identify & Discuss SDC/SDPi Application in Australia**

What else?

Shout out to our workshop sponsors …

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Session #1
IEEE SDC & IHE SDPi Deep Dive

SDC@IHE SDPi Workshop

Acronyms:

MDI   Medical Device Informatics / Interoperability

DPI   Device Point-of-Care (PoC) Interoperability

SDC   Service-oriented (WS-*) Device Connectivity

SDPi   Mash-up of SDC+DPI @ IHE PCD SDC Profiles

NOTE: SDC focuses on *High-Acuity Contexts*: OR, ICU, ED

1st Consider 4 Core Use Cases …

#1 Functional Endoscopic Sinus Surgery – OR Integration

#2 NITRD / FDA MDI Scenario (military evacuation)

#3 IHE PCD "Quiet Hospital" – Device to Clinician & Back Again

#4 Preeclampsia During Pregnancy (PDP) Across the Continuum of Care

NOTE: SDC focuses on High-Acuity Contexts: OR, ICU, ED

4 Core Use Case Examples

Example #1: Functional Endoscopic Sinus Surgery (FESS)

John Miller (13yrs, m) has chronic rhinosinusitis, which is an inflammatory condition in which the nose and his left maxillary sinus is swollen and the drainage of the mucus is prevented. John's chronic rhinosinusitis doesn't respond to medication anymore. After consulting with his physician, he and his parents decide to resolve the issue with a Functional Endoscopic Sinus Surgery (FESS). The FESS will be done in as a day surgery, so that John can get home in the evening.

*Before the day of the surgery, a **CT scan** is taken that is used to guide the surgeon during the surgery.*

*In order for the surgery to start, John is put under general **anesthesia** and monitored with a **patient monitor** by a pediatric anesthesiologist, esp. his mean arterial blood pressure which has been reduced in order to provide optimal visibility of the surgical field due to reduced capillary bleeding.*

*During the intervention, the Surgeon has a **constant view of the patient's vitals** (including MABP) and the **control functions** to execute the intervention.*

*During the procedure one of the surgical devices has a technical issue. It generates a **technical alert** which notifies the responsible biomedical technician. He/she decides to replace the device and connects it to the network where it is **automatically discovered and configured** allowing the intervention to continue.*

There are no additional technical or clinical problems, the surgery is a success and John can go home with his parents.

NOTE: Proposed for the HIMSS'20 SDC Showcase Demo

FESS narrative includes the following component use cases:

SDC/FESS.1	Surgeon view of patient vitals
SDC/FESS.2	Surgeon control of OR table and lights
SDC/FESS.3	Surgeon control of surgical tools
SDC/FESS.4	Device reports technical issue to responsible BMET
SDC/FESS.5	Seamless exchange of Medical Devices

Example #2: NITRD '19 MDI Use Case

From the online narrative …

NITRD.1 – Seamless changes of medical devices

NITRD.2 – Capture of data and settings

NITRD.3 – Supervisory control established

NITRD.4 – Autonomous patient therapy

NITRD.5 – Data flows through the Continuum of Care

NITRD.6 – Capture of equipment configurations

NITRD.7 – Black Box Recorder

Source: https://www.nitrd.gov/nitrdgroups/index.php?title=Medical-Device-Interoperability-2019

4 Core Use Case Examples

Example #3: Quiet Hospital

Sam, a nurse in University Hospital's high-acuity intensive care unit is continuously bombarded with alert sounds emanating from a variety of medical devices including infusion devices, ventilators, nurse call systems, patient monitors and/or associated central monitoring systems. This can result in alarm fatigue, especially since only a portion of these alerts are intended for her. In addition, Kelly – one of Sam's patients, hears many of the same alarm sounds increasing his overall level of stress as well as interrupting his rest.

The Quiet Hospital (QH) introduces the concept of "Alarm/Alert Delegation" which allows one medical device (usually SaMD) to act as an alarm proxy for other medical devices/sensors. For example, an SpO2 monitor, blood pressure monitor or infusion device on an SDC network can delegate its alarm signaling to a local patient monitor (on the same network). In turn, a ventilator and the patient monitor can delegate their alarm signaling to a central station. The central station (acting as a PCD AR or via an independent SDC device gateway acting as an AR) can, in turn, delegate the function of alarm signaling to an alert communications manager which sends alert notifications directly to Sam's smart phone or another personal device. This can result in reducing or eliminating the noise level in the care unit as well as the potential for alarm fatigue. The reduced noise level also reduces Kelly's level of stress and allows for uninterrupted periods of rest.

Given the possibility of communication errors or system failures which could affect patient safety, appropriate feedback loops must be in place to mitigate any hazards that may result in dropped Alerts or other malfunctions.

Finally, in order to support longer term alert logging and analysis of alert patterns a separate SDC to FHIR gateway can be installed to capture the alert traffic and "serve" results to interested applications.

NOTE: Isolation ICU extension also included

4 Core Use Case Examples

Quiet Hospital narrative includes the following component use cases:

|	
SDC/QH.1	Device alert signal delegation to single-pt. alert aggregator
SDC/QH.2	Single pt. alert aggregator alert signal delegation to multi-pt. aggregator
SDC/QH.3	Device alert signal **_delegation_** to Alert Communication Manager
SDC/QH.4	Multi-pt. aggregator to Alert Communication Manager
SDC/QH.5	SDC to FHIR Gateway.
SDC/QH.6	Alert Communications Manager to care-giver Alert Communicator
SDC/QH.7	Alert Communicator failure
SDC/QH.8	Alert Communications Manager failure
SDC/QH.9	Multi-pt. aggregator failure
SDC/QH.10	Single pt. aggregator failure

4 Core Use Case Examples

Example #4: Preeclampsia During Pregnancy (PDP)

*Holly, a pregnant mom, goes to the **clinic** for a **regular check-up** where hypertension + proteinuria are detected resulting in a diagnosis of preeclampsia. She is **monitored** for preeclampsia (hypertension) during the remainder of her pregnancy utilizing a **personal health device** (PHD) blood pressure monitor and urine analyzer. A **Clinical Decision Support (CDS) system** is integrated to help with the real-time monitoring of Holly's condition. During Holly's final pre-natal exam, it was determined that the infant was under stress and an **emergency C-section** was performed. After delivery (postnatal) everyone expected her blood pressure to return to normal within a few days or weeks; however, to ensure this is the case, as part of her discharge Holly is prescribed to continue her **home monitoring** regimen and the CDS system oversight is also continued. Shortly after her discharge, Holly's BP spikes which is detected by the CDS and the physician is alerted to action. It's a good thing that she was being actively monitored. The problems were quickly identified, her caregivers alerted, and she was re-admitted to hospital before the condition progressed to eclampsia and seizures.*

Example #4: SDC with DoF (PoCD / PHD)
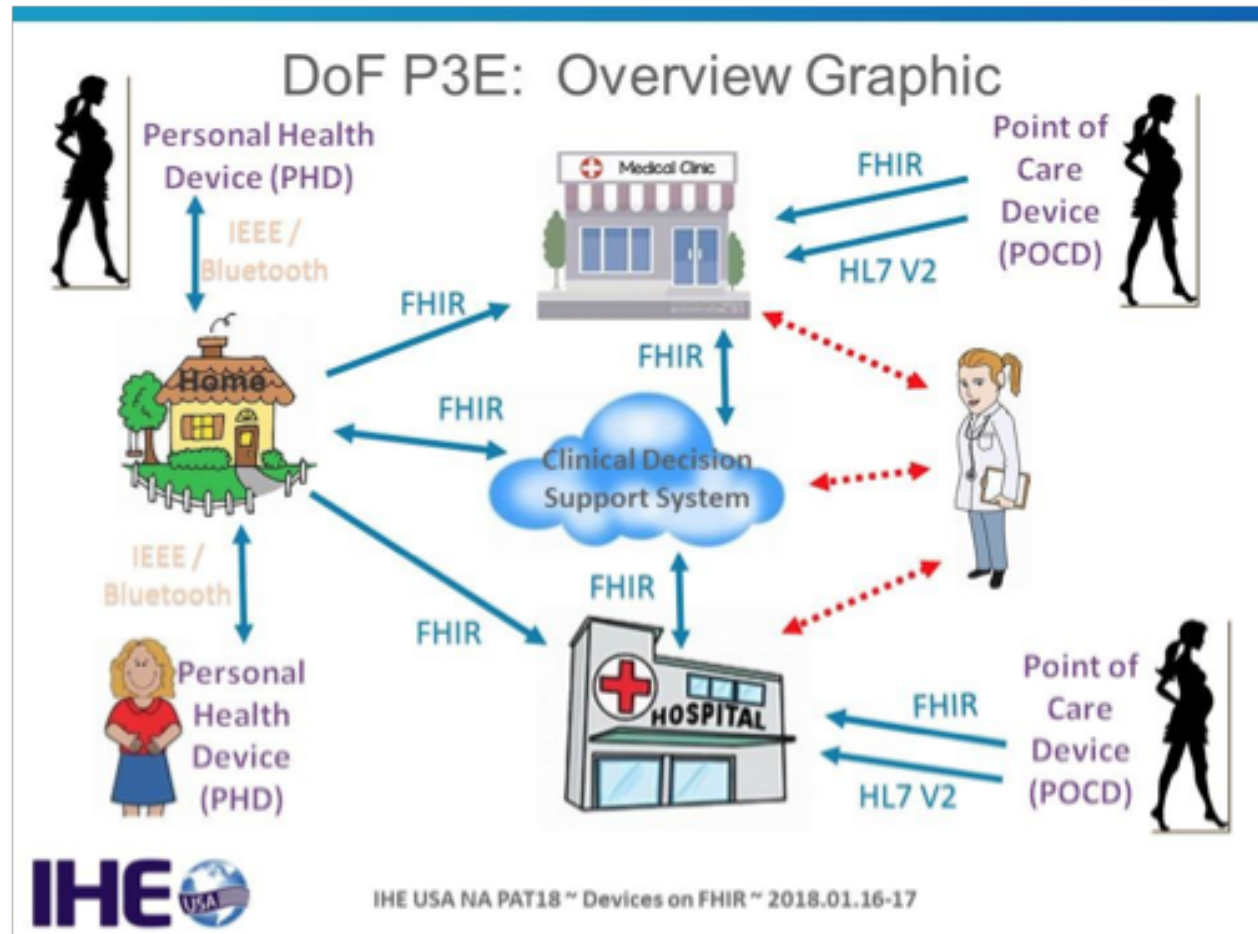
Source: **IHE DoF PAT '18 + HL7 FHIR DevDays**

A wealth of MDI use cases have been developed over the last few decades …

SDC & IHE SDPi build upon this rich heritage!

Download @
https://wiki.ihe.net/index.php/SDC@IHE_White_Paper

Integrating the Healthcare Enterprise

IHE Patient Care Devices (PCD)

Compendium of Medical Device Oriented Use Cases

Companion to the "Service-oriented Device Point-of-Care Interoperability (SDPi)" White Paper

Device-to-Device Connectivity in High-Acuity Healthcare Environments using Web Services Technology

Revision 1.0

Date: August 1, 2019
Author: IHE PCD Technical Committee
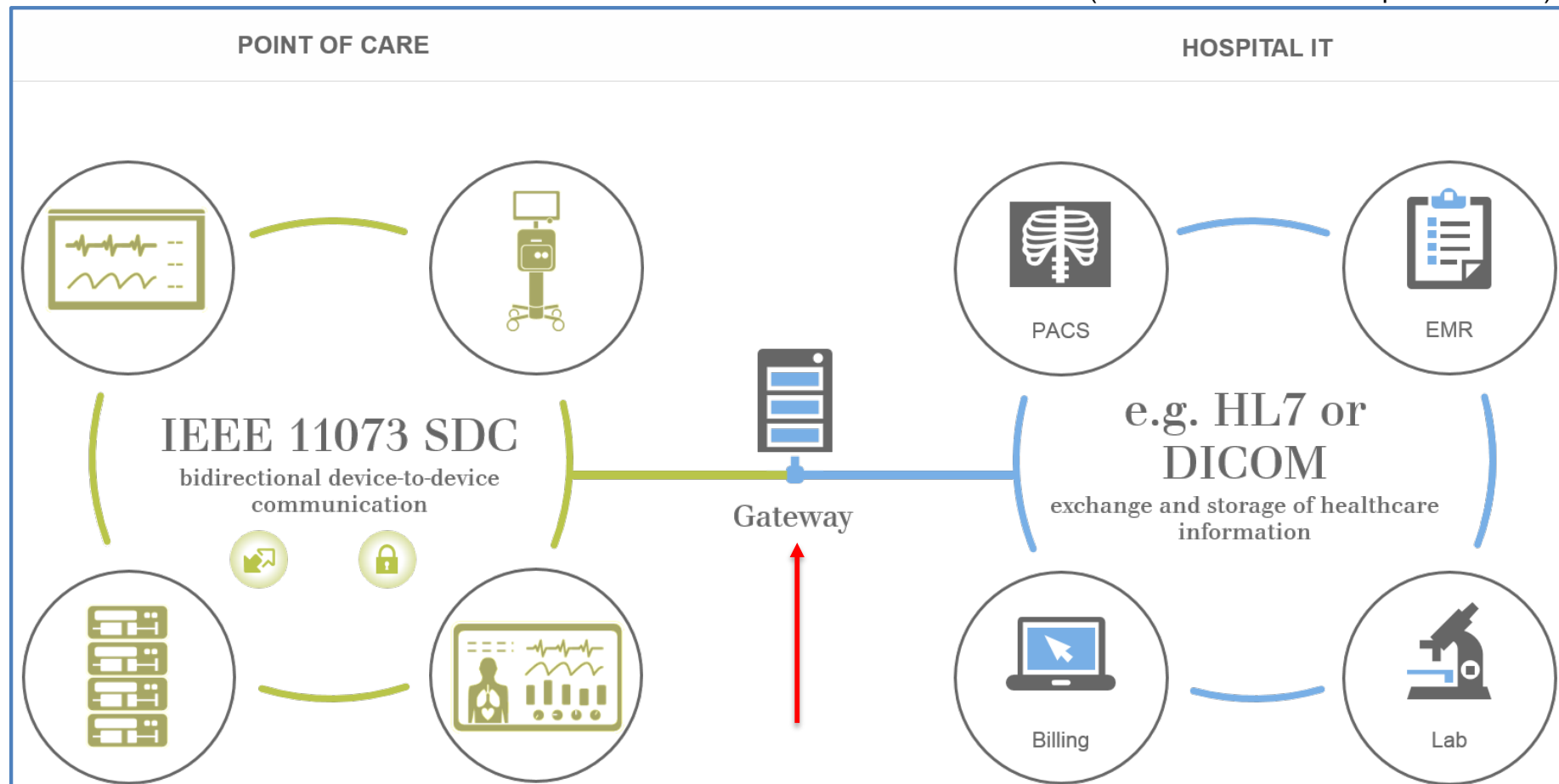Email: pcd@ihe.net

IEEE 11073 SDC Deep Dive

SDC Standards & Functional Capabilities

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SDC Point-of-Care Context   IHE "Enterprise" Context

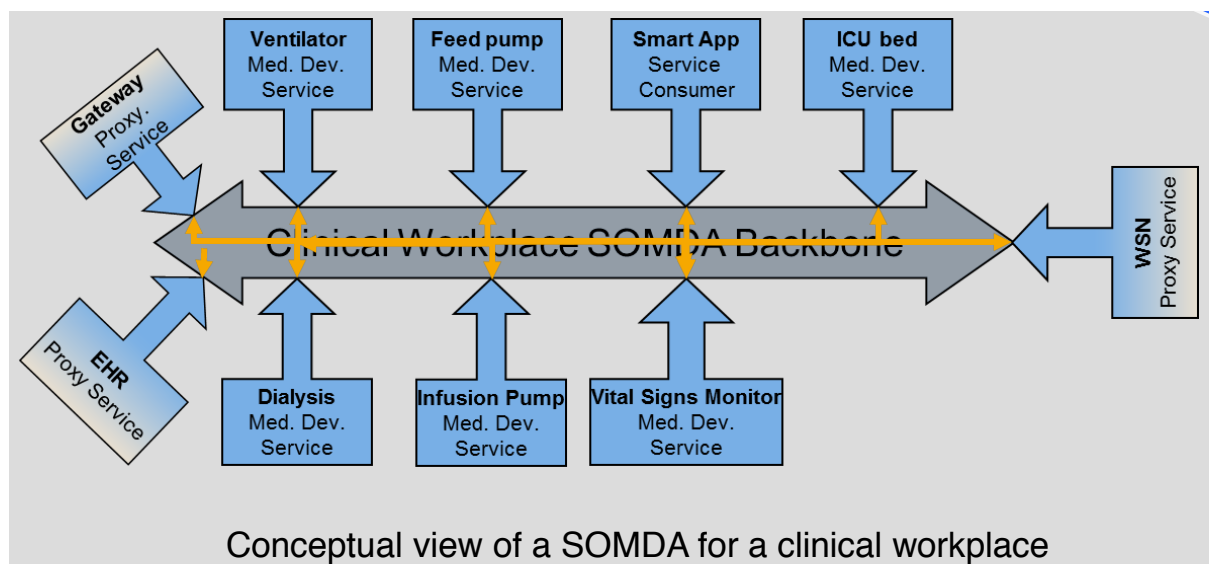# SDC Standards & Functional Capabilities

The concept of a

clinical workplace service-oriented medical device architecture

transfers the concept of a

service-oriented architecture

to the domain of

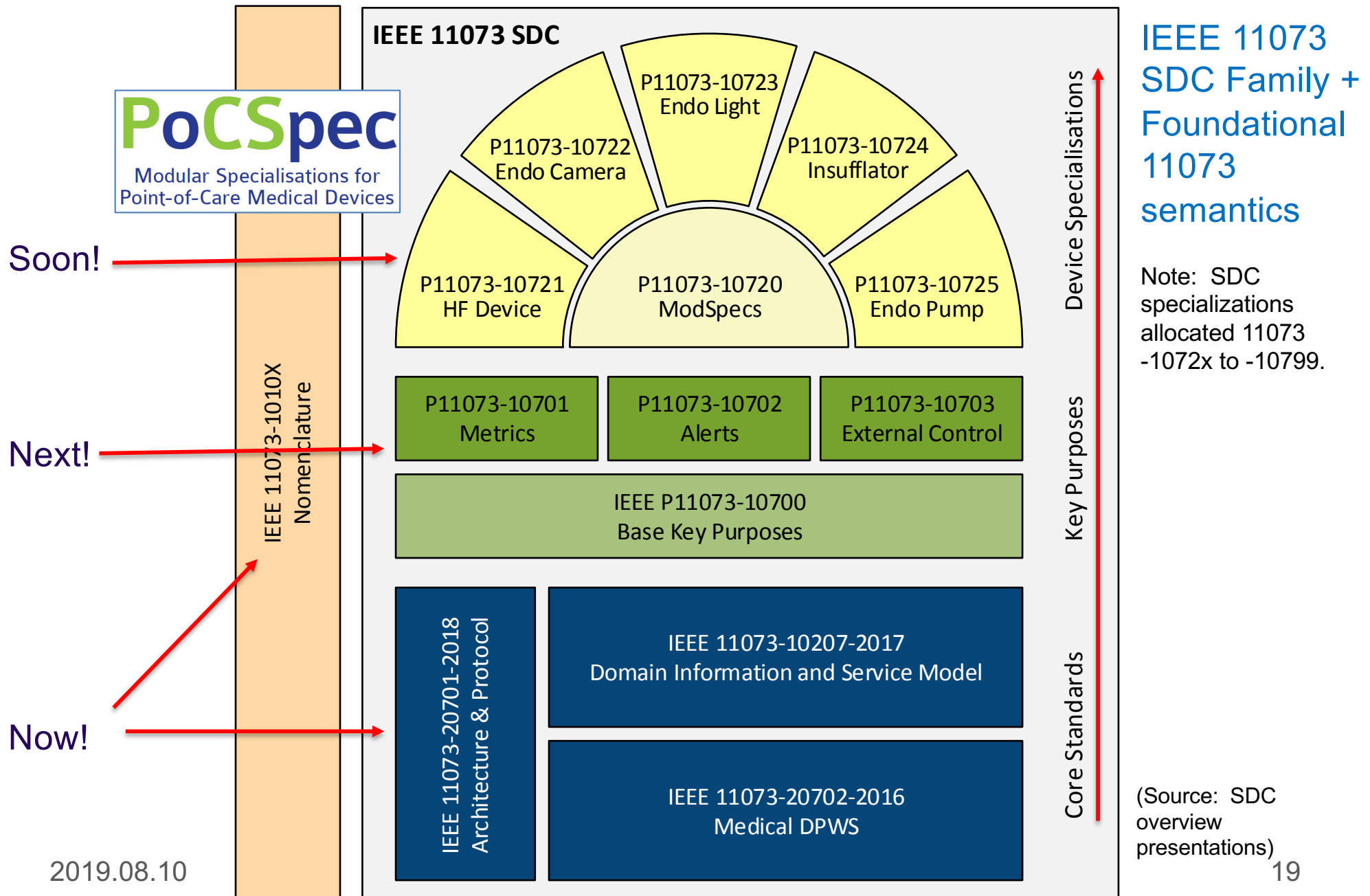**distributed system of medical devices for one clinical workplace**.
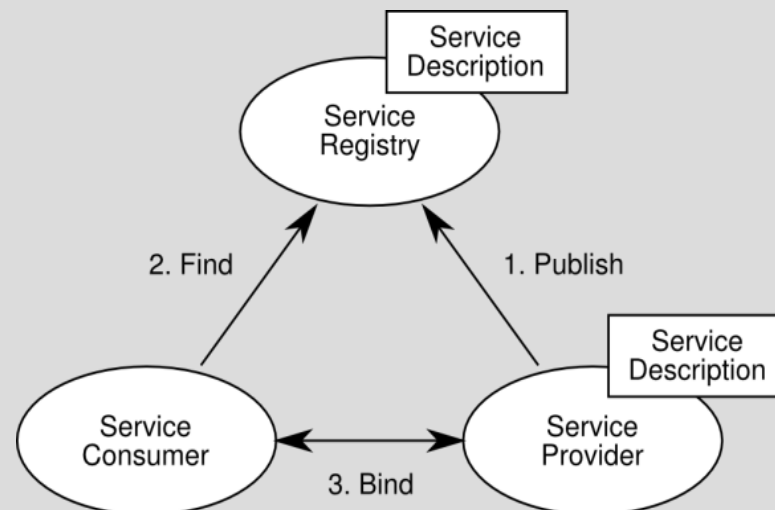
(Sources: SDC overview presentations)

Device-to-Device

Conceptual view of a SOMDA for a clinical workplace

2019.08.10

SDC Standards & Functional Capabilities

IEEE 11073 SDC

IEEE 11073 SDC Family + Foundational 11073 semantics

Note: SDC specializations allocated 11073-1072x to -10799.

Device Specialisations

- P11073-10722 Endo Camera
- P11073-10723 Endo Light
- P11073-10724 Insufflator
- P11073-10721 HF Device
- P11073-10720 ModSpecs
- P11073-10725 Endo Pump

Key Purposes

- P11073-10701 Metrics
- P11073-10702 Alerts
- P11073-10703 External Control
- IEEE P11073-10700 Base Key Purposes

Core Standards

- IEEE 11073-20701-2018 Architecture & Protocol
- IEEE 11073-10207-2017 Domain Information and Service Model
- IEEE 11073-20702-2016 Medical DPWS

PoCSpec
Modular Specialisations for Point-of-Care Medical Devices

IEEE 11073-1010X Nomenclature

Soon!

Next!

Now!

(Source: SDC overview presentations)

2019.08.10

19

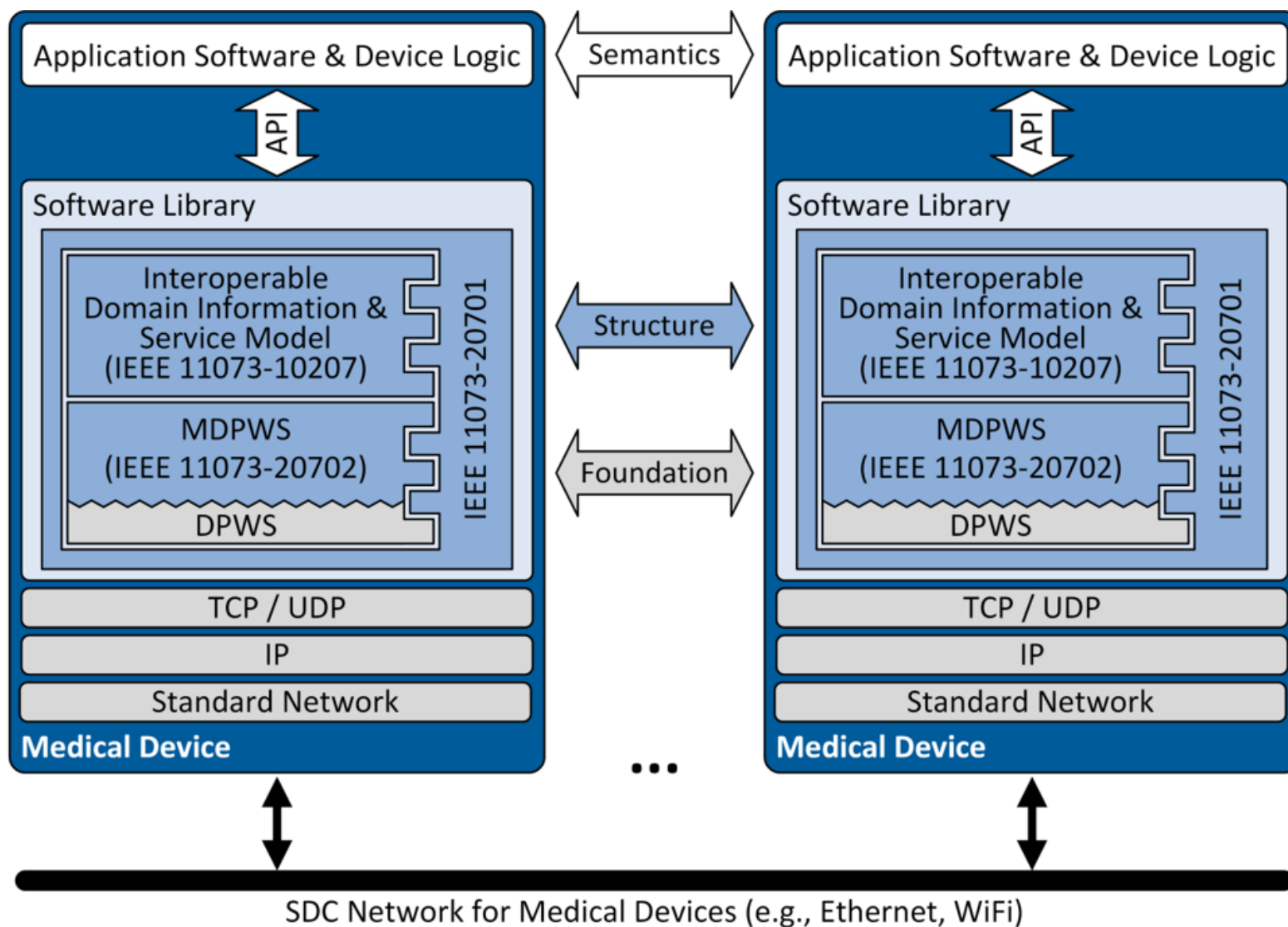## SDC FDA Workshop 2019-04 presentations

1. **IEEE 11073 SDC Standards Family Overview**
2. **IEEE 11073-10207 SDC BICEPS Overview**
3. **IEEE 11073-20701 SDC SOMDA "Glue" Overview**
4. **IEEE 11073-20702 SDC MDPWS Overview**
5. **BICEPS - Demo SpO2 Example**

SDC Standards & Functional Capabilities
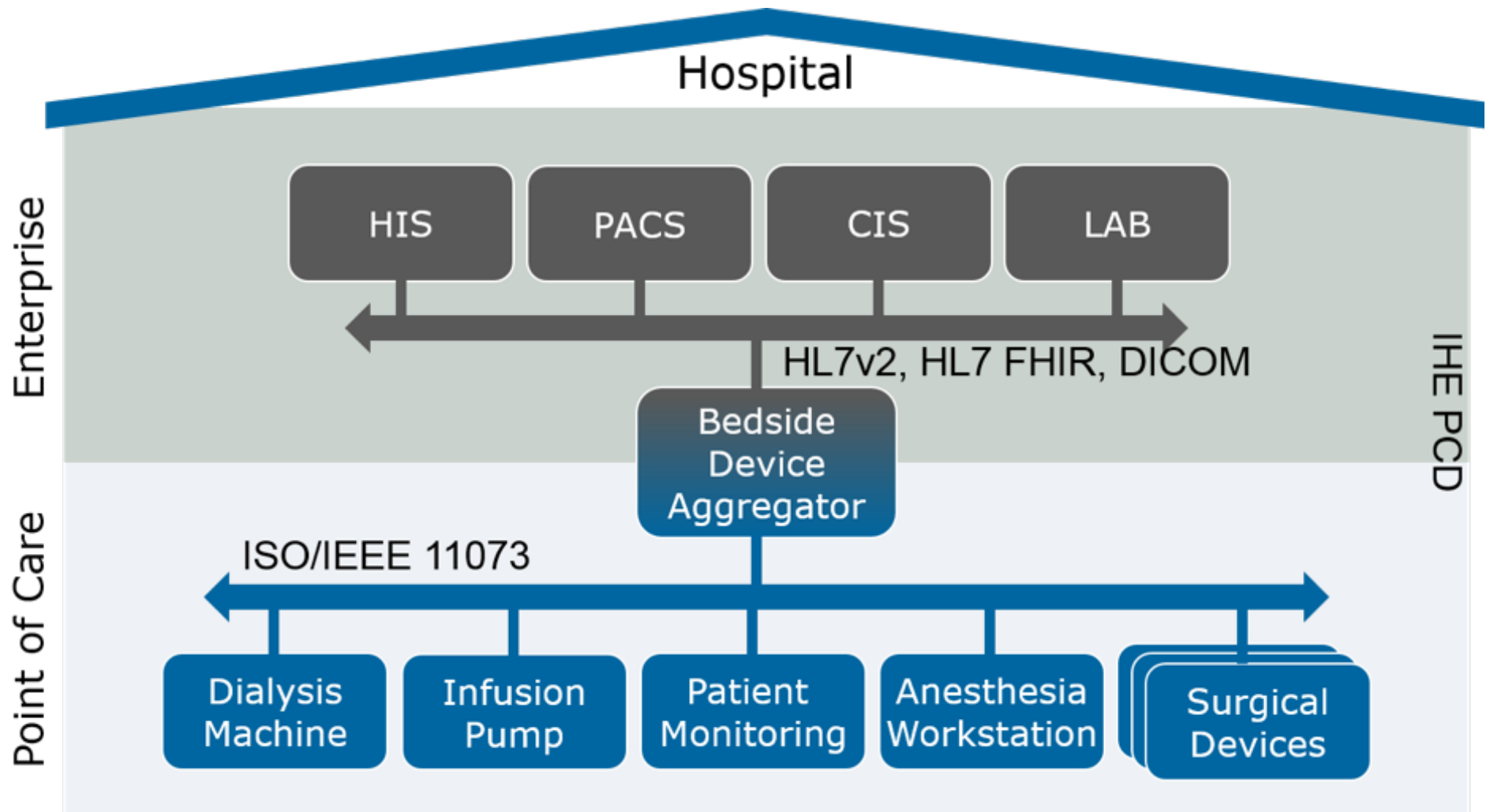
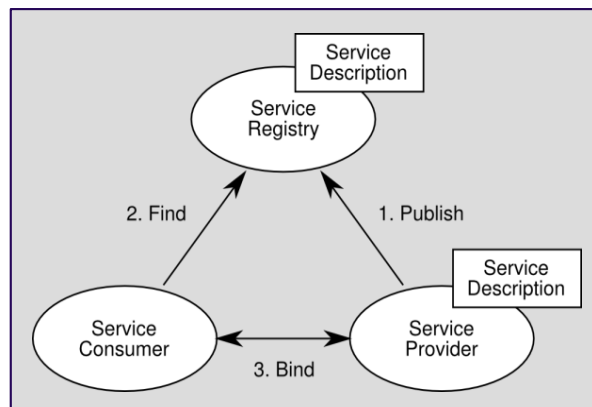(Source: SDC overview presentations)
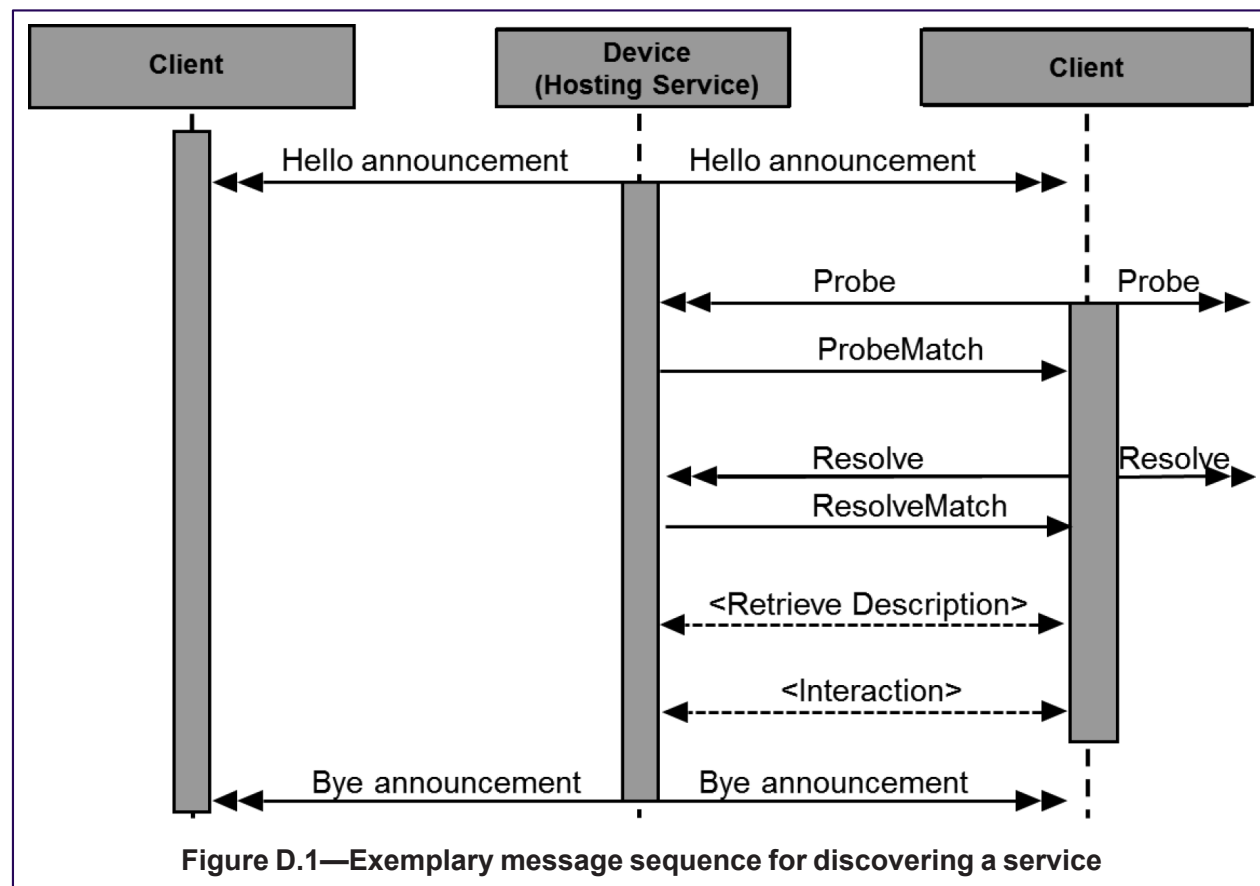
SDC Standards & Functional Capabilities

Basic Discovery & Exchange

(note: distributed "registry" architecture)

Figure D.1—Exemplary message sequence for discovering a service

(Source: 11073:20702)

MDI Maturity Models

Infrastructure

Transport level connectivity including security; technology independent of systems and applications

Contextual / Dynamic

Ability of devices and applications to share data based on the patient and clinical workflow

Syntactic

Use of recognized formats to communicate and exchange information

Conversational Complexity

Extent and sophistication of information exchange including orchestration

Terminology / Semantic

Use of recognized vocabularies, nomenclatures, and ontologies as well as information models

BASIC
INTERMEDIATE
ADVANCED

Source: Ken Fuchs (C4MI) at ACCE/AAMI 2016 Conference & Expo, Tampa, Florida

SDC Community

OR.NET
History of Research and development activities

- ✓ Standards
- ✓ Open Sources
- ✓ Testing Tools

OR.NET Association

1st Devices

IEEE 11073 SDC

PoCSpec

MoVE

OR.NET Project

ZiMT

DOOP

smartOR

TeKoMed

FUSION

OrthoMIT

2005 … 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020

Blue: Research
Orange: Standardization
Red: Industry
Green: OR.NET Association

OR.NET e.V.
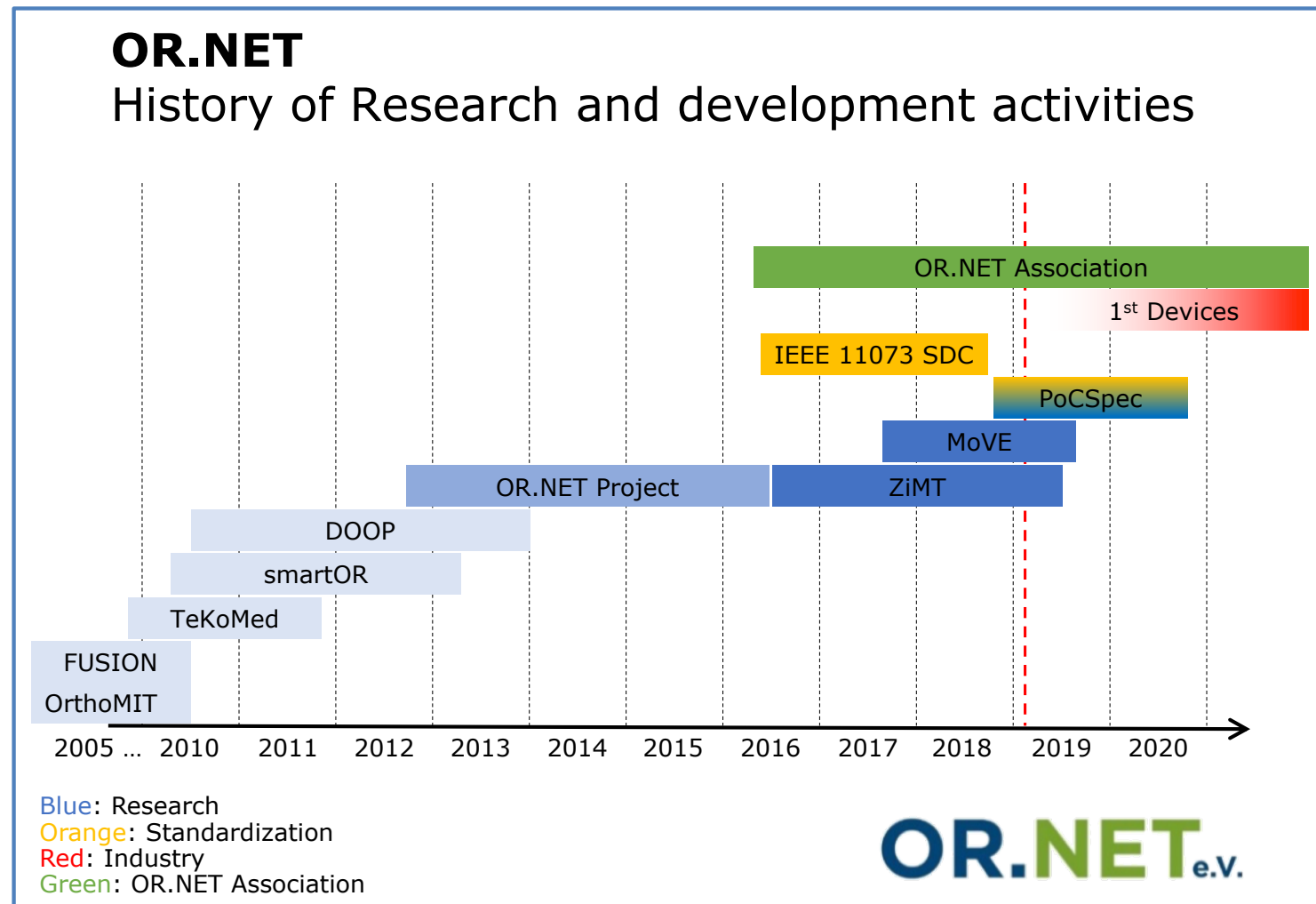
See IHE SDPi White Paper Appendix B for references.

IHE PCD Overview

IHE Patient Care Devices (PCD)

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IHE Technical Framework

Develop tech. specs

Testing at IHE Connectathons

HIMSS Demos featuring IHE

Products with IHE

Identify available standards

Document Use Case Requirements

Improved safety, quality & efficiency!
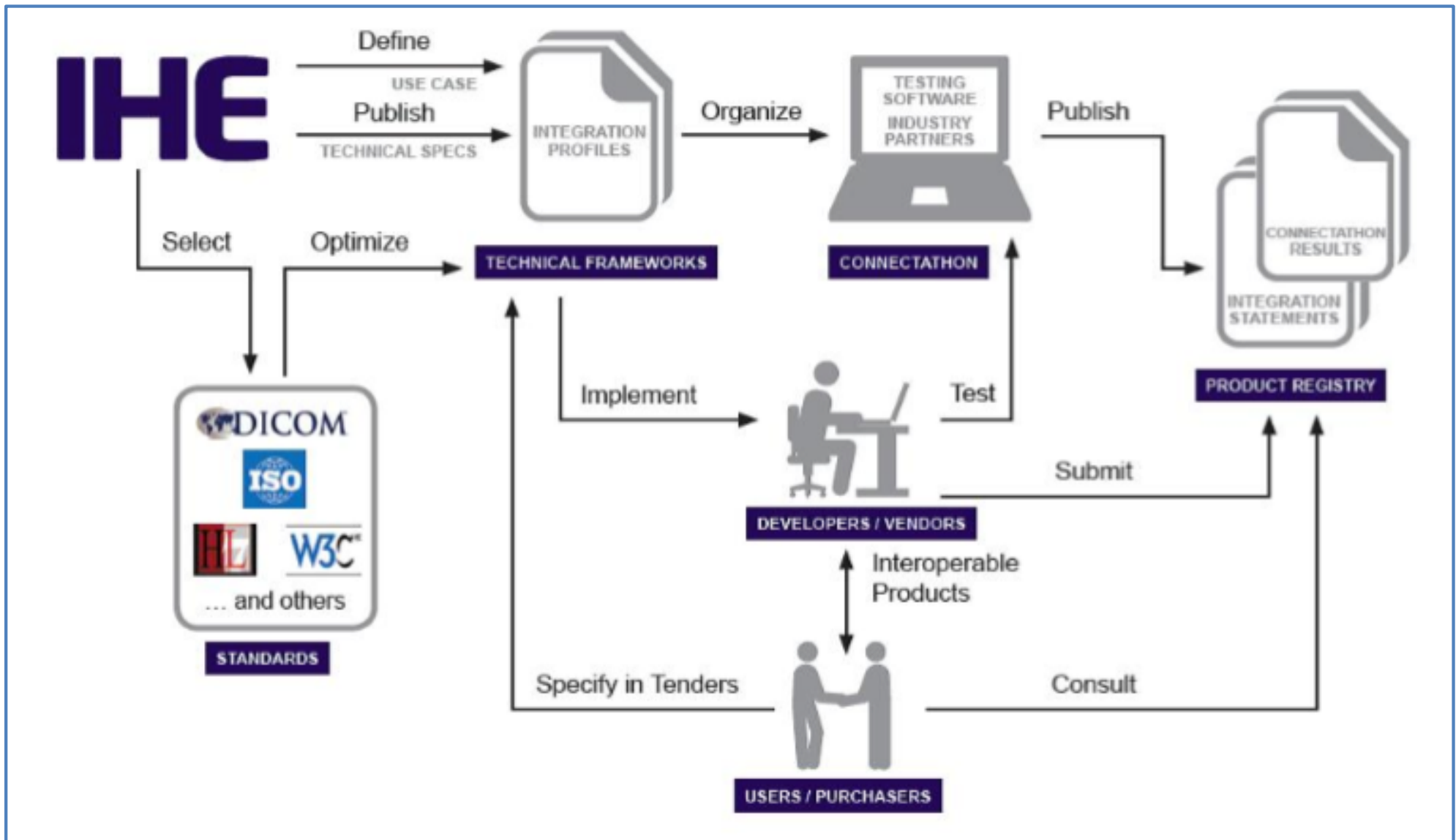
Easy to integrate products
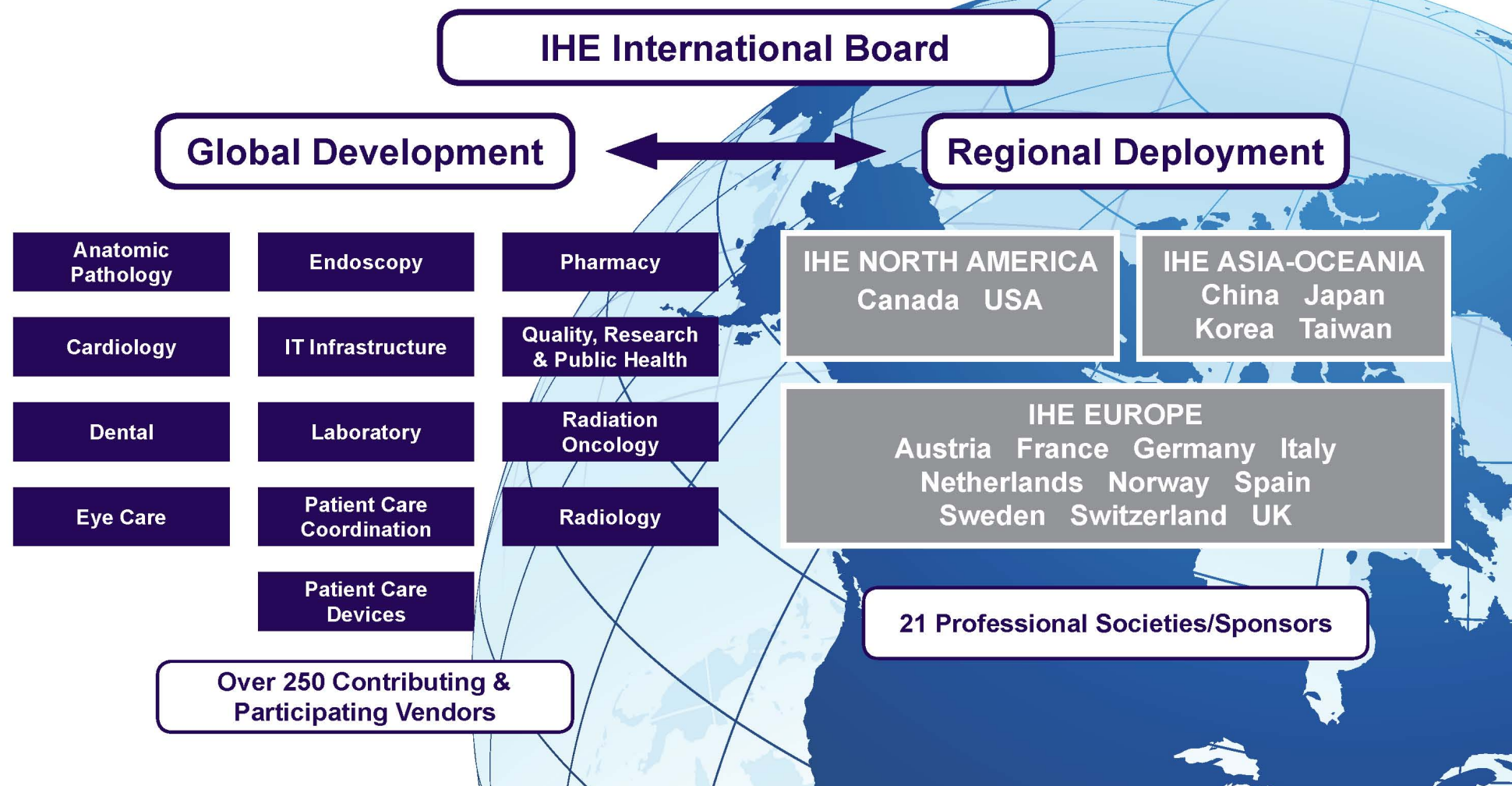
IHE International

What is IHE?

IHE Netherlands Video …

https://www.youtube.com/channel/UC_7Rx9Mr
acVwqVXDOH8Hj5Q

IHE Patient Care Devices (PCD)

IHE Integrating the Healthcare Enterprise

IHE Organization

IHE International Board

Global Development ⟷ **Regional Deployment**

Anatomic Pathology	Endoscopy	Pharmacy
Cardiology	IT Infrastructure	Quality, Research & Public Health
Dental	Laboratory	Radiation Oncology
Eye Care	Patient Care Coordination	Radiology
	Patient Care Devices	

Over 250 Contributing & Participating Vendors

IHE NORTH AMERICA
Canada   USA

IHE ASIA-OCEANIA
China   Japan
Korea   Taiwan

IHE EUROPE
Austria   France   Germany   Italy
Netherlands   Norway   Spain
Sweden   Switzerland   UK

21 Professional Societies/Sponsors

IHE Patient Care Devices (PCD)

IHE Asia-Oceania	IHE Europe	IHE North America	South America	Middle East
Australia	Austria	Canada	Brazil	Saudi Arabia
China	Finland	U.S.A.	Colombia	
Japan	France			
Korea	Germany			
Taiwan	Italy			
	Spain			
	Switzerland			
	The Netherlands			
	Turkey			
	Luxembourg			
	United Kingdom			

IHE Patient Care Devices (PCD)

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IHE Plug-a-thons

- Rigor: Low
- Iterative testing process based on use cases
- Similar to Hackathon
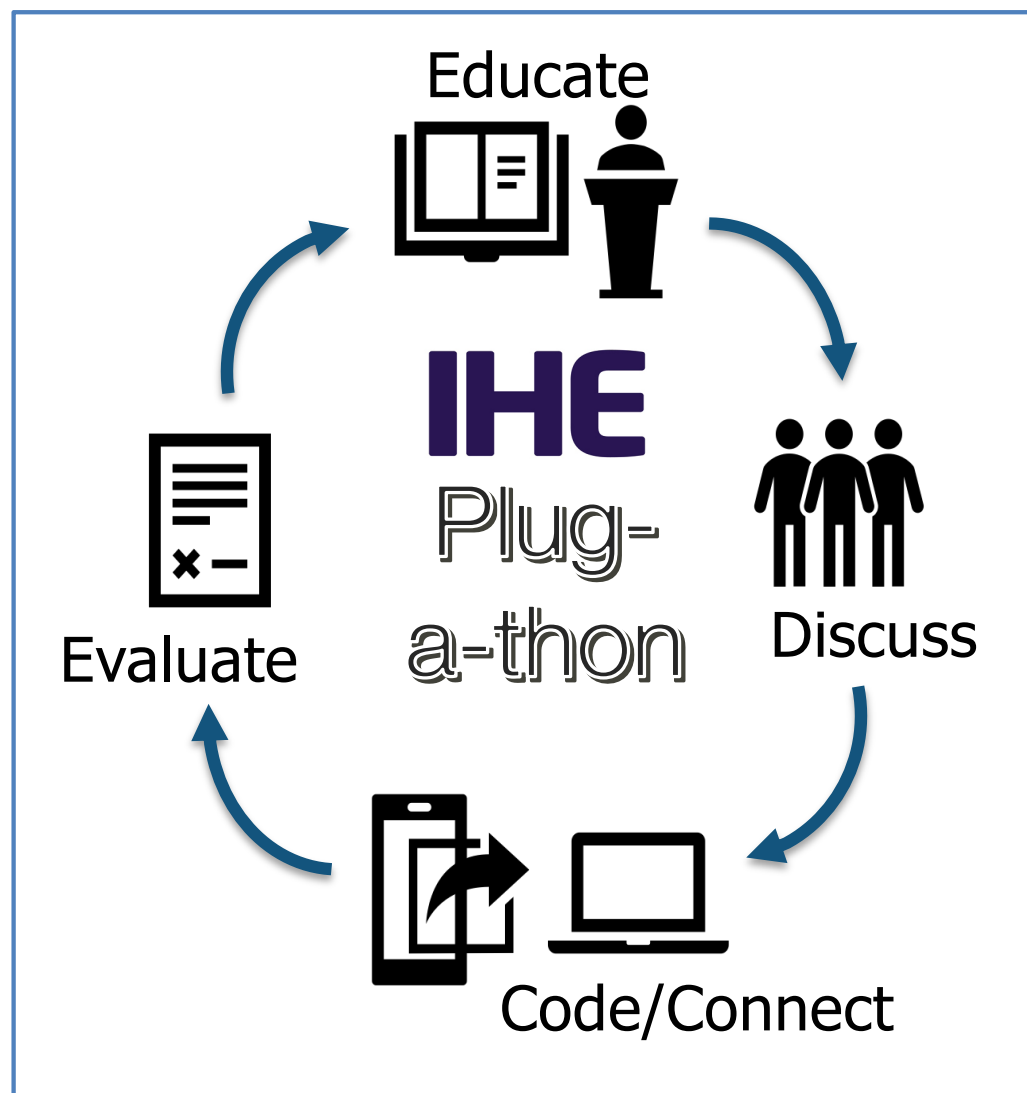- Standards and code in development
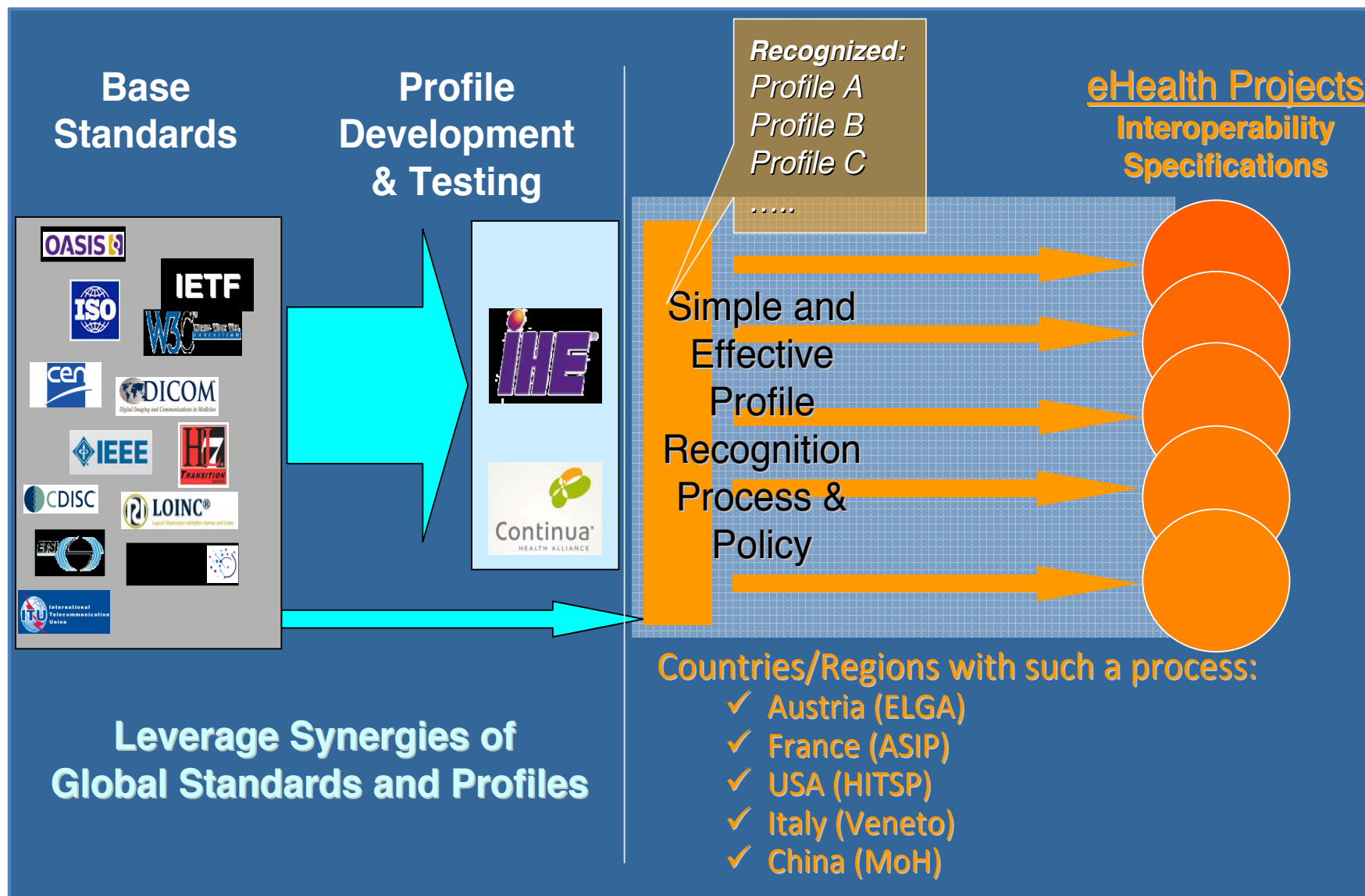- Code will change on-site

IHE Connectathons

- Rigor: Medium
- Structured, Peer-to-Peer testing
- Conformance
- Multiple standards
- Established standards
- Code might change on-site

IHE Conformity Assessment

- Rigor: High
- Selected IHE Profiles in Final Text
- ISO accredited test labs
- Strict version controls of product & tools
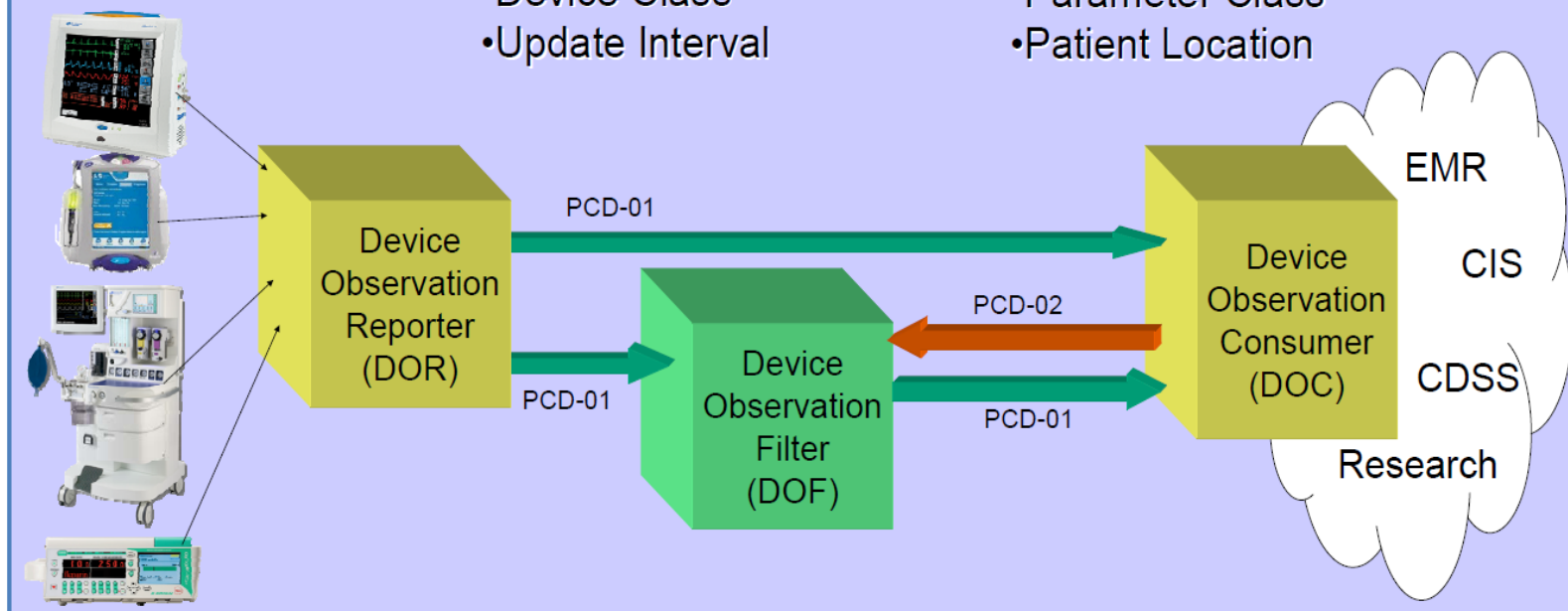
IHE Patient Care Devices (PCD)

IHE Patient Care Devices (PCD)

Base Standards

Profile Development & Testing

Recognized:
Profile A
Profile B
Profile C
.....

eHealth Projects
Interoperability Specifications

Simple and Effective Profile Recognition Process & Policy

Leverage Synergies of Global Standards and Profiles

Countries/Regions with such a process:
- ✓ Austria (ELGA)
- ✓ France (ASIP)
- ✓ USA (HITSP)
- ✓ Italy (Veneto)
- ✓ China (MoH)

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
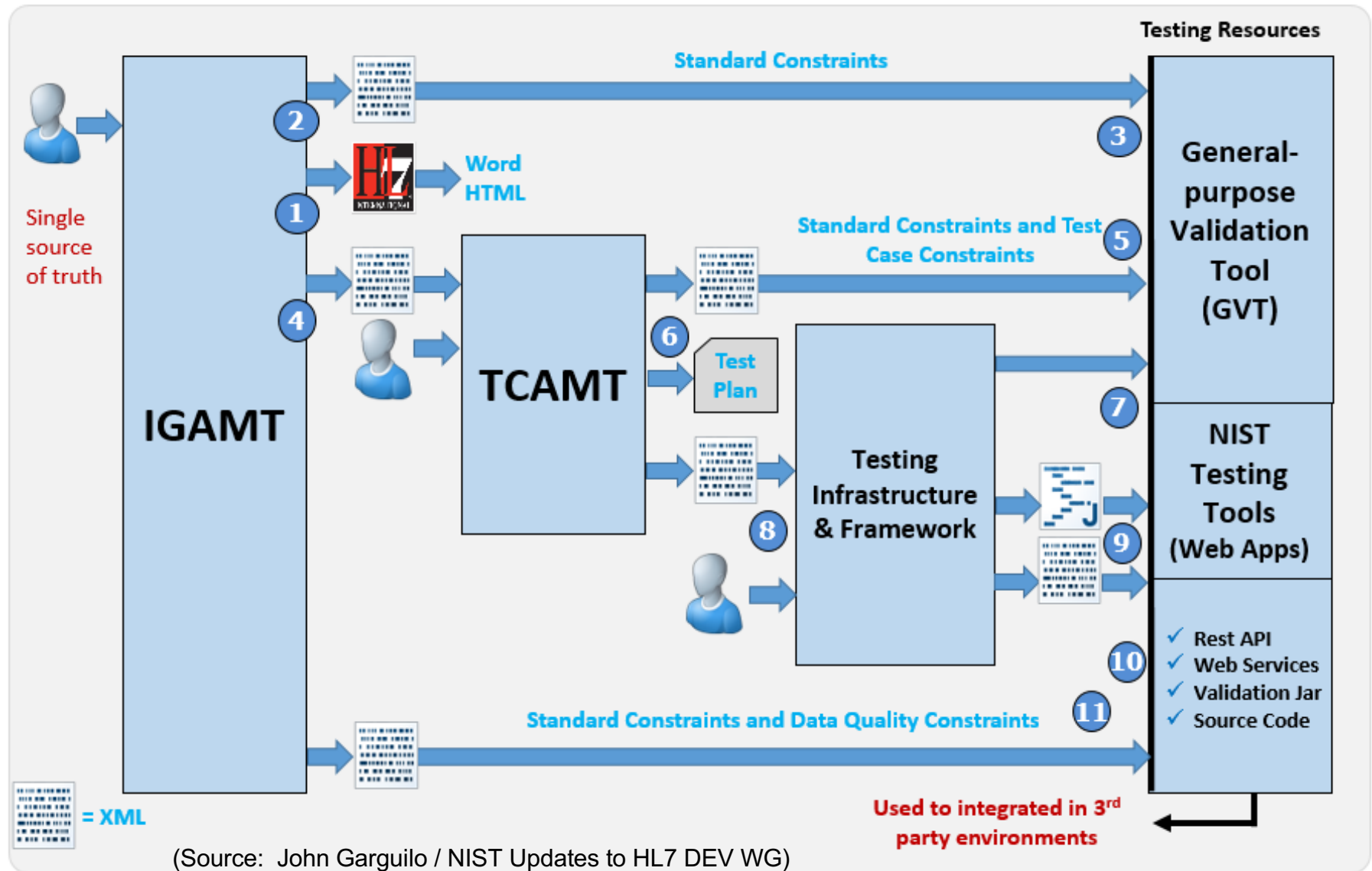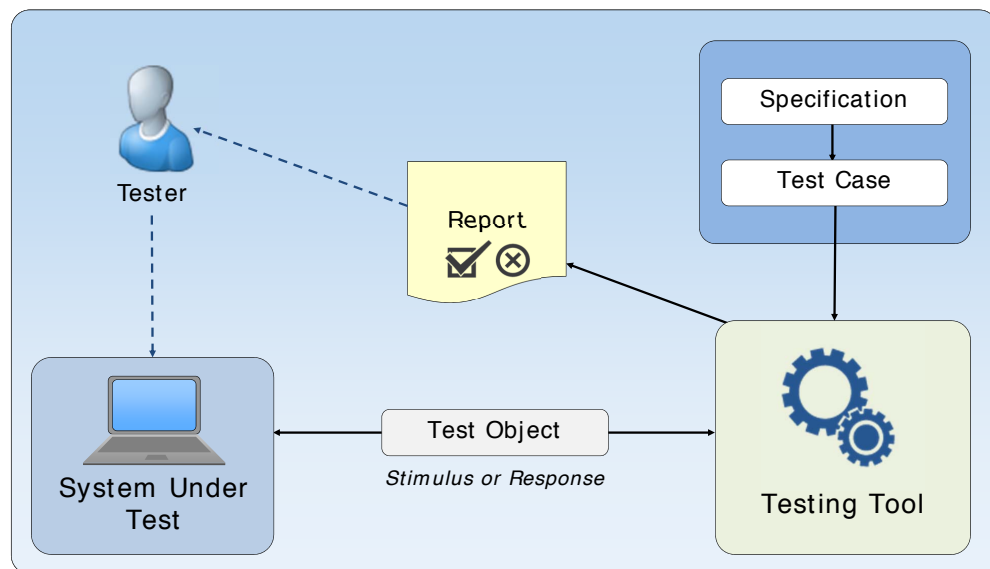- Patient Location

See 2018 PCD Webinars @
https://www.ihe.net/education/webinars/2018-webinars/#pcd
Sign up for 2019 PCD Webinar August 15 @
https://www.ihe.net/education/webinars/#pcd

IHE / NIST Tooling

NIST Validation Tools

Today – V2 / Future – CDA etc.

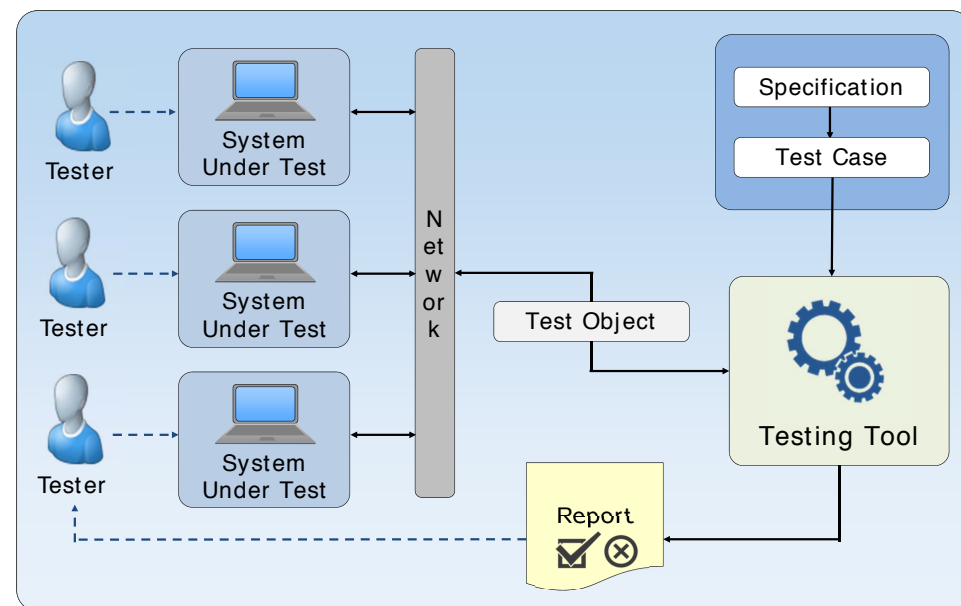(Source: John Garguilo / NIST Updates to HL7 DEV WG)
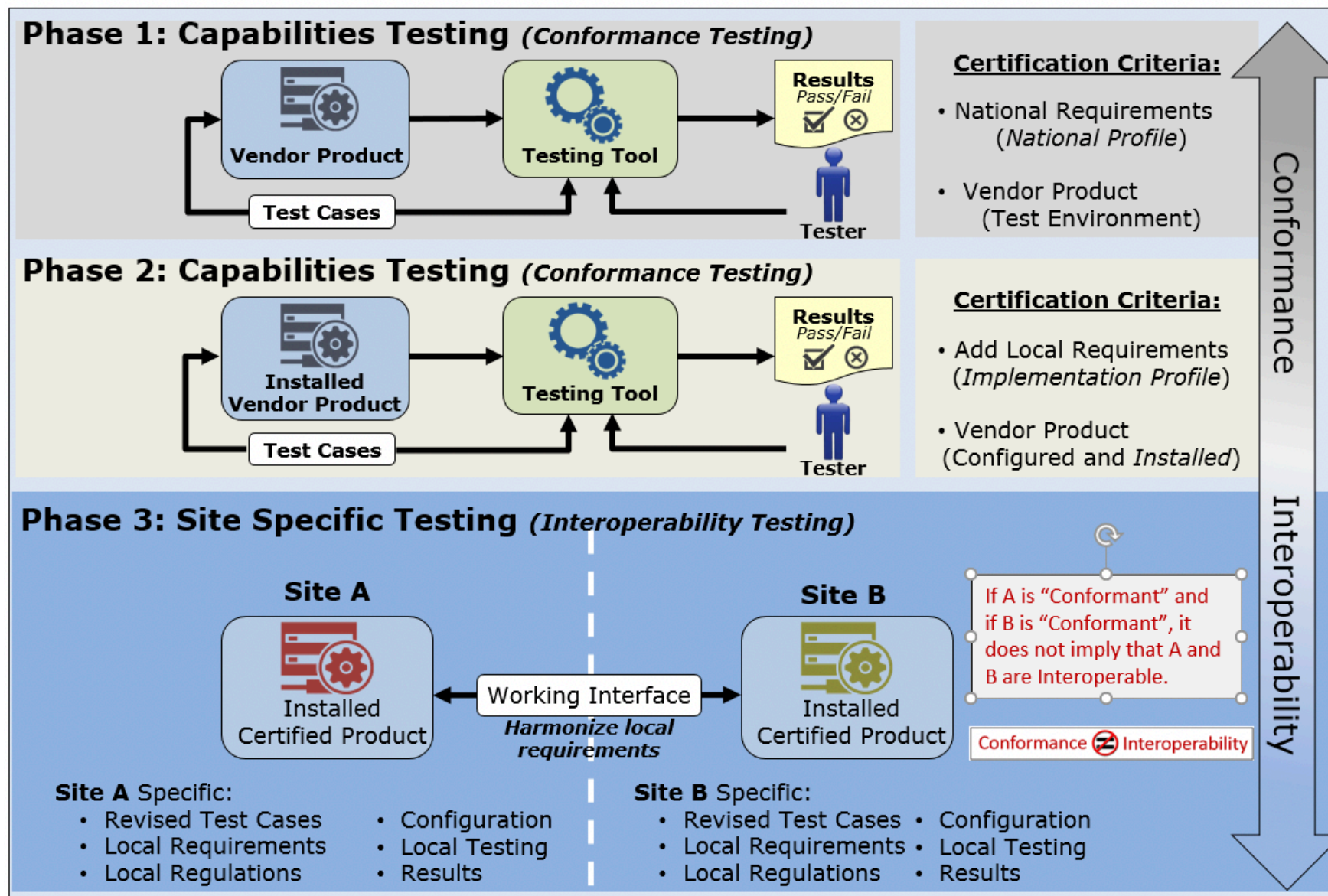
IHE / NIST Tooling

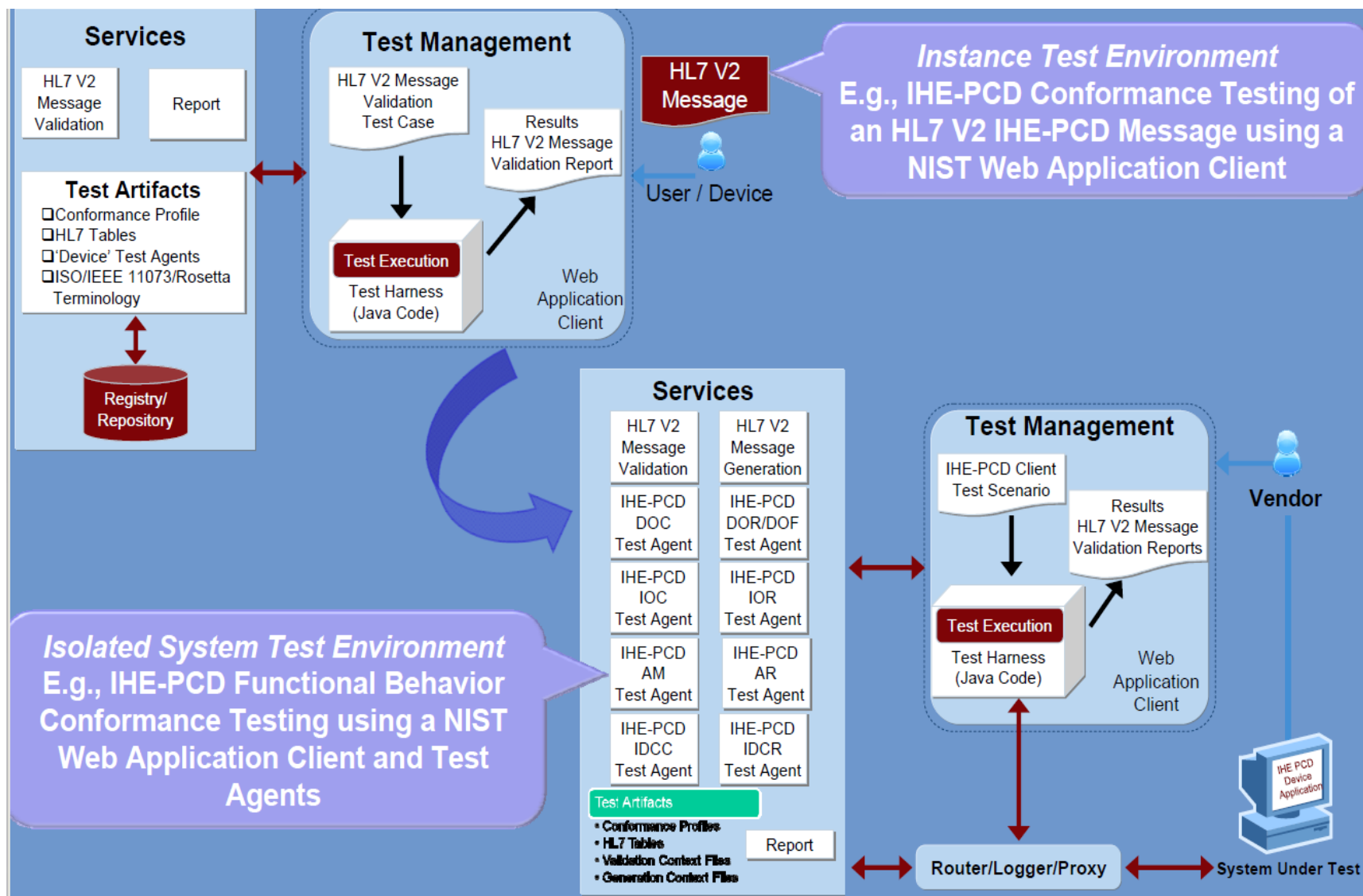Isolated System Testing

Progress from standalone to networked P2P
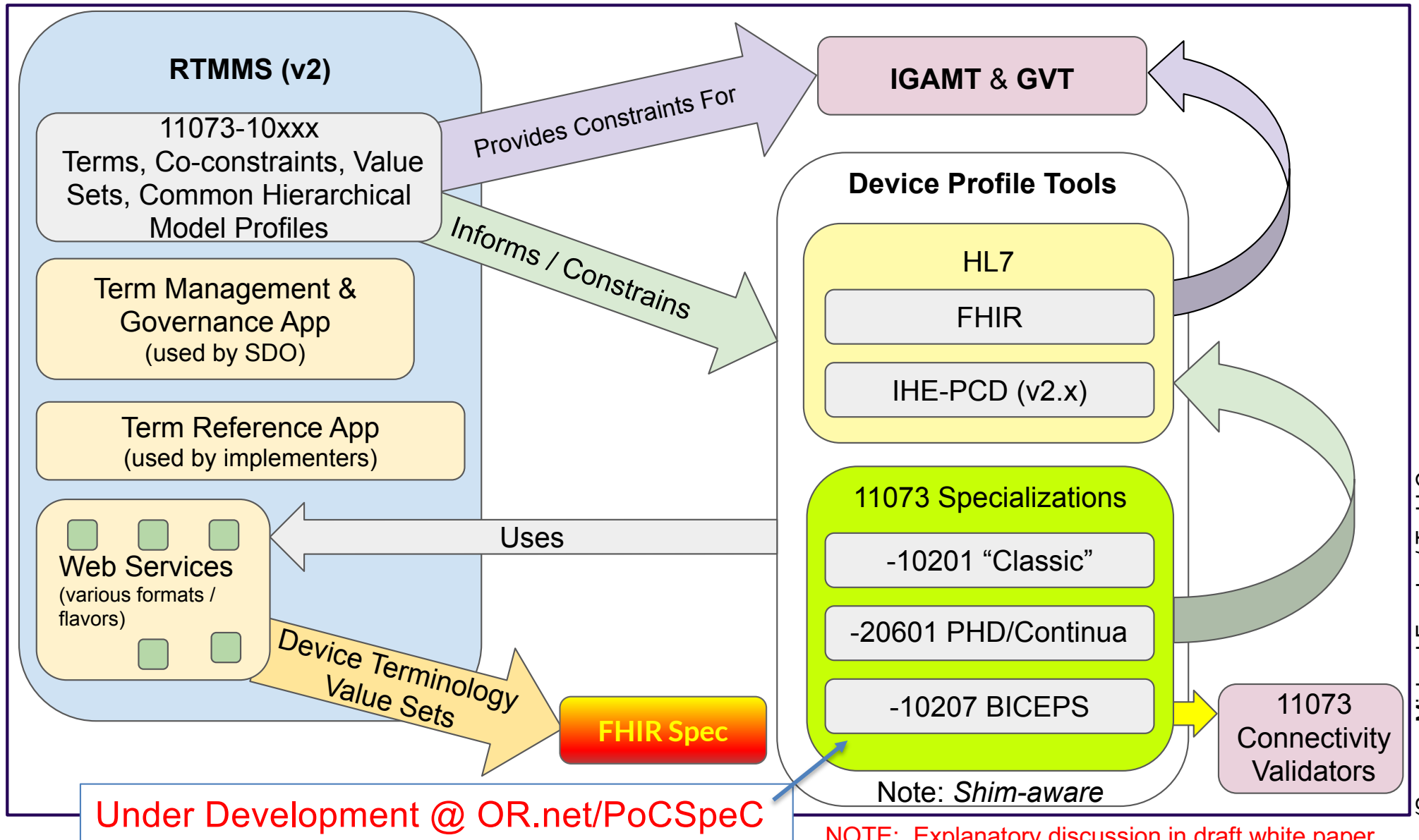
Peer-to-Peer System Testing (a la SOMDA!)

(Source: John Garguilo / NIST Updates to HL7 DEV WG)

(Source: John Garguilo / NIST Updates to HL7 DEV WG)

IHE / NIST Tooling

IHE / NIST Tooling

Proposed Framework to support SDC profiling …

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RTMMS (v2)

11073-10xxx
Terms, Co-constraints, Value Sets, Common Hierarchical Model Profiles

Term Management & Governance App
(used by SDO)

Term Reference App
(used by implementers)

Web Services
(various formats / flavors)

Provides Constraints For

Informs / Constrains

IGAMT & GVT

Device Profile Tools

HL7

FHIR

IHE-PCD (v2.x)

Uses

11073 Specializations

-10201 "Classic"

-20601 PHD/Continua

-10207 BICEPS

Note: *Shim-aware*

Device Terminology Value Sets

FHIR Spec

11073 Connectivity Validators

Under Development @ OR.net/PoCSpeC

NOTE: Explanatory discussion in draft white paper.

(Source: Michael Faughn / Todd Cooper)

**Session #2
IHE SDPi White Paper
*Review & Feedback***

Review & Comment

- ✓ **What is missing?** (esp. for Australian application)

- ✓ **What will be the greatest challenges?**

- ✓ **Where should start – early wins to finishing the plan?**

Download @
https://wiki.ihe.net/index.php/SDC@IHE_White_Paper

Integrating the Healthcare Enterprise

IHE

IHE Patient Care Devices (PCD)

White Paper

Service-oriented Device Point-of-Care Interoperability (SDPi)

Device-to-Device Connectivity in High-Acuity Healthcare Environments using Web Services Technology

Revision 1.0 – Draft for Public Comment

Date: August 1, 2019
Author: IHE PCD Technical Committee
Email: pcd@ihe.net

Session #3
IHE SDPi in Australia –
Challenges & Opportunities

Challenges & Opportunities for MDI/SDPi?

Open discussion considering …

1. Compelling Community-building Use Cases?
2. MDI @ Technical Challenges – Low hanging fruit?
3. Business Model Challenges – Who receives what value & how?
4. Regulatory (TGA) Engagement … role of IHE Australia?
5. Advancing disruptive innovation? Lowering the interop barrier
6. eHealth pain points to rally behind?
7. …

NOTE: Review ?'s collected into the parking lot

Workshop Wrap-up & Planning

Workshop Objectives

1. **Understanding of the challenges and current state of open standards-based medical device interoperability (MDI)**

2. **Detailed understanding of ISO/IEEE 11073 SDC interoperability**

3. **Review of the IHE SDPi Profile Proposal** (in comment period)

4. **Identify & Discuss Challenges with PnP MDI Realization**

5. **Identify & Discuss SDC/SDPi Application in Australia**

Workshop Wrap-up & Planning

Review …

- ✓ Takeaways … ?
- ✓ Next steps: Personally & IHE/MDI AU Community?

Changing the Way Healthcare CONNECTS

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