



Safe, Effective & Secure Device SDC-SDPi+FHIR Interoperability

Establishing a framework for

Trusted Interoperable Product Decoupling

Using ISO/IEEE 11073 SDC / IHE SDPi / HL7 FHIR + ISO/IEC JWG7 SES Standards



FHIR is a trademark of Health Level 7, International.

SDC is a registered trademark of OR.NET

OR.NET_{e.v.}

SES MDI using SDC-SDPi+FHIR Briefing & Proposal

Safe, Effective & Secure MDI using SDC-SDPi+FHIR

The Question

Journey from SDC to SDPi+FHIR ...

Overview of SDC & SDPi for MDI

From Narratives to Plug-n-Trust

SES MDI – Proposed “Getting Started” Roadmap

SES SDC-SDPi Device Interoperability

Problem: Medical device interoperability (MDI) standards & Medical Technology Safety, Effectiveness & Security (SES) standards exist in **parallel universes** BUT products allowed for patient use must meet both the informatics interoperability technology requirements + quality, regulatory, and legal requirements.

Question: Can a framework be created to enable
Trusted Interoperable Product Decoupling
Using
ISO/IEEE 11073 ***SDC***, IHE ***SDPi*** & HL7 ***FHIR Interoperability Standards***
+
ISO/IEC ***JWG7 Safety, Effectiveness & Security Standards?***

NOTE: MDI standards align with ISO/TC 215 WG2; SES with ISO/IEC JWG7

Acronyms

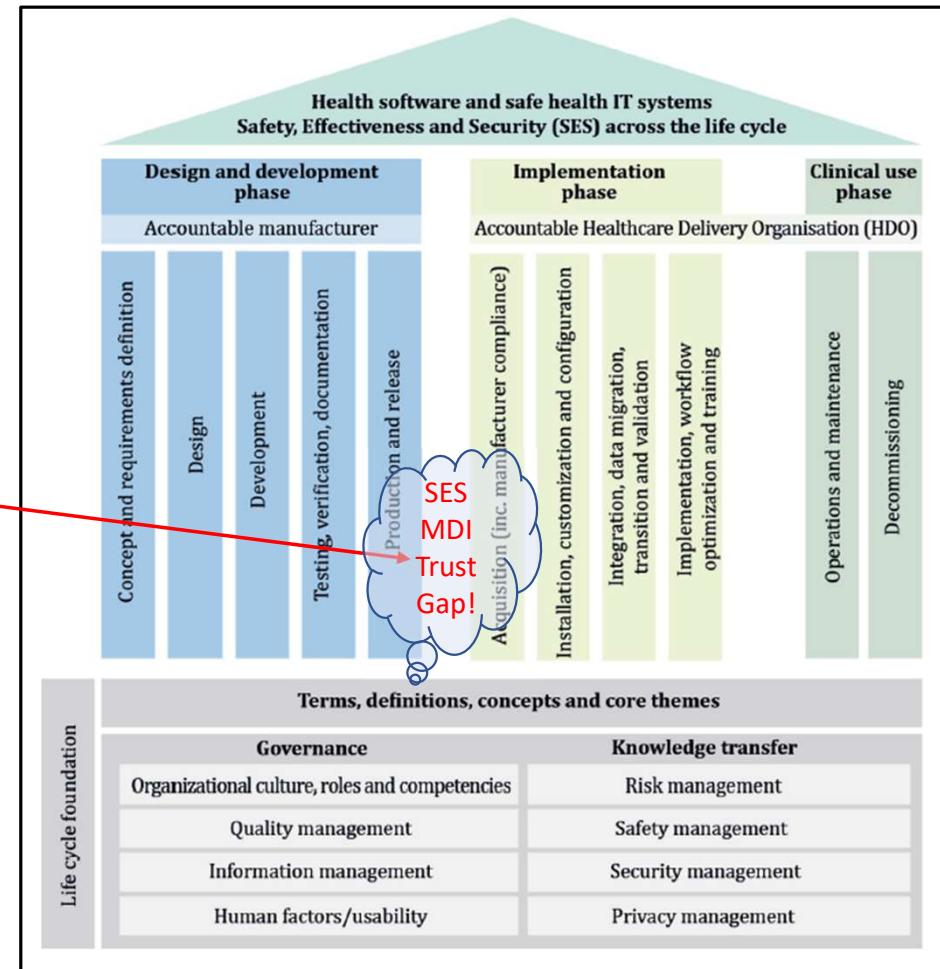
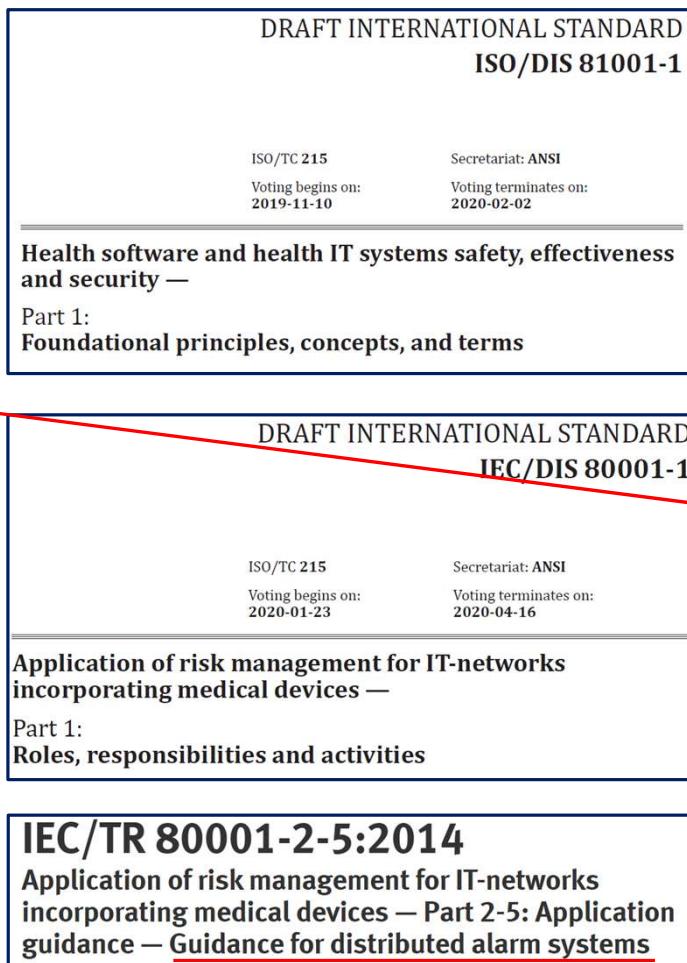
SES	Safety, Effectiveness & Security – A handy way to refer to the JWG7 focus and family of standards
SDC	Service-oriented Device Connectivity – Family of ISO/IEEE/CEN 11073 device interoperability standards (see TC215 WG2)
DPI	Device Point-of-care Interoperability – IHE Devices sub-group designation
SDPi	Service-oriented Device Point-of-care Interoperability – IHE Devices profiles using SDC & FHIR (and HL7 V2 ...)
MDI	Medical Device Interoperability – General label covering entire subject area
FHIR	Fast Healthcare Interoperability Resources – General purpose resource-based health information exchange standards typically using RESTful architecture
QRL	Quality / Regulatory / Legal stakeholder communities – For lack of a better TLA!
IHE	Integrating the Healthcare Enterprise – An international standards “profiling” organization (ISO/TC 215 Liaison A)
JWG7	Joint Working Group between ISO/TC 215 & IEC/SC 62A – Home of the SES family of standards

A word about “Safety, Effectiveness & Security”

As explained to the
SDC-SDPi+FHIR MDI
community ...

**Primary focus area
of SES @
SDPi+FHIR white
paper project**

Two+ ISO/IEC standards & guidance documents that address SES MDI across the life cycle of health software, Health I.T. & Incorporated devices.



MDI Journey so far recent history

ISO/IEEE 11073 SDC – 15 Year Journey

2004

2004

2010

2011

2013

2015

2016

2017

2018

BMBF Vision SOMIT
FUSION / OrthoMIT
Foundation for the idea of
interoperability

TekoMed
Feasibility study to
prove the SOA
approach for
medical devices

Dienst-Orientierte OP
Integration (DOOP)
Networking project with
various medical vendors to
implement DPWS and
demonstrate interoperability

BMBF-OR.NET
A project funded by the German
Ministry of Education and Research
to consolidate all medical device
interoperability research activities
in Germany

OR.NET e.V.
An association of different
stakeholders in medical
device interoperability

IEEE 11073-20702
Standard approved
Medical Devices
Communication
Profile for Web
Services

IEEE 11073-10207
Standard approved
Domain Information
and Service Model for
Service-Oriented
Point-of-Care Medical
Device
Communication

IEEE 11073-20701
Standard approved
Service Oriented
Medical Device
Exchange Architecture &
Protocol Binding



Demonstrator, 2011



NOTE: This roughly parallels the timelines
for IHE Devices Domain & HL7 Devices WG

IHE SDPi – Building on the ISO/IEEE & HL7 Core

Integrating the Healthcare Enterprise

IHE

**IHE Patient Care Devices (PCD)
White Paper**

5

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

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

20 Revision 1.1 – Published

25 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

SDC@IHE 2019
**Initiative laid the
foundation for IHE**

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

**profile family for
“PRACTical” device-to-
device interoperability**

Integrating the Healthcare Enterprise

IHE

**IHE Patient Care Devices (PCD)
Compendium of Medical Device
Oriented Use Cases**

5

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

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

20 Revision 1.0

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

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

2020 Joint HL7-IHE Gemini Project



Device Interoperability using Service-oriented SDPi + FHIR™

A Joint HL7-IHE Gemini Program Proposal

Full slide deck @ confluence.hl7.org
“Device Interoperability using
SDPi+FHIR” page

2020.04.21

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e.V.

Gemini Project Deliverables & Governance

One set of cohesive, coordinated deliverables

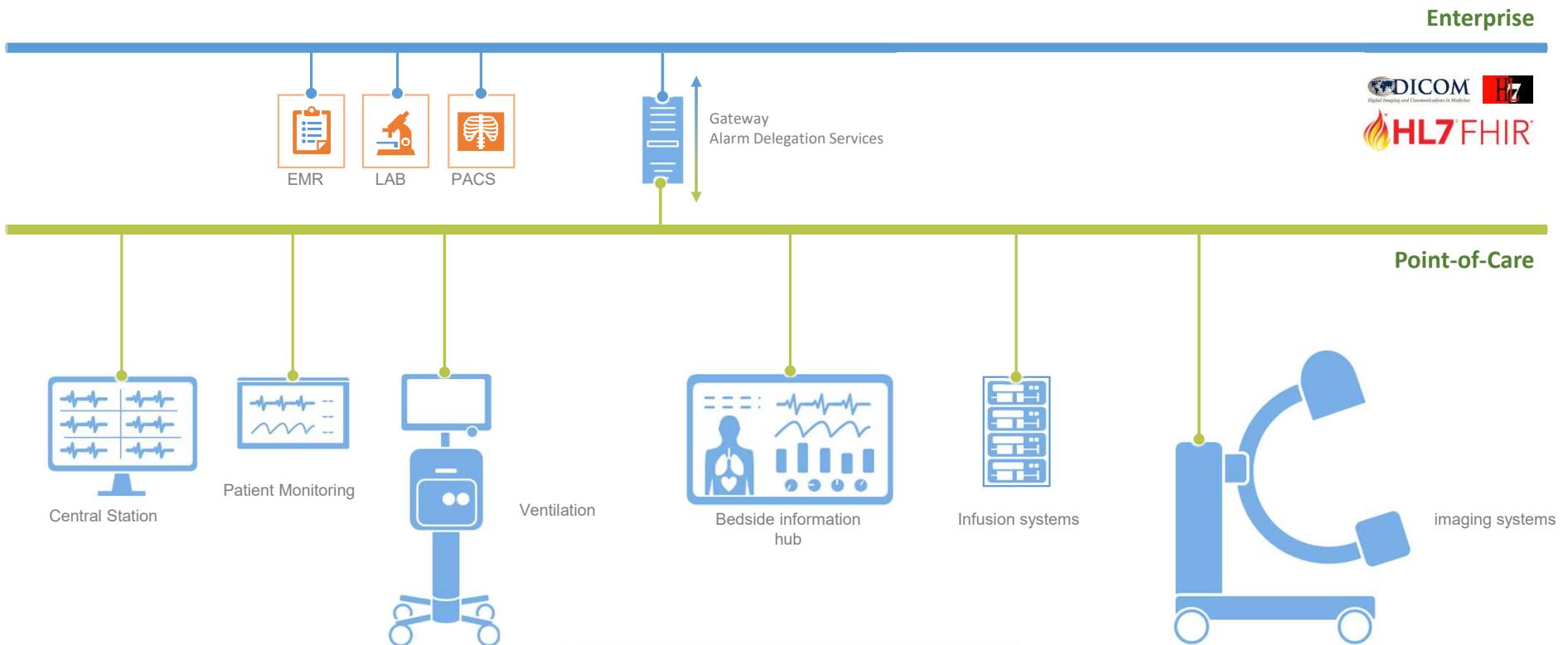
1. **IHE SDPi Supplement** – published 2020 JUL, PAT/CAT testing Q3/4 '20
2. **HL7 DoF IG** supporting **SDC integration & Alerting** – ballot in 2020
 - ✓ DoF IG (proposed) for *Device Information Consumers* (title TBD)
3. Joint White Papers:
 - ✓ “**What is a device?**” - including AI/ML SAMD, across use context geographies
 - ✓ “**Safe, Effective & Secure MDI Using SDC/SDPi + FHIR**” – Quality / Regulatory / Legal Considerations
 - ✓ “**Accelerating Safe, Effective and Secure Remote Monitoring and Mobile Health Interoperable Solutions**” – How do you know that a rapid response to address crisis (e.g., pandemic) challenges is safe enough, effective enough, and secure enough to allow for implementation & use?

Governance based on HL7 or IHE project home organization processes

A bit more on ...

SDC-SDPi+FHIR

... for MDI



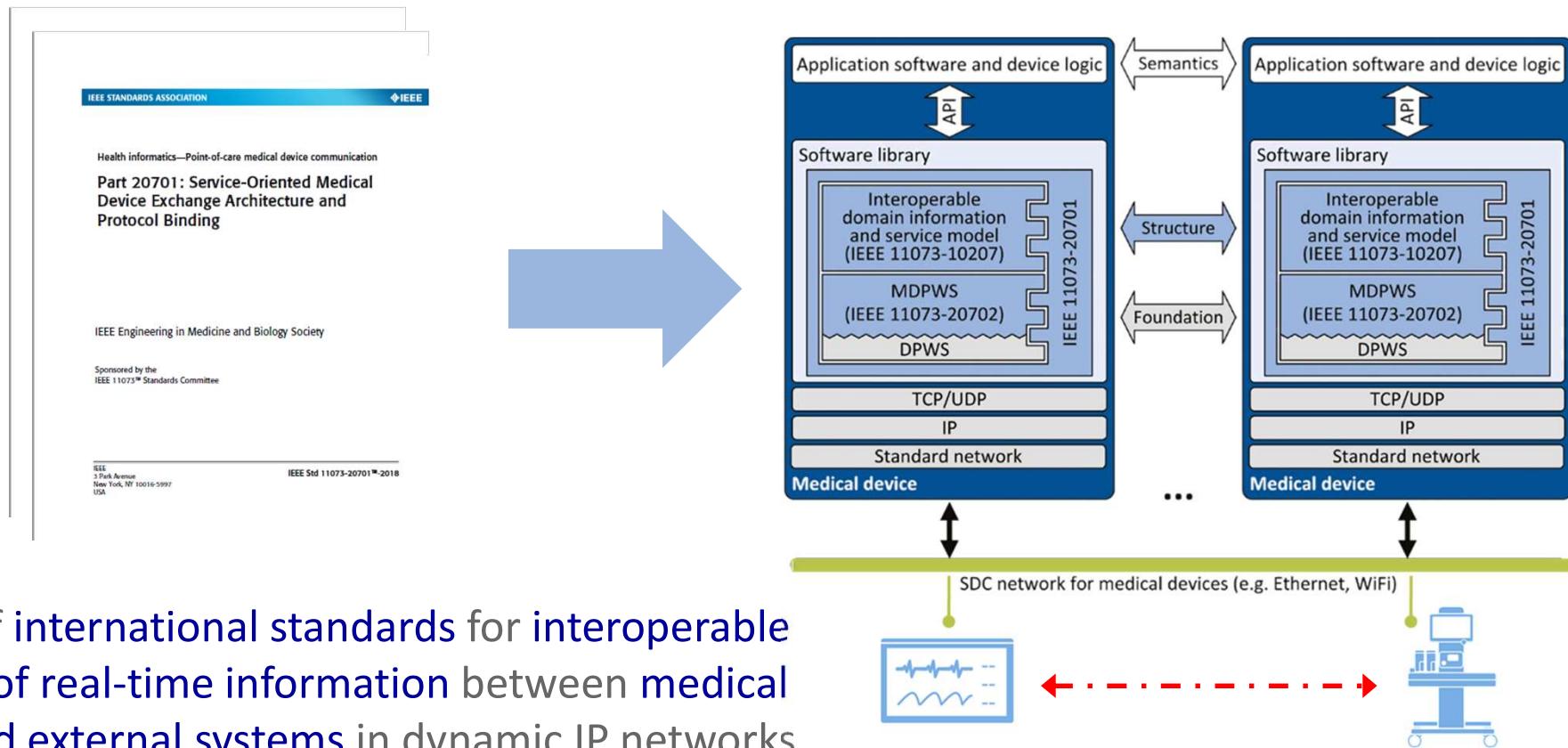
Standards for device-to-device interoperability at Point-of-Care ?



SES MDI using SDC-SDPi+FHIR Briefing & Proposal

What is SDC?

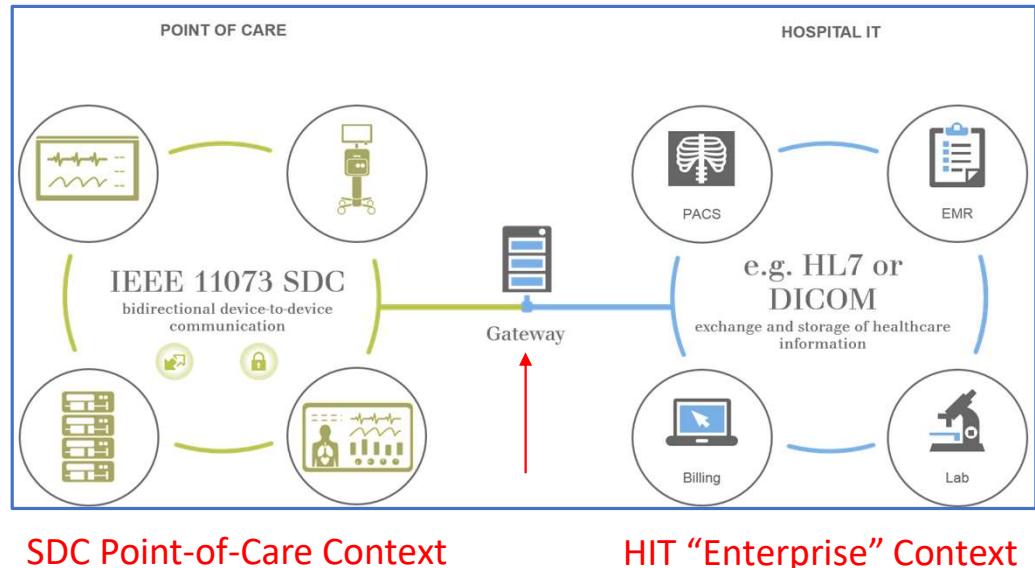
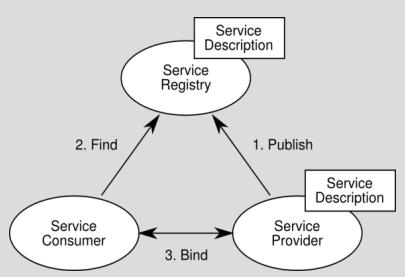
Service-oriented Device Connectivity



A family of **international standards** for interoperable exchange of real-time information between medical devices and external systems in dynamic IP networks

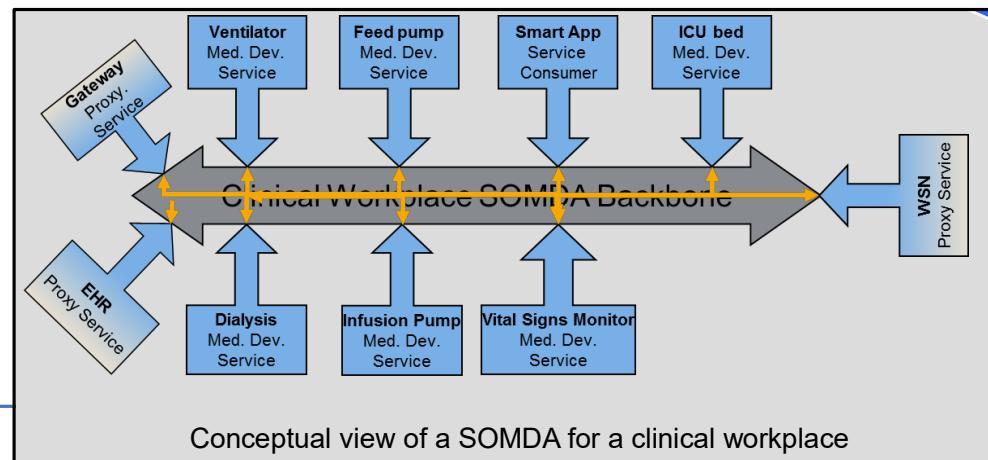
SDC Basics ...

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**.

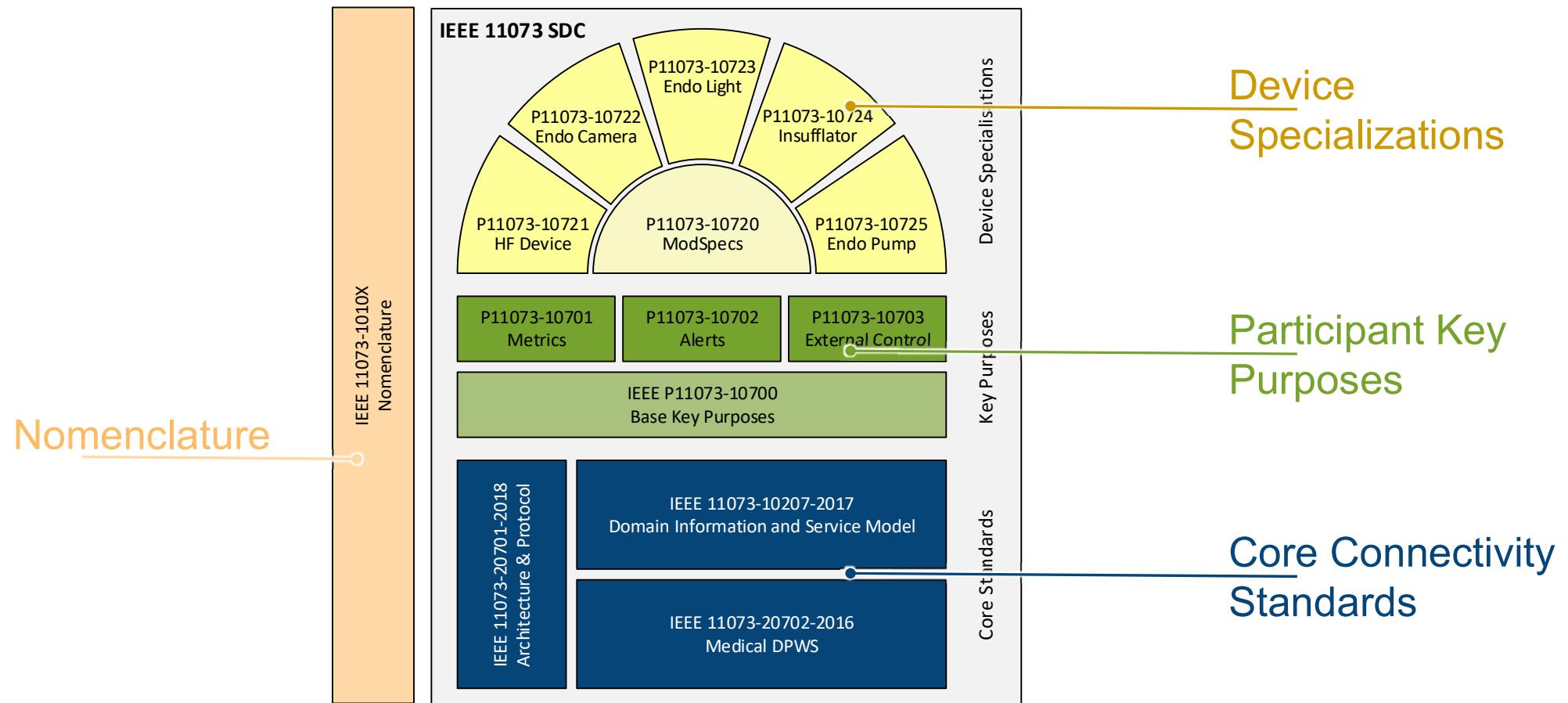


Device-to-Device Plug-and-Play for Reporting / Alerting & Controlling

(PRACTical Interoperability)



IEEE 11073 SDC Standards “Cathedral”



Example: Quiet Hospital / Silent Hospital Narratives

"Quiet Hospital" Story

Early through Kelly's stay in the ICU, the ICU staff decide to deploy a "Quiet Hospital" mode. This routes alert notifications from all of the patient care devices associated to Kelly directly to the responsible nurse's communication device with the proper information for each event. In this mode, for non-life critical events Sam can use her mobile device to temporarily pause the bedside alarm audio for a few minutes, allowing her time to go to the bedside to resolve it. After this mode is enabled Kelly immediately notices that the ICU is considerably quieter without constant alerts sounding, allowing him to get much more rest. Sam is also enjoying the relative quiet and able to better care for her patients. With quiet hospital engaged she can triage lower priority events from her mobile device, allowing her to prioritize more critical tasks with other patients without forcing Kelly to listen to the constant noise from these events in his room while he waits for her to arrive. Sam can also focus on just the notifications from her patients since the noise on the unit is lowered and all of the alerts related to Kelly are now coming to devices carried by Sam and others specifically assigned to Kelly's care. The sound in Kelly's room and surrounding environment has now been diminished with only critical alarms sounding from the devices assigned for his care and Sam has lower fatigue with higher patient satisfaction for her patients since she can better attend to the needs of all of her patients.

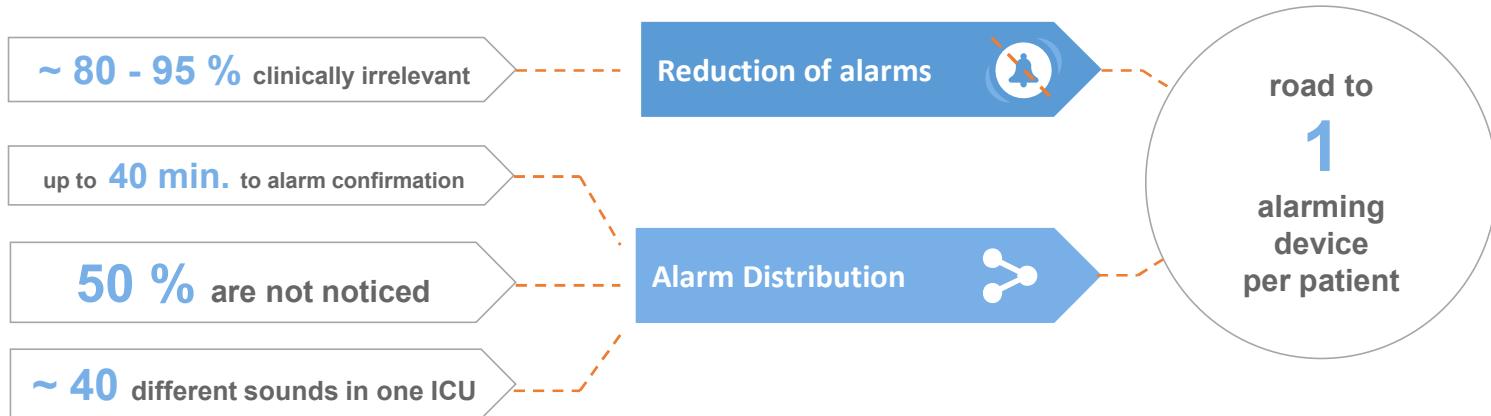
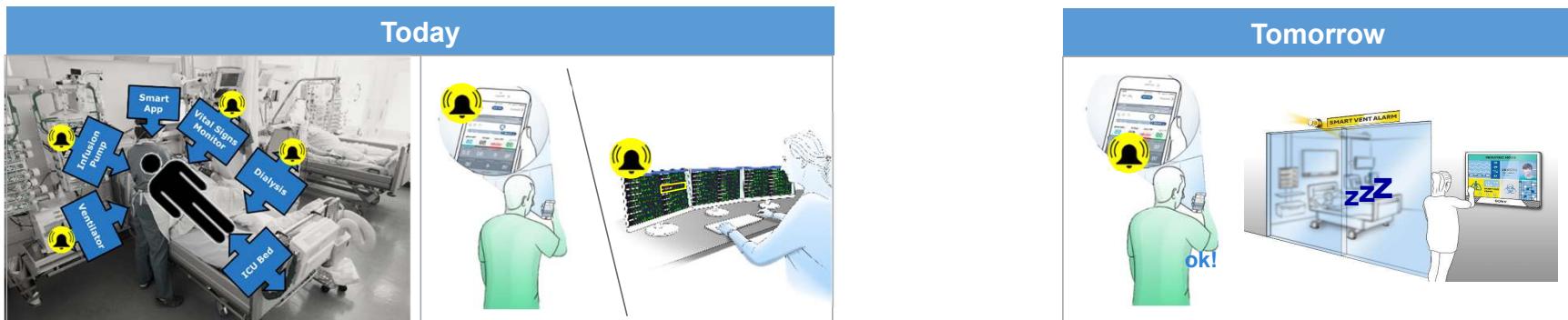
"Silent Hospital" Story

Given the success with the "Quiet Hospital" feature, the staff decide to go one step further and enable "Silent Hospital" mode a couple days later. (This works the same as Quiet Hospital but the nurse can completely reset an alert (if appropriate) and does not

NOTE: Current version of these narrative documents are available on the Gemini SDPi+FHIR Quiet Hospital Confluence pages.

SDC & Quiet Hospital/Silent ICU @ HIMSS'20 ...

SILENT ICU BY ALARM SIGNAL DELEGATION



SDC & Quiet Hospital/Silent ICU @ HIMSS'20 ...

SILENT ICU BY ALARM SIGNAL DELEGATION

- REQUIREMENTS

“Delegation” – *Safely enabling one system to annunciate alerts on the behalf of another system*



1. The alarm producer has to make **all information available** that are necessary for the remote alarm notifiers, like alert condition presence, alert manifestation, etc. **Interoperability** and semantical interpretability have to be ensured.
2. The system has to be suitable for **multiple alarm producers** and **several remote alarm notifying devices**.
3. The alarm producer has to be able to determine whether other devices are **ready to generate the alarm notification**.
4. The alarm producer has to be able to observe that the **alarm is generated correctly**.

Some more information: „A Safe and Interoperable Distributed Alarm Notification System for PoC Medical Devices using IEEE 11073 SDC”, Kasparick et al.

ALERT SIGNAL DELEGATION

USE CASE



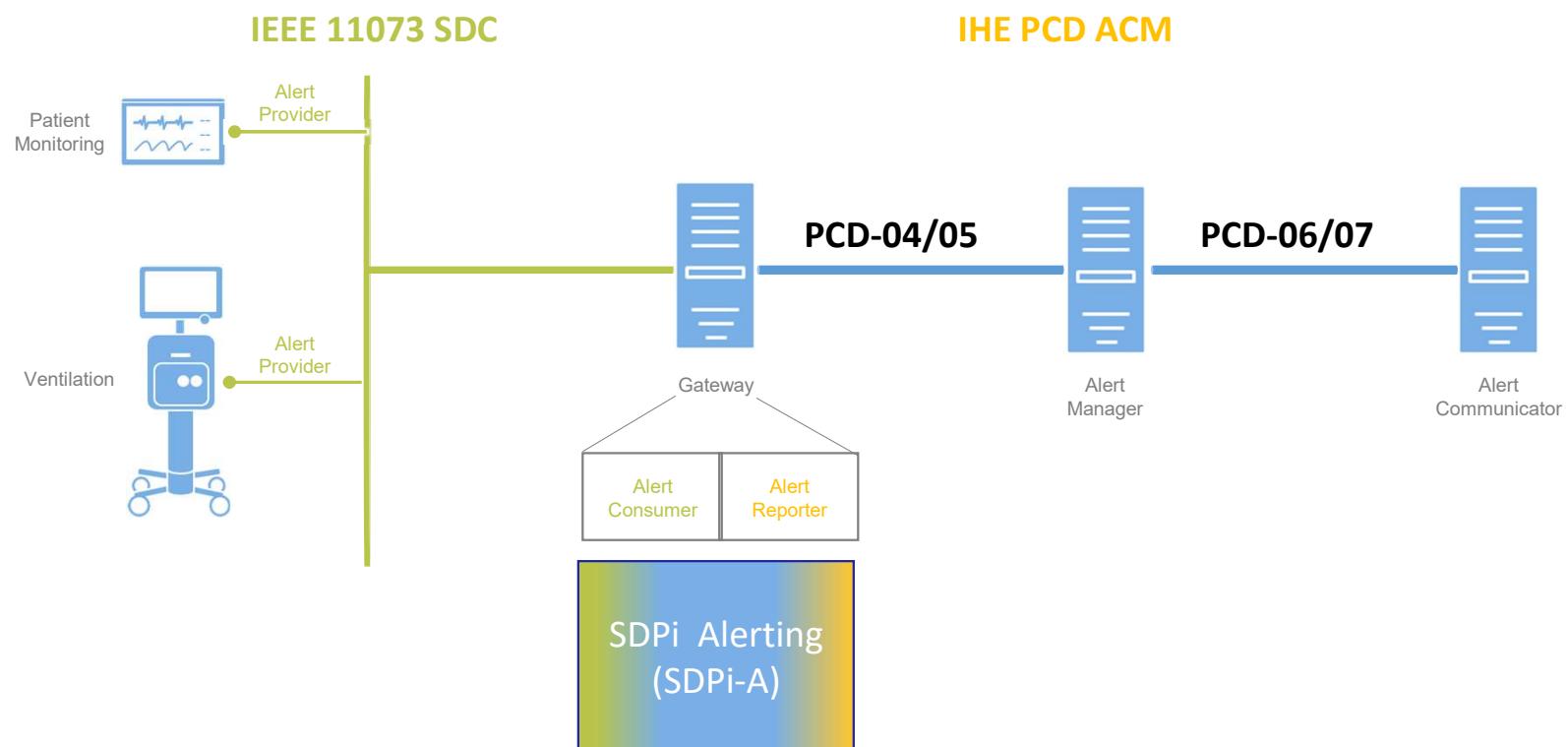
From IEEE 11073-10207 (BICEPS)

ALERT SIGNAL DELEGATION is the capability of a POC MEDICAL DEVICE to let another PARTICIPANT generate a POC MEDICAL DEVICE's ALERT SIGNAL as primary ALERT SIGNAL in order to remotely indicate the presence of an ALERT CONDITION on the POC MEDICAL DEVICE.

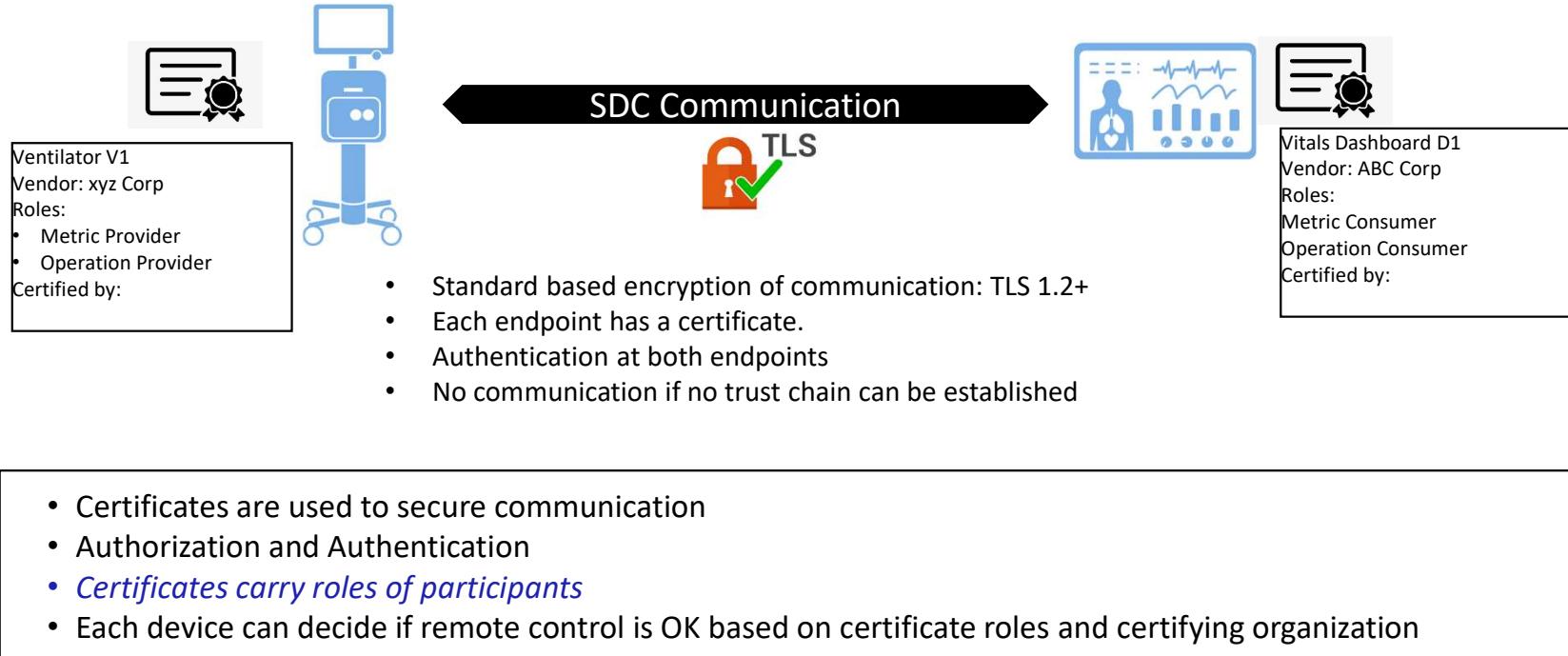
- ➔ a POC MEDICAL DEVICE delegates its ALERT SIGNAL generation to another PARTICPANT, e.g., to facilitate a silent workplace
- ➔ **Delegable & Fallback Alert Signals**

Alert Signal Distribution

Combining IEEE 11073 SDC & IHE PCD ACM



SDC – Security is a Core Capability



SDC = Enables *Trusted Interoperable Product Decoupling*

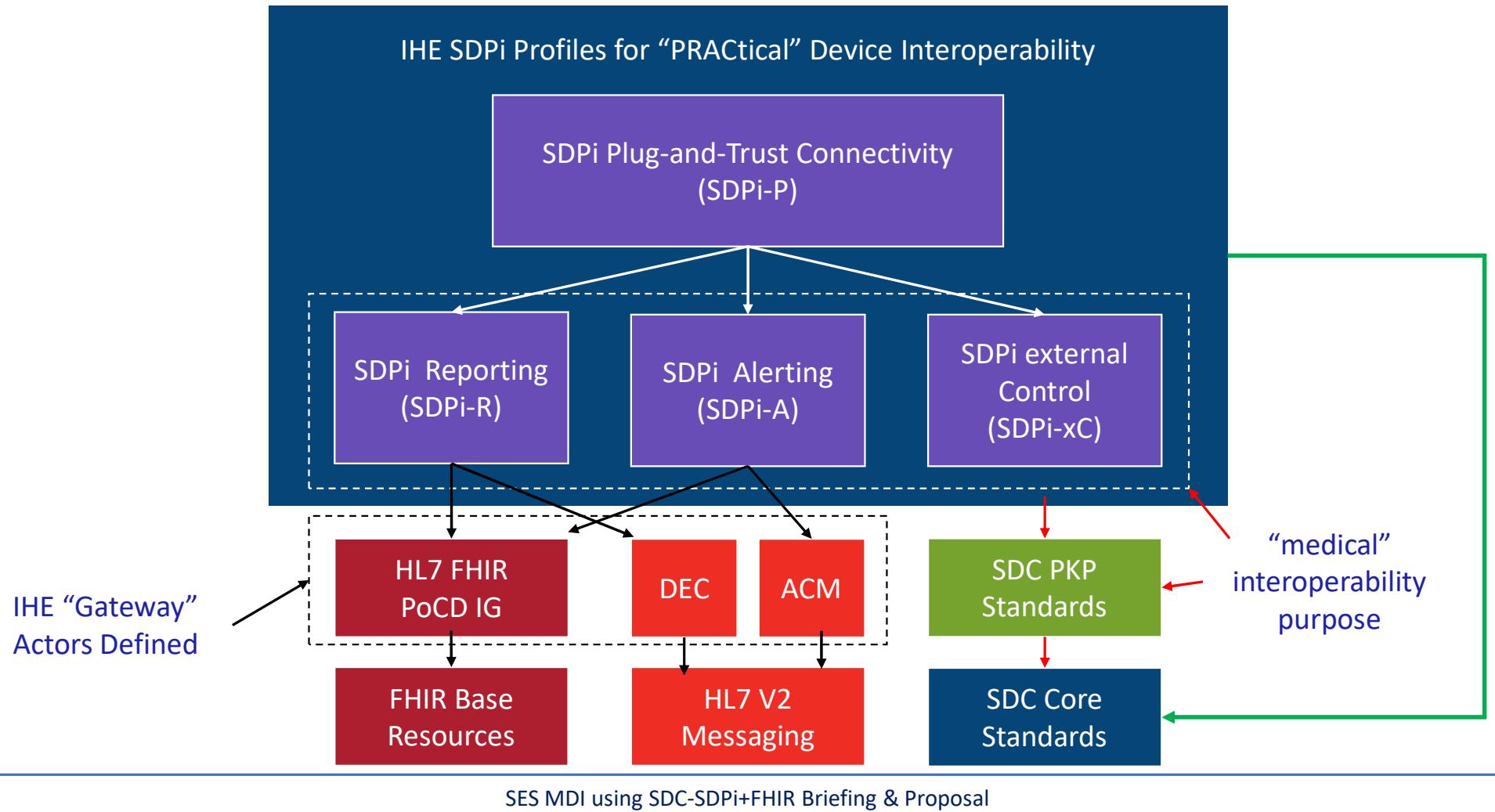
(Stretch goal: **Computable IFU discoverable at Plug-n-Trust network connection & configuration** ... just sayin' ...)

SDPi+FHIR Technical Concept

- ✓ IHE Devices domain Technical Framework Approach Established
- ✓ IHE SDPi Supplement w/ 4 profiles under development – in parallel
- ✓ Will include content for TF-1 -2 & -3
- ✓ IHE Connectathon testing planned for 2020

The Amsterdam Sessions
2019.11

IHE SDPi – Building on the ISO/IEEE & HL7 Core

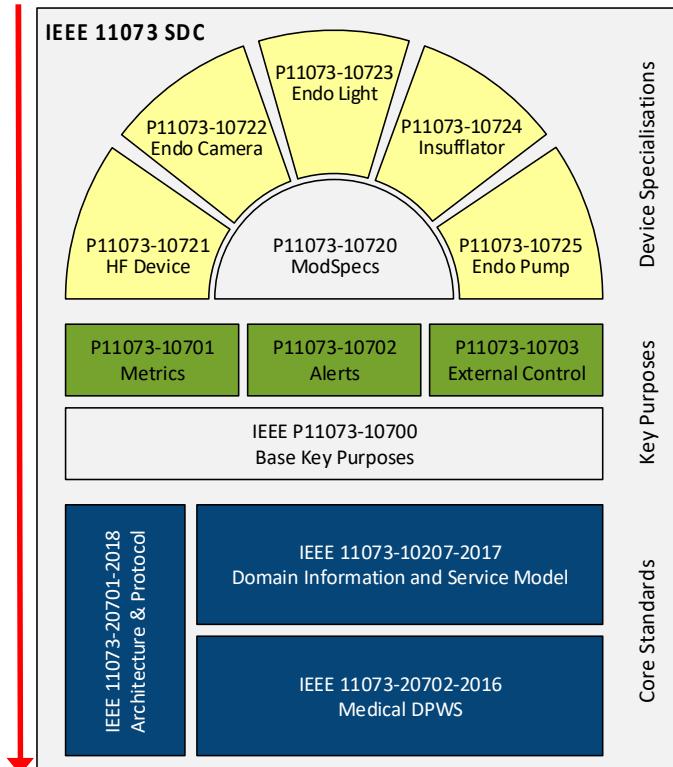


SDC PKP's – Pathway to Trust at the Interface

SDC SES Design Approach

1. Establish **Key Purposes** of Interoperability from MDS to interface:
 - Connectivity
 - Reporting
 - Alerting
 - External Control
2. Integrate “testable assertions” into each standard (“Rxxxx”)
3. Bind Rxxxx from layer to layer, incl. **risks** from one layer **mapped** into **RCMs** in the next
4. Address both Functional & Non-functional (RM) Aspects
5. Per-device **System Function Contribution** defined

BICEPS / Dev Specializations



MDPWS/WS-*

SDC Conformance Principles

OR.NET* white paper lays foundation for *traceability* from PKPs to Conformity Assessment (CA) and *certified safe-effective-secure (SES) interoperable medical device* system components.

IEEE 11073 -10700 Base PKP standard includes annex with summary of Conformance Principles

* Germany-based non-profit academic / industry group

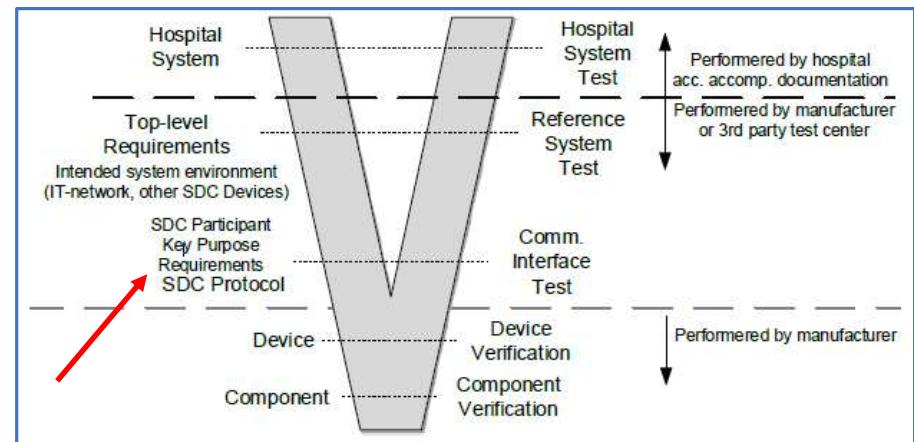
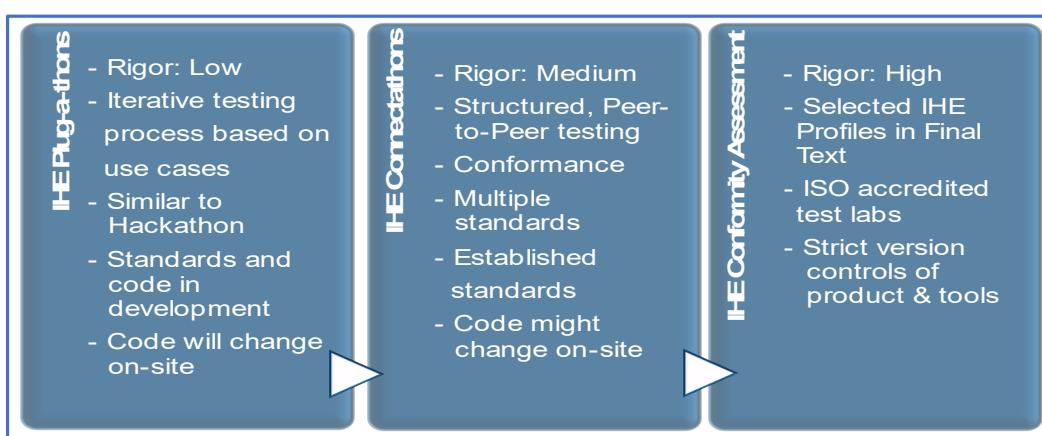


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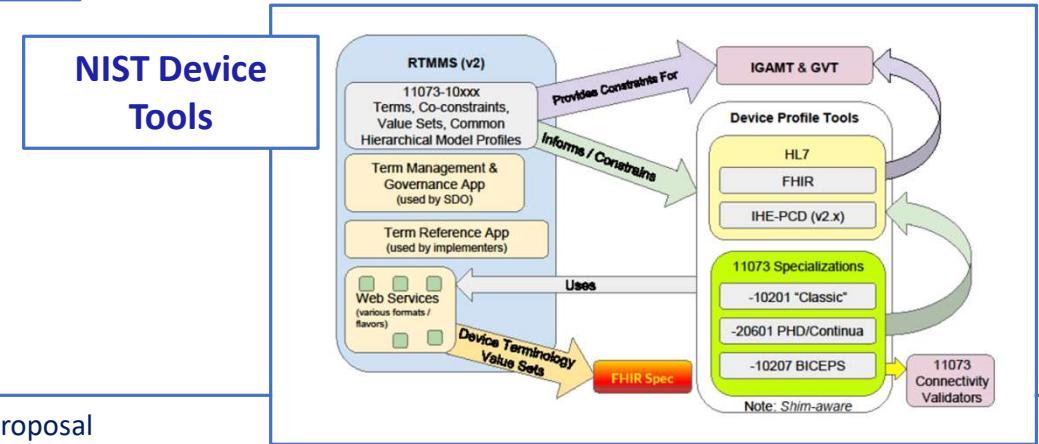
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SES Plug-n-Trust Requires Rigorous Testing

Leverage the established Device Interoperability tooling ...



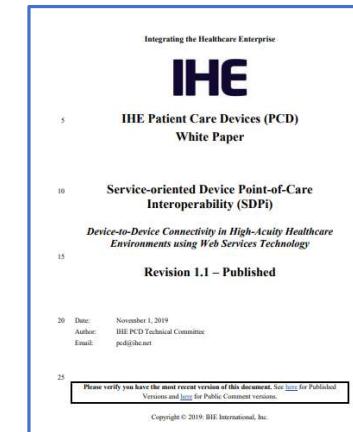
Objective: *Leverage IHE Test & Tooling to establish an SDC-enabled interoperable medical technology ecosystem where certified test reports can be directly included in regulatory submissions*



For more general SDC-SDPi+FHIR Info ...

- ✓ Primary source: confluence.hl7.org “SDPi+FHIR Community”
- ✓ Schlichting / Unity presentation @ <https://bit.ly/Record-MDI>
- ✓ HIMSS'20 Klotz/Cooper SDC MDI digital session (to be posted)
- ✓ IHE DEV SDPi White Paper –

Wealth of info including Bibliography with useful links to papers and presentations and open source Implementations, etc.



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

**Connecting the dots from
... inspiring narratives
... to Plug-n-Trust!**



From Inspiring Narratives to Plug-n-Trust

A Joint HL7-IHE Gemini SDPi+FHIR Device Interoperability Project Proposal

2020.05.12

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SDC is a registered trademark of OR.NET



Gemini SDPi+FHIR From Narratives to Plug-n-Trust

Full slide deck @ [confluence.hl7.org “SDPi+FHIR Tools” page](https://confluence.hl7.org/display/SDPITools)

From Inspiring Narratives to Plug-n-Trust

Establishing a framework strategy for ...

- (1) Capturing detailed requirements from *use narratives* in a clear and computable manner;
- (2) Enabling *mapping & traceability* & simulation through each technology and quality specification layer;
- (3) Testing *V&V conformity assessment* at the interoperable component and system of interoperable products level

... an ecosystem of trusted, safe, effective & secure, plug-and-play device & health software solutions using

SDC-SDPi + FHIR

Journey starts @ Inspiring Narratives

Gemini SES MDI Project:

1. Functional Endoscopic Sinus Surgery / *Operating Room Integration*
2. *Quiet Hospital* / Silent ICU
3. JHU/APL *MDIRA/ICE* for Military & Disaster Casualty Care
4. Preeclampsia During Pregnancy – *Home to Clinic to Hospital*
5. (in process) “Loopers” Type 1 Diabetes – *Person-crafted Closed-Loop Control*

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

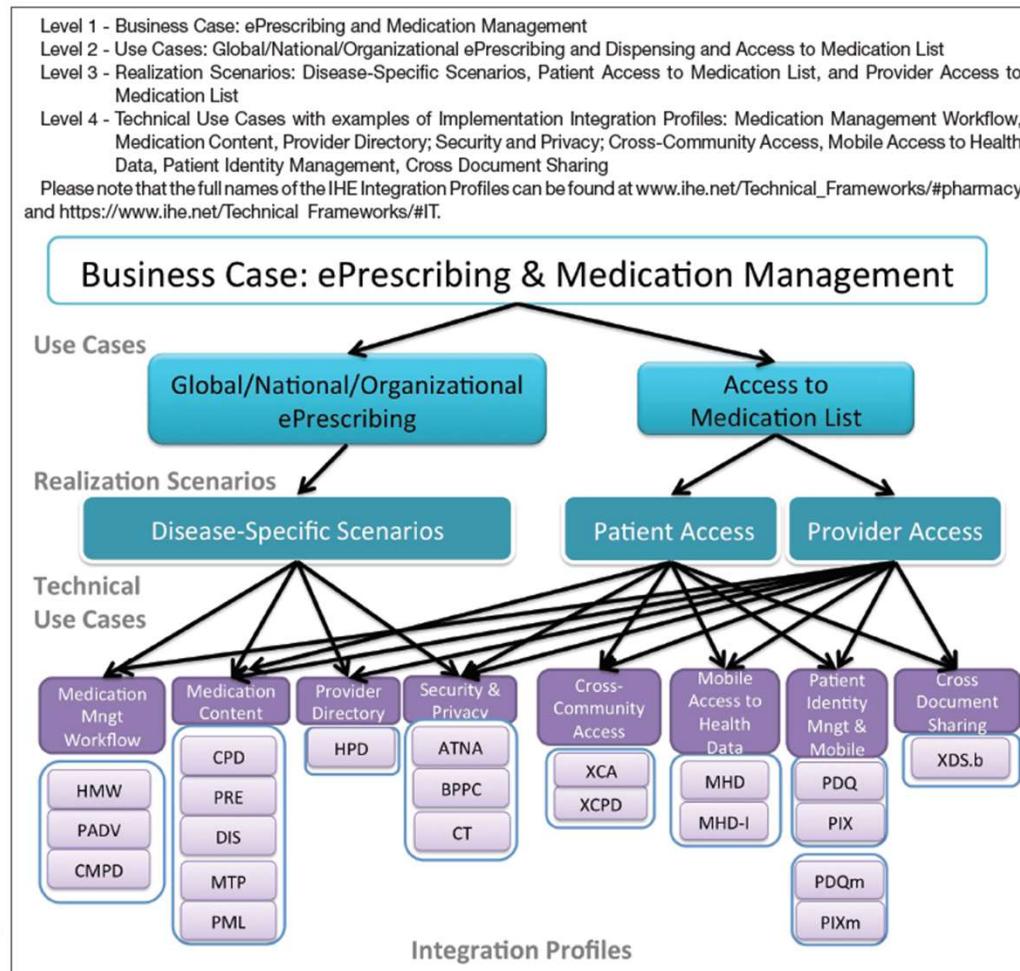
Date: August 1, 2019
Author: IHE PCD Technical Committee
Email: pcd@ihe.net

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

Gemini SES MDI Use Case home pages @
[HL7 Confluence “Device
Interoperability using
SDPi+FHIR”/SDPi+FHIR Use Cases](#)

IHE Use Case Analysis – Hierarchy of Concepts

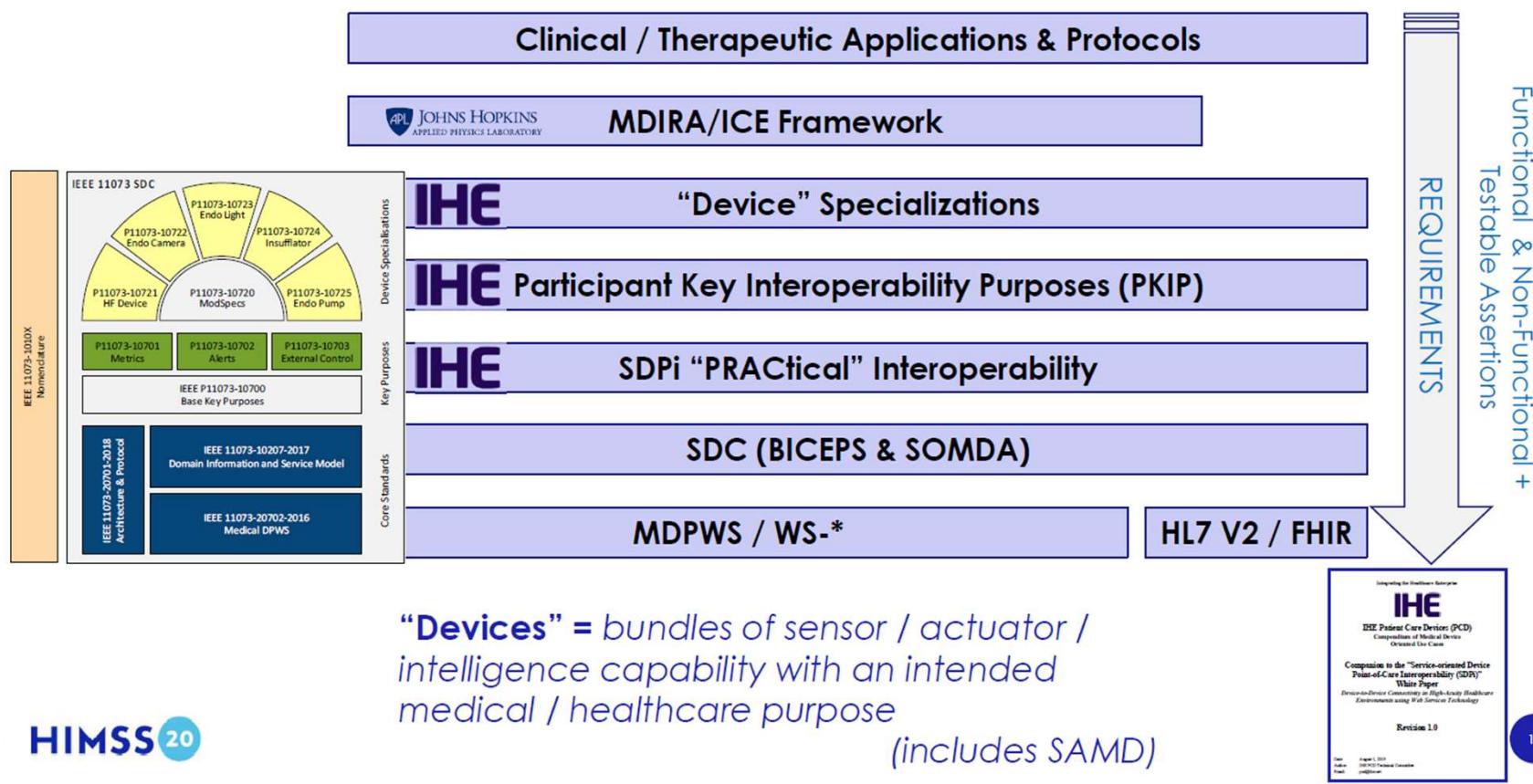
Figure 1: Illustration of the Hierarchy of Concepts



Source: Journal of AHIMA,
2017 July – October series,
“Understanding User
Needs for Interoperability:
Standards for Use Cases in
eHealth”

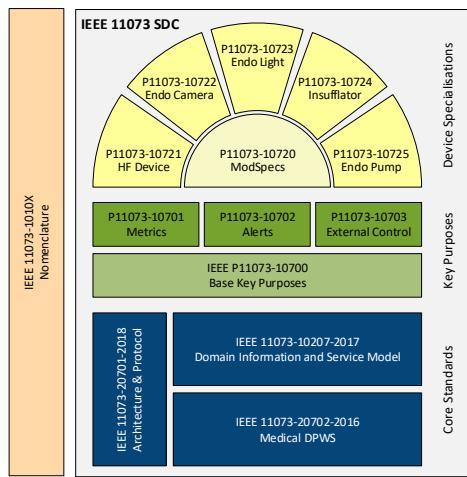
“SDPi+FHIR” – Introduced @ HIMSS’20 ...

“SDC+FHIR” – Foundation for MDI Use Cases

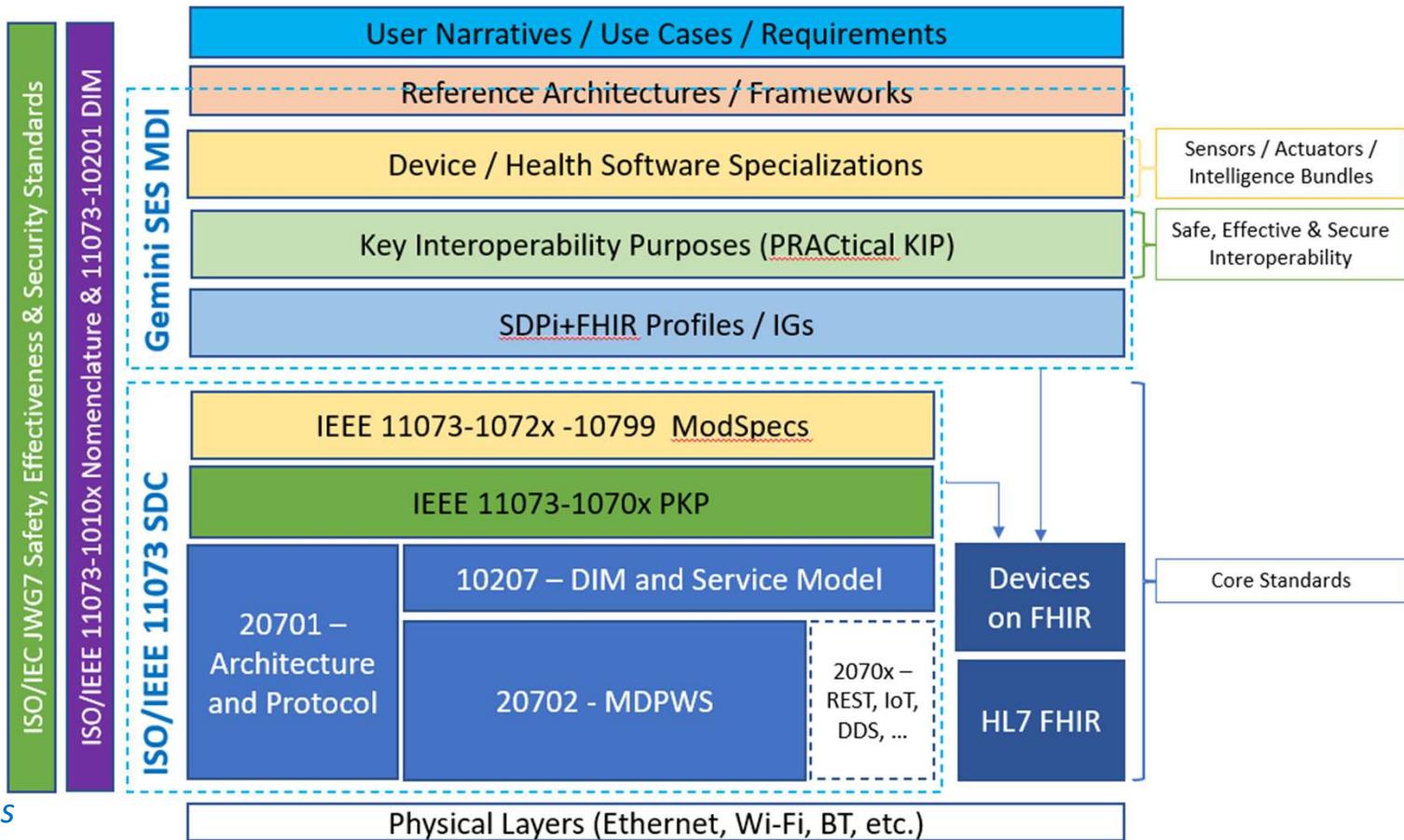


Expanding the Requirements-to-Interfaces Model

ISO/IEEE 11073 SDC – “Cathedral” Model



- ✓ *Multiple Standards / Specifications*
- ✓ *Multiple Organizations / SDOs*
- ✓ *Multiple Projects / Initiatives*



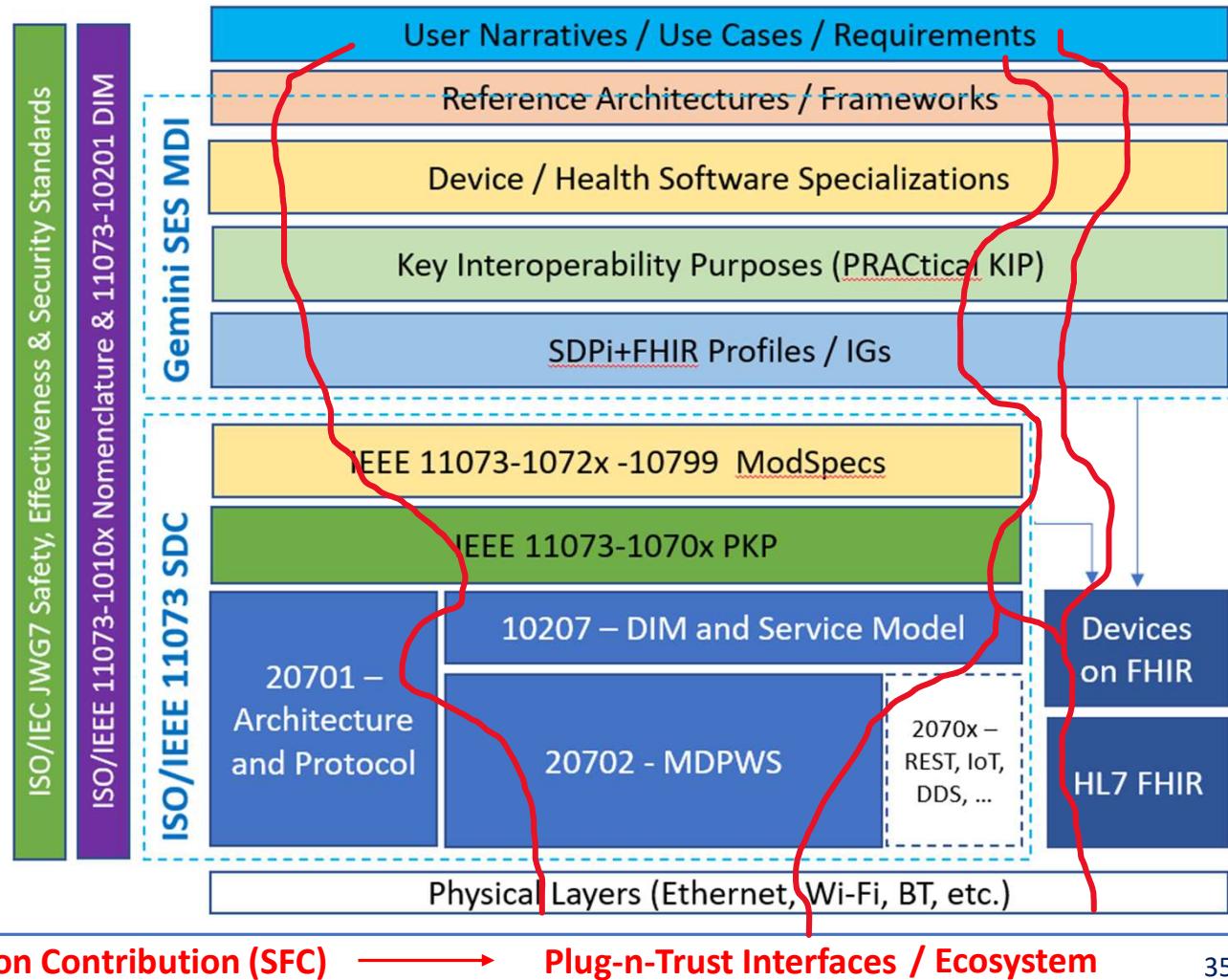
Note: model is *not perfect* ... but very *useful!*

Charting the course from narratives to interfaces

Traceability from Narrative to Plug-n-Trust Interface!

- ✓ Each “layer” specifies requirements to be mapped to the next
- ✓ Each “layer” adds its own set of requirements
- ✓ Requirements align with **safety, effectiveness & security (SES)**

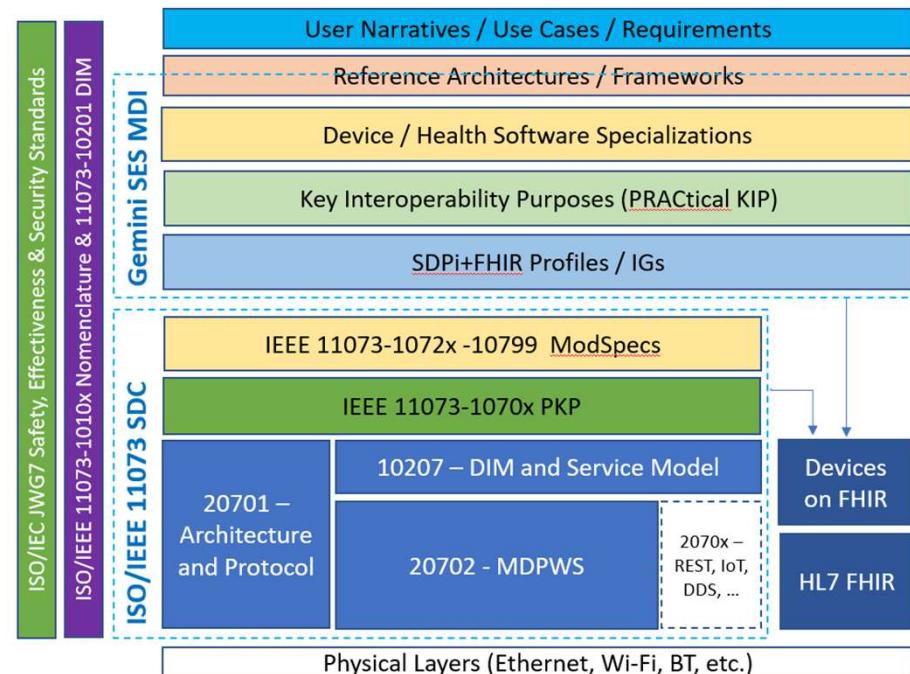
NOTE: **Null layers** allowed but generally required to achieve the SES Plug-n-Trust objective.



Charting the course from narratives to interfaces

The Challenge ...

1. Establish *computable traceability* from top to bottom (*plug-n-trust*) interface
2. Automate mapping and testability
3. Scale from simple to complex
4. Layer-specific and layer-to-layer (*mapped*) requirements representation
5. Lower the bar for specification creation, adoption, implementation and use
6. Maximize use of off-the-shelf open, “free”, widely adopted and used tooling
7. Ensure integration with corporate enterprise-grade tooling (including DOORS, Enterprise Architect, MagicDraw, etc.)
8. Support V-model CA and 3rd party (17025) “test houses”
9. ...



“Mapping” remains the hardest nut to crack in this list of challenges. Especially across multiple standards, organizations and projects!

Capturing Computable Use Narrative Requirements

User Narratives / Use Cases / Requirements

Question: *How to capture computable, testable requirements starting with user narratives?*

Narrative “User Story” Text

Objective: Real-world user *detailed descriptions of what is to be supported; narrative may conform to a general template / questions.*

Use Cases / Scenarios Analysis

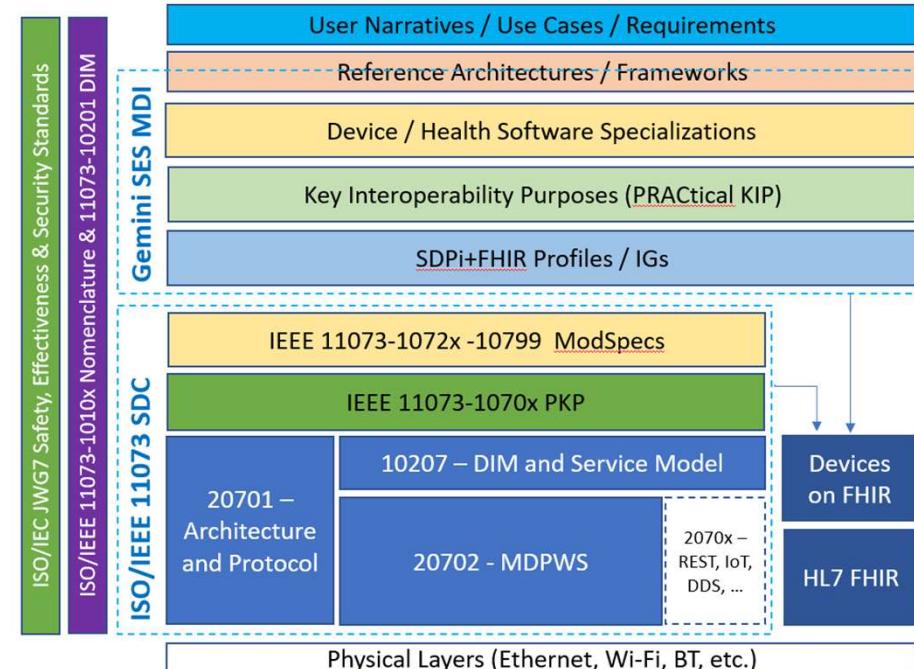
Objective: Analyze the “business case” narratives into use cases, realization scenarios & technical use cases (using standardized templates)

Gherkin / Cucumber Representation

Objective: Standard computable use case / scenario representation. Basis for test tooling & transformation to ReqIF specifications.

ReqIF (Requirements Interchange Format) Representation

Objective: Formal requirements modeling (including “relations” mapping) that forms the basis for bi-directional traceability + testing & tooling



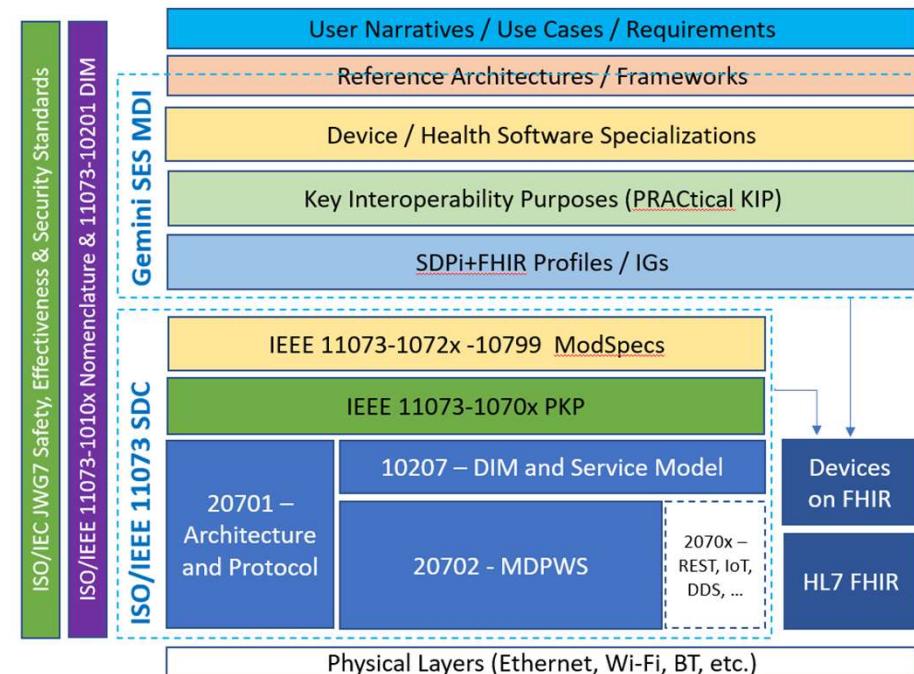
Note: See ReqIF background information below.

Examples for tracing Narrative to Plug-n-Trust

Exemplar considerations from Quiet Hospital

Narratives:

1. Identify (4) scenario-based requirements that can be verified during CA test
2. Include (4) alert priorities: Event + High/Medium/Low Alarms
3. Trace through the (4) KIP standards
4. Include both Physiological & Technical Alarms
5. Include at least (2) modalities + modality-specific alarms (e.g., AIL)
6. Include DIS, DAS & C-DAS support, scaling from simple to complex
7. Include both Quiet & Silent Hospital requirements
8. Include both SDC and FHIR endpoints



Note: *SDC alert delegation integrates all four interoperability purposes & SDPi profiles*

What if ...

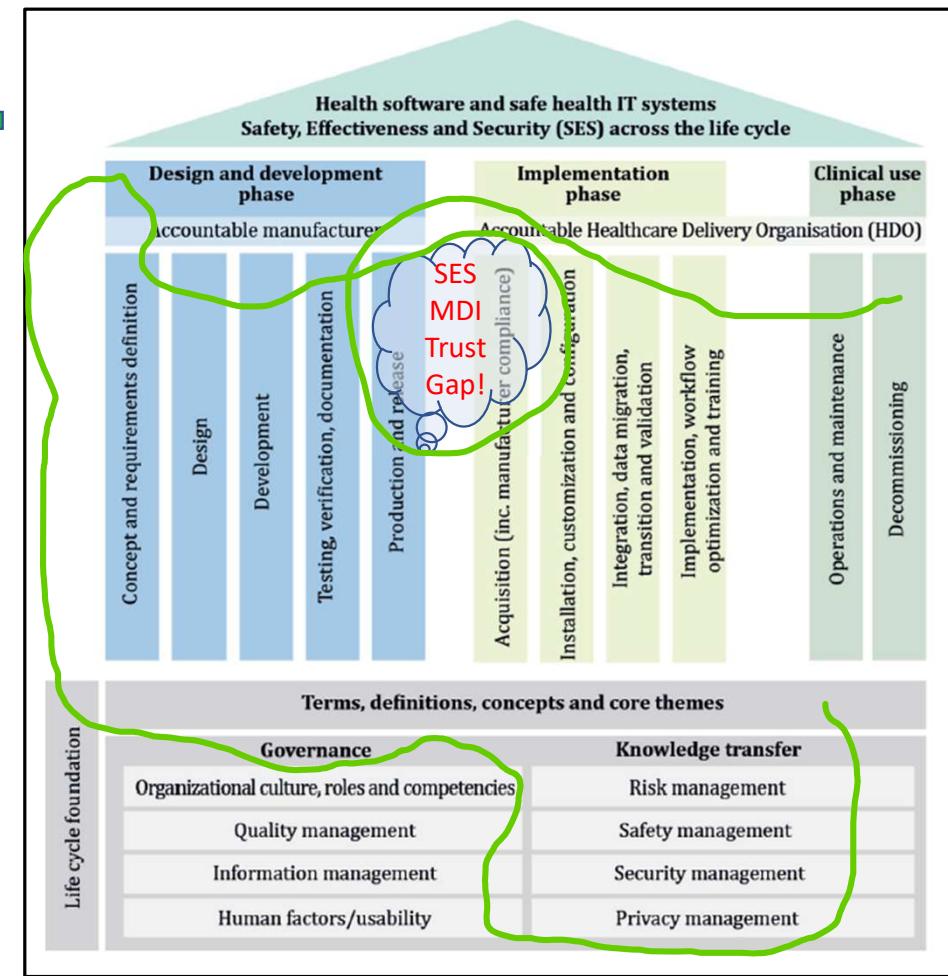
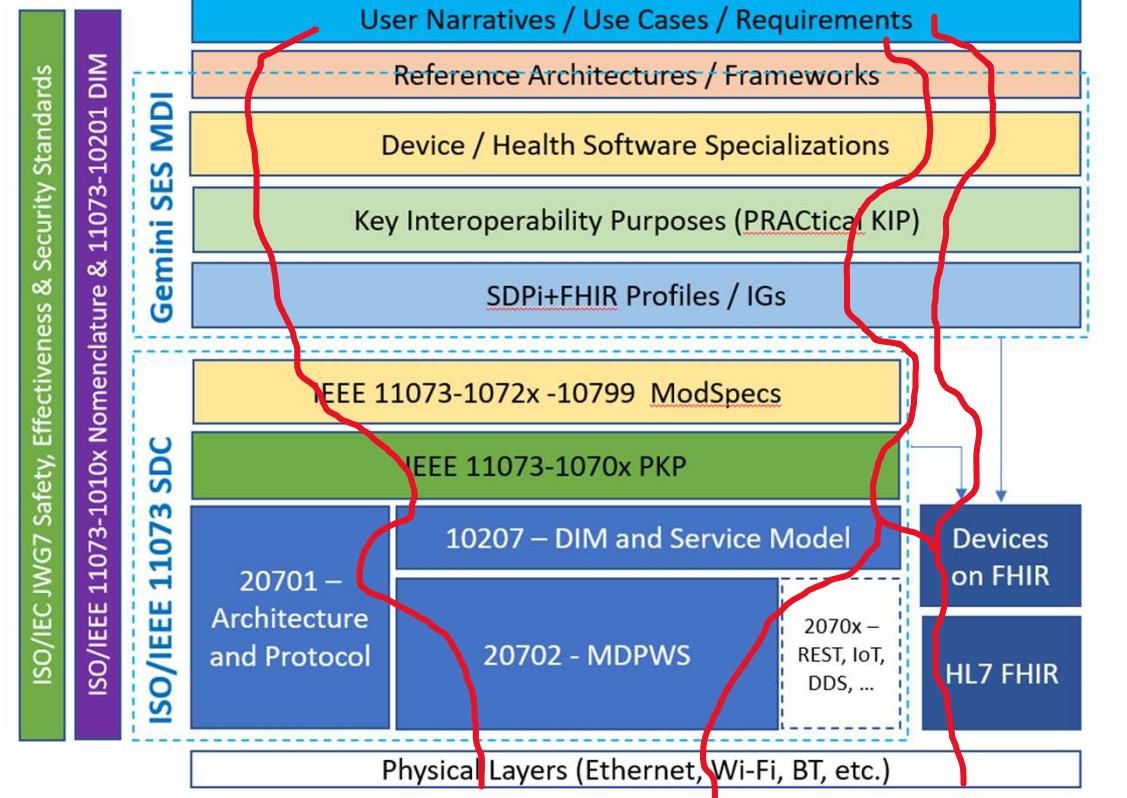
We mashed together the

MDI & SES

Communities & Standards!?

A Framework for *Trusted Interoperable Product Decoupling*

Addressing the SES MDI Ecosystem “Trust Gap” ...



SES MDI – *Roadmap Proposal*

- ✓ Develop an **IHE-HL7 Gemini SES MDI framework concept white paper** (underway):
 - See [confluence.hl7.org “SDPi+FHIR Paper - SES MDI” page](#)
 - “Safe, Effective & Secure MDI Using SDC/SDPi + FHIR” (working title)
 - Intent is to think through what would be involved in establishing a standards-based framework for Trusted Interoperable Product Decoupling (as identified in the preceding slides)
 - See below for potential content and discussion topics
 - White paper intended to be jointly balloted and published by IHE & HL7
 - *Participation is open to all* experts – no organizational membership or \$\$\$ required
- ✓ Add 2020-June **TC/215 WG2 & JWG7 TR PWI** for the above white paper
 - Anticipate Gemini SDPi+FHIR white paper to be submitted to JWG7 via IHE Liaison “fasttrack” process mid-2020
 - White paper will include recommendations to JWG7 for standards coordination and development
- ✓ Invite **WG2 & JWG7 members** and **parent committee experts** to participate in the white paper
- ✓ Consider **recommendations to WG2 & JWG7** later in 2020; may include a proposal for an SES MDI international standard and guidance (e.g., 81001-7-x) leveraging content in the white paper

SES MDI using SDC-SDPi+FHIR - Content

White Paper content may include:

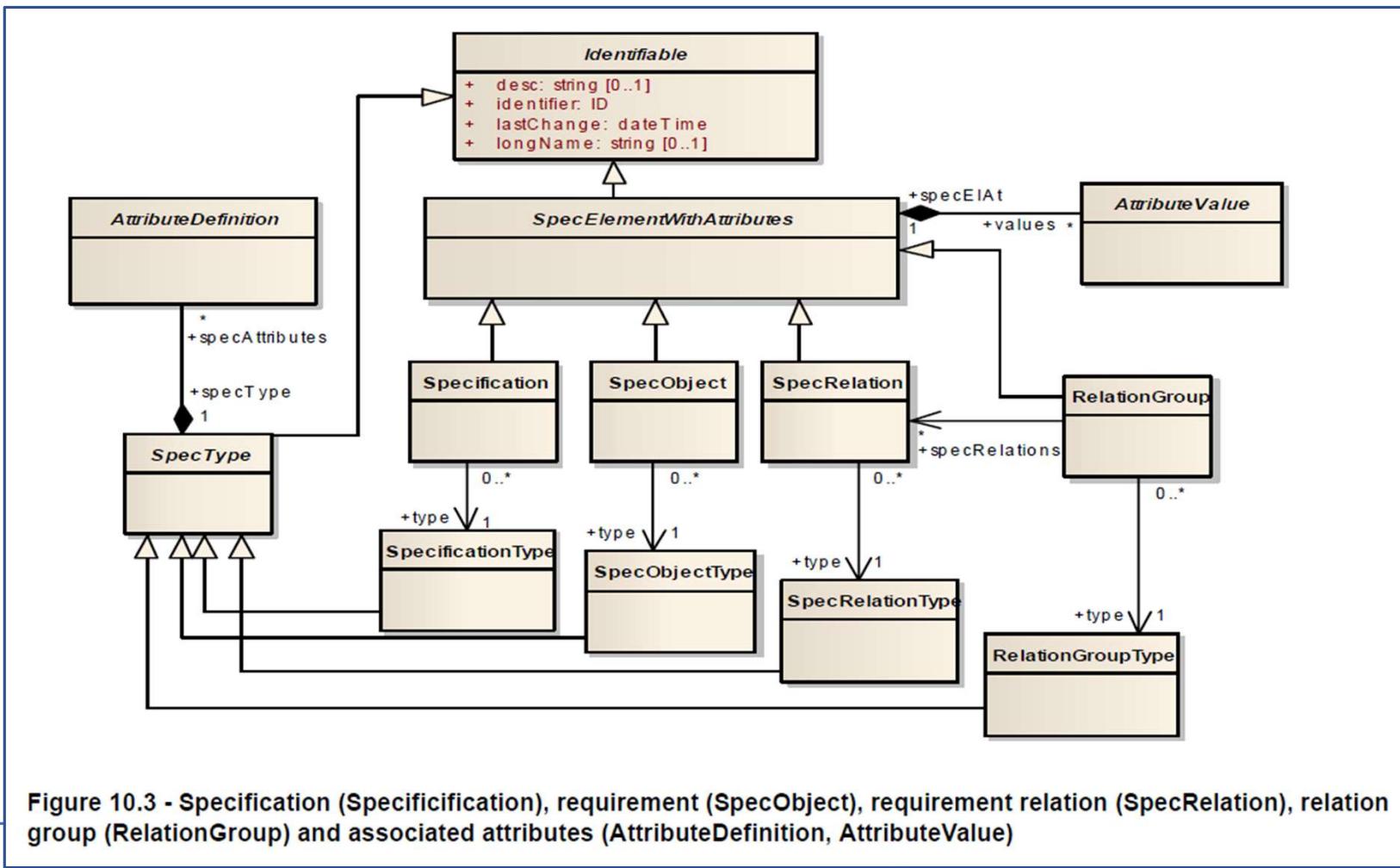
- ✓ Subtitle: Strategy for enabling an ecosystem of trusted interoperable decoupled products
- ✓ Consider the Plug-n-Trust “pathway” through the SES Temple + MDI Layers
- ✓ Identify and discuss the application of standards to be considered ...
 - Including coordination with and normative references to/from related standards ...
 - ISO/IEEE 11073 SDC, HL7 FHIR, JWG7 81001-1, 80001-1/-2X, 82304-X, 62304,...)
 - In the parent committees (e.g., 60601-2-x & 11073 family)
 - Other ISO/IEC committees (e.g., JTC1, ISO TC210)
- ✓ SES MDI computable assurance case concept, aligned with related JWG7 work
- ✓ Address the use of OMG ReqlIF to represent both MDI and SES requirements
- ✓ Consider how to integrate ReqlIF specifications + Plug-n-Trust SFC CA results into computable assurance cases
- ✓ Strategy and roadmap recommendations for addressing standards gaps, implementation and test tooling, and multi-stakeholder collaboration & coordination, etc., necessary to address the ...



Additional Information

OMG Requirements Interchange Format (ReqIF) “Mapping” Background

OMG ReqIF: Base Model



ReqIF: Requirement Hierarchies & Relationships

“mapping”
between
Source & Target Requirements

Two requirements may have a relation to each other, for example to establish traceability between a Customer Requirements Specification and a System Requirements Specification. Having a relation is represented by an association of one SpecRelation element to two SpecObject elements, one being the source, one the target of the relation.

The two specifications that are related to each other (in the above example: a Customer Requirements Specification and a System Requirements Specification) are referred to by the sourceSpecification and targetSpecification association of a RelationGroup instance.

The hierarchical structure of a requirement specification is represented by SpecHierarchy elements.

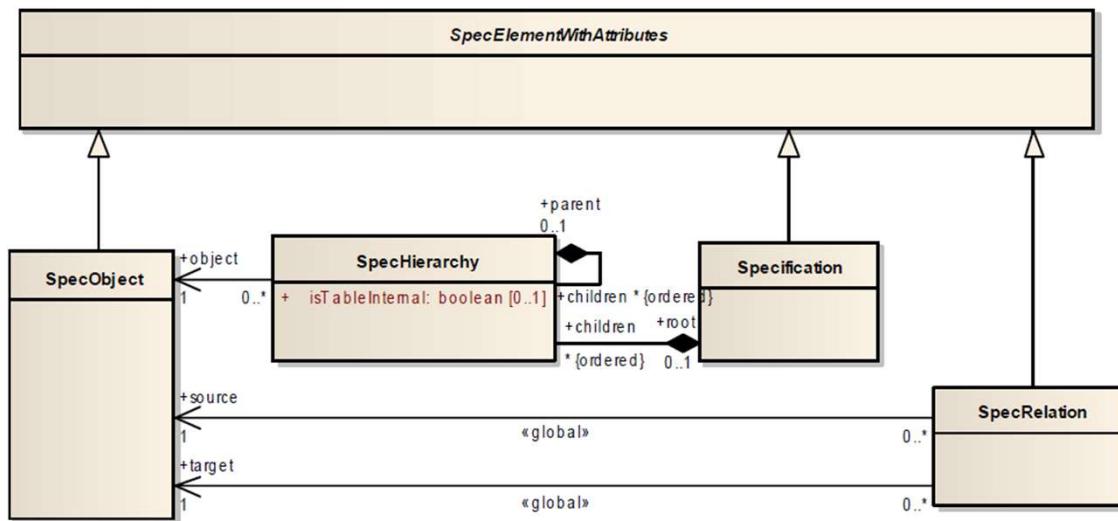


Figure 10.6 - Requirements, requirement relations and how requirements are structured hierarchically in a specification