IHE | Integrating
the Healthcare
Enterprise

IHE PCD 2.0
Proposal *Update & Discussion*

IHE PCD @ 15 Years!

In 15 years, IHE PCD has become the **ONLY** successful standards-based initiative for the seamless exchange of device-sourced content.

2019.10.14 - 17

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IHE Patient Care Devices Domain – Rich History, Promising Future

IHE Integrating the Healthcare Enterprise for **20 Years**

Contributors: Raymond Peter Zambuto, CCE-e FHIMSS FACCE, Paul Sherman, CCE FACCE, Elliot B. Sloane, PhD CCE FACCE FHIMSS, and Todd Cooper

The IHE Patient Care Devices (PCD) domain traces its origins to 2001 when a task force of the American College of Clinical Engineering (ACCE) began working with IHE's Strategic Development Committee (SDC) to develop a plan to support medical devices. In February of 2005, the SDC ratified ACCE's proposal to address medical devices, and shortly thereafter the sponsoring organizations formally appointed ACCE to manage this new "Patient Care Devices" domain.

That year's Annual IHE Survey conducted by HIMSS indicated that most respondents believed that medical devices should be given a priority for inclusion in the IHE. Medical devices held the potential to posed potential connectivity numbers that would quadruple the number of IT devices. Medical devices were rapidly becoming "smarter," and manufacturers were moving to establish proprietary networking protocols. The time was right for the PCD Domain.

IHE PCD Group at HIMSS 2006. From left: Elliot B. Sloane, Jack Harrington, Emanuel Furst, Raymond Zambuto, Todd Cooper.

PCD 2.0 Rationale

Why "fix" a success story?!

World has changed! Especially with coordinated care that spans time and geography

Care delivery is now as much about health & well-being as health*care*
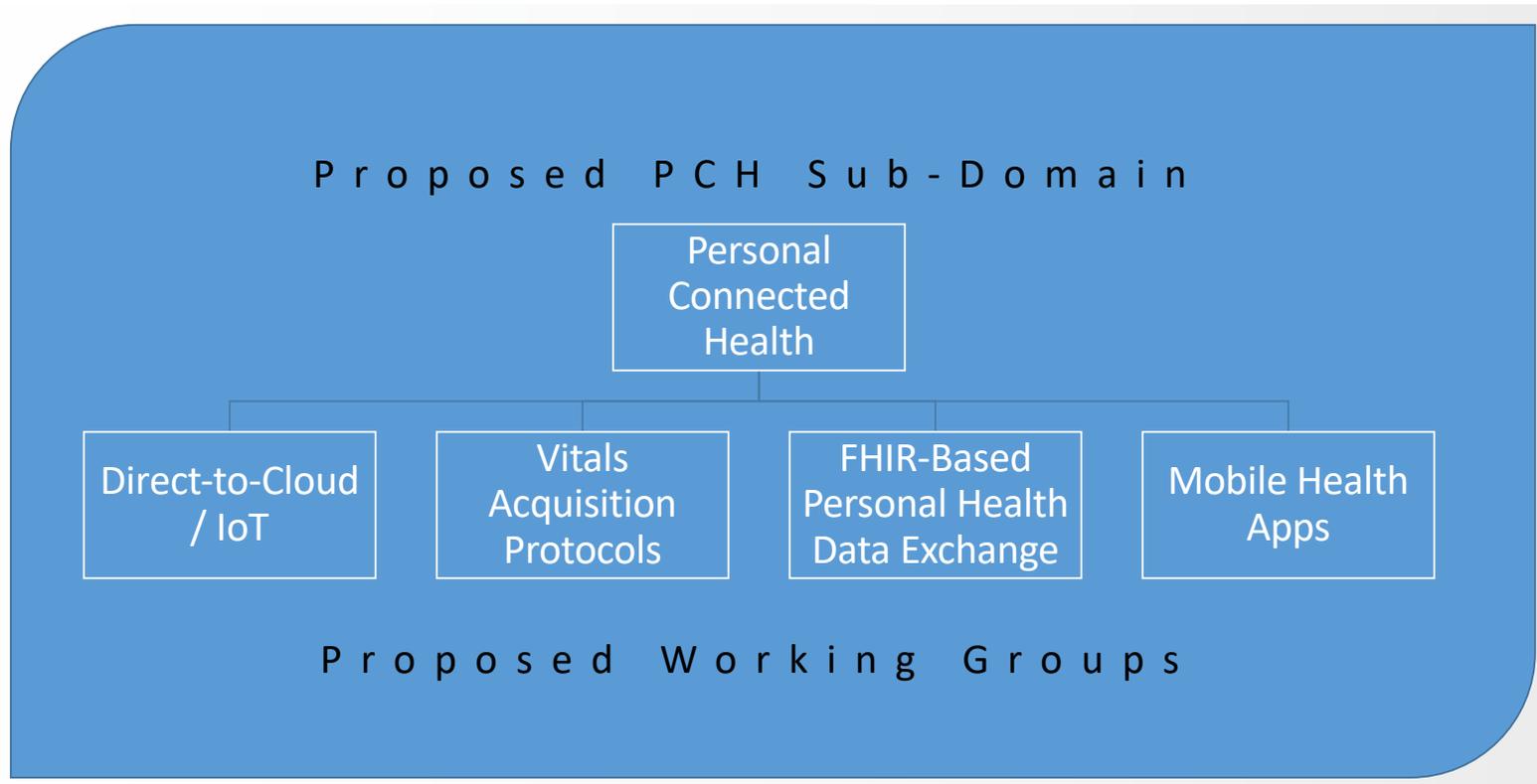
Technology & Standards present new opportunities & challenges …

Global marketplace is rapidly changing – a simple, clear "devices" message & "place" is needed

15 years is … 15 years! (time for a freshening up…)

PCD 2.0 Proposal - Overview
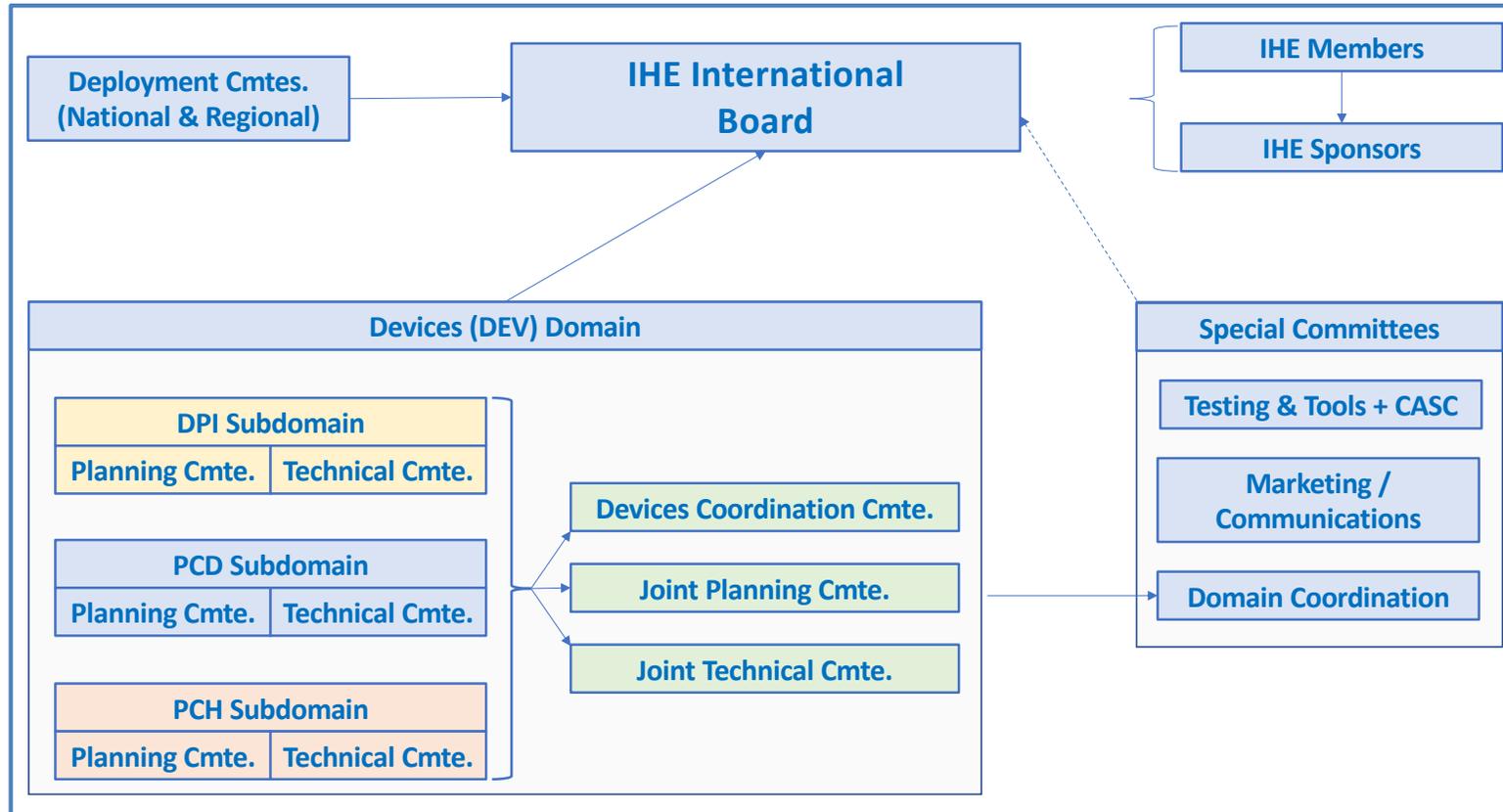
1. Approved by IHE PCD leadership & PC / TC members
2. Simple name – Devices – Organized by (3) primary device use contexts
3. Subdomains maintain established, globally recognized brand labeling
4. Single TF w/ shared domain + specialized subdomain content
5. Domain external relationships unchanged + broadened …
6. New Domain Sponsors: PCHAlliance for PCH & OR.net for DPI

PCD 2.0 Proposal @ PCH

Proposed PCH Sub-Domain

Personal Connected Health

| Direct-to-Cloud / IoT | Vitals Acquisition Protocols | FHIR-Based Personal Health Data Exchange | Mobile Health Apps |

Proposed Working Groups

1. Joint Exploration Committee – Finalizing IHE – PCHAlliance MoU
2. PCD 2.0 Proposal Coordinated with exploration committee planning
3. Focused joint PCD & PCHA "launch" discussions in Boston next week

PCD 2.0 - Timeline

2019.10.16-17   Joint PCD / PCHA Meeting & Reorg. "Launch"

2019.10.18 to 12.31   Finalize all intra-domain coordination / governance

2020 January   15TH Anniversary – PCD 2.0 Devices Domain
                          Public Launch @ NA CAT '20

Approved 2019.10.10

As the IHE PCD domain embarks on this next leg of the journey, it's members have the following requests of the IHE International Board to approve:

1. **Domain name change** …

   From   "Patient Care Devices (PCD)"

   To: "Devices (DEV)"

2. **Endorse the high-level intra-domain reorganization approach** of …

   ✓ (3) Subdomains: DPI, PCD & PCH

3. **General timeline** from Boston meetings to Cleveland CAT

Approved 2019.10.10

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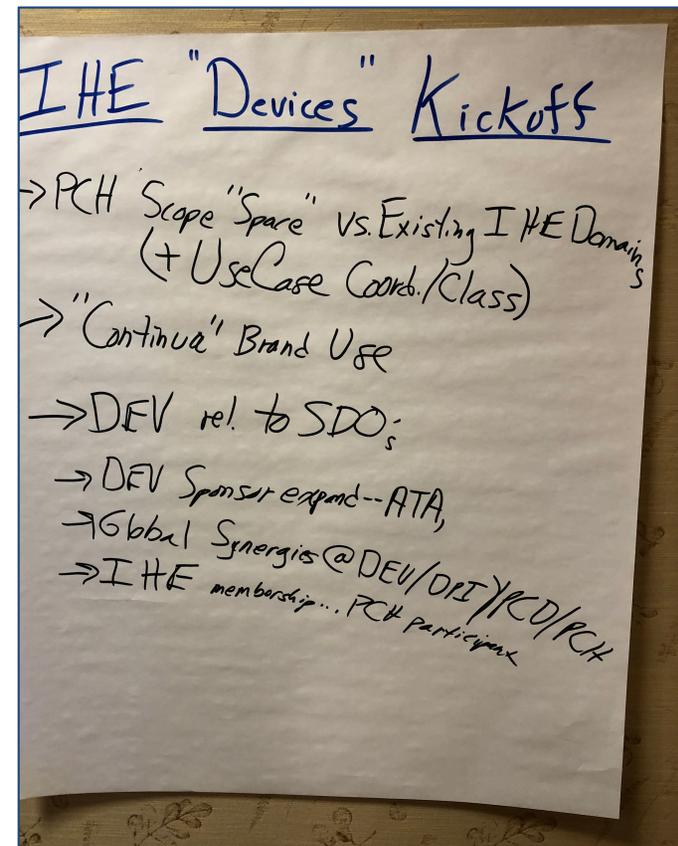
    To: "Devices (DEV)"

2. **Endorse the high-level intra-domain reorganization approach** of …

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3. **General timeline** from Boston meetings to Cleveland CAT

What now … ?!

What now …

Is a "Device"

PCD 2.0: "Device"?
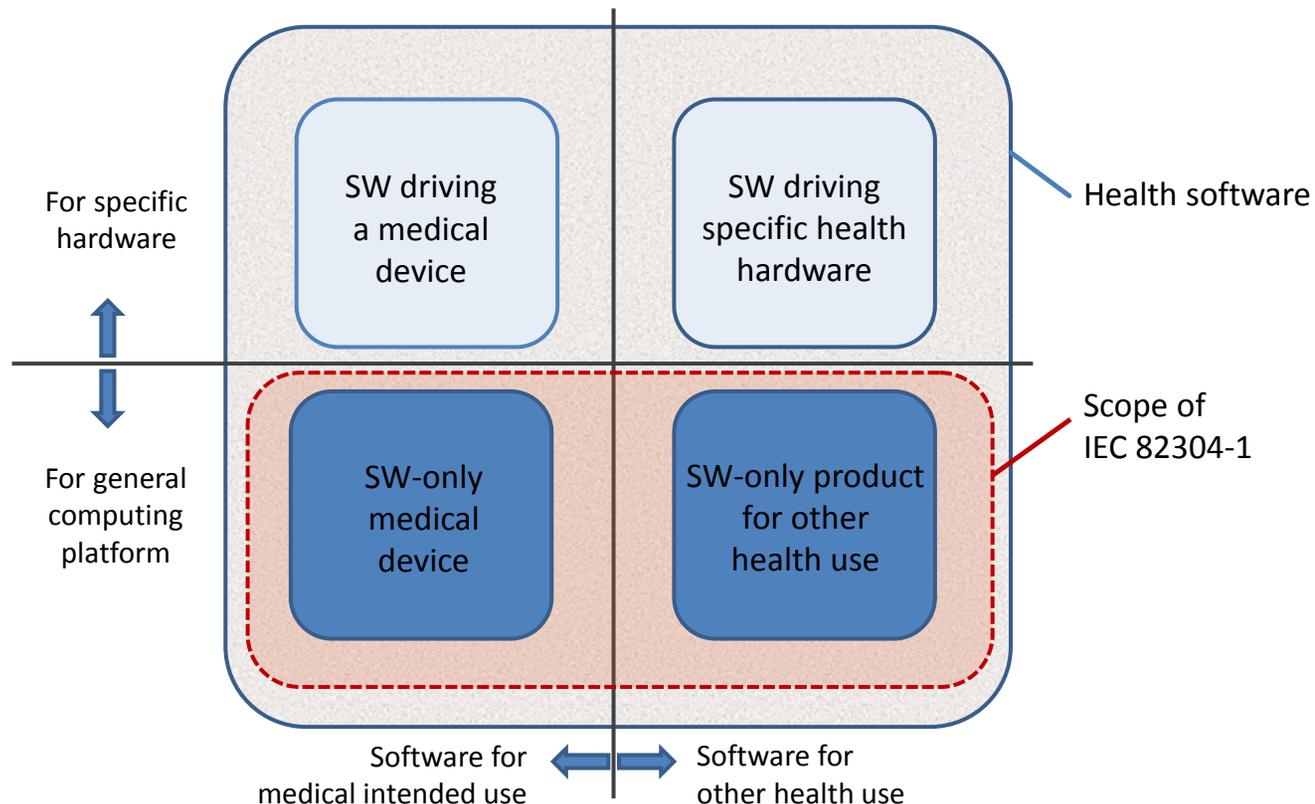
IEC CDV 82304-1 © IEC 2015   – 6 –   62A/1013/CDV

HEALTH SOFTWARE –
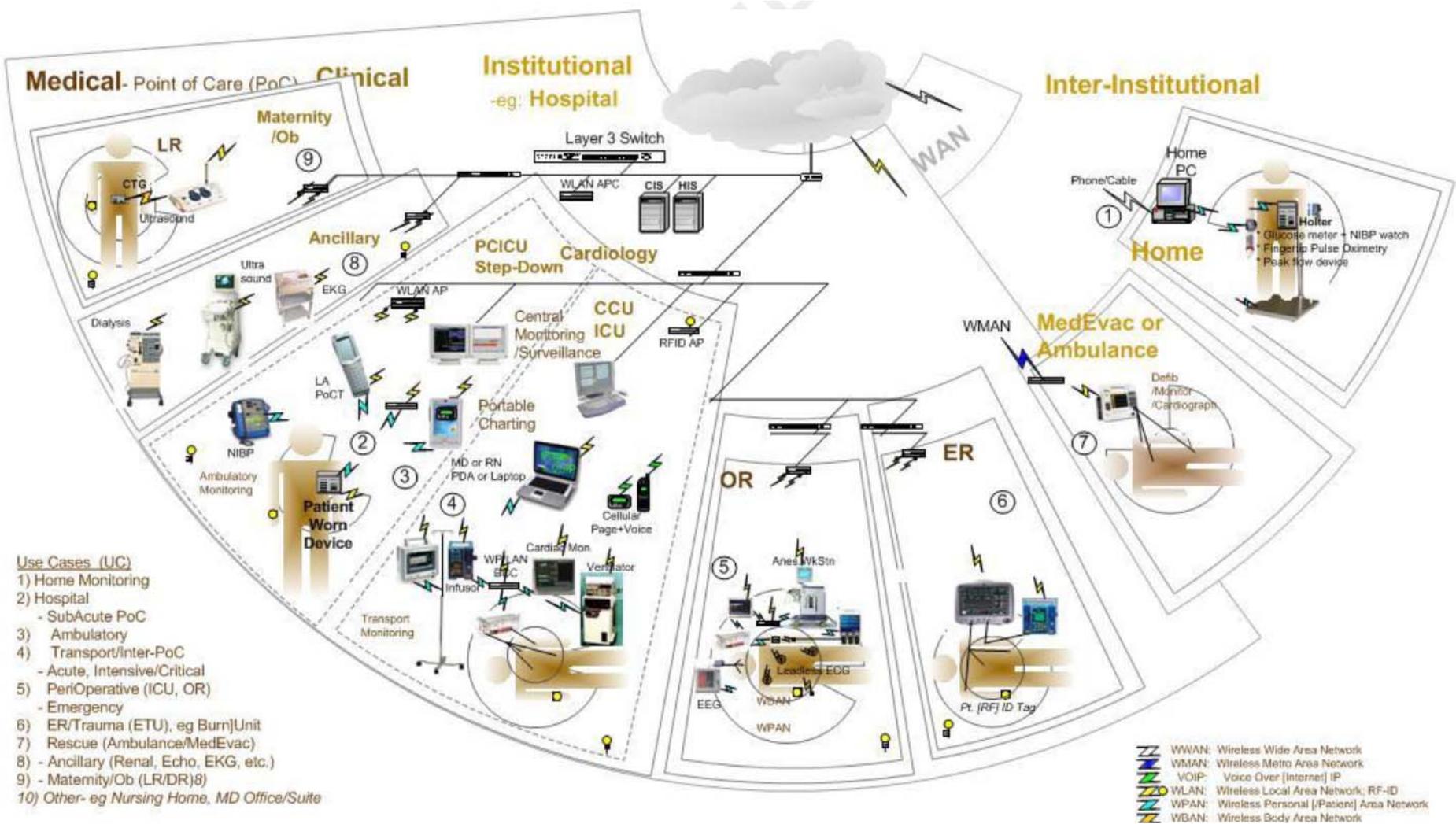
Part 1: General requirements for product safety

1 Scope

1.1 Purpose

This International Standard applies to the SAFETY of HEALTH SOFTWARE PRODUCTS designed to operate on general computing platforms and intended to be placed on the market without dedicated hardware, and its primary focus is on the requirements for MANUFACTURERS.

For specific hardware

For general computing platform

SW driving a medical device

SW driving specific health hardware

Health software

SW-only medical device

SW-only product for other health use

Scope of IEC 82304-1

Software for medical intended use

Software for other health use

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MDI: *The Big Picture*

(Source: Jan Wittenber, Philips Medical)

IHE "Devices" & AI/ML SaMD?

Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)
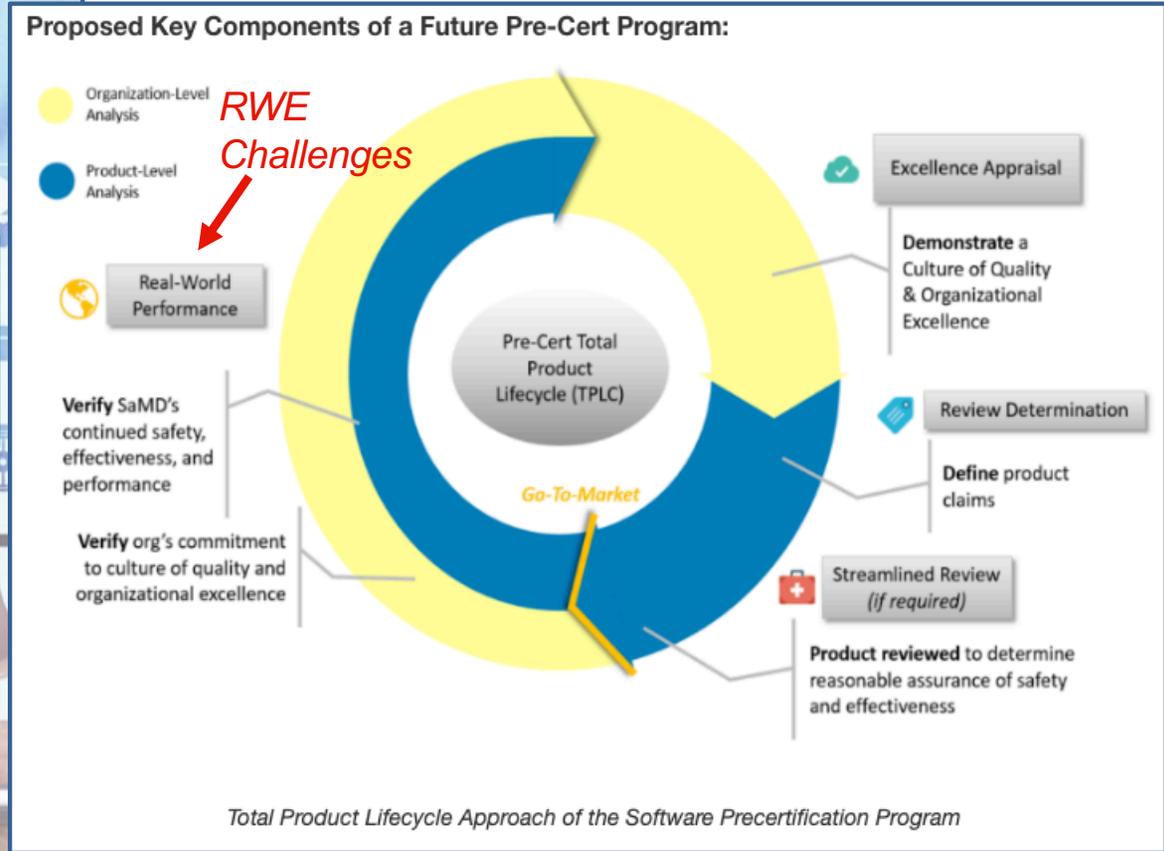
Discussion Paper and Request for Feedback

Released @

https://www.fda.gov/downloads/MedicalDevices/Digital Health/SoftwareasaMedicalDevice/UCM635052.pdf?

+ Two new IEEE 11073 WGs on Artificial Intelligence Medical Devices (AI MD WGs) recently launched … in China!

+ IEEE EMBS projects on
  ✓ Medical IoT
  ✓ mHealth

FDA Digital Health & RWE
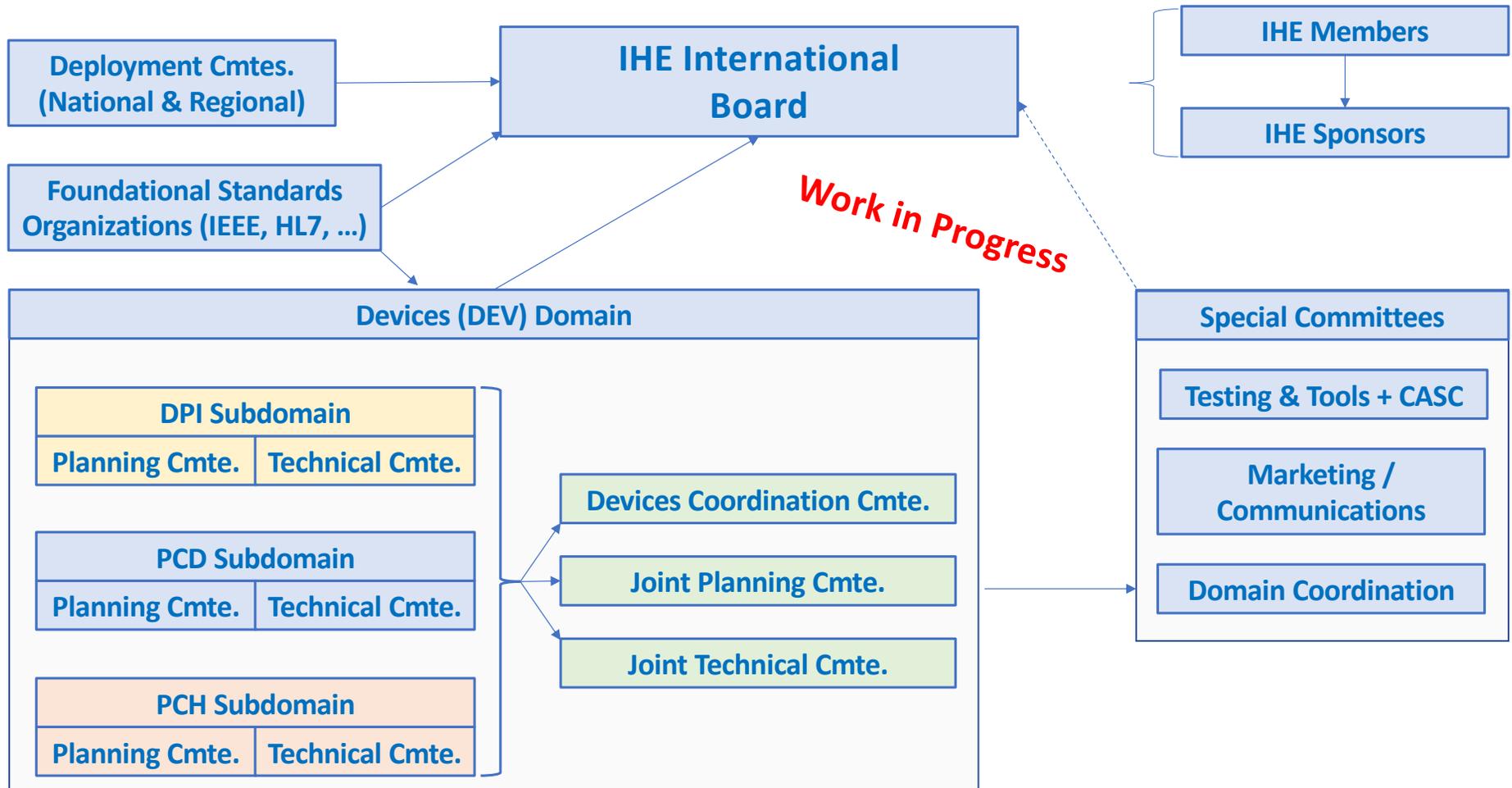
X73 Scoping Considerations

- **Use Cases** - both that are distinct to a specific use context and that involve two or three and require cross-context coordination
- **Use Contexts** - are the (3) suggested appropriate or should there be a further breakdown? Architectures?
- **Ecosystem** – Intra & Inter Context Providers / Consumers (e.g., EHR consumers of PoC device content)
- **Risk => Criticality => Regulatedness**: Clearly this is involved in all three use contexts, but at different levels?
- **Quality** – including process requirements (e.g., ISO 13485)
- **User** - professional clinician to personal grandpa or family caregiver
- **Technology** - esp. with the advent of Medical IoT, mobile FHIR-based, AI/ML MD ... EMBS SC initiatives? Etc.
  - Consider RWE needs of FDA and others @ AI MDs ... melding a few of the above aspects
- ...

PCD 2.0: Scoping

Notes from Boston discussions …

- Who is missing from the "health device" discussion … esp. given the large volume of health data that is being communicated today … across all use contexts?
  - Vision => Future State "Why?" To what end …
  - + Domain / Subdomain Scope + Vision + Mission
- Engagement (value prop) esp. for PCH-related stakeholders / ecosystem members esp. … persons
- …

What now …

@ "Subdomains"? & Governance

PCD 2.0 Proposal - Overview

IHE — Integrating the Healthcare Enterprise

Deployment Cmtes. (National & Regional)

Foundational Standards Organizations (IEEE, HL7, …)

IHE International Board

IHE Members

IHE Sponsors

Work in Progress

Devices (DEV) Domain

DPI Subdomain
Planning Cmte.	Technical Cmte.

PCD Subdomain
Planning Cmte.	Technical Cmte.

PCH Subdomain
Planning Cmte.	Technical Cmte.

Devices Coordination Cmte.

Joint Planning Cmte.

Joint Technical Cmte.

Special Committees

Testing & Tools + CASC

Marketing / Communications

Domain Coordination

IHE DEV Sponsors: **AAMI**, **ACCE** & **HIMSS** + **PCHAlliance** & **OR.net**

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PCD 2.0: Governance

- Do all domain "votes" happen at the Domain ("Joint …") level or subdomains or both …?

- Subdomain formal "recommendation" for Domain Joint cmtes. (similar to WG votes to take to Joint committees)

- How to effect coordination @ formal votes w/o lengthening the process …

- What is within the Domain Joint level (use cases, artifacts, activities, etc…) vs. Subdomain?

- How to ensure that one subdomain doesn't negatively impact the work of another group w/o due diligence … Analogy of ISO governance from WG to TC to TMB…

- Analogy (?): PCC Nursing "subdomain" …

What now …

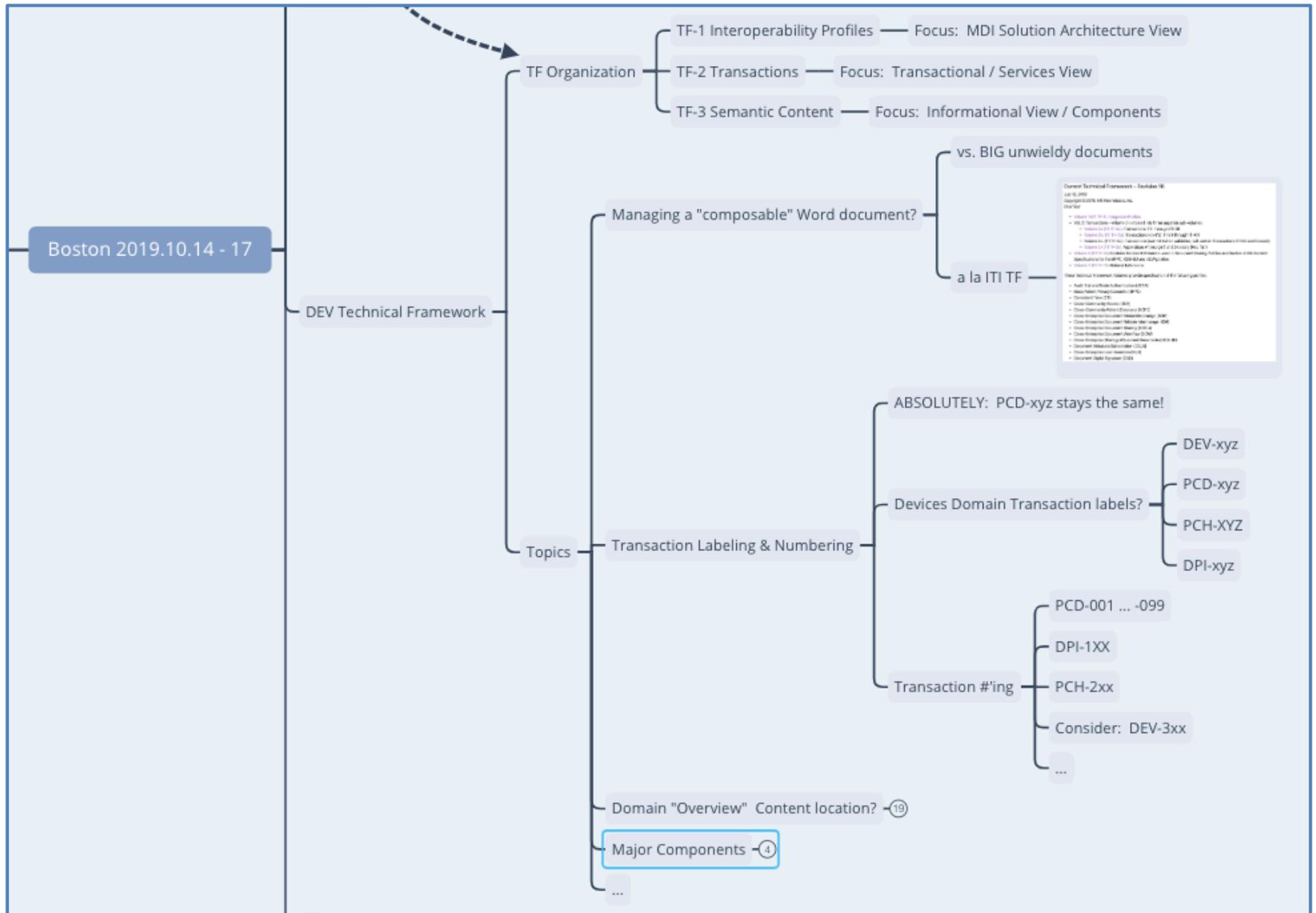# @ '20 Meetings?

What now …

@ Single TF? Vol's? Transaction Labels? …

Notes from Boston discussions …

Boston 2019.10.14 - 17
- TF Organization
  - TF-1 Interoperability Profiles — Focus: MDI Solution Architecture View
  - TF-2 Transactions — Focus: Transactional / Services View
  - TF-3 Semantic Content — Focus: Informational View / Components
- DEV Technical Framework
  - Managing a "composable" Word document?
    - vs. BIG unwieldy documents
    - a la ITI TF
  - Topics
    - Transaction Labeling & Numbering
      - ABSOLUTELY: PCD-xyz stays the same!
      - Devices Domain Transaction labels?
        - DEV-xyz
        - PCD-xyz
        - PCH-XYZ
        - DPI-xyz
      - Transaction #'ing
        - PCD-001 ... -099
        - DPI-1XX
        - PCH-2xx
        - Consider: DEV-3xx
        - ...
    - Domain "Overview" Content location? -⑲
    - Major Components -④
    - ...

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What now …

@ DEV Use Case Compendium?

What now …

@ Transaction Labels?

![IHE logo — Integrating the Healthcare Enterprise]

What now …

@ Testing & Tooling?

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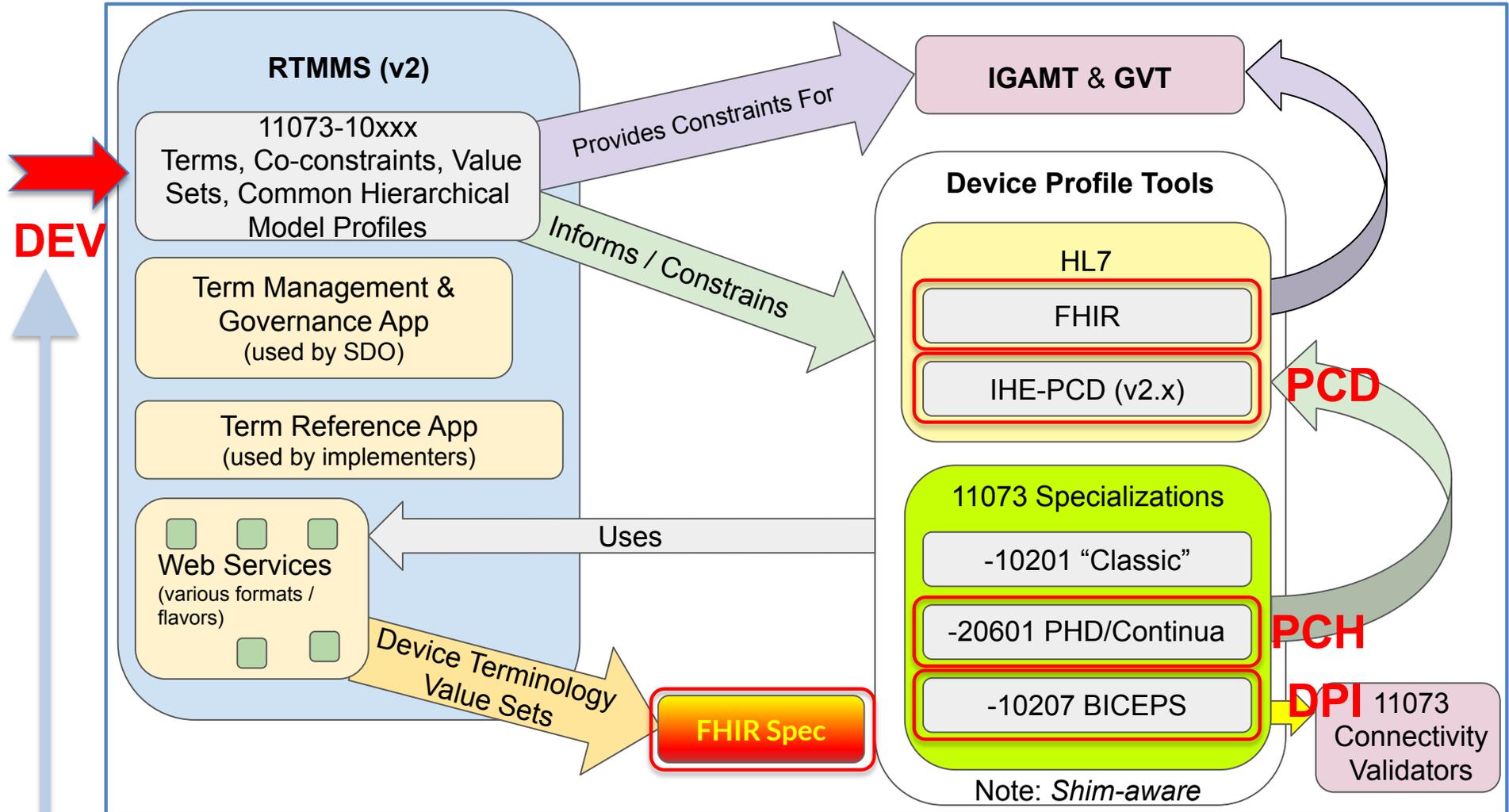
What now …

@ Pre-CAT, CAT, CAS

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