

IHE Patient Care Devices
SDC Initiative Group
2019-06-27

IHE

Integrating
the Healthcare
Enterprise

SDC@IHE

White Paper Topics for Discussion

Topics for Discussion

1. Core Use Case Examples – **6/27**
2. SDC Standards & Functional Capabilities – **2/27**
3. SDC Mapping to IHE Tech Framework Constructs - **6/27**
4. SDC CA Framework (testing & tooling) – 7/3
 - *NOTE: See ongoing discussion in IHE PCD Standards & Tooling weekly (a.k.a. “DPI Call”)*
5. Device Profiling: From Normative “Gold” to On-the-Wire Validation – 7/3

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Core Use Case Examples

White paper contains:

- ✓ Four core use cases that can be used to establish the core requirements for integrating SDC-enabled devices and systems into IHE TF.
- ✓ Appendix identifying and referencing the large body of use cases that have been developed to understand interoperability of devices in high acuity healthcare contexts.

Key Questions:

- ✓ Right (4) use cases to target?
- ✓ Folded into TF-1? Where?
- ✓ Level of detail in white paper – actor diag? transactions? High-level only (like QH example)?

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.

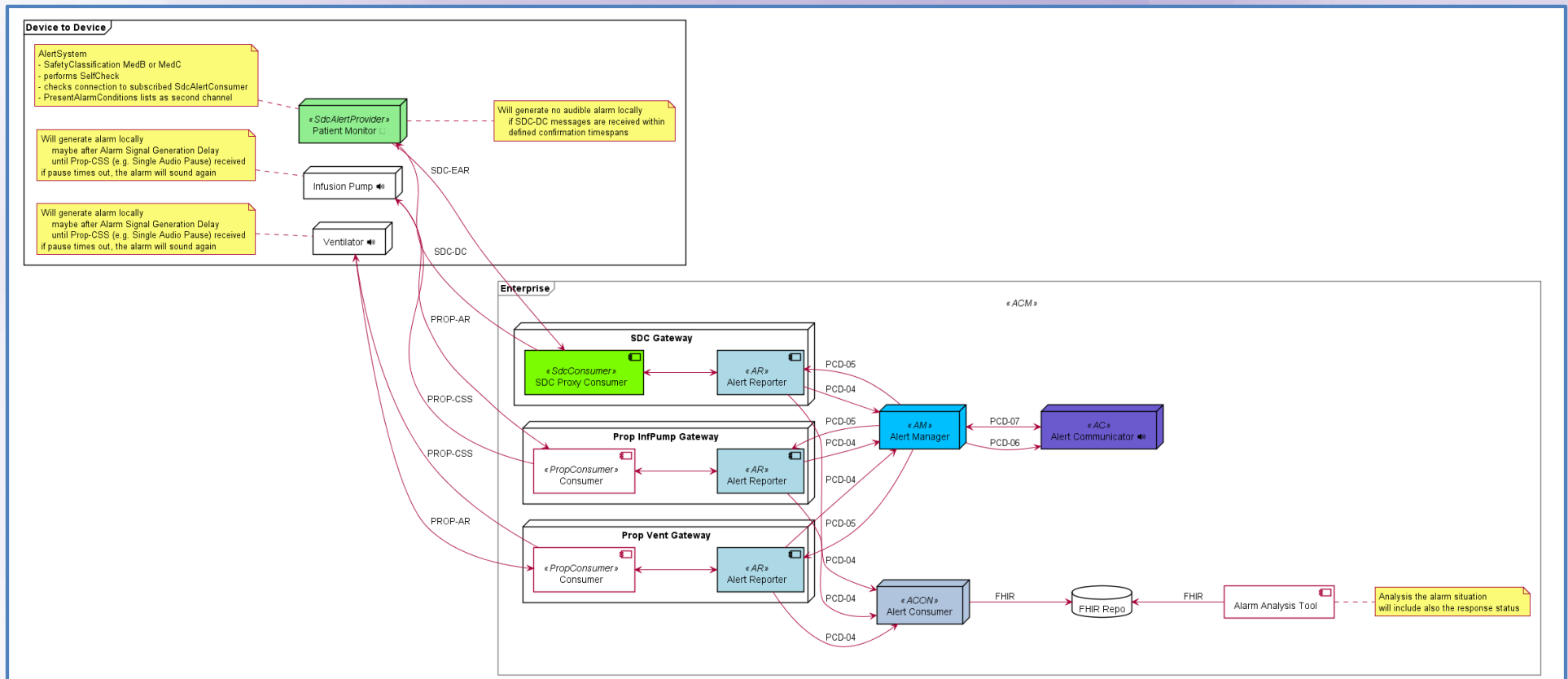
NOTE: Proposed for the HIMSS'20 SDC Showcase Demo

Example #2: NITRD '19 MDI Use Case

- 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*

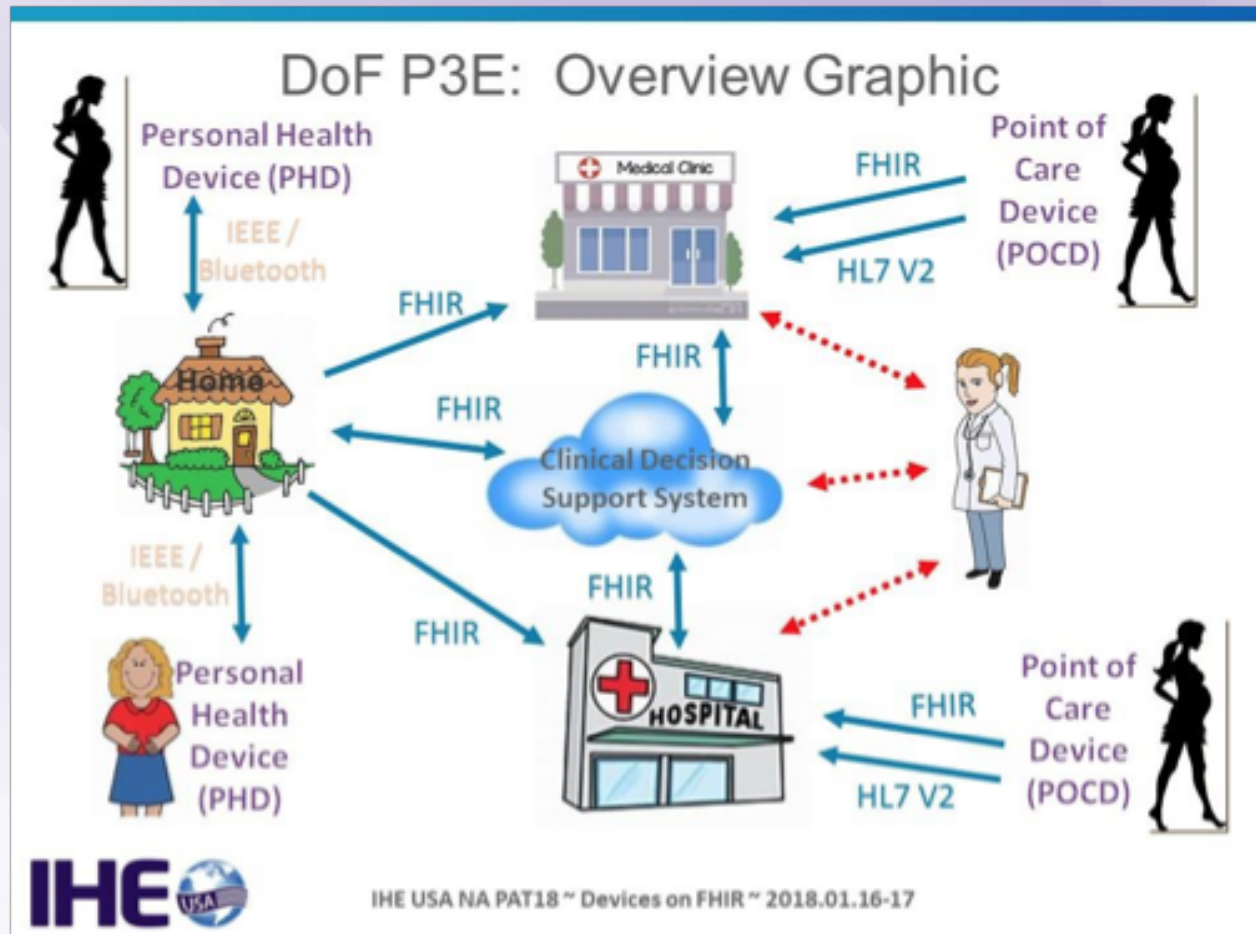
Source: <https://www.nitrd.gov/nitrdgroups/index.php?title=Medical-Device-Interoperability-2019>

Example #3: SDC to Enterprise



Source: IHE PCD **Quiet Hospital** initiative; HIMSS'20 Showcase proposal; graphic is version 3 – work in progress

Example #4: SDC with DoF (PoCD / PHD)



Source: IHE DoF PAT '18 + HL7 FHIR DevDays
2019.06.27 SDC@IHE White Paper – Topics for Discussion

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The text 'SDC Standards & Functional Capabilities' is centered on the page in a bold, dark blue, sans-serif font. The background features a stylized globe with latitude and longitude lines, and several overlapping, semi-transparent purple and blue shapes that create a sense of depth and movement.

SDC Standards & Functional Capabilities

SDC Core Elements:

- ✓ Standards set (baseline & in-process)
- ✓ General Architecture (device-to-device w/ Gateway)
- ✓ TF-1 Functions: reporting, alerting, controlling
- ✓ TF-2 Functions: Core SDC services

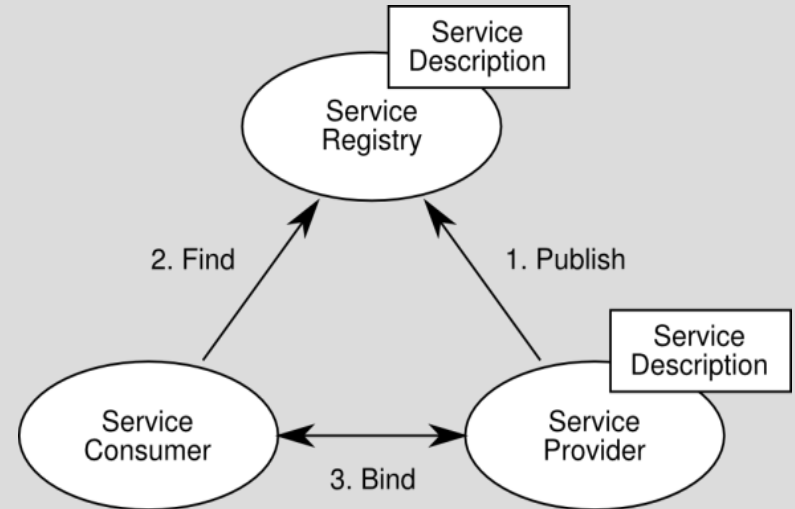
Key Questions:

- ✓ Safety, security & risk mitigation for Key Purposes?
- ✓ Device Specializations?
- ✓ Imaging integration?
- ✓ ...

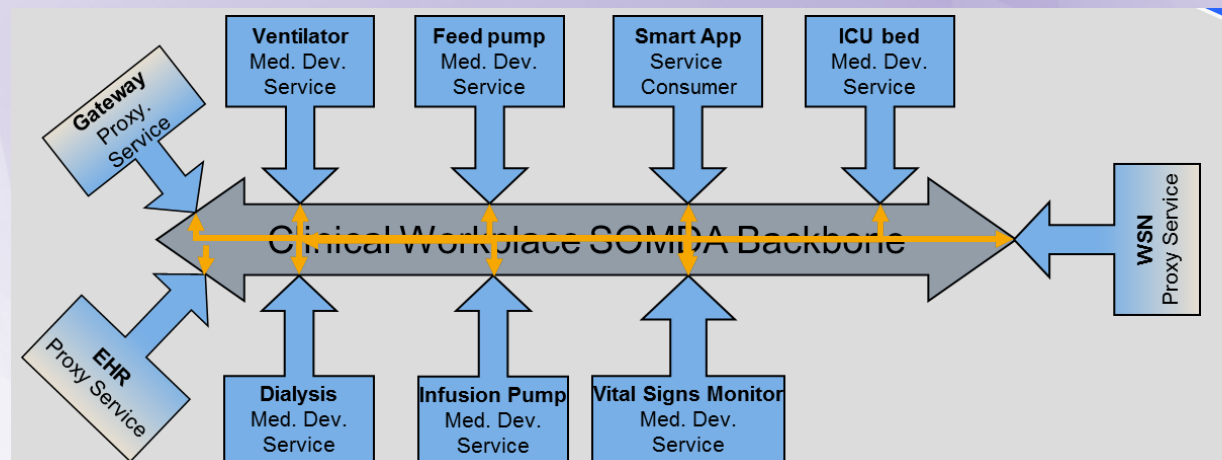
SDC Standards & Functional Capabilities

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.**

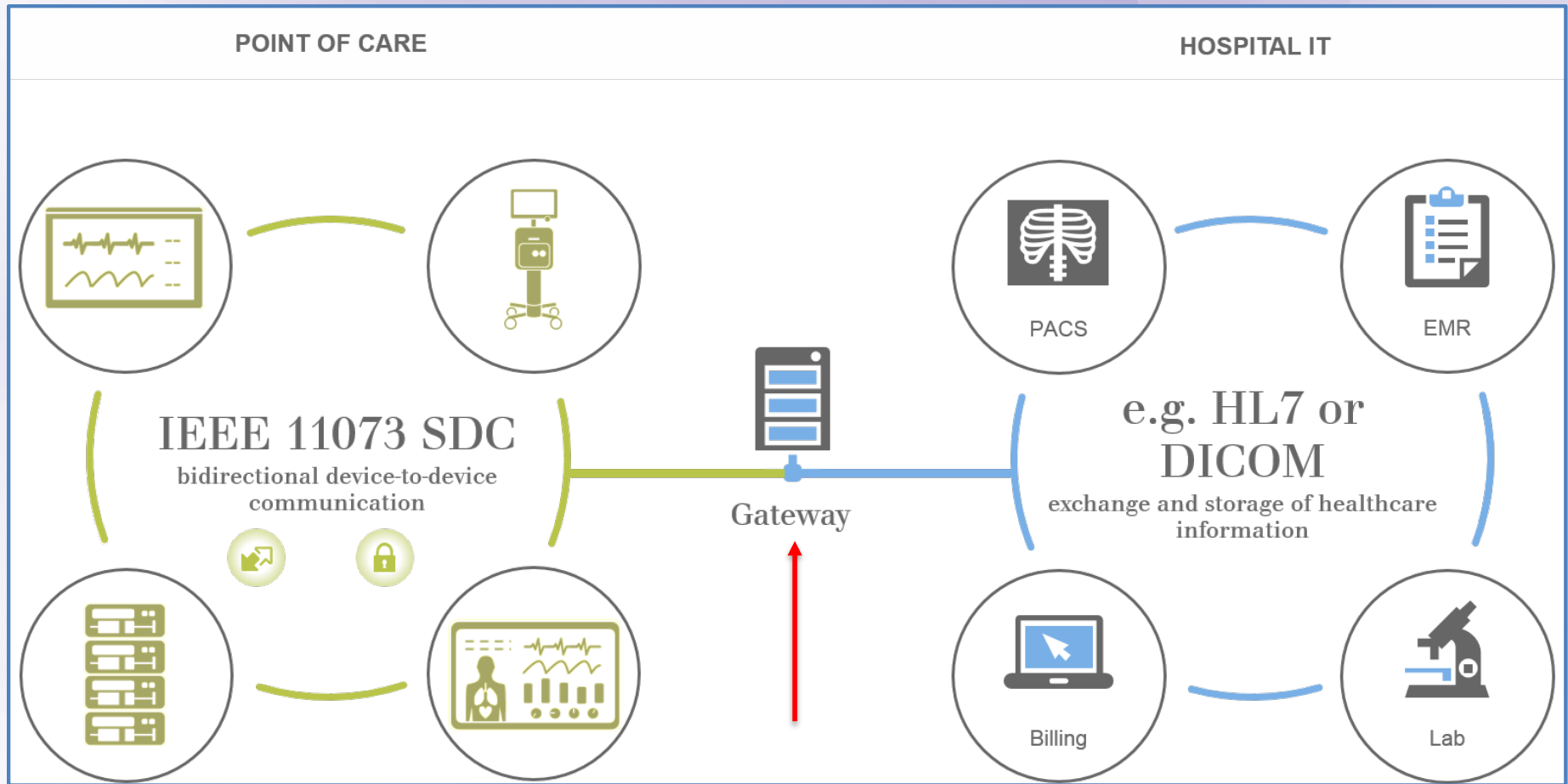
Actors?



Device-
to-
Device



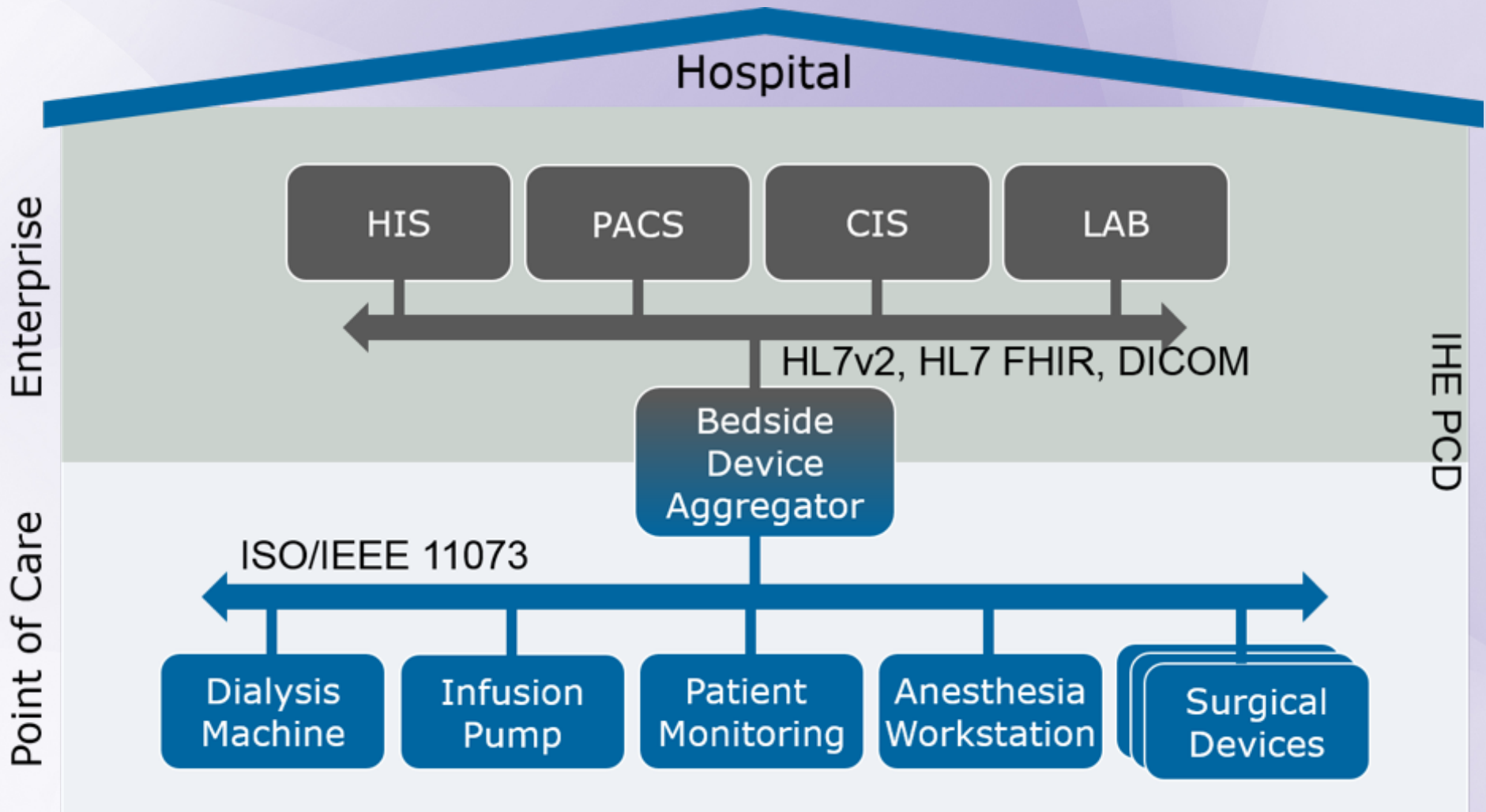
SDC Standards & Functional Capabilities



SDC Point-of-Care Context

IHE "Enterprise" Context

SDC Standards & Functional Capabilities



SDC Standards & Functional Capabilities

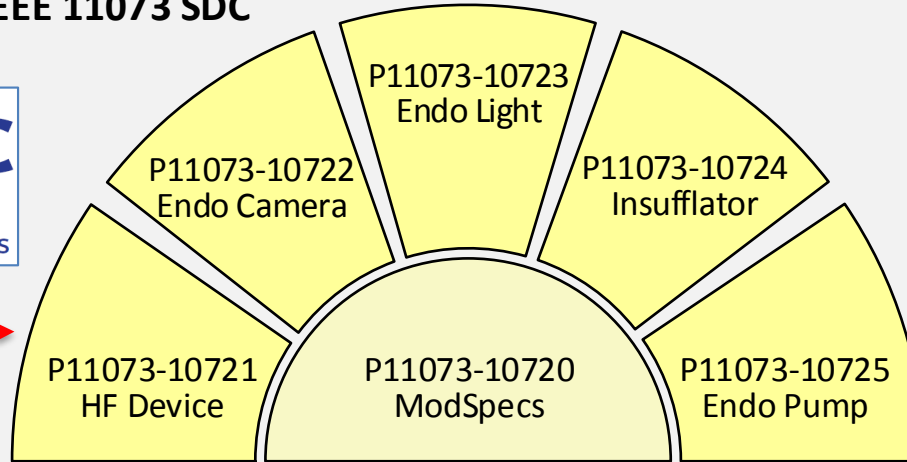
PoCSpec
Modular Specialisations for
Point-of-Care Medical Devices

Soon!

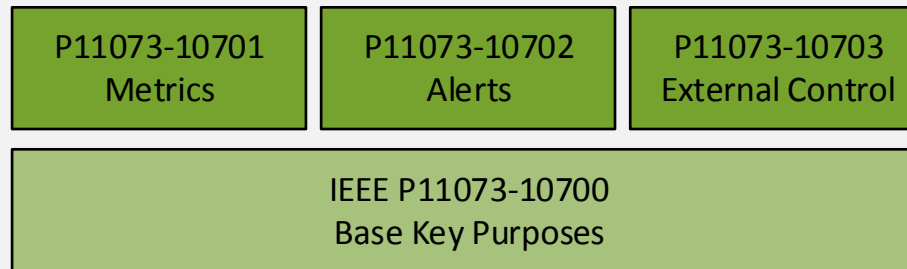
Next!

Now!

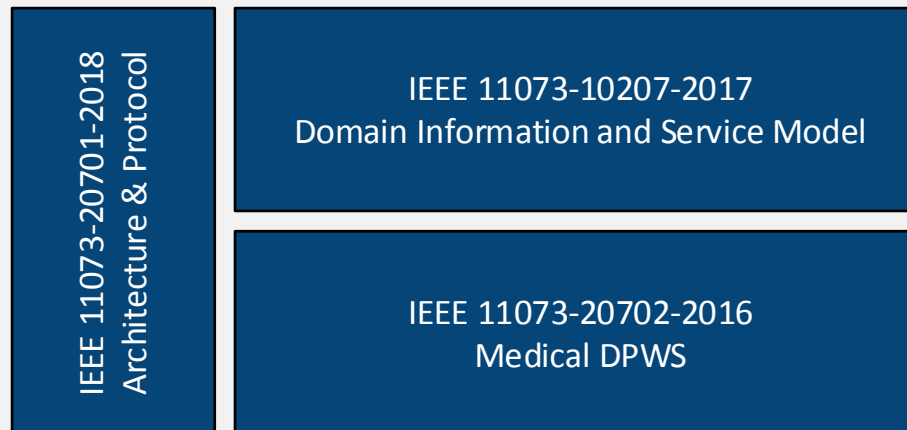
IEEE 11073 SDC



Device Specialisations



Key Purposes



Core Standards

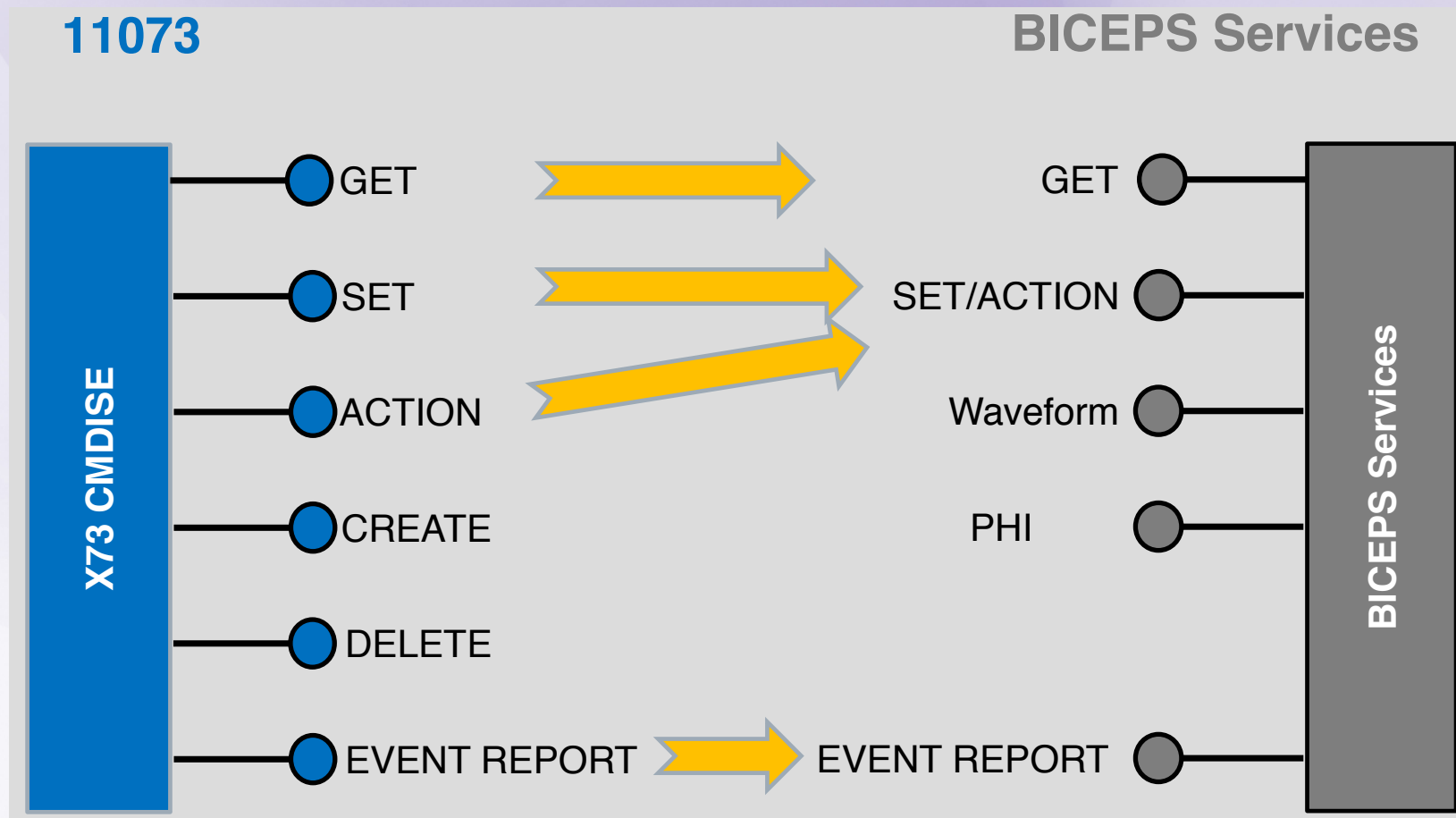
IEEE 11073-1010X
Nomenclature

Safety considerations section?

SDC Standards & Functional Capabilities

Questions:

1. Map BICEPS Services to TF-2 transactions?
2. ...



SDC Standards & Functional Capabilities

Questions:

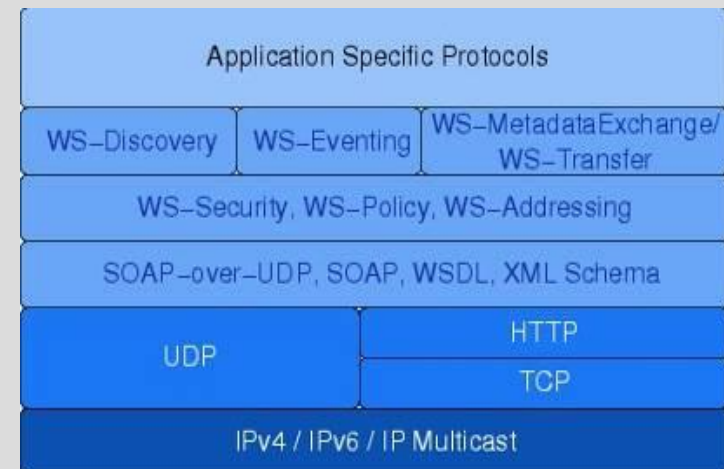
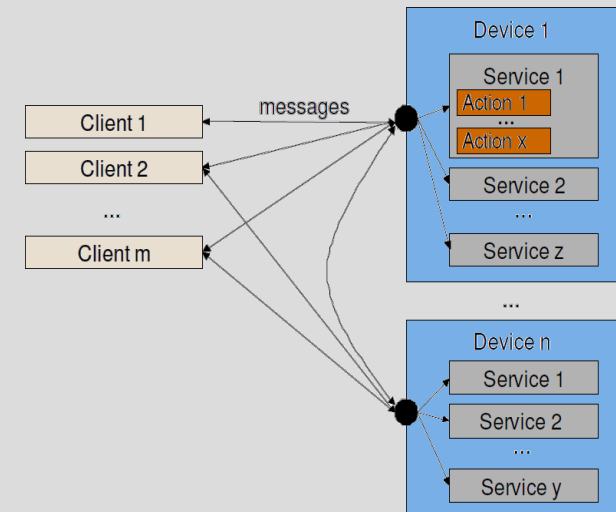
1. Map **MDPWS** Services to TF-2 transactions also?
2. Security Considerations section?
3. Relationship to ITI WS-* Appendix (used for DEC @ IHE-KR CAT)

■ DPWS:2009* is the core of MDPWS

- OASIS standard (since 07/2009)
- Utilizes a subset of the WS-* standard
- Covers
 - Service discovery,
 - Interface description,
 - Messaging,
 - Event propagation, and
 - Secure information transmission
- Designed for resource-constrained devices

■ MDPWS

- Added some missing parts e.g. safe transmission of control requests



SDC Standards & Functional Capabilities

Questions:

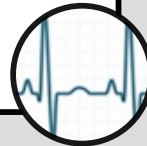
1. Where to include these **MDPWS** extensions?

Profile options:

1. Binary XML?
2. Secure exchange?
3.

- WS-Streaming based on SOAP-over-UDP for (numeric) data streaming
- Maybe unreliable
- Multiple receivers

Waveform
Streaming



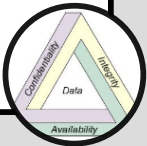
- Safe & reliable data exchange based on
- WS-SafetyInformation
 - e.g. Dual Channel
- Liveliness assurance

Patient
Safety



- Access control for critical operations
- Secure transmission

Access
Control



- XML Manifestation doesn't need to be UTF-8
- Optional binary XML (EXI) for reduced message sizes

Compression



- Policy assertions
- Limit options in DPWS spec
- New Device Type for Discovery

General



- Add some sequence diagrams

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SDC Mapping to IHE Tech Framework Constructs

(Conceptual Approach Only!)

Mapping considerations:

- ✓ IHE TF Volumes & Components (traditional)
- ✓ Scale from basic SDC to specializations to therapeutic protocols & clinical workflow

Key Questions:

- ✓ Where to present SDC architecture content (TF-1 / 2)?
- ✓ Profiling: Family vs. Profile vs. Options
- ✓ How to relate to existing IHE PCD profiles for reporting, alerting and (limited) controlling @ Enterprise context?

#1 Challenge for SDC@IHE



IHE TF-1 – Interoperability Profiles:

- ✓ Perspective: Primarily clinical
- ✓ Actors / Transactions / Options / Constraints / Dependencies
- ✓ Use Cases / Process Flows / Sequence Diagrams
- ✓ General Principles / Concepts (see XDS.b ITI TF-1)
- ✓ Implementation Strategies / Considerations

IHE TF-2 – Transactions:

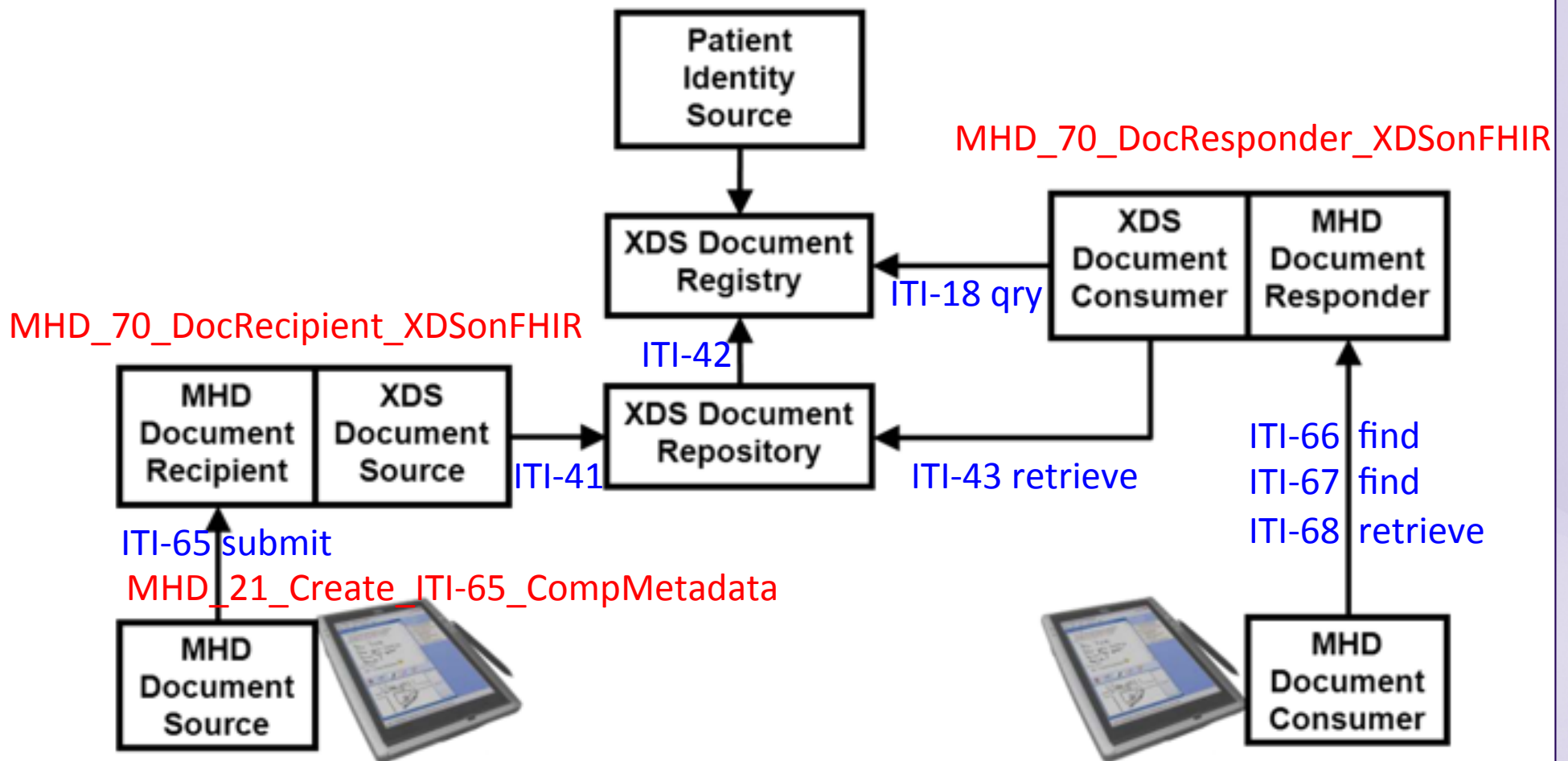
- ✓ Core tech reference detail to SDC standards

IHE TF-3 – Semantic Content:

- ✓ General terminology use to device specializations
- ✓ Value sets bindable to actors & transactions

The "XDS on FHIR" Option - MHD in an XDS Environment

'Conversion' of MHD transactions into XDS transactions
These are tests run by MHD actors that have this capability.



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Changing the Way Healthcare **CONNECTS**

<http://www.ihe.net>

The logo for the Integrating the Healthcare Enterprise (IHE) initiative, consisting of the letters 'IHE' in a bold, dark blue, sans-serif font.

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Additional Information

