# IHE Germany
# SDC / SDPi Plug-a-Thon -

## *Overview Briefing*

**20-21 October 2020**

# IHE Germany – SDC / SDPi Plug-a-Thon – Briefing

**IHE Plug-a-Thon Basics**

**From ISO/IEEE 11073 SDC to IHE SDPi to PATs & CATs**

**Orientation Tour:  IHE Technical Framework & SDPi Profiles**

**Real-world Narrative:  Pandemic Patients in an Isolation ICU**

**SDC/SDPi PAT – Objectives**

# First … Term Usage & Assumptions

**SDC** — **S**ervice-oriented **D**evice **C**onnectivity

Family of ISO/IEEE 11073 SDC standards

Assumption: PAT participants have a working understanding of SDC

**SDPi** — **S**ervice-oriented **D**evice **P**oint-of-care **I**nteroperability

Set of (4) IHE technical framework profiles based on ISO/IEEE 11073 SDC standards

Assumption: PAT participants may have some working knowledge of IHE & TF profiles

**PAT** — **P**lug-**a**-**t**hon

IHE testing event intended for early, informal exploration of new tech & new profiles

Assumption: PAT participants may have background in "hackathons", plugfests, etc.

**CAT** — **C**onnect**at**hon

IHE formal interoperability testing event for published profiles; includes independent monitors, test management tooling; published results

Assumption: PAT participants may have background in formal test invents

# Second … Profiles? Why?!

**IHE Profile**

A technical specification that ***constrains*** a set of general open standards for application to a specific interoperability or integration need (described by a set of use cases) [1]

**Why profiles?**

As users and implementers agree how to use standards to address specific integration needs, optionality must be minimized, coordinated usage of multiple standards considered, and national / regional allowances factored

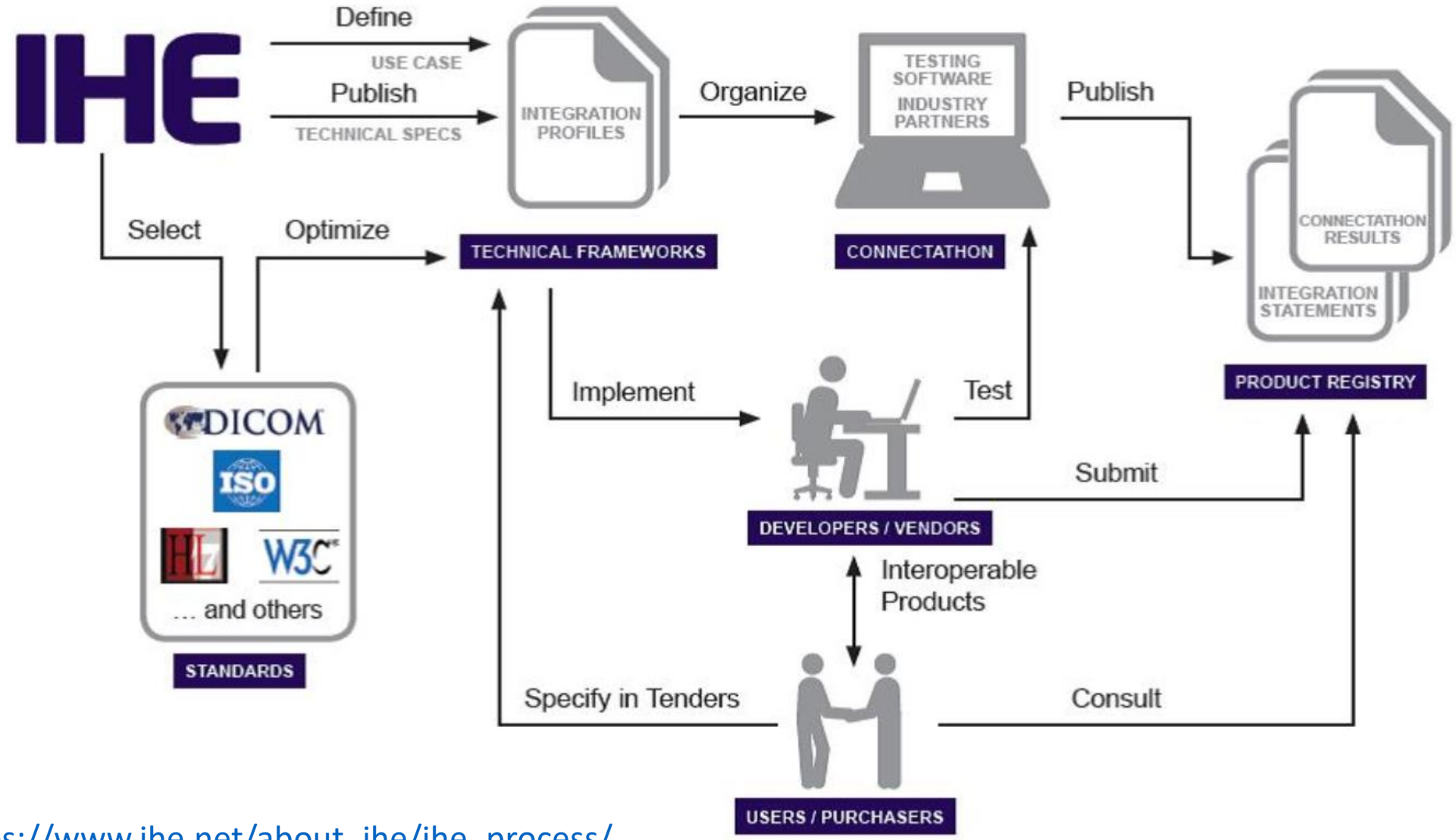
## Isn't a well architected family of standards sufficient?

The needs of an implementation community are often both narrower than the set of possible applications that are covered by foundational / core standards, such as ISO/IEEE 11073 SDC, as well as broader in scope requiring additional standards to be integrated.



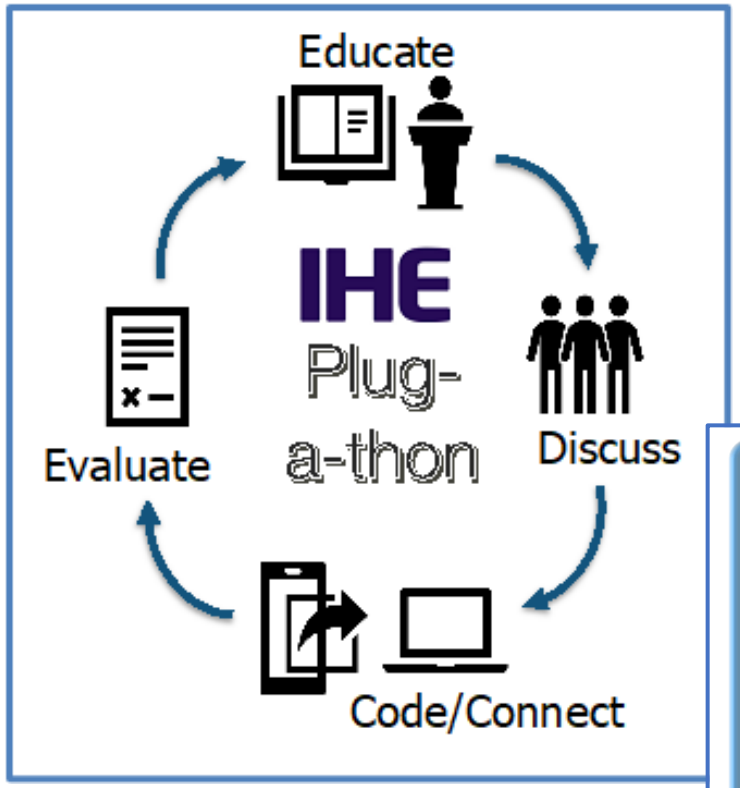
[1] Not to be confused with an HL7 FHIR Profile, which is similar in concept but very different in application

# IHE Process Overview




Source: https://www.ihe.net/about_ihe/ihe_process/

# IHE Plug-a-thon (PAT) Basics




## IHE Testing Events – Pathway to CA & Certification!

**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

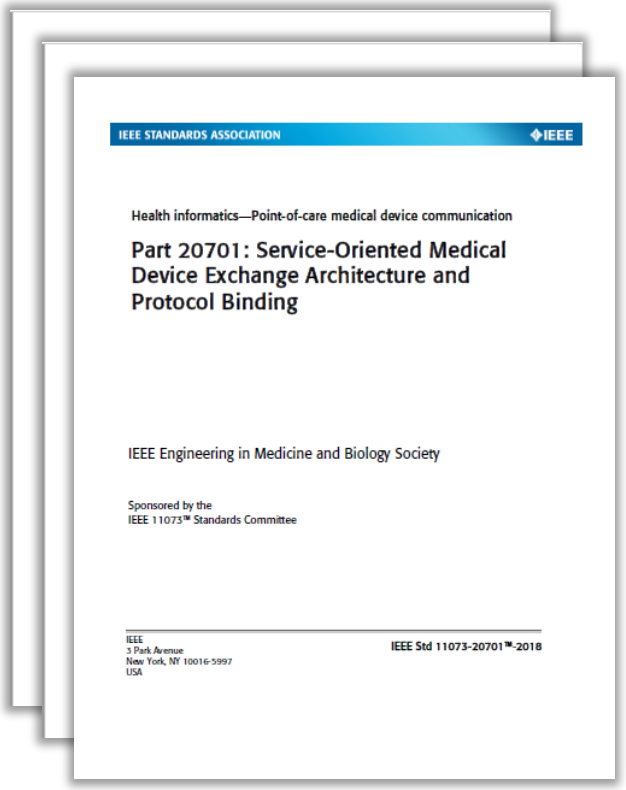
**IHE Connectathons**

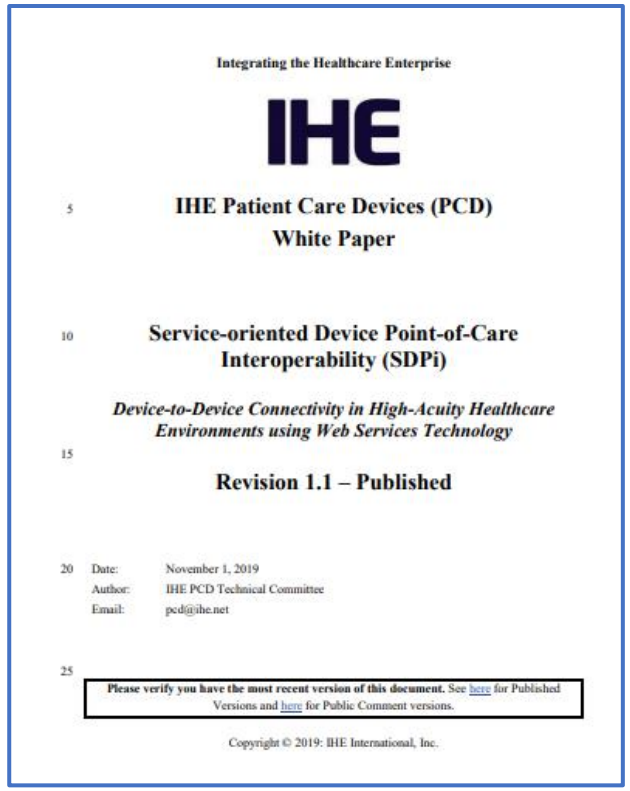
- Rigor: Medium
- Structured, Peer-to-Peer testing
- Conformance
- Multiple standards
- Established standards
- Code might change on-site

**IHE Conformity Assessment**

- Rigor: High
- Selected IHE Profiles in Final Text
- ISO accredited test labs
- Strict version controls of product & tools

# Orientation Tour: IHE TF & SDPi Profiles





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 1.1 – Published

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

Please verify you have the most recent version of this document. See here for Published Versions and here for Public Comment versions.

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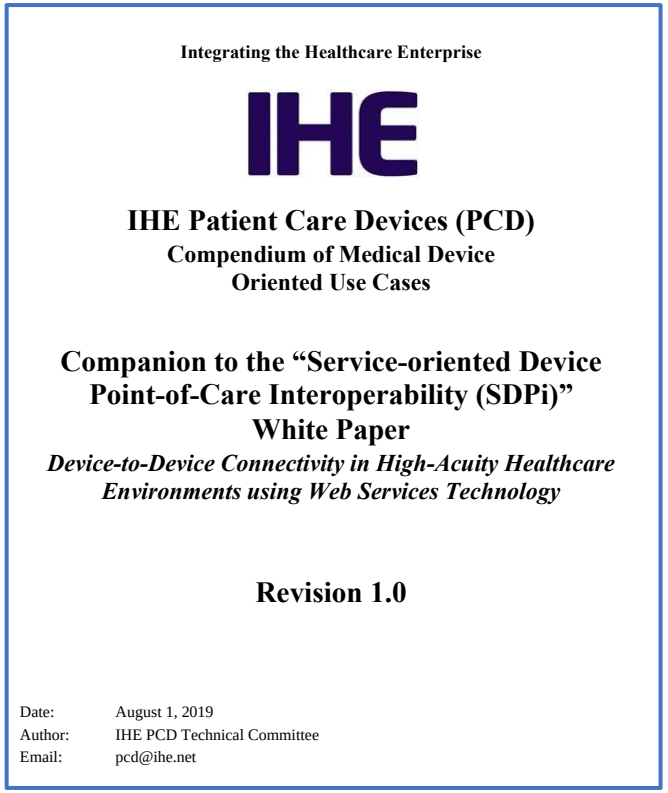
https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_WP_SDPi_Rev1-1_Pub_2019-11-01.pdf


Integrating the Healthcare Enterprise

IHE

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

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

***2019 SDPi paper established rationale and strategy for profiling ISO/IEEE 11073 SDC in IHE Technical Framework profile specifications.***

# Orientation Tour: IHE TF & SDPi Profiles

## 5 Structure of the IHE Technical Frameworks

The IHE Technical Frameworks define specific use of established standards. They are updated annually and maintained regularly through the identification and correction of errata. The Technical Framework volumes are augmented by supplements and change proposal documents as described in Section 8. The latest versions of Technical Framework documents are always available at http://www.ihe.net/Technical_Frameworks.

The Technical Framework for each domain consists of several volumes:

- Volume 1 provides high-level overviews of each profile, the use cases it addresses, the actors involved, and references to the Transactions and Content Modules used.
- Volume 2 provides detailed technical descriptions of each IHE Transaction.
- Volume 3 provides detailed technical descriptions of each IHE Content Module.
- Volume 4 describes National Extensions to the Technical Framework such as country-specific code sets or national patient privacy requirements.

Source: https://www.ihe.net/uploadedFiles/Documents/Templates/IHE_TF_General_Introduction.pdf

# Orientation Tour: Example – IHE DEC Profile

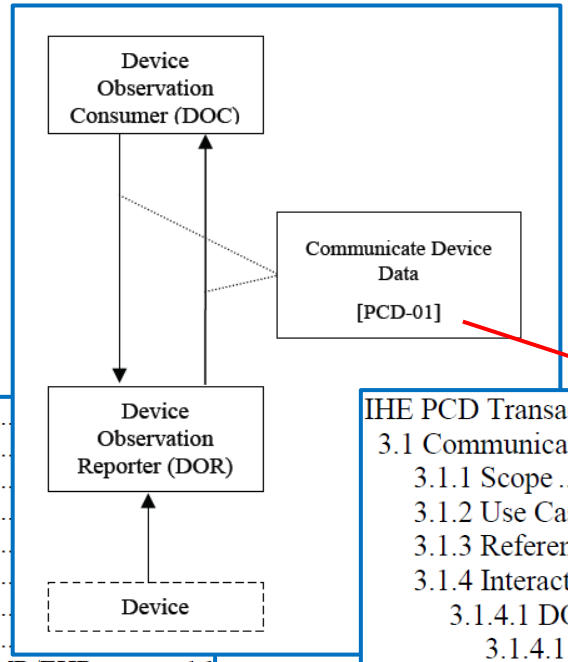
Integrating the Healthcare Enterprise

IHE

IHE Patient Care Device (PCD) Technical Framework

Volume 1
IHE PCD TF-1
Profiles

**TF-1 Profile calls out TF-2 Transaction(s) – may add usage constraints**






Integrating the Healthcare Enterprise

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IHE Patient Care Device (PCD) Technical Framework

Volume 2
IHE PCD TF-2
Transactions



**TF-2 Common Transaction Message Elements Specified Once in Appendices**



NOTE: Only message profiling specifications included, relying on references to base message standards for all additional details.

# Orientation Tour: Example – IHE DEC Profile

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**IHE Patient Care Device (PCD) Technical Framework**

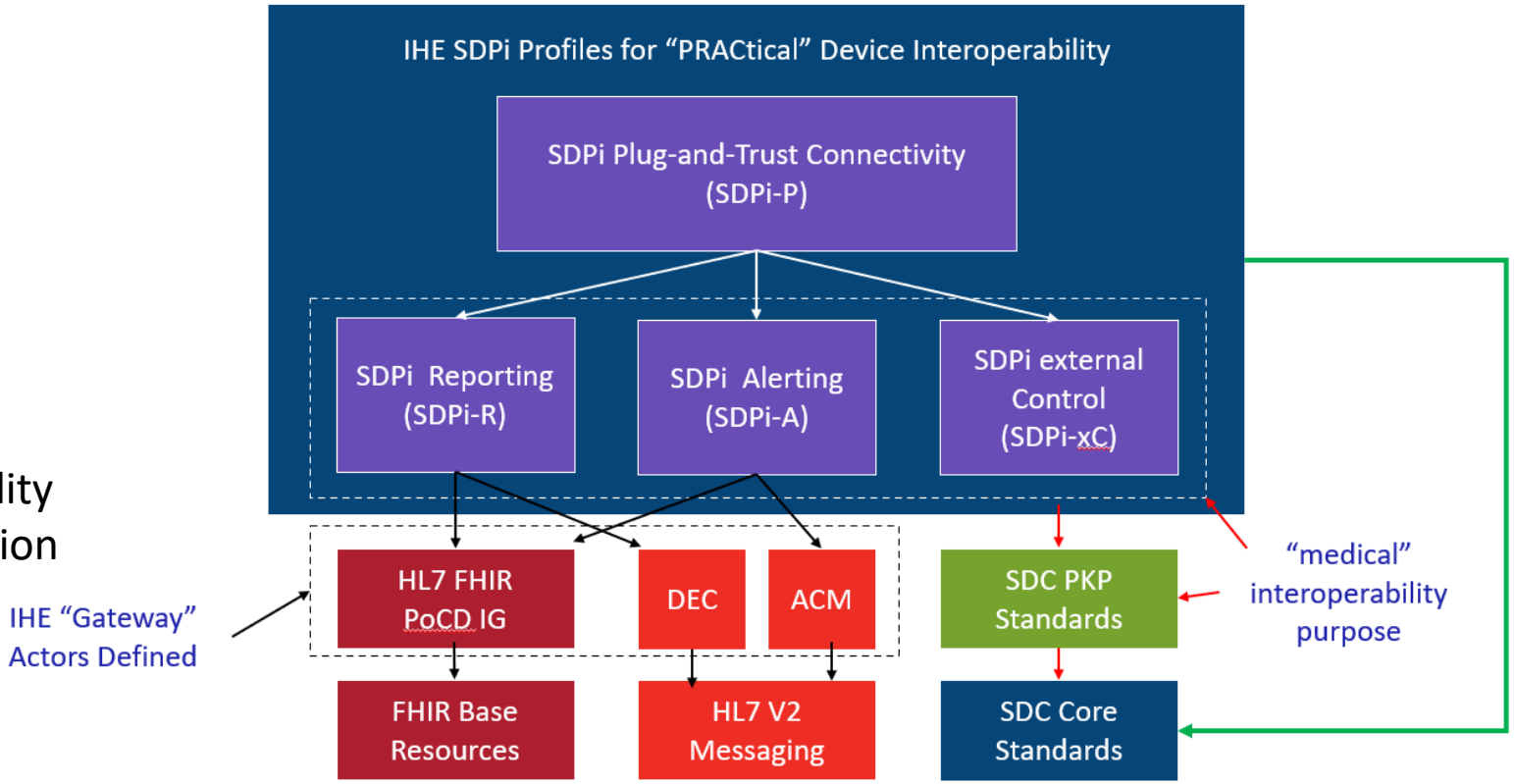
**Volume 3**
**IHE PCD TF-3**
**Semantic Content**

TF-3 Bindings only generally specified in DEC profile & DEV-01 Transaction

# Orientation Tour: IHE TF & SDPi Profiles

## Service-oriented Device Point-of-care Interoperability (SDPi)

- ✓ **Four profile specifications:**
  - SDPi-P for Plug-and-Trust Interoperability
  - SDPi-R for Reporting Medical Information
  - SDPi-A for Alerting
  - SDPi-xC for External Controlling
- ✓ **Three IHE DEV TF Volumes:**
  - TF-1 Profiles / use cases / actors / …
  - TF-2 Transactions / MDPWS messaging
  - TF-3 BICEPS content modules / device specializations




See draft SDPi Supplement Word Document for additional content detail & outline (https://github.com/IHE/sdpi-fhir/tree/master/SDPi%20%20Supplement/SDPi%20Rev%201.0)

# Orientation Tour: From Volume 1 to 2 to 3

## SDPi TF Supplement Vol.1 Integration Profiles

***SDPi-P Profile***

- Profile Actors & Transactions & Content Modules
- Profile Actor Options
- Profile Overview (Concepts & Use Cases)
- SES Considerations

***SDPi-Reporting Profile*** …

***SDPi-Alerting Profile*** …

***SDPi-xControl Profile*** …

**M:N Profiles & Transactions**

***Appendix A: Requirements Management for Plug-n-Trust Interoperability***

***Appendix B: ISO/IEEE 11073 SDC Requirements Coverage***

<including *ISO/IEEE 11073 SDC ICS tables*>

***Appendix C: Device Point-of-care Interoperability Use Cases***

<including *Gherkin detail & links to Compendium* etc.>

## SDPi TF Supplement Vol.2 Transactions

**DEV-23 *Announce Network Presence***

- Scope
- Actor Roles & *Referenced Standards*
- Messages (*at BICEPS level w/ links to Appendix A*)
- Protocol Requirements
- SES Considerations

**MDPWS Message Detail in Appendix**

**DEV-24 *Discover Network Participants***

…

**DEV-44 *Invoke Medical Control Services***

***Appendix A: ISO/IEEE 11073 SDC / MDPWS Message Specifications (Normative)***

- SDC/BICEPS to SDC/MDPWS Message Specifications
- Messages for BICEPS Discovery Model
  - <specific MDPWS message links>
  - <example exchanges & library calls>

See SDPi Supplement (1.0) document in the IHE sdpi-fhir Github repository for full details.

# Orientation Tour: From Volume 1 to 2 to 3

## SDPi TF Supplement Vol.1 Integration Profiles

***SDPi-P Profile***

- Profile Actors & Transactions & Content Modules
- Profile Actor Options
- Profile Overview (Concepts & Use Cases)
- SES Considerations

***SDPi-Reporting Profile*** …

## SDPi TF Supplement Vol.2 Transactions

**DEV-23** ***Announce Network Presence***

- Scope
- Actor Roles & Referenced Standards
- Messages (*at BICEPS level w/ links to Appendix A*)
- Protocol Requirements
- SES Considerations

**DEV-24** ***Discover Network Participants***

…

**Bindings – General & Specific**

## SDPi TF Supplement Vol.3 Content Modules

***DEV Semantic Content Modules***

- General Device Content Considerations
  - …
  - *SDC / BICEPS Semantic Content*

***DEV Specialization Content Modules***

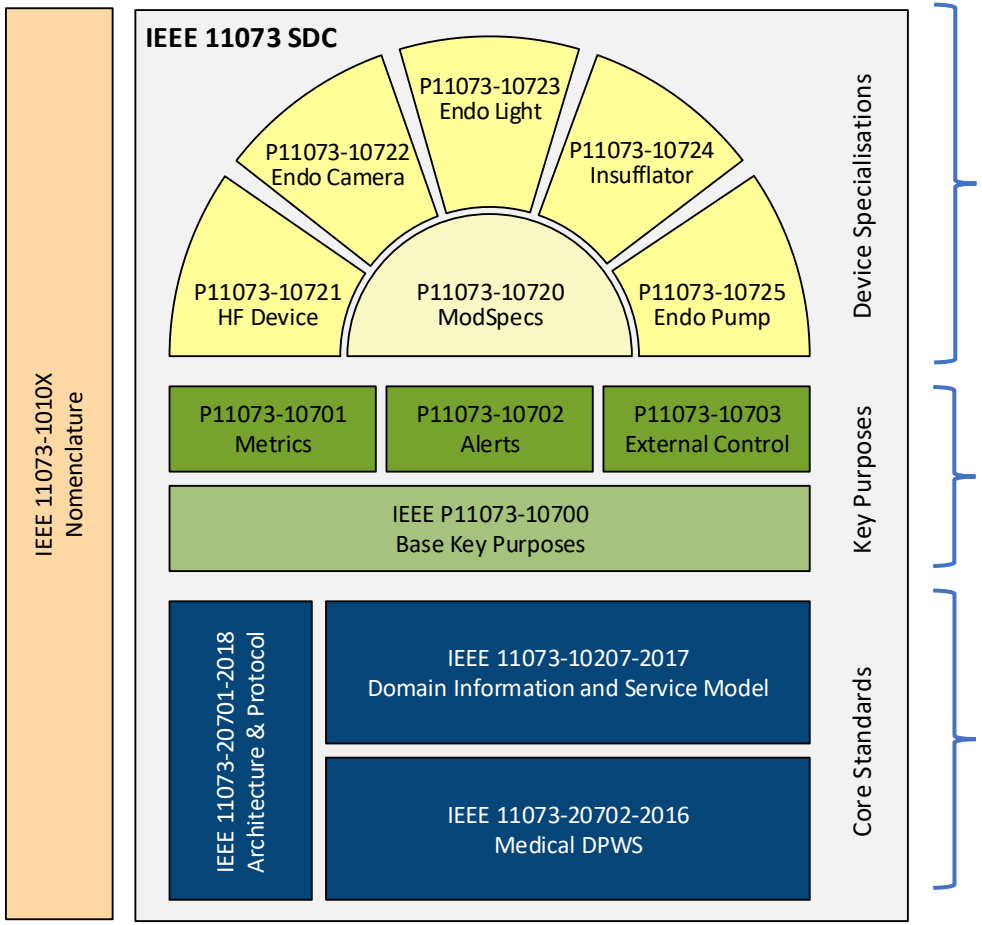
- Device: Infusion Pump
  - …
  - *SDC / BICEPS Content Module*
- Device: Ventilator …
- Device: Physiologic Monitor …
- Devices: Surgery … (new)
- Devices: Anesthesia … (new)
- Devices: Dialysis … (new)

See SDPi Supplement (1.0) document in the IHE sdpi-fhir Github repository for full details.

# Orientation Tour:  From 11073 SDC to SDPi

- <diagram with cathedral & where specific standards content is profiled in TF-1 & TF-2 & TF-3>
- BICEPS MDPWS SOMDA PKP SPECIALIZATIONS

# Orientation Tour: From 11073 SDC to SDPi




- ✓ Initially, map to **TF-3 DEV** *Content Modules / Device Specializations*
- ✓ Can include content **before** specializations published
- ✓ Eventually, may inform IHE DEV Device-Specific Profiles

- ✓ Pre-publication, will reference in SDPi SES sections (TF-1, -2 & -3)
- ✓ Post-publication, can fully integrate requirements into SDPi (incl. TF-1 Appendix B conformance)
- ✓ NOTE: (4) profiles are aligned with these (4) key purposes

- ✓ SDC/BICEPS (-10207) Referenced in all (3) volumes (TF-1, -2 & -3)
- ✓ SDC/SOMDA (-20701) Referenced in TF-1 & TF-2
- ✓ SDC/MDPWS (-20702) Referenced primarily in TF-2 (esp. Apdx. A)

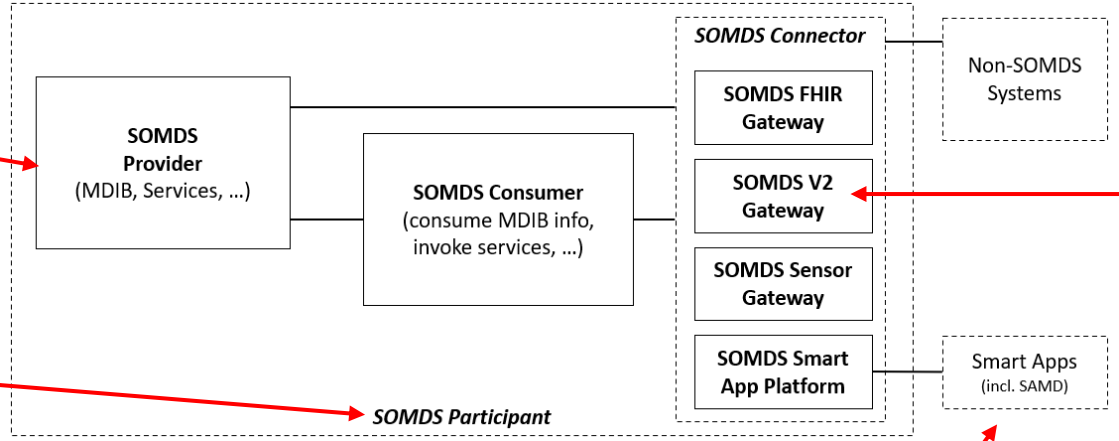
# Orientation Tour: IHE Profile Actor Diagrams

## IHE Actor

"information systems or components of information systems that produce, manage, or act on health information"

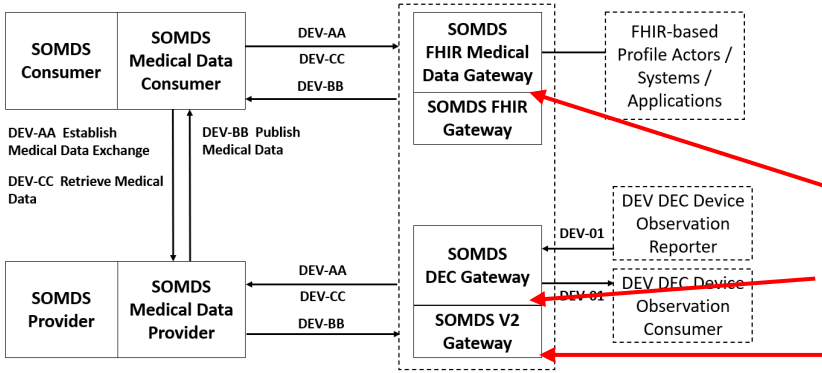
## IHE Abstract Actor

Specifies behavior that is shared across / inherited by a set of IHE Actors (*actor name in italics* & dotted line around concrete actors)




## Profile "External" Actor

Indicates actors that are outside the scope of the profile but interact with profile actors (dotted box) Note: actor may be defined in other profiles

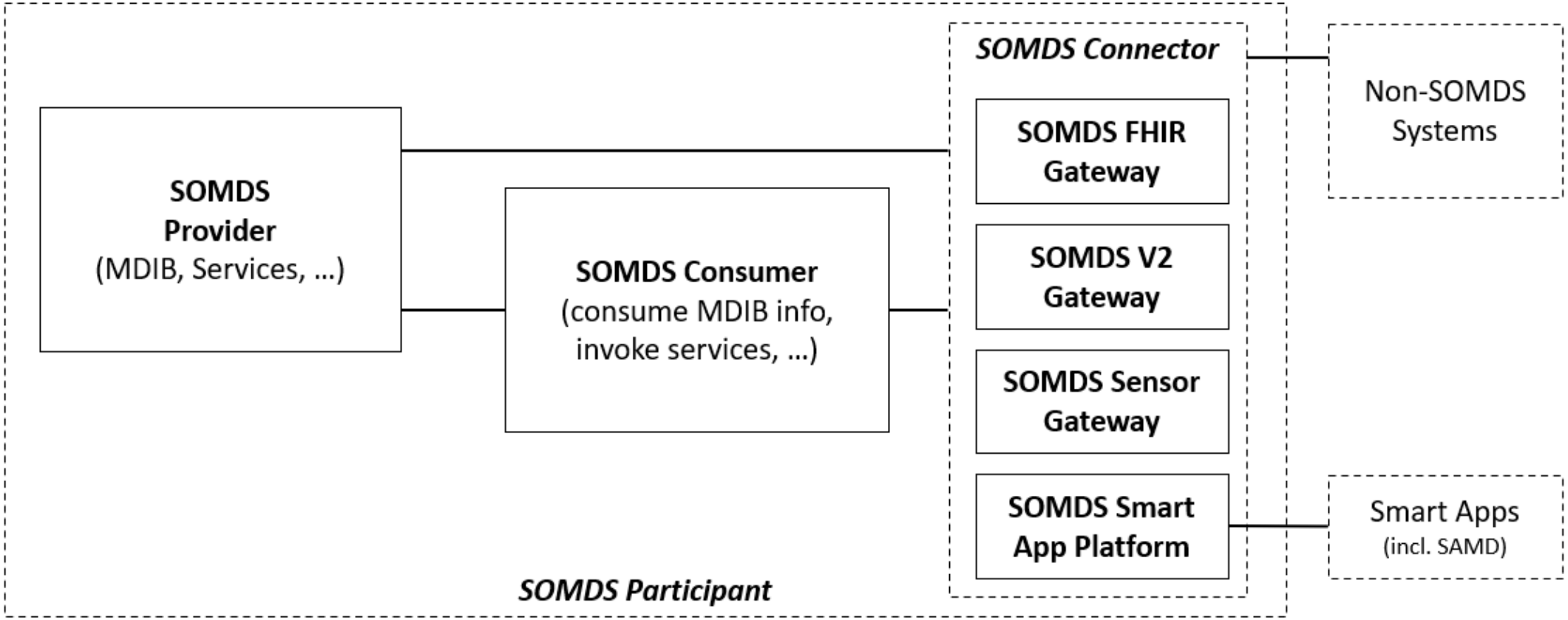



## IHE Grouped Actor

Indicates actors that integrate with other actors to provide their functionality (two rectangles joined side-by-side)

# Orientation Tour: SDPi-P (Plug-and-Trust)

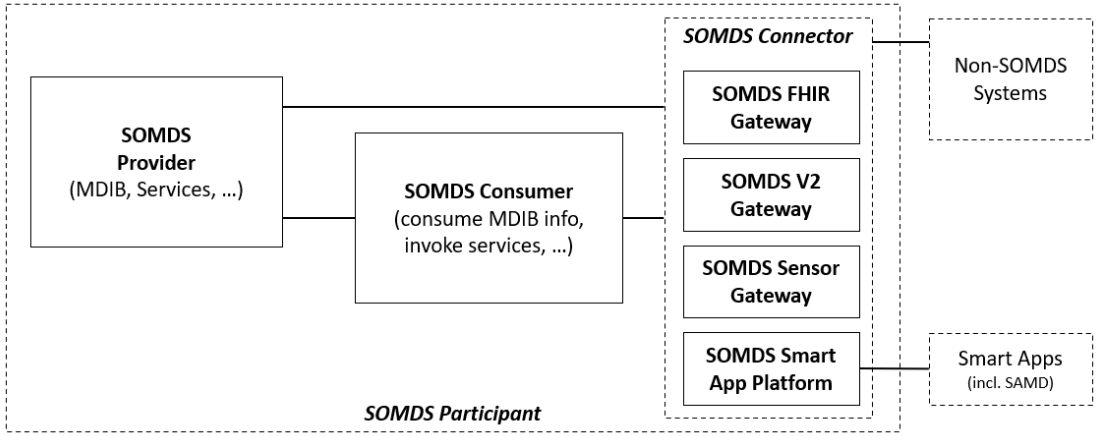
## SDPi-P Actor Model




NOTE: ***SOMDS Participant*** actors may be devices, system applications, SAMD, "smart apps" …

# Orientation Tour: SDPi-P (Plug-and-Trust)

## SDPi-P Actor Model



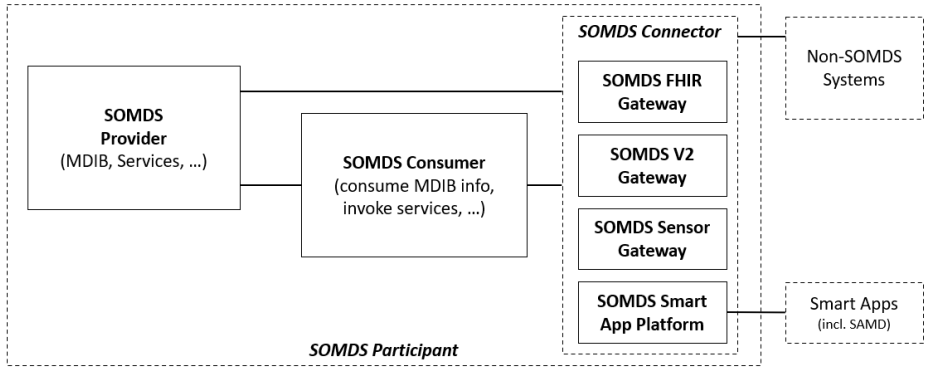

## SDPi-P Options (partial)

**Table 10.2-1: SDPi-P – Actors and Options**

| Actor | Option Name | Reference |
|---|---|---|
| SOMDS Participant | No options defined | |
| SOMDS Provider (See Note 1) | Streaming Option [Editor's Note: Which can be waveform or other content; but is that in SDPi-R vs. here? And should we have a waveform option? What about SCO or polling mode type support options?] | DEV TF-1 *10.2.1 Streaming Option* |
| | Safe Data Transmission Option | DEV TF-1 *10.2.2 Safe Data Transmission Option* |
| | Compact Representation Option | DEV TF-1 *10.2.3 Compact Representation Option* |
| | Patient Context Management Option | DEV TF-1 *10.2.4 Patient Context Management Option* |
| | Archive Service Option | DEV TF-1 *10.2.5 Archive Service Option* |
| | Localization Service Option | DEV TF-1 *10.2.6 Localization Service Option* |
| | Ensemble Participation Option | DEV TF-1 *10.2.7 Ensemble Participation Option* |
| SOMDS Consumer (See Note 1) | Streaming Option | DEV TF-1 *10.2.1 Streaming Option* |
| | Safe Data Transmission Option | DEV TF-1 *10.2.2 Safe Data Transmission Option* |
| | Compact Representation Option | DEV TF-1 *10.2.3 Compact Representation Option* |
| | Patient Context Management Option | DEV TF-1 *10.2.4 Patient Context Management Option* |

# Orientation Tour: SDPi-P (Plug-and-Trust)

## SDPi-P Actor Model



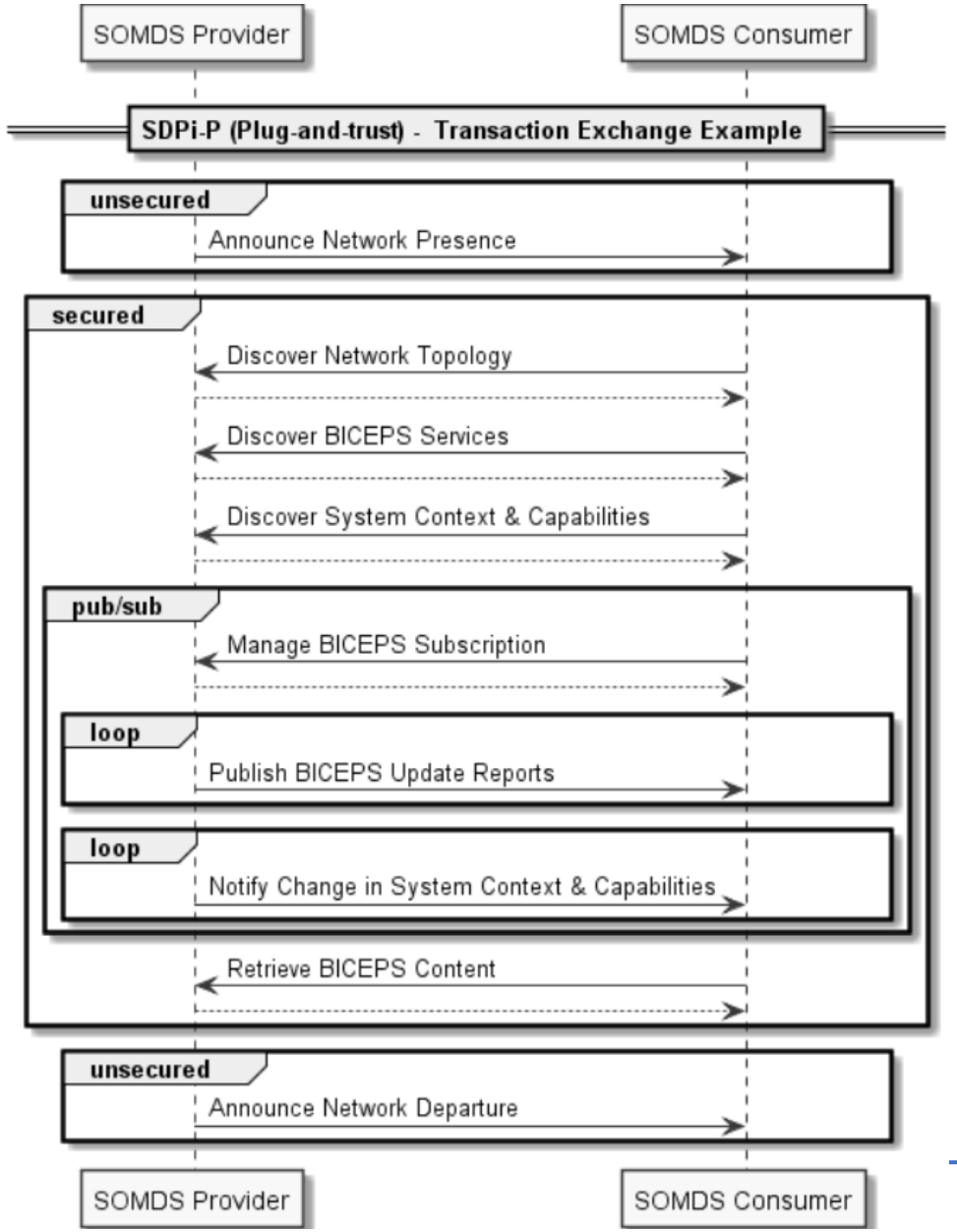

## SDPi-P Transactions

5 **Table 10.1-1: SDPi-P Profile - Actors and Transactions**

| Actors | Transactions | Initiator or Responder | Optionality | Reference |
|---|---|---|---|---|
| *SOMDS Participant* | [Editor's Note: TBD specific transactions / abstract actor!] | | | DEV TF-2:3.xyz |
| SOMDS Provider | Announce Network Presence | Initiator | R | DEV TF-2:3.23 |
| | Discover Network Topology | Responder | R | DEV TF-2:3.24 |
| | Discover BICEPS Services | Responder | R | DEV TF-2:3.25 |
| | Discover System Context and Capabilities | Responder | R | DEV TF-2:3.26 |
| | Manage BICEPS Subscription | Responder | R | DEV TF-2:3.27 |
| | Notify Change in System Context and Capabilities | Initiator | O ( See Note 1) | DEV TF-2:3.28 |
| | Publish BICEPS Update Reports | Initiator | R | DEV TF-2:3.29 |
| | Retrieve BICEPS Content | Responder | O | DEV TF-2:3.30 |
| | Set Provider State | Responder | O | DEV TF-2:3.31 |
| | Retrieve Archive Data | Responder | O | DEV TF-2:3.32 |
| | Retrieve Localization Information | Responder | O | DEV TF-2:3.33 |
| | Announce Network Departure | Initiator | R | DEV TF-2:3.34 |
| SOMDS Consumer | Announce Network Presence | Consumer | O | DEV TF-2:3.23 |
| | Discover Network Topology | Initiator | R | DEV TF-2:3.24 |
| | Discover BICEPS Services | Initiator | R | DEV TF-2:3.25 |

# Orientation Tour: SDPi-P (Plug-and-Trust)

## Example of an SDPi-P transaction exchange …



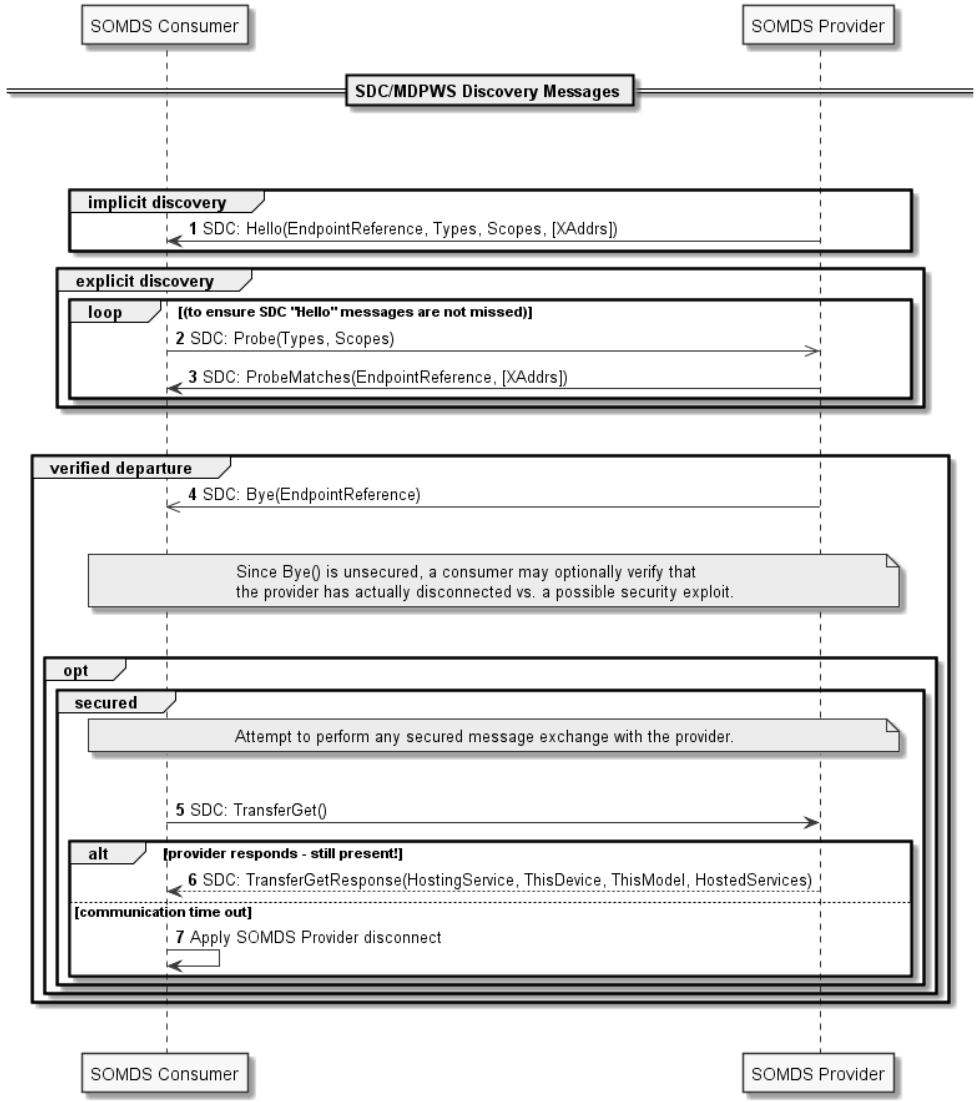

NOTE: Definition of "BICEPS" abstraction level for SDPi transactions.

For a full set of profile-specific MDPWS sequence exchanges, see:

https://confluence.hl7.org/display/GP/SDPi+Technical+Framework+Models

# Orientation Tour: SDPi-P (Plug-and-Trust)

## Example of an SDPi-P transaction MDPWS sequence …

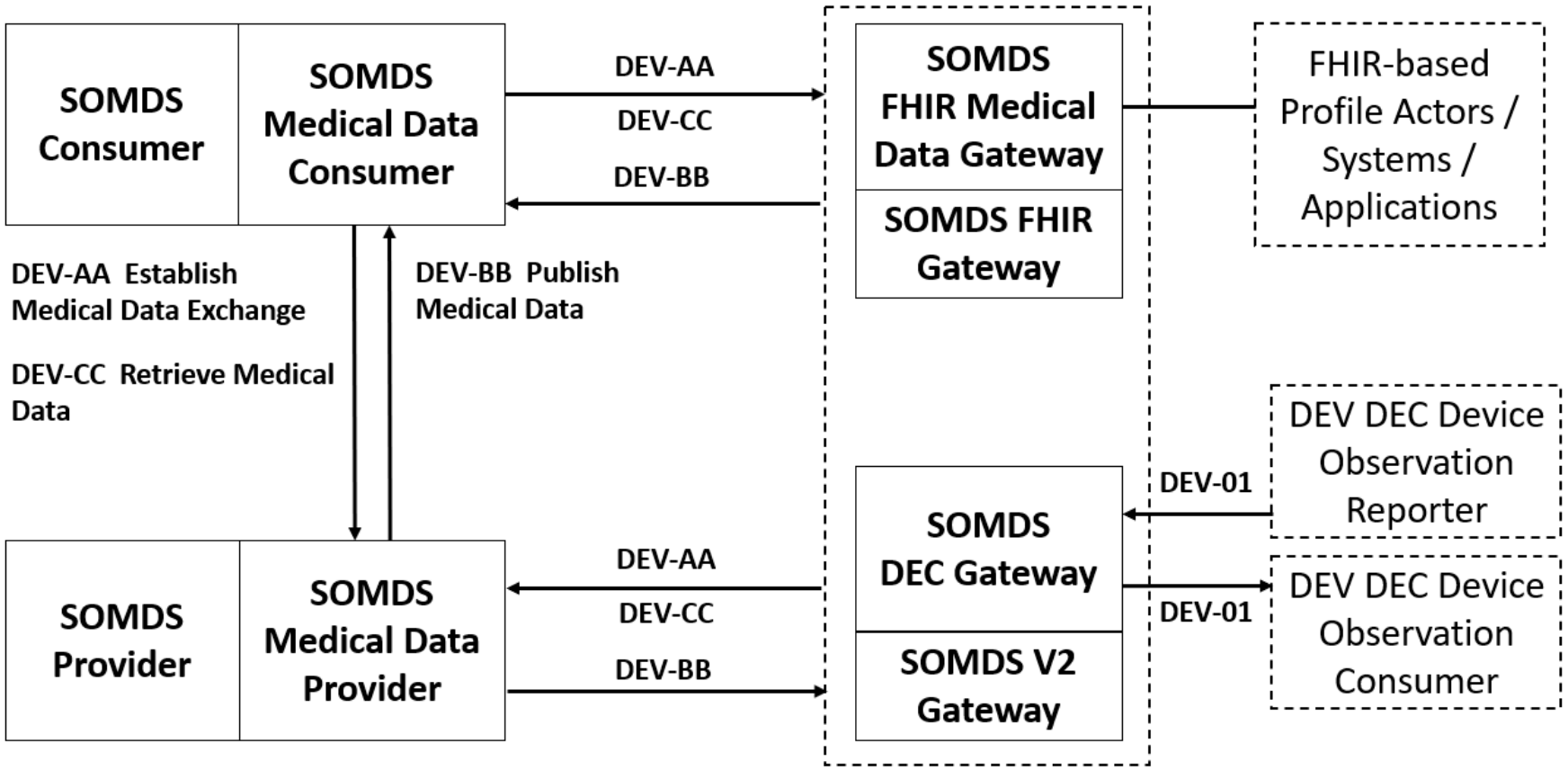



For a full set of profile-specific MDPWS sequence exchanges, see:

https://confluence.hl7.org/display/GP/SDPi+Technical+Framework+Models

# Orientation Tour: SDPi-R (Reporting)

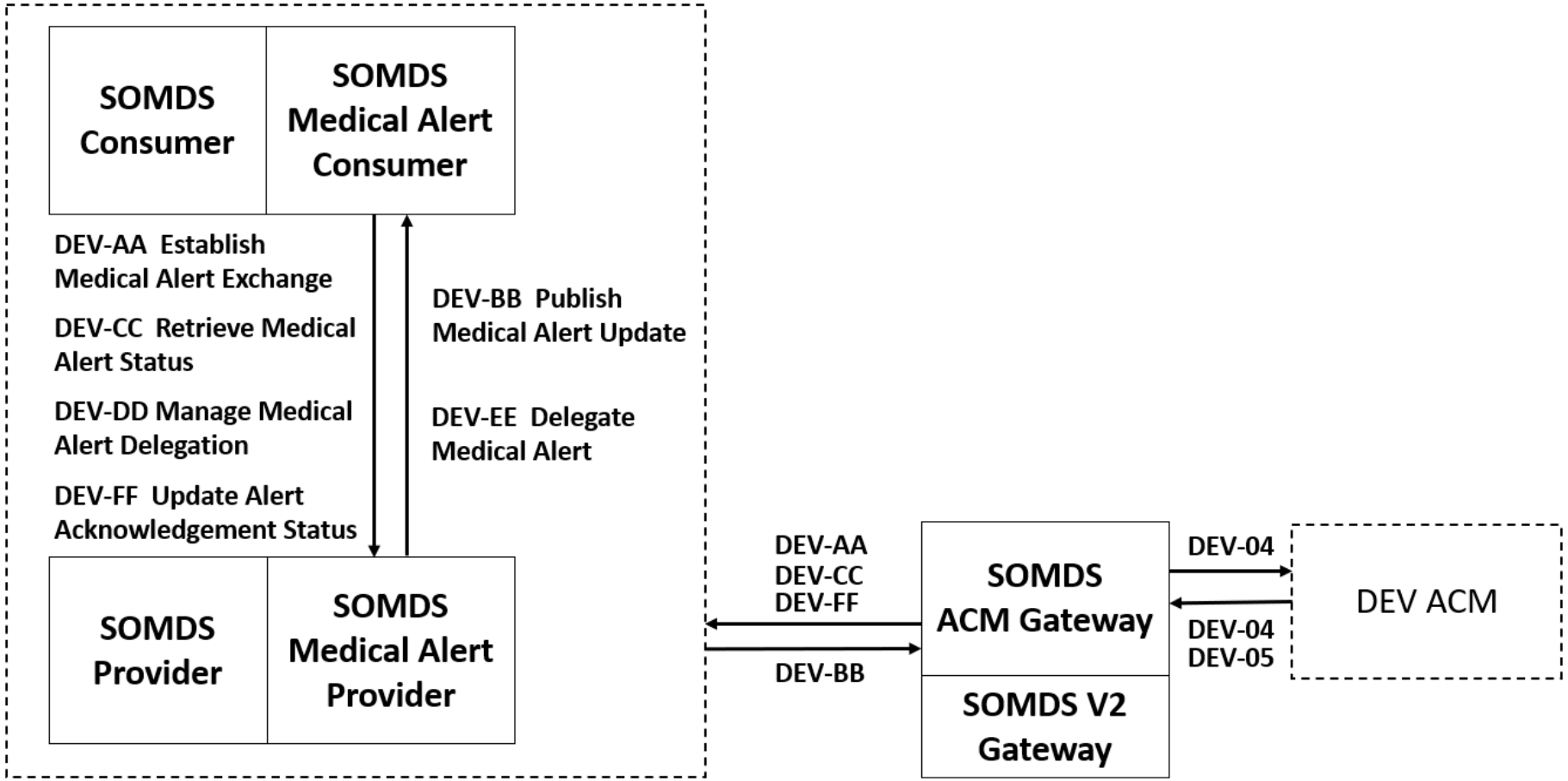
## SDPi-R Actor Model




NOTE: Transactions are drawn to the dotted box around the gateways, indicating that they can be either Provider and / or Consumer SDPi-R actors

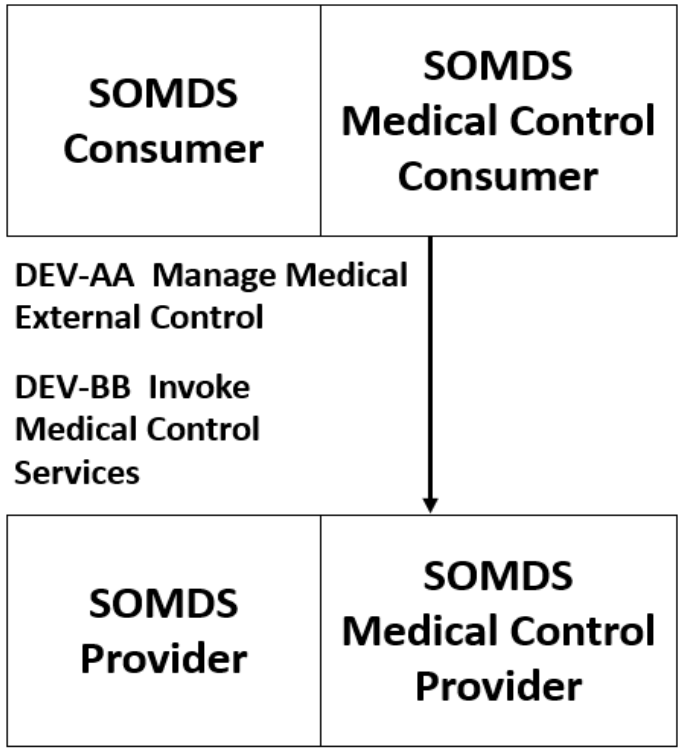
# Orientation Tour: SDPi-A (Alerting)

## SDPi-A Actor Model



# Orientation Tour:  SDPi-xC (External Control)

## SDPi-xC Actor Model



# Real-world Narrative: Isolation ICU

## Pandemic Patients in an Isolation ICU – EUA Remote Control Narrative

*In dealing with severely infectious patients, healthcare workers (HCWs) are at a significantly greater risk of infection than the overall population due to their frequency and time in contact with the infected patients. The HCWs will enter the patient room to administer care to the patient and manage the therapeutic equipment. This management of the patient's therapy may require frequent device adjustments which may be delayed due to the need for the HCWs to protect themselves by donning PPE prior to entering the patient room and doffing the PPE upon leaving. This donning and doffing processes can exceed 15 minutes depending on the specific PPEs used. A recent study (Suen, 2018) reported times of 7 minutes for donning and 10 minutes for doffing, with the doffing process providing the opportunity for "considerable" self-contamination.*

*Infectious diseases confer a synergistic burden on and risk to the patient due to the requirements for isolating the patient (Abad et al., 2010) including poorer care and impaired coordination of care, (Mehrotra et al., 2013), significantly fewer HCW and family visits (relative to patients not on precautions) (Morgan et al., 2013), increased rate of adverse events (Stelfox et al., 2003) and increased depression (compared to other inpatients). (Day et al., 2011). The use of remote control and monitoring can be used to eliminate some treatment delays, reduce the infection risk to the HCW, and help preserve the limited supplies of PPE and improve patient care.*

*Critically ill patients with an infectious disease will often require monitoring with physiologic monitors and therapeutic support with ventilators and infusion pumps. As previously explained, entering the room to view parameters or adjust any settings can require 15 minutes for something that may take less than 1 minute. Medical devices that support open interoperability technology can provide remote access to view parameters and adjust settings thereby increasing efficiency, saving the costs of the PPE and most importantly increasing the safety of the HCW.*

Source: Adapted from AAMI CR Proposal: "Emergency Use Guidance for Remote Control of Medical Devices"

# Real-world Narrative:  Isolation ICU

## Pandemic Patients in an Isolation ICU – Scenarios?

For the purposes of this PAT, what scenarios are of greatest interest?

1. Participant Discovery / Security / Service Exchange?
2. Patient / Participant Association (Patient & Location & Workflow context establishment)?
3. Alert delegation / Alert Limit Adjustment / Alert confirmation / Silence ... ?
4. Which devices, systems, applications?  Monitors, vents, pumps, central … others?
5. Integration with EHR or other system?
6. Use of IHE-based FHIR profiles for integration with non-SDPi / non-SDC SOMDS systems?
7. …

**Other Use Cases / Scenarios?** (e.g., surgery focused)

# SDC/SDPi PAT – Objectives

**1st IHE SDPi Testing Event!!!**

**Build SDC / SDPi Competency for Implementer Community**

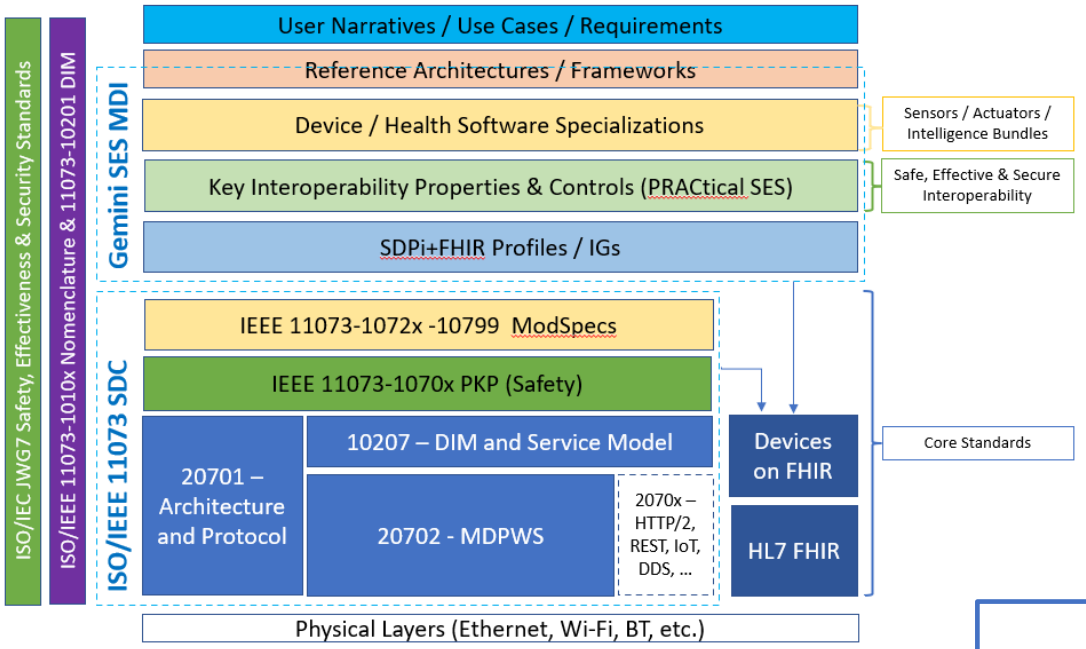
**Validate SDPi Profiling Approach (Actors & Transactions & SDC …)**

**Advance SDC / SDPi Testing & Tooling strategy into 2021!**

# Additional Information

# Hanging Gardens: *After SDPi 1.0 …*

**NOTE:** *Profile Titles are notional – hopefully useful too!*




**Devices-In-Care (PDP) Profile**

**Device Specialization Profile**

**Surgery PoC Profile**

**ICU PoC Profile**

**MDIRA ICE Profile**

**SOMDS@home Profile**

## IHE (Official) Profile Types:

Transport, Content, Workflow

Or a combination of all (3)

## Other types?

Architecture (SOA, MDIRA, SDC, ….?

Single domain / multi-domain?