

IHE Germany SDC / SDPi Plug-a-Thon - *Overview Briefing*

20-21 October 2020

SDC is a registered trademark of OR.NET

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

Service-oriented Device Connectivity

Family of ISO/IEEE 11073 SDC standards

Assumption: PAT participants have a working understanding of SDC

SDPi

Service-oriented Device Point-of-care Interoperability

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

Plug-a-thon

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

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

CAT

Connectathon

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 events

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

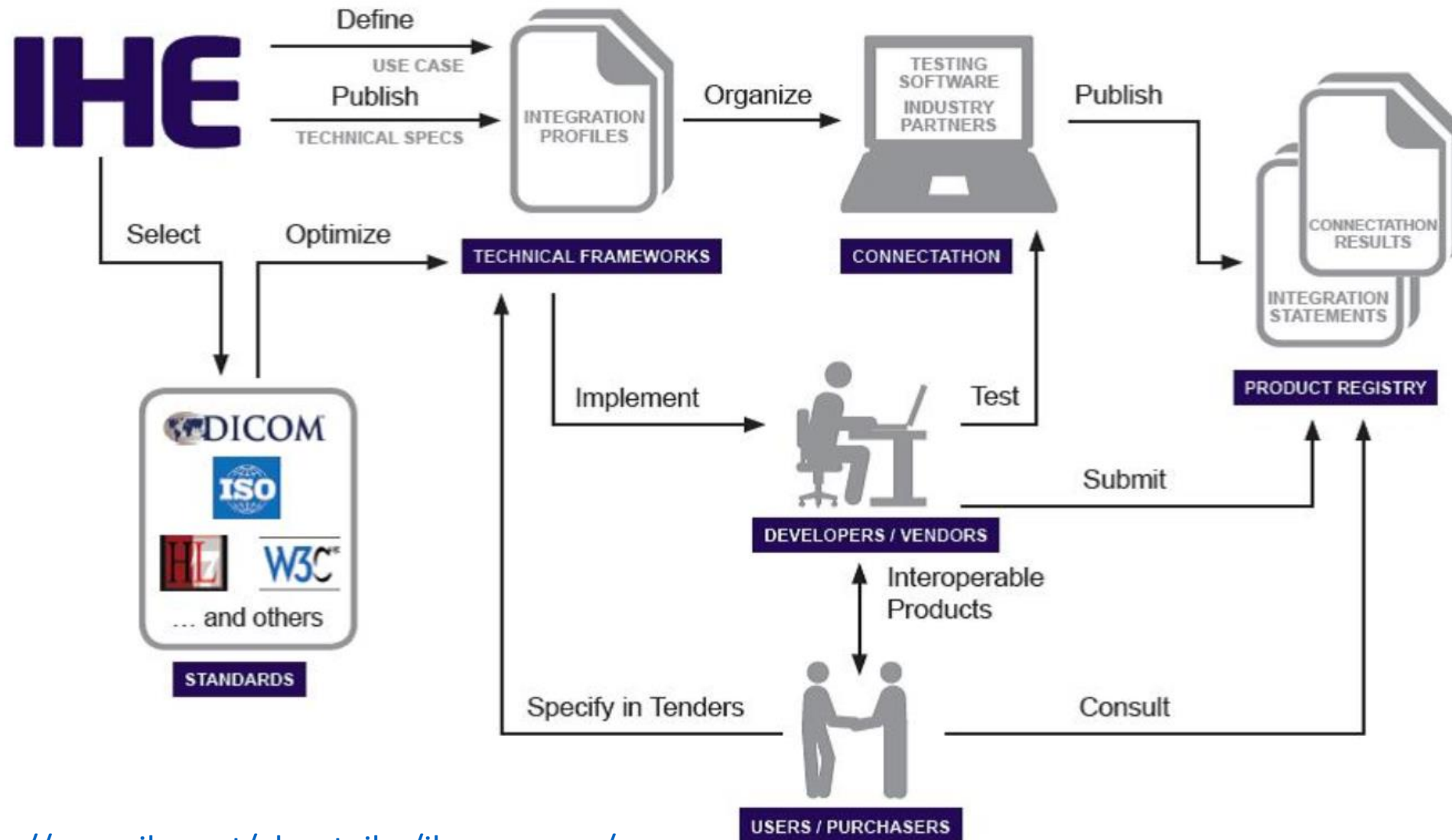
Why profiles?

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?

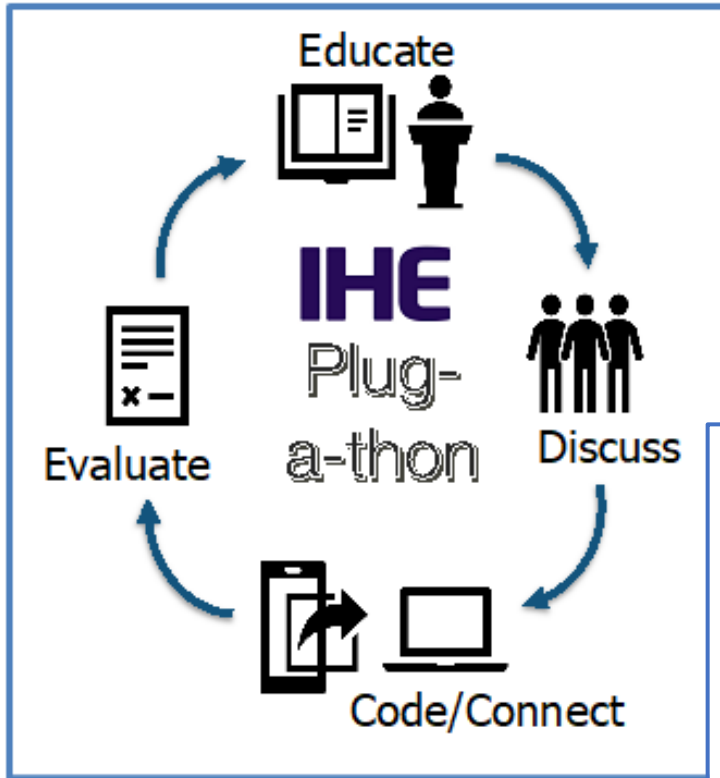
The needs of an implementation community are often both narrower than the set of possible applications that are covered by foundational / core standards, such as ISO/IEEE 11073 SDC, as well as broader in scope requiring additional standards to be integrated.

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

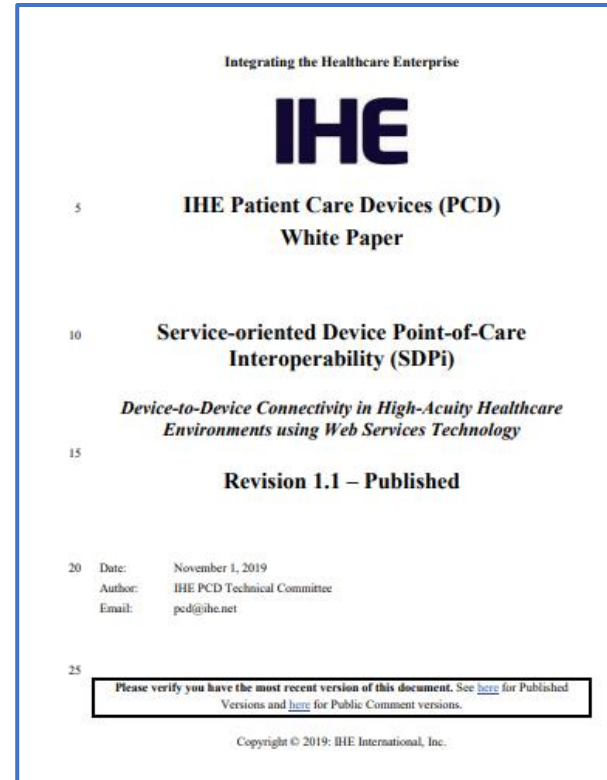
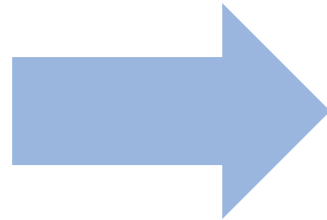
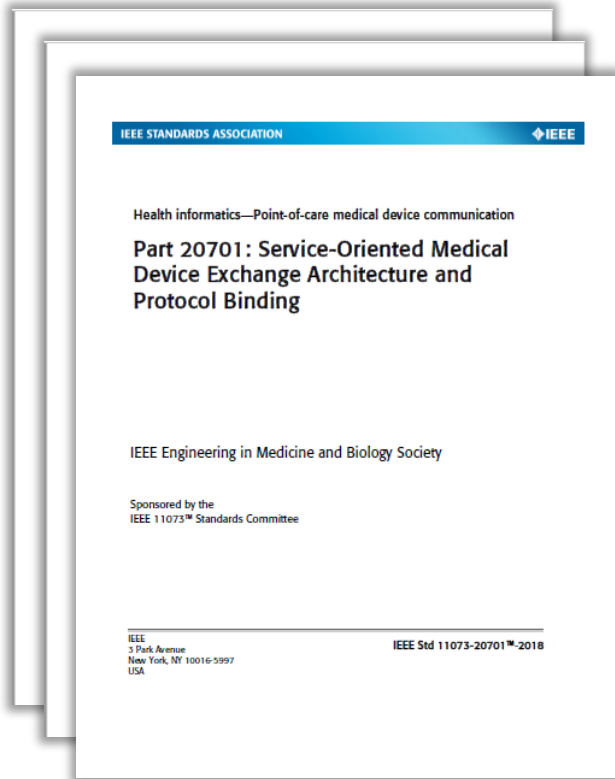
IHE Connectionathons

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

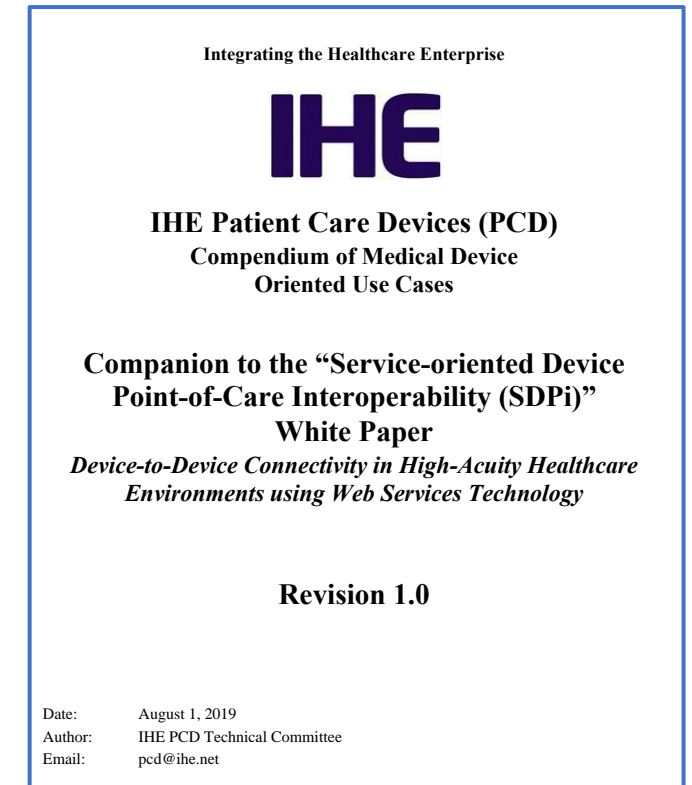
IHE Conformity Assessment

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

Orientation Tour: IHE TF & SDPi Profiles



https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_WP_SDPI_Rv1-1_Pub_2019-11-01.pdf



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

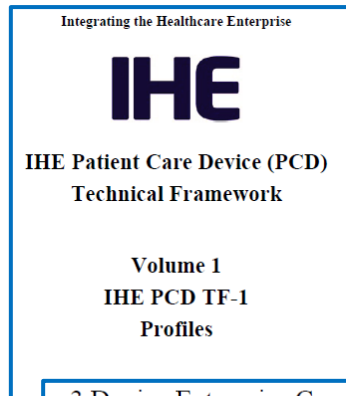
The IHE Technical Frameworks define specific use of established standards. They are updated annually and maintained regularly through the identification and correction of errata. The Technical Framework volumes are augmented by supplements and change proposal documents as described in [Section 8](#).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

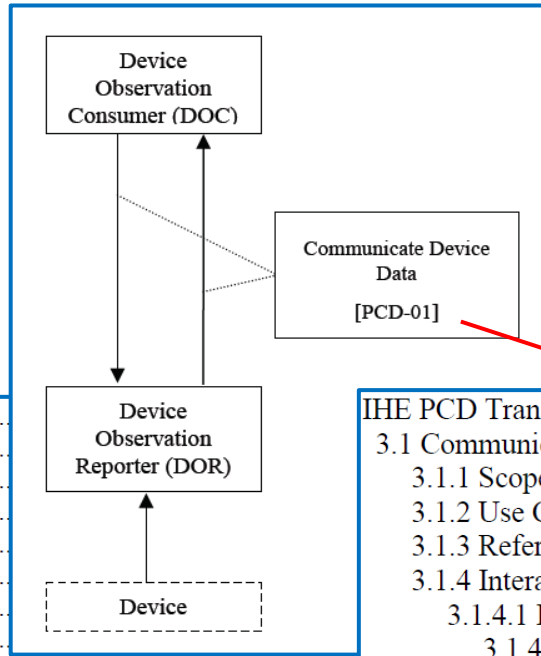
Source: https://www.ihe.net/uploadedFiles/Documents/Templates/IHE_TF_General_Introduction.pdf

Orientation Tour: Example – IHE DEC Profile



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

3 Device Enterprise Communication (DEC) Profile	
3.1 DEC Actors and Transactions	
3.1.1 Patient Demographics – Recommended Transactions	
3.2 DEC Profile Options	
3.3 DEC Overview	
3.3.1 Note on Patient Identification	
3.4 DEC Use Cases	
3.4.1 Standard Use Cases	
3.4.1.1 Case DEC-1: Communicate patient identified DEC data to EMR/EHR	16
3.4.1.2 Case DEC-2: Communicate validated periodic DEC data to EMR/EHR	16
3.4.2 Optional Use Cases for Automatic Patient Demographics Acquisition	17



IHE PCD Transactions	12
3.1 Communicate PCD Data [PCD-01]	12
3.1.1 Scope	12
3.1.2 Use Case Roles	12
3.1.3 Referenced Standards	13
3.1.4 Interaction Diagrams	13
3.1.4.1 DOR communicates with DOC	13
3.1.4.1.1 PCD-01 Communicate PCD Data (ORU^R01^ORU_R01) static definition	14
3.1.4.1.2 Trigger events	15
3.1.4.1.3 Message Semantics	16
3.1.4.1.4 Expected Actions	16
3.1.5 Security Considerations	16

TF-2 Common Transaction Message Elements Specified Once in Appendices

Appendix A Mapping ISO/IEEE 11073 Domain Information Model to HL7	70
A.1 ISO/IEEE Nomenclature mapping to HL7 OBX-3	73
Appendix B Common Segment Descriptions	75
B.1 MSH – Message Header Segment	75
B.2 MSA – Message Acknowledgement Segment	81
B.3 ERR – Error Segment	82
B.4 NTE - Notes and Comment Segment	84
B.5 PID - Patient Identification segment	86
B.5.1 PID Segment requirements for ACM Transaction PCD-04	93

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

Orientation Tour: Example – IHE DEC Profile

Integrating the Healthcare Enterprise

IHE

**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

3	Overview of device semantic content profiling	10
3.1	General device content considerations.....	10
3.1.1	Hierarchical containment tree information.....	10
3.1.2	Device semantics & controlled terminologies	12
3.1.3	Overview of the ISO/IEEE 11073 nomenclature/terminology.....	13
3.1.4	Private terms and scope	13
3.1.5	New or non-specified terms.....	14
3.1.6	Episodic vs. periodic data updates.....	14
3.1.7	Alternative units of measurement mapping.....	16
3.2	Alert and event semantics	17
3.3	Body site semantics.....	19
3.4	Basic data type specifications	19
3.5	MDS semantics	22
3.6	VMD semantics	23
3.7	Channel semantics	24

3	Overview of device semantic content profiling	10
3.1	General device content considerations.....	10
3.1.1	Hierarchical containment tree information.....	10
3.1.2	Device semantics & controlled terminologies	12
3.1.3	Overview of the ISO/IEEE 11073 nomenclature/terminology.....	13
3.1.4	Private terms and scope	13
3.1.5	New or non-specified terms.....	14
3.1.6	Episodic vs. periodic data updates.....	14
3.1.7	Alternative units of measurement mapping.....	16
3.2	Alert and event semantics	17
3.3	Body site semantics.....	19
3.4	Basic data type specifications	19
3.5	MDS semantics	22
3.6	VMD semantics	23
3.7	Channel semantics	24
4	Reserved.....	26
5	Reserved.....	26
6	Reserved.....	26
7	Device specialization content modules	27
7.1	Device: Infusion Pump	27
7.1.1	Containment tree.....	27
7.1.2	Channel: Source.....	27
7.1.3	Channel: Delivery.....	28
7.2	Device: Ventilator.....	29
7.2.1	Containment tree.....	29
7.2.2	Channel: Ventilator.....	30
7.2.3	Channel: Airway Pressure	30
7.2.4	Channel: Airway Volume	31
7.2.5	Channel: Airway Breath Pattern.....	31
7.3	Device: Physiologic Monitor	32
7.3.1	Containment tree.....	32

Orientation Tour: IHE TF & SDPi Profiles

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

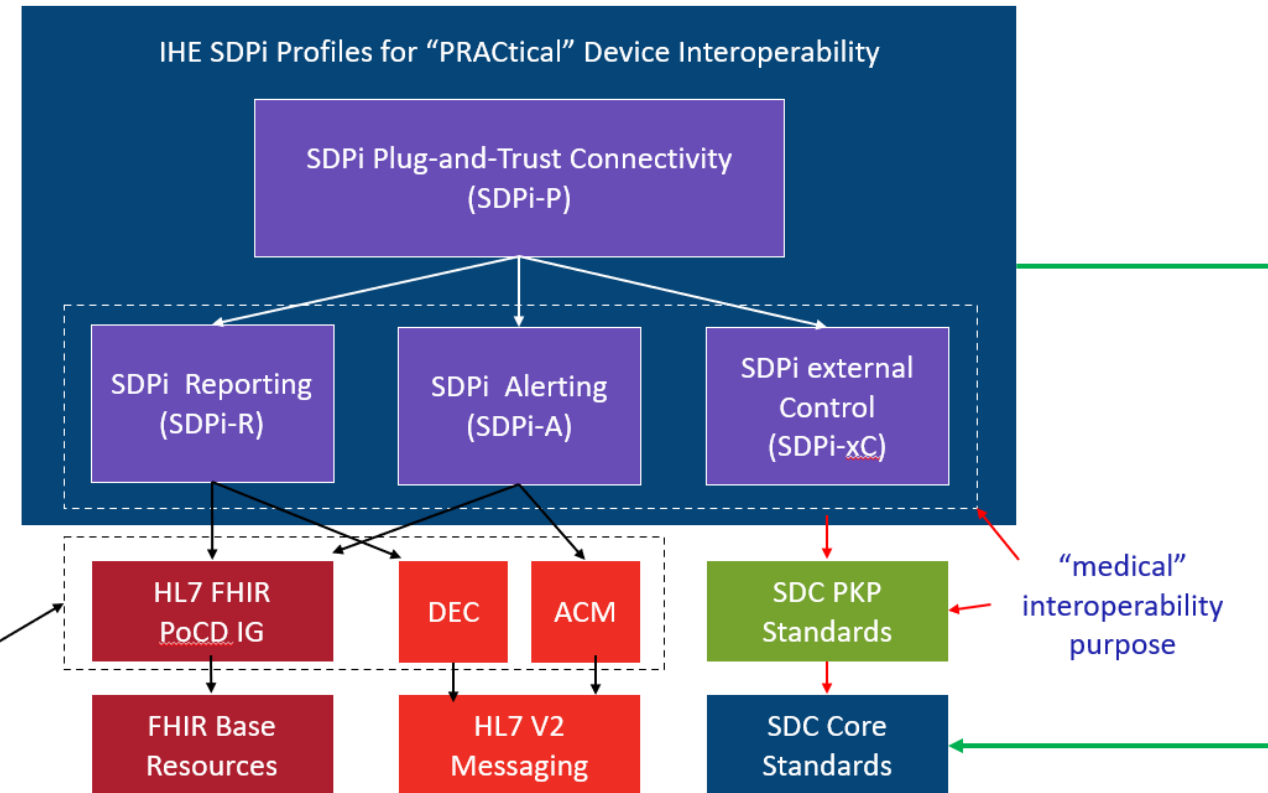
✓ Four profile specifications:

- 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

IHE “Gateway”
Actors Defined



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

...

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)*

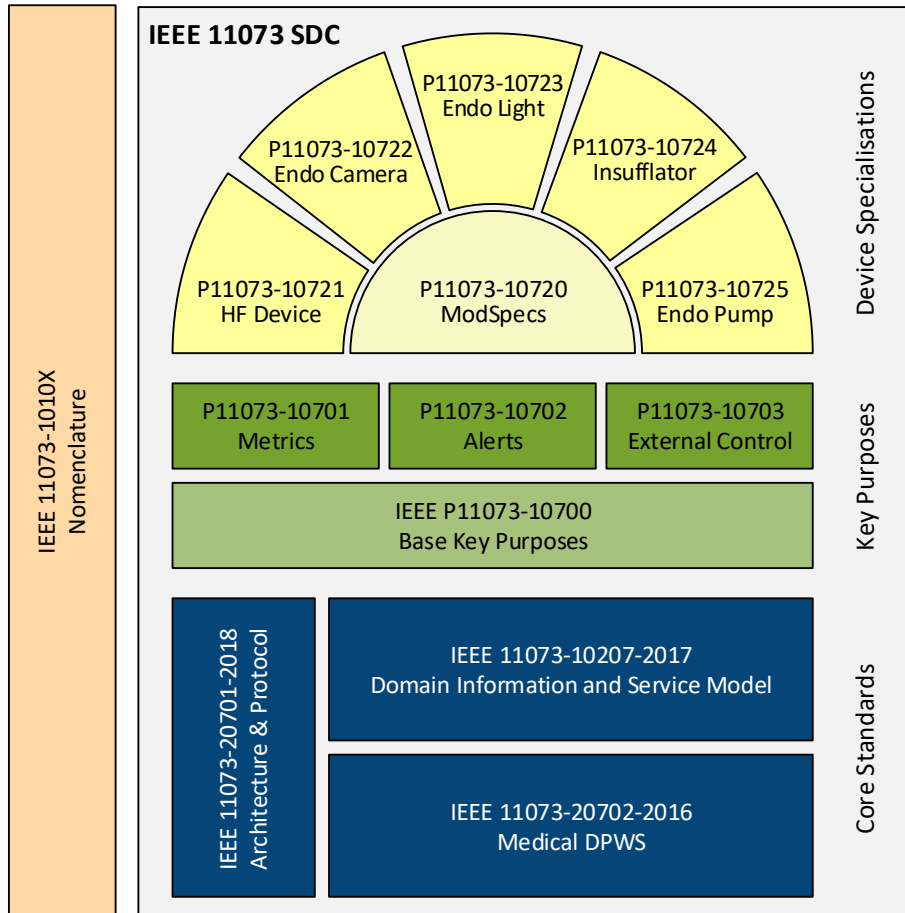
Devices: *Anesthesia ... (new)*

Devices: *Dialysis ... (new)*

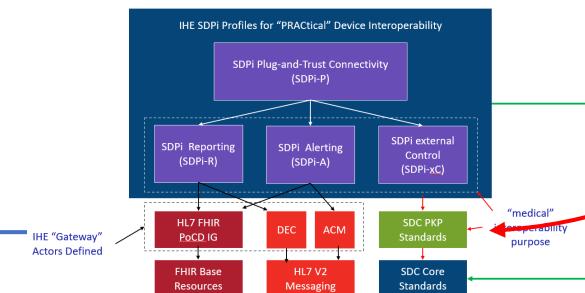
**Bindings –
General & Specific**

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

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)



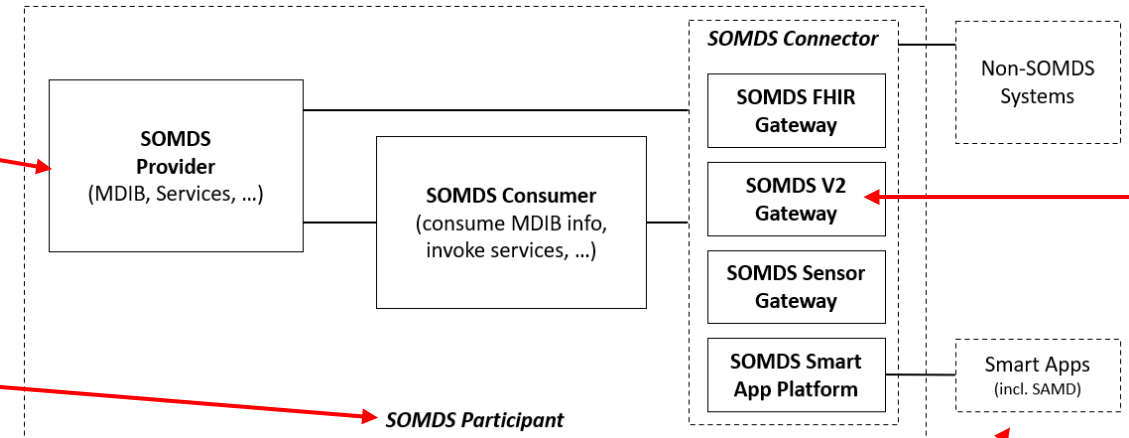
Orientation Tour: IHE Profile Actor Diagrams

IHE Actor

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

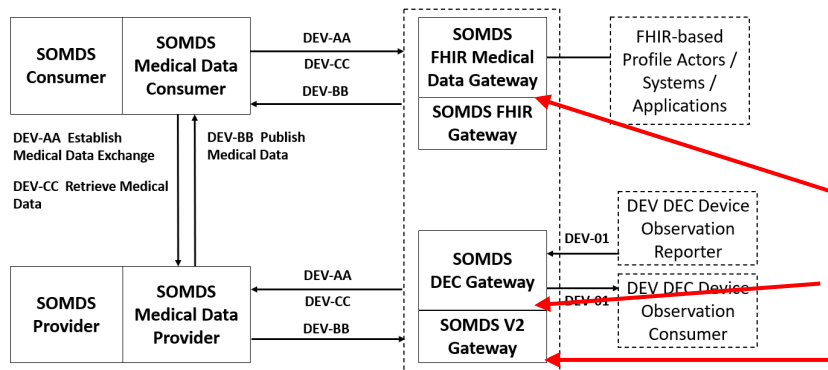
IHE Abstract Actor

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

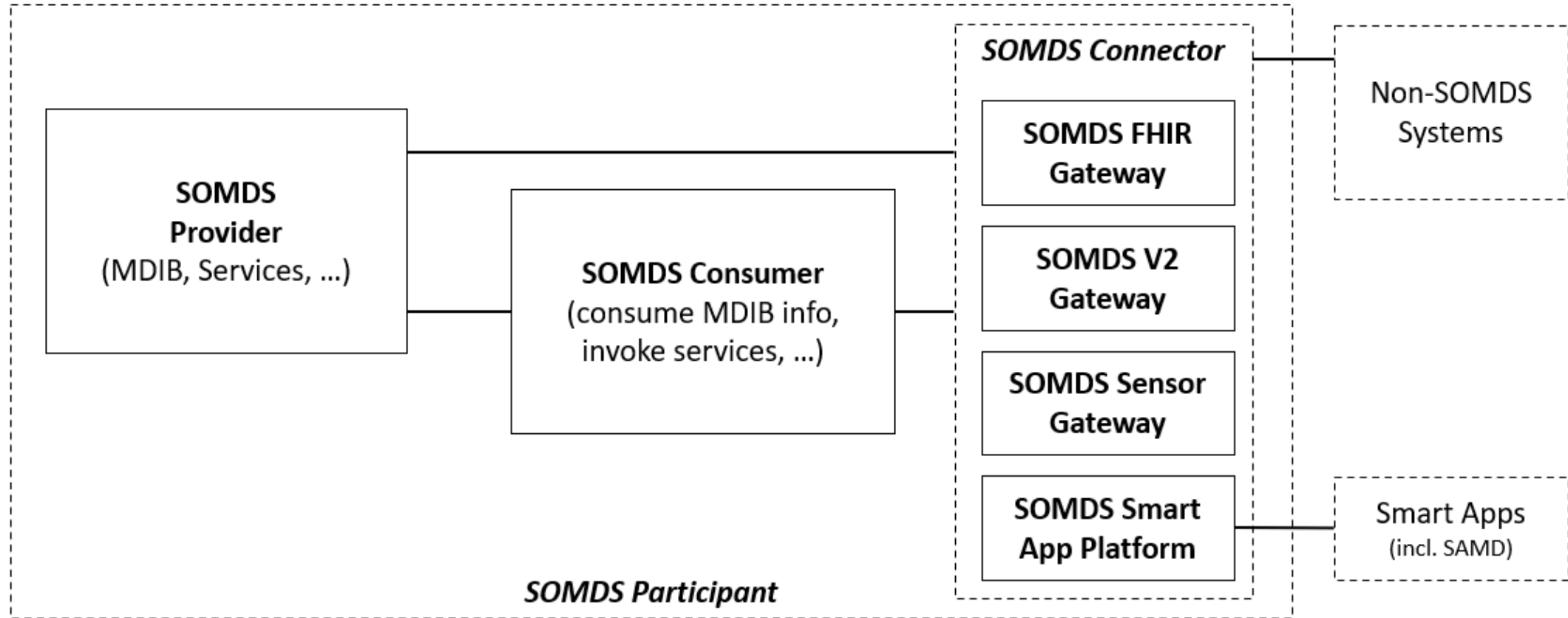


IHE Grouped Actor

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

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

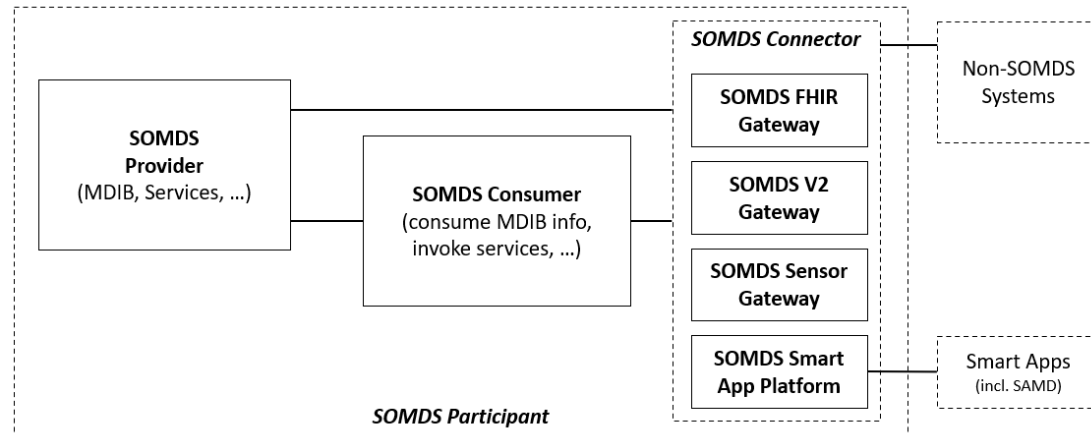
SDPi-P Actor Model



NOTE: **SOMDS Participant** actors may be devices, system applications, SAMD, “smart apps” ...

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

SDPi-P Actor Model



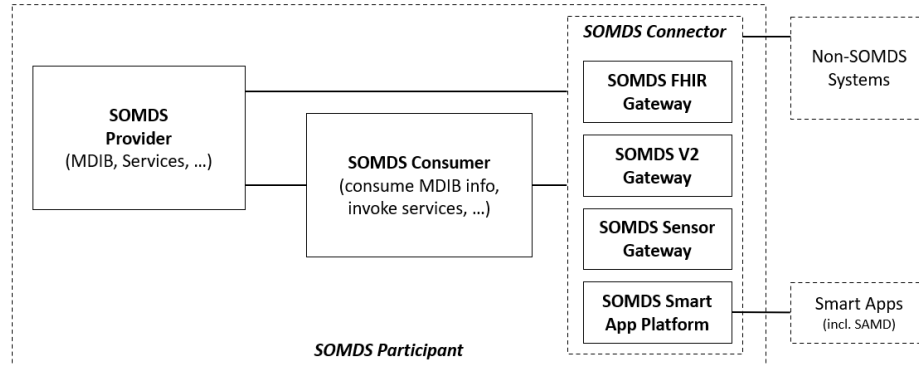
SDPi-P Options (partial)

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

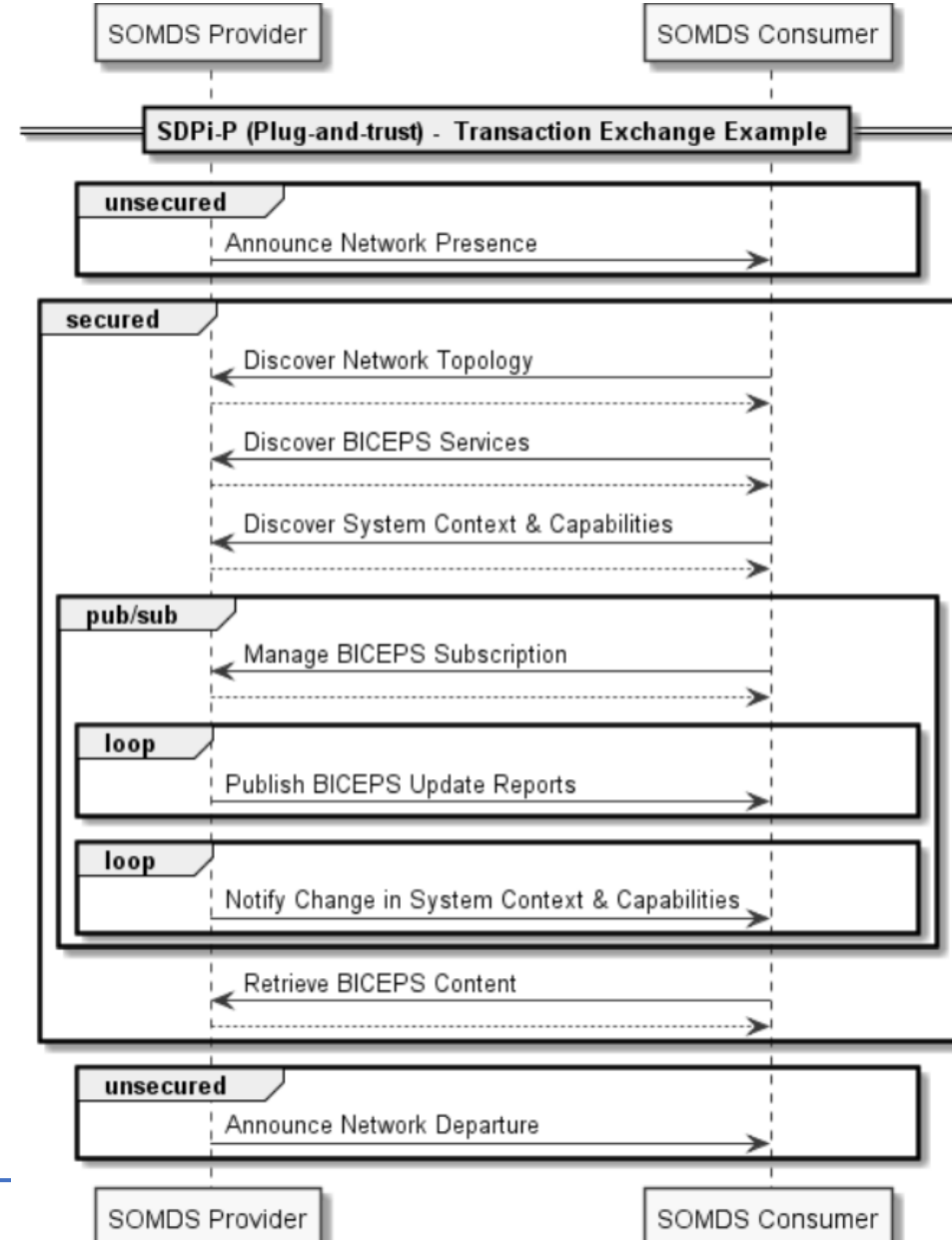
5

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

Actors	Transactions	Initiator or Responder	Optionality	Reference
<i>SOMDS Participant</i>	[Editor's Note: TBD specific transactions / abstract actor!]			DEV TF-2:3.xvz
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
	Announce Network Presence	Consumer	O	DEV TF-2:3.23
SOMDS Consumer	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.

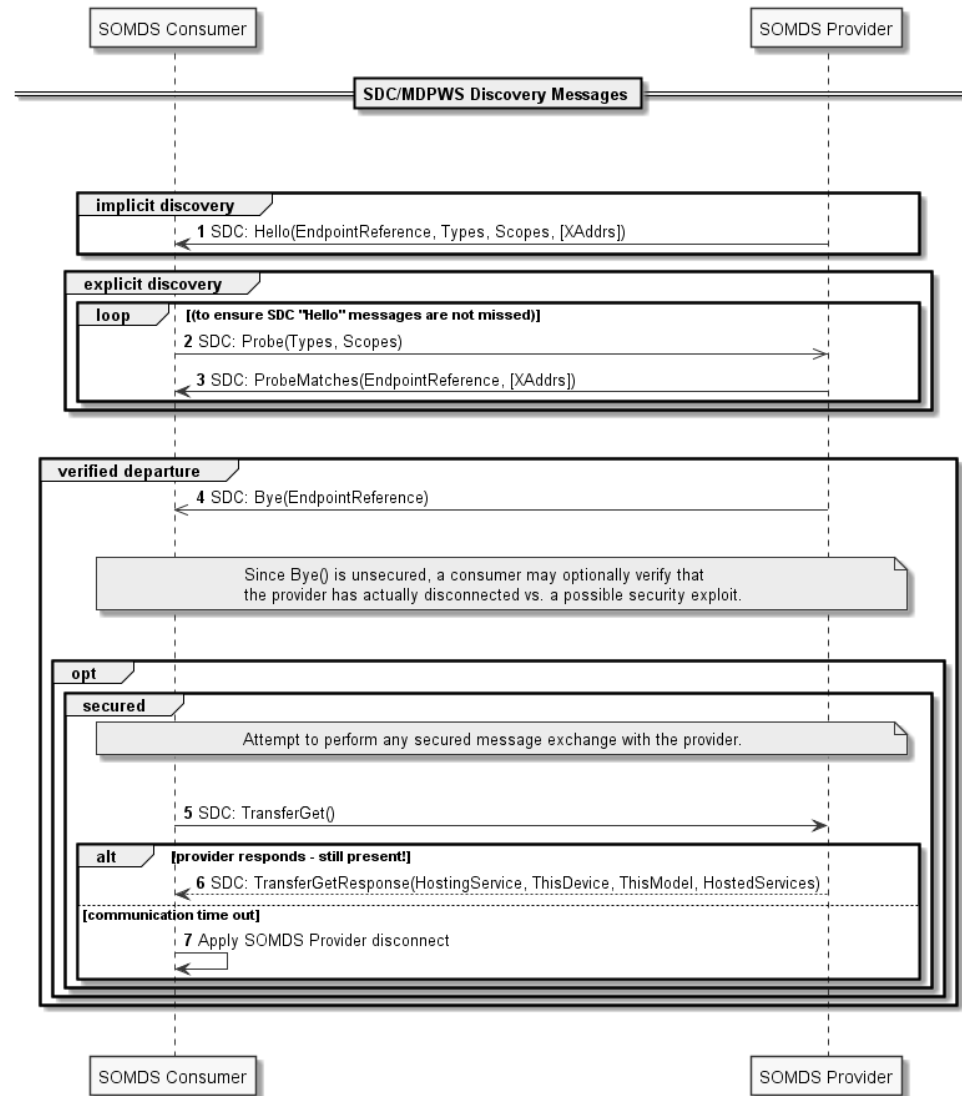
For a full set of profile-specific MDPWS sequence exchanges, see:

<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

...

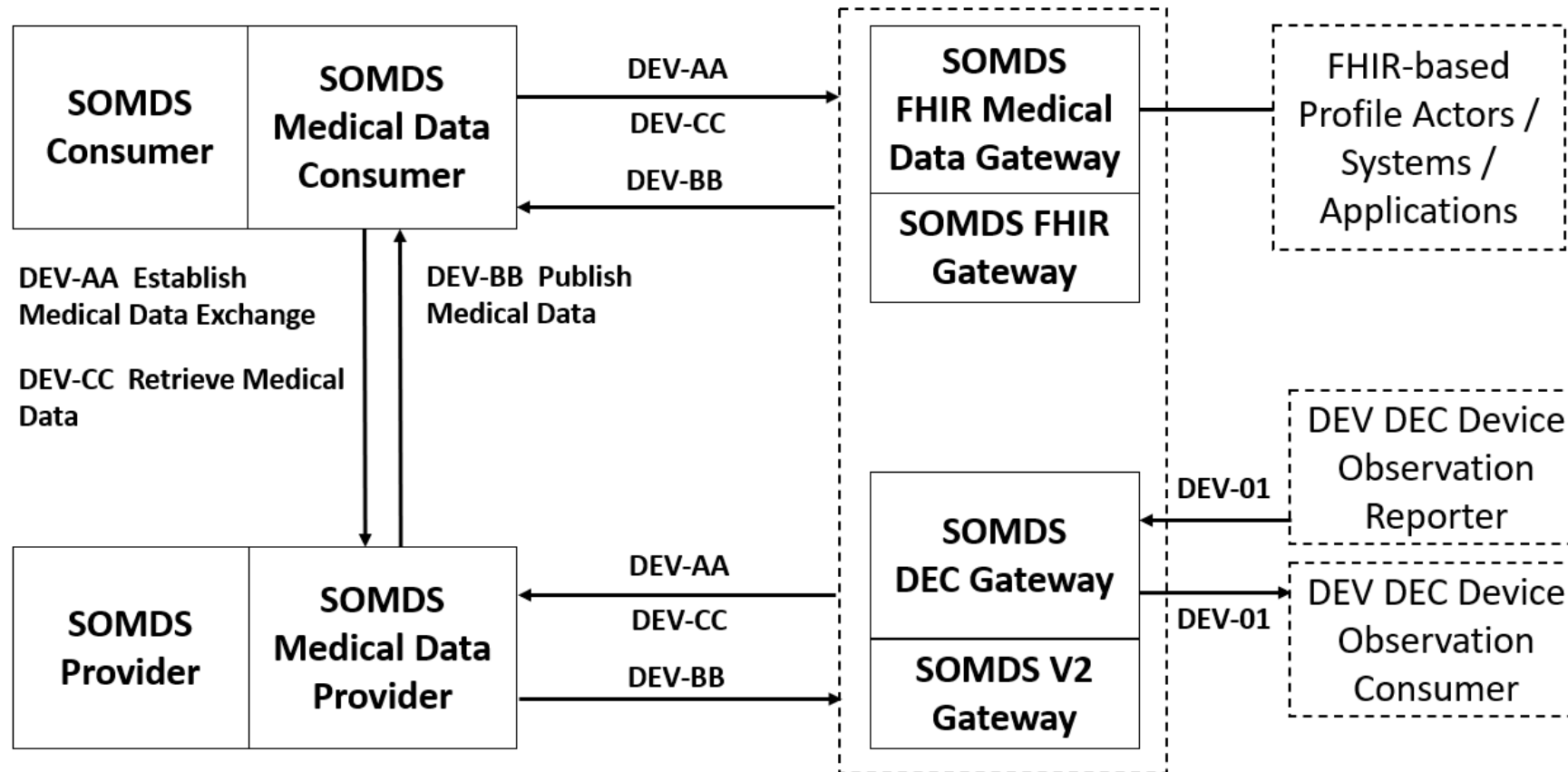


For a full set of profile-specific MDPWS sequence exchanges, see:

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

Orientation Tour: SDPi-R (Reporting)

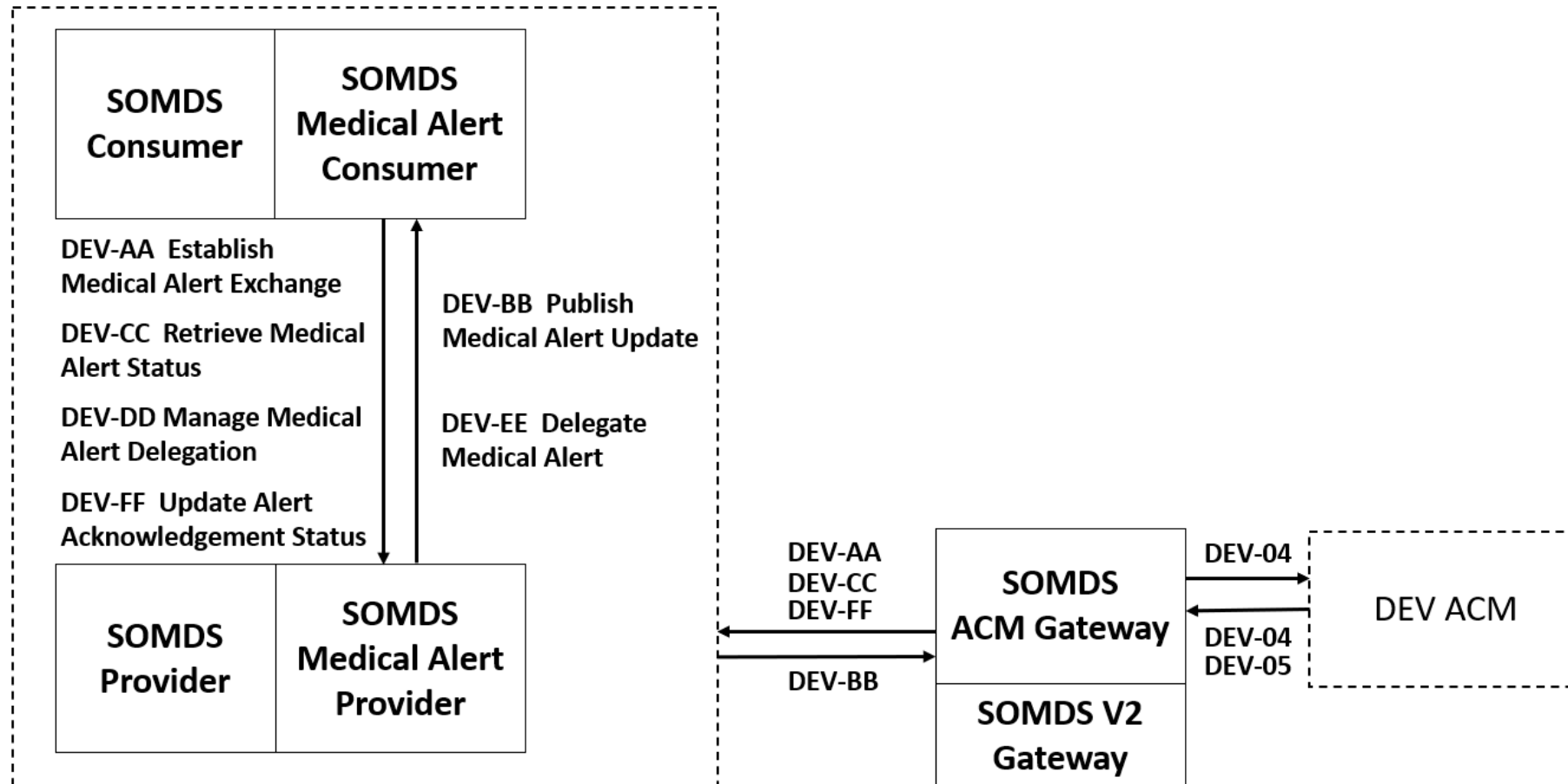
SDPi-R Actor Model



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

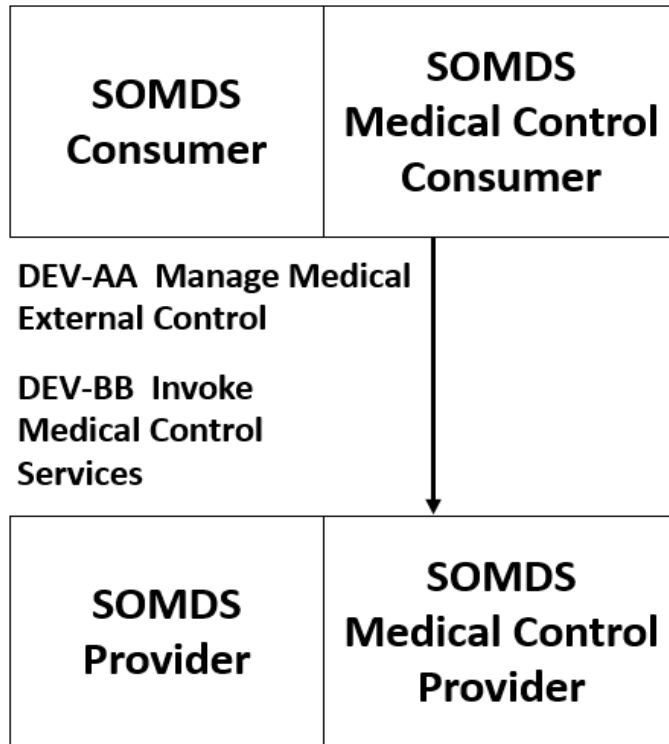
Orientation Tour: SDPi-A (Alerting)

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

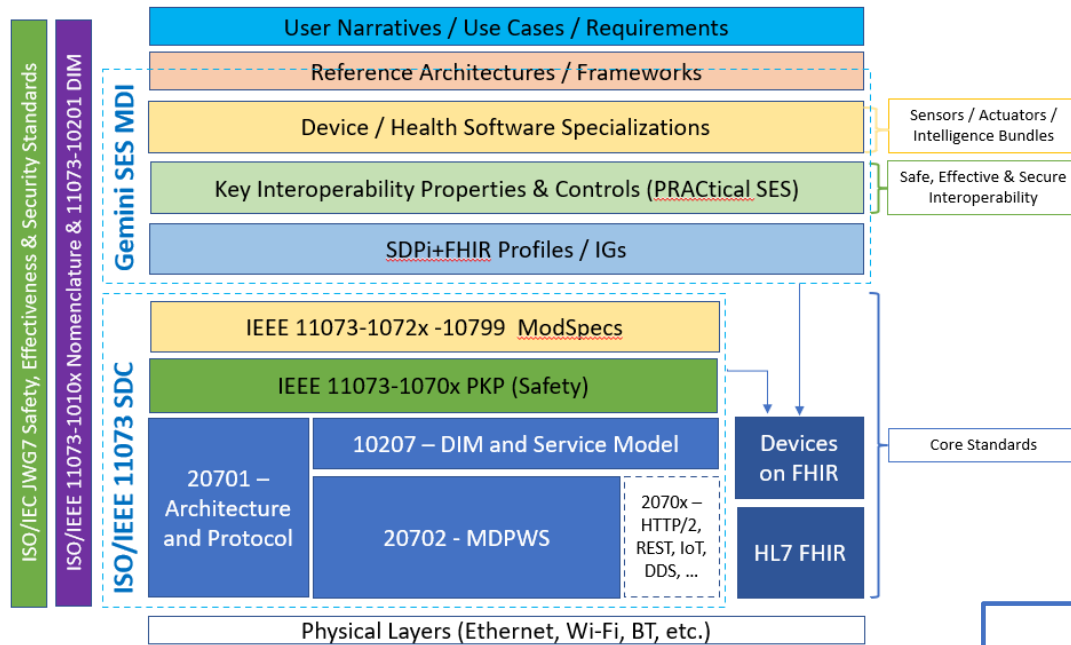
Validate SDPi Profiling Approach (Actors & Transactions & SDC ...)

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?

