



# IHE-HL7 Gemini SES+MDI – *Ecosystem Pathway –* Foundations & Operationalization

Updated: 2022.02.15

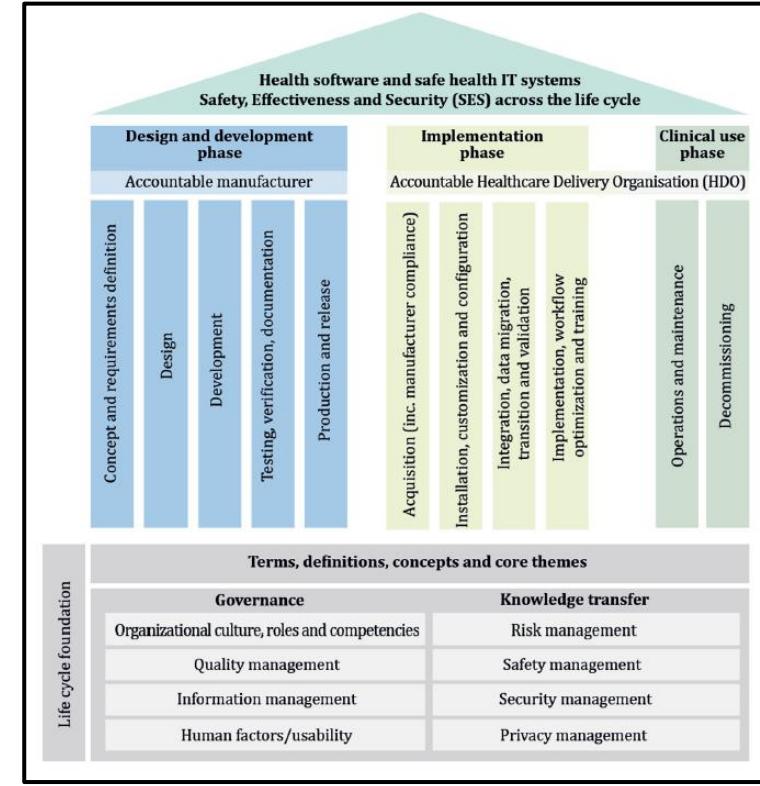


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**OR.NET**<sub>e.v.</sub>

# Gemini SES+MDI Ecosystem Pathway Operationalization



**Developing SES EP Requirements & Guidance (How)**  
**SES Standards Context for application to the Gemini Project**  
**Formalizing SES EP Guidance (What)**  
**Focus: Role of the IEEE 11073-1070x PKP Standards**

# Gemini SES+MDI / Ecosystem Pathway – *Developing Requirements & Guidance*

**How** will the EP work group accomplish its charter of developing SES requirements and guidance for a product development pathway to a trusted ecosystem of component products?

# Gemini EP Objective

**Objective:** *Develop open, consensus requirements and guidance for a total product life cycle pathway that enables the establishment of a multi-vendor ecosystem of independently developed (“decoupled”) plug-and-trust component products that contribute to a defined set of clinical system functions – safely, effectively & securely (SES), utilizing the SDC/SDPi+FHIR medical device interoperability (MDI) standards*

**Note:** Not an abstract exercise!

*Specific implementations of  
specific products deployed in  
Specific clinical functions.*

*Specific standards (SES+MDI) for  
Specific acute care contexts to achieve*

# Gemini EP Work Group Operating Principles

Core principles for how the group will achieve its objective:

## Open

Operates under IHE-HL7 Governance but no firewalls, up-front membership requirements, publicly viewable / transparent, etc.

## Consensus

Agreement of those who care, silence of those who don't  
*(Requires participation of the appropriate stakeholder experts!)*

## SES Standards

Application of existing “foundational” standards (e.g., 80001-1)

## MDI Standards

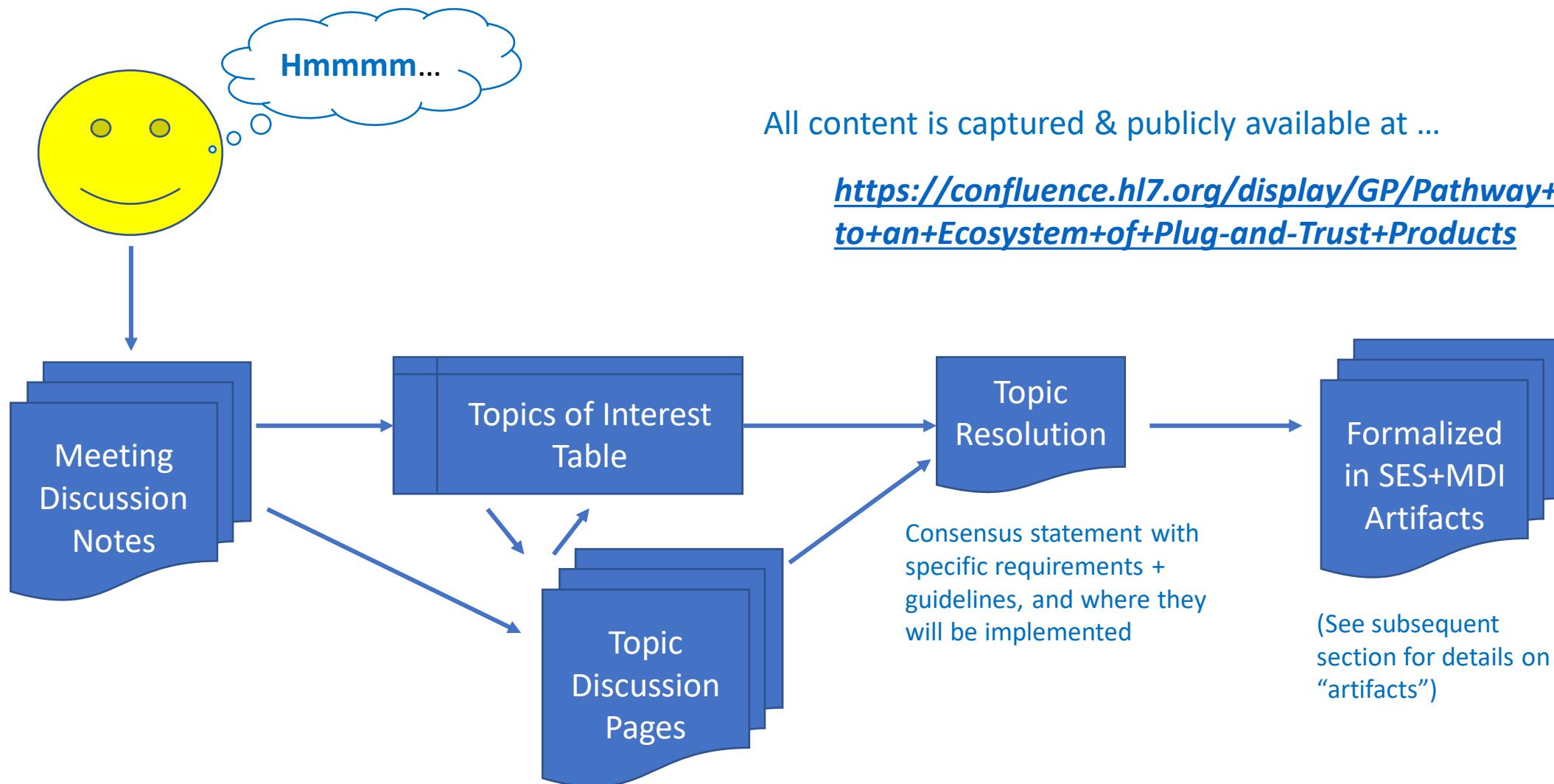
Application focus is on the SDC/SDPi+FHIR standards framework

## SES Requirements

Guidance will focus on specific, testable requirements

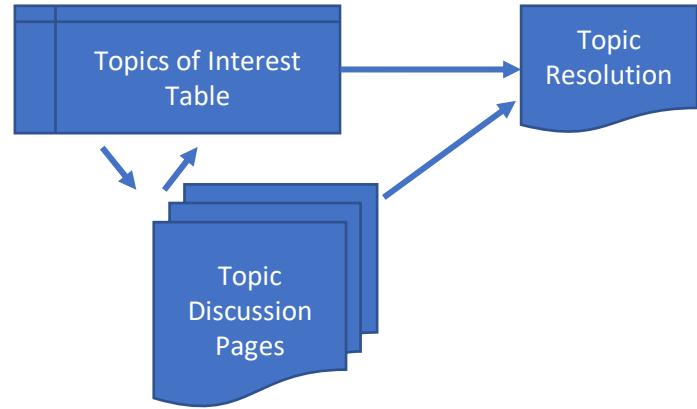
**Total Product Life Cycle** Pathway will include the entire lifecycle from concept to market to implementation to use to decommissioning

# Gemini EP Process & Deliverable “Artifacts”



Gemini “sdpi-fhir” Github repository folders provided @  
[github.com/IHE/sdpi-fhir/tree/master/Ecosystem Pathway](https://github.com/IHE/sdpi-fhir/tree/master/Ecosystem%20Pathway)

# Gemini EP “Topics of Interest” Table



The screenshot shows a Confluence page titled "Device Interoperability using SDPi+FHIR". On the left, there's a sidebar with various links related to device interoperability and Gemini projects. The main area displays a table titled "Topics of Interest".

Priority	Topic	Date	Proposer(s)	Lead(s)	Synopsis	Status	SES+MDI
	Topic: Tracing the FDA Design considerations for interoperable systems to 510(k) submission documents	2022.02.01	@ Matthias Marzinko		Where on the 510(k) ToC the design documentation for interoperable products refer to. Which content can be segregated to review the submission in regard of clinical functionality, supported by the SDC interface.	initiating	
	Topics: SES Standards Landscape	2022.02.01	@ Matthias Marzinko		An important scoping exercise for the Ecosystem Pathway group is identification of those SES standards and guidelines that need to be considered, beyond the technical interoperability specifications as part of the MDI effort.	initiating	
	Topic: Coordination of the FDA ASCA Process to Gemini SES+MDI / CA Process	2022.02.01	@ Todd Cooper		The FDA has successfully advanced a pilot program "Accredited Standards Conformity Assessment" (ASCA) to establish how formal test reports can be recognized and accepted to meet standards conformance claims within product regulatory submission. How might this be applied to the CA test reports for Gemini SDC/SDPi+FHIR product implementations? (Note: This discussion was begun in 2020 as part of the Gemini project, but has not advanced significantly since then.)	initiating	
1-high	Topic: SDPi-xC with Mixed Device Safety Classes	2020.06.23	@ David Gregorczyk @ Peter Kranich		What are the rules and guidelines for a SERVICE PROVIDER that supports external control services, and when a SERVICE CONSUMER of a different safety class wants to invoke the control? (see Meeting Logs & Notes - 2020.06.23) (SDPi 1.0) 8/20	initiating	

1. **Topic “row” created (need Confluence acc’t)**
2. **Short “Topic: ...” name created; proposal Date & Proposer(s) w/ Interested Parties & Synopsis created; Status=“initiating”**
3. **EP group review & acceptance; Priority & Lead(s) set, sub “Topic Discussion” page created and linked to Topic text; Status=“discussing”**
4. **Lead(s) manage discussion and resolution**
5. **Priority indicates which topics the group needs to resolve first (synched with EP Roadmap)**
6. **Topic Resolution is memorialized at the top of its specific discussion page & status updated to the Tol Table**
7. **Resolutions include which EP “artifacts” are to be created and updated as a result of the discussion**

(See EP “Topics of Interest” Table)

# Gemini EP Roadmap Development

## Ecosystem Pathway Roadmap to be developed ...

1. 3+ Year Window
2. Major product pathway milestones including ***1<sup>st</sup> product Conformity Assessment “RR” test report capability***
3. Factor in “priorities” / resolutions / artifacts from “Topics of Interest” discussions
4. Coordinate with other roadmap workstreams, including MDI Technical (SDC/SDPi+FHIR and MDIRA profile specifications), CA & Tooling, Testing (CAT & PAT) & Demo & Educational/Workshop events, etc.
5. See also “Requirements & Guidance” section below

# Gemini SES+MDI / Ecosystem Pathway – *SES Standards Landscape Context*

The EP effort does not start from scratch with a blank slate – there are a core set of foundational standards and specifications – both MDI and SES – that are to be evaluated and appropriately applied. Understanding this standards landscape context significantly focuses the work of the group!

# Gemini EP SES Standards Objective

**Objective:** *Identify and apply **existing** quality, safety, security – SES – standards to SDC/SDPi+FHIR – MDI – ecosystem product implementations, specifying the relevant principles, requirements and guidance, along with the V&V that will ensure their proper use across all components. Gaps and revisions may be proposed back to the responsible authors.*

**Note:** We know these standards!

*Consistent linkages to SDC/SDPi+FHIR standards +*

*Consistent implementation & Conformity Assessment of products*

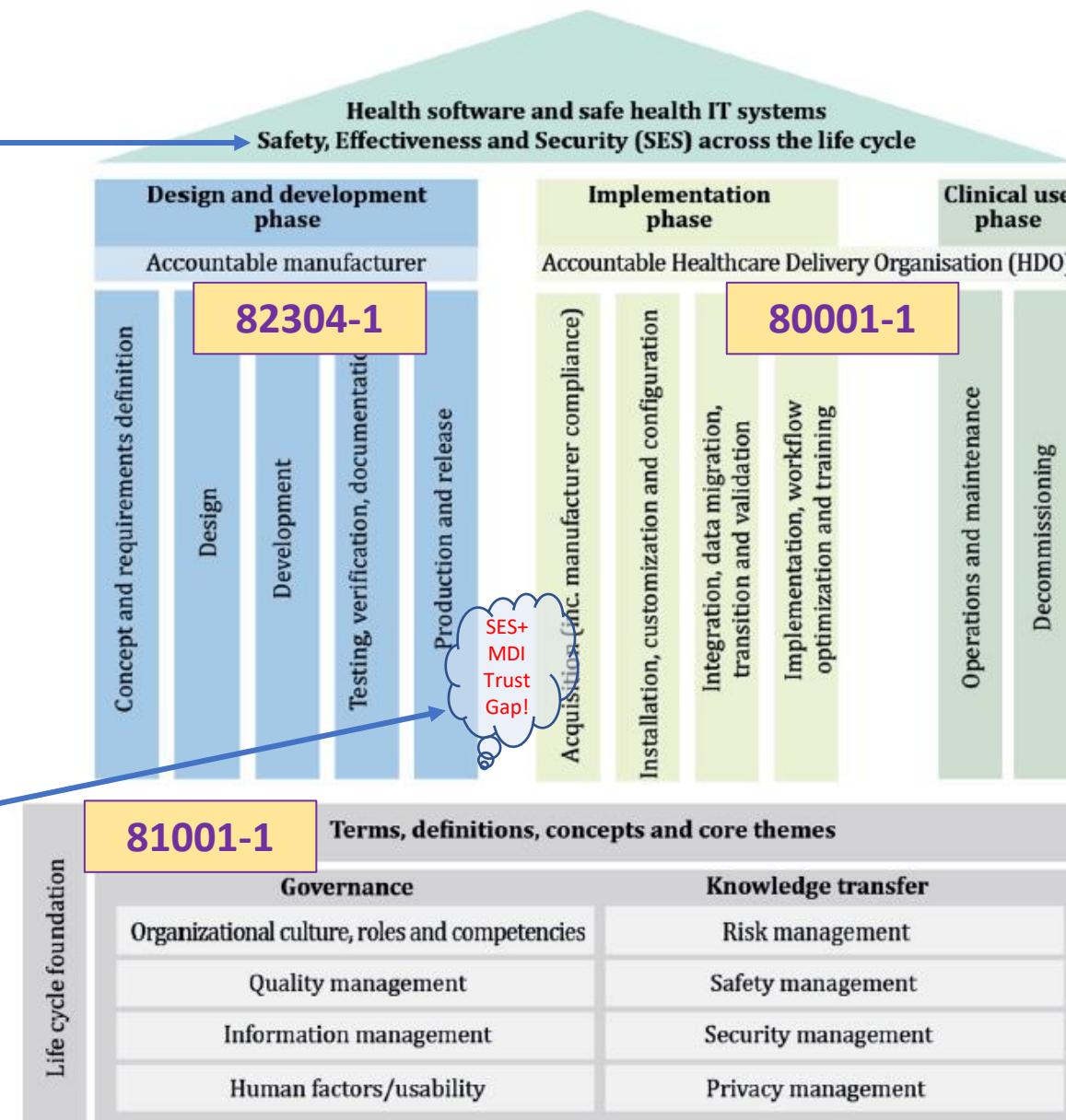
is another problem altogether!

# JWG7 SES “Temple” Diagram

Model developed over last 10 years  
in response to better manage the  
interrelations ...

- ✓ Across Stakeholders ...
- ✓ Across Product Lifecycles ...
- ✓ Across Subject Areas
- ✓ Across Multiple Standards

**Problem:** *SES+MDI “Trust Gap”*  
*recognized but no practical real-world solutions – too resource & labor intensive*

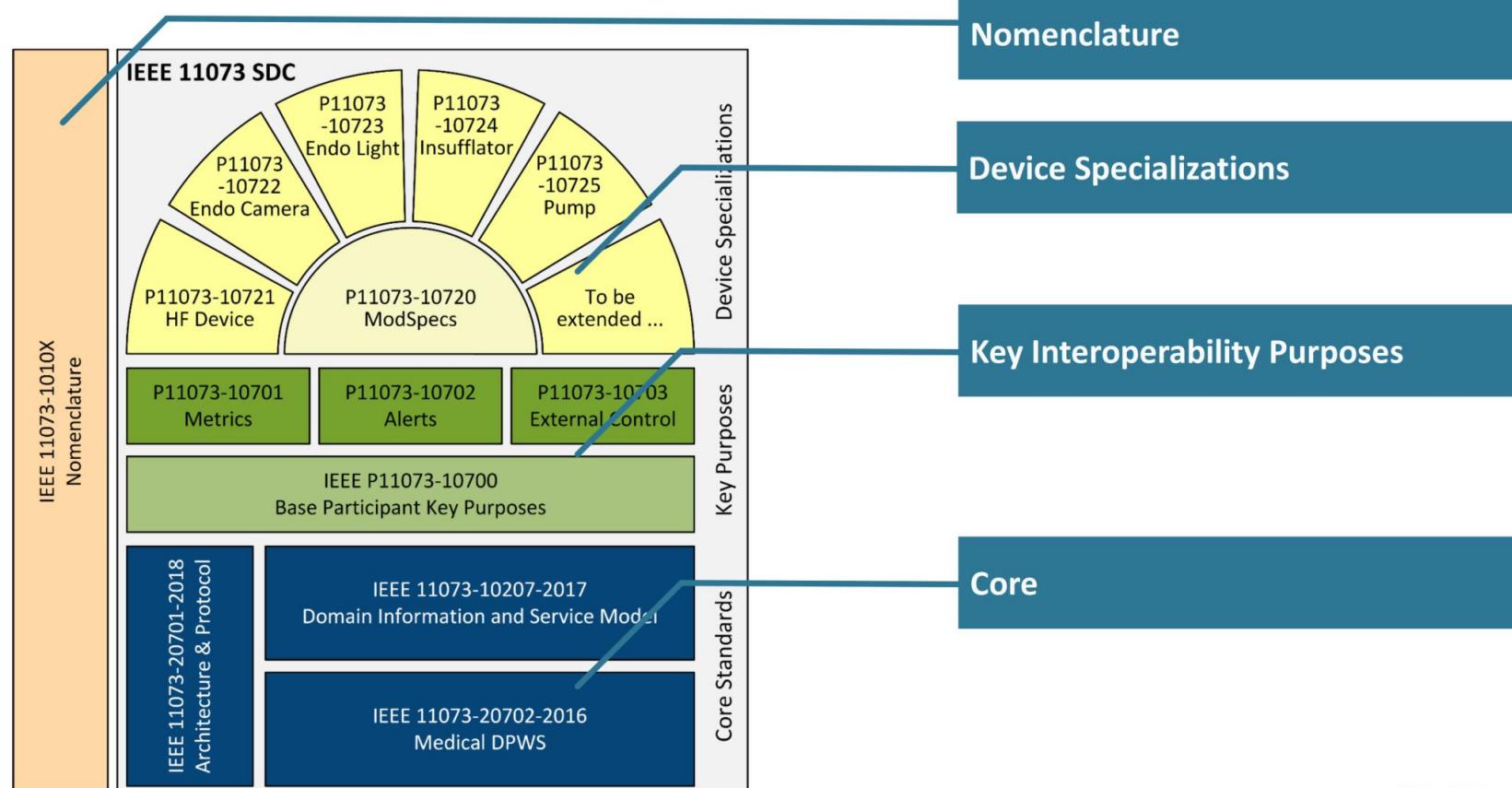


# ISO/IEEE 11073 SDC MDI “*Cathedral*” Model

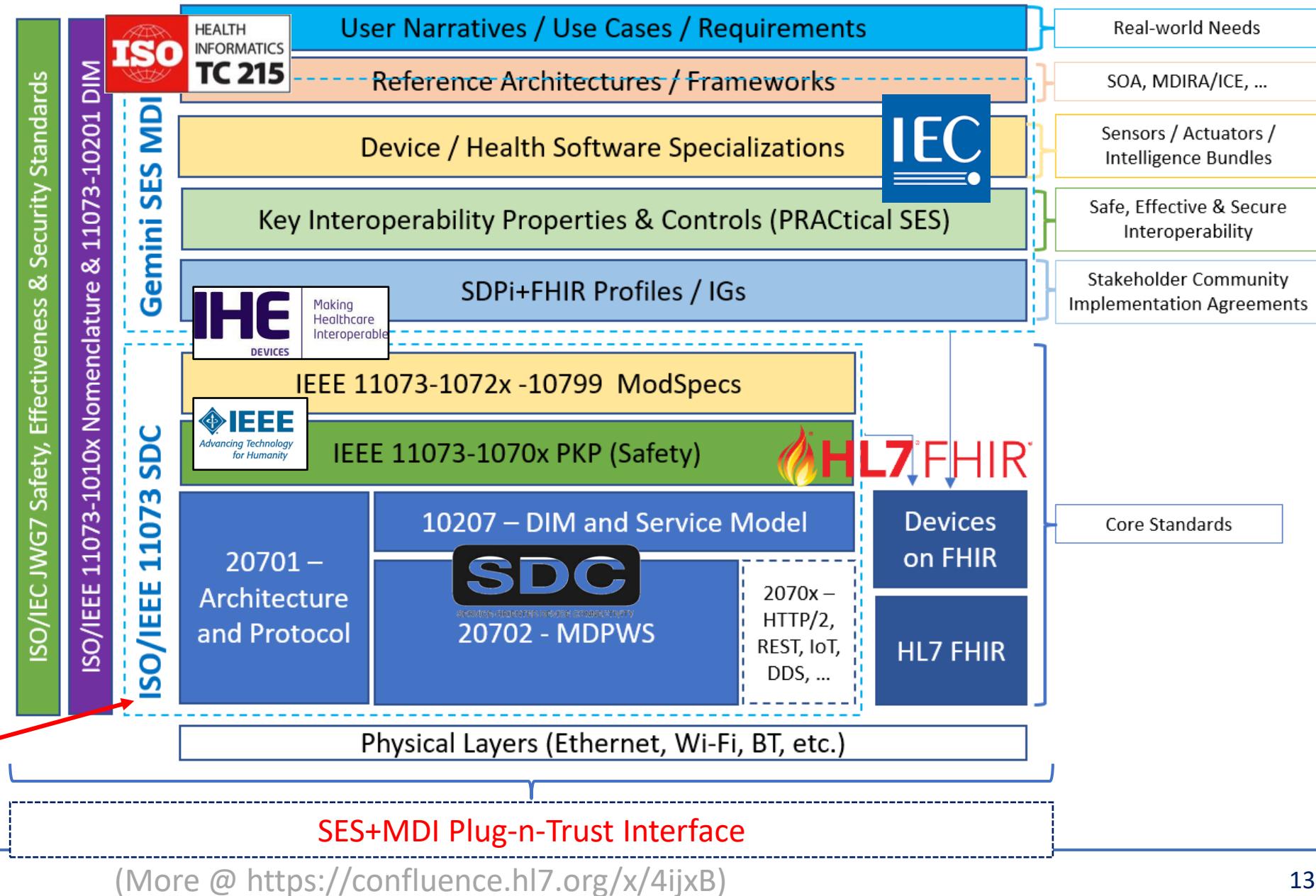
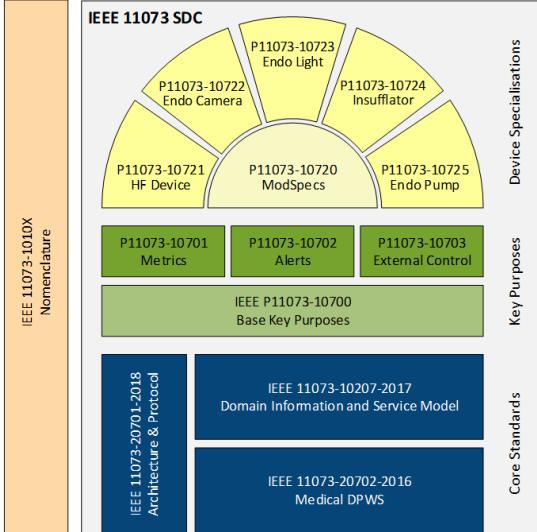
## The SDC Standards Family



“Cathedral”  
Model

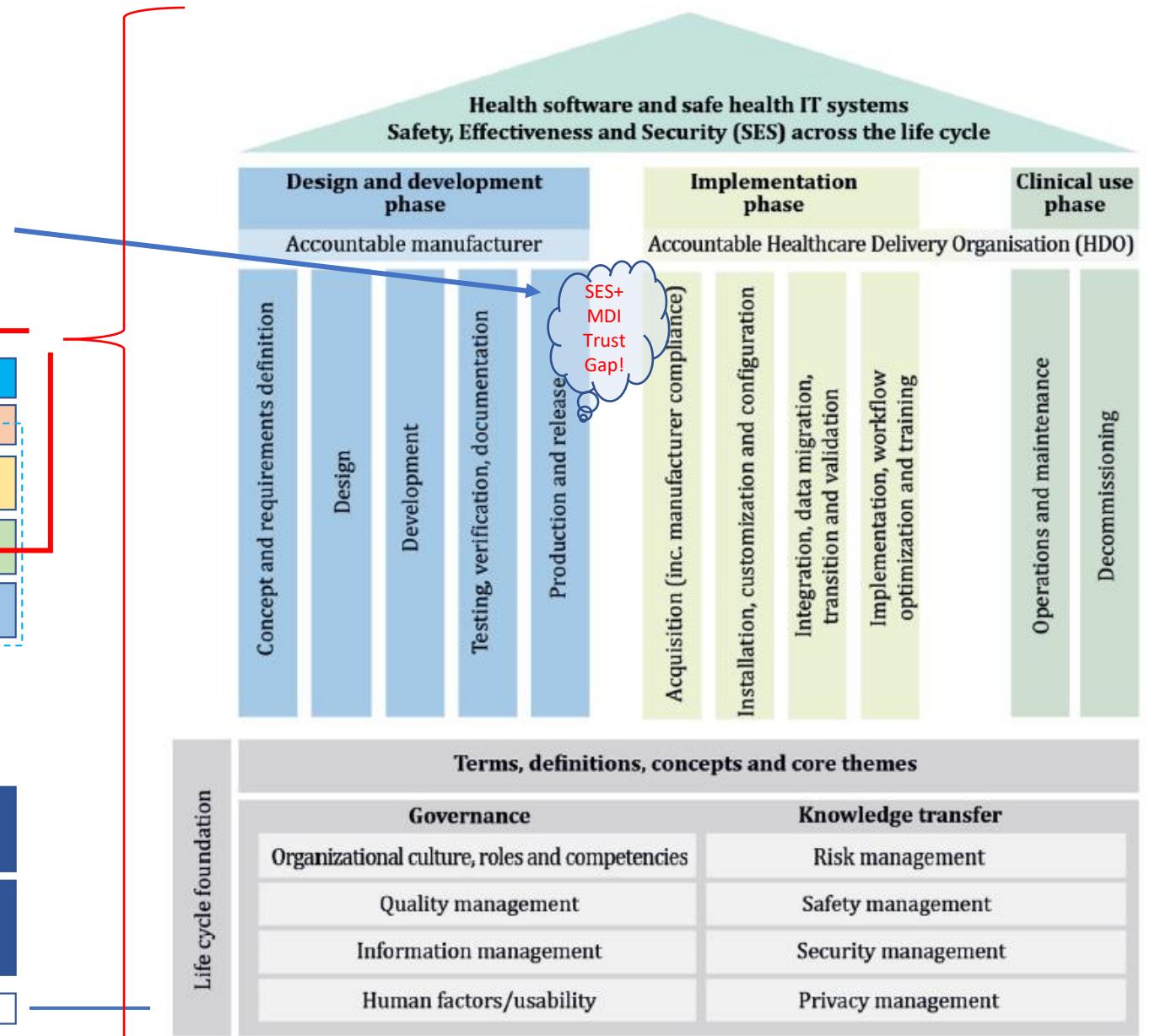
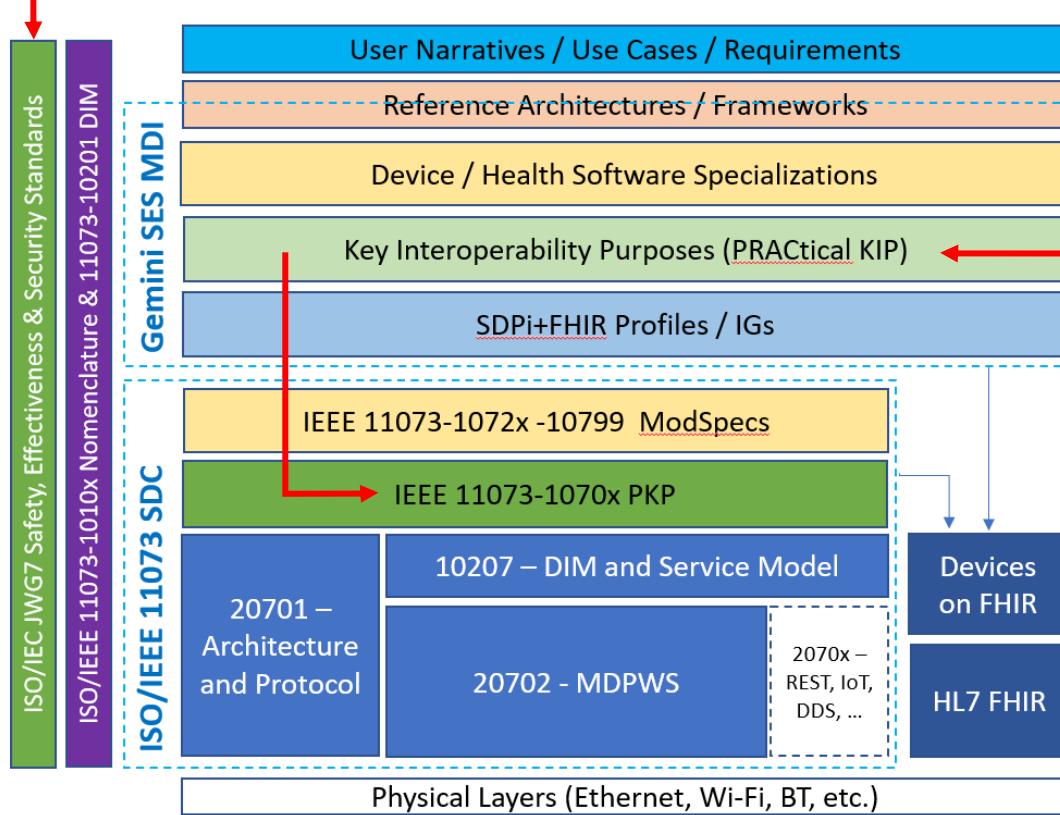


# Gemini SES+MDI “Hanging Gardens” Framework



# Gemini SES+MDI & Ecosystem Pathway ...

**Problem?** Ecosystem Pathway group will leverage the *SES+MDI “Hanging Gardens” Framework* ... to address the pesky “*Trust Gap*” product ecosystem challenges!



# Gemini EP SES Standards Landscape

## Ecosystem Pathway will ...

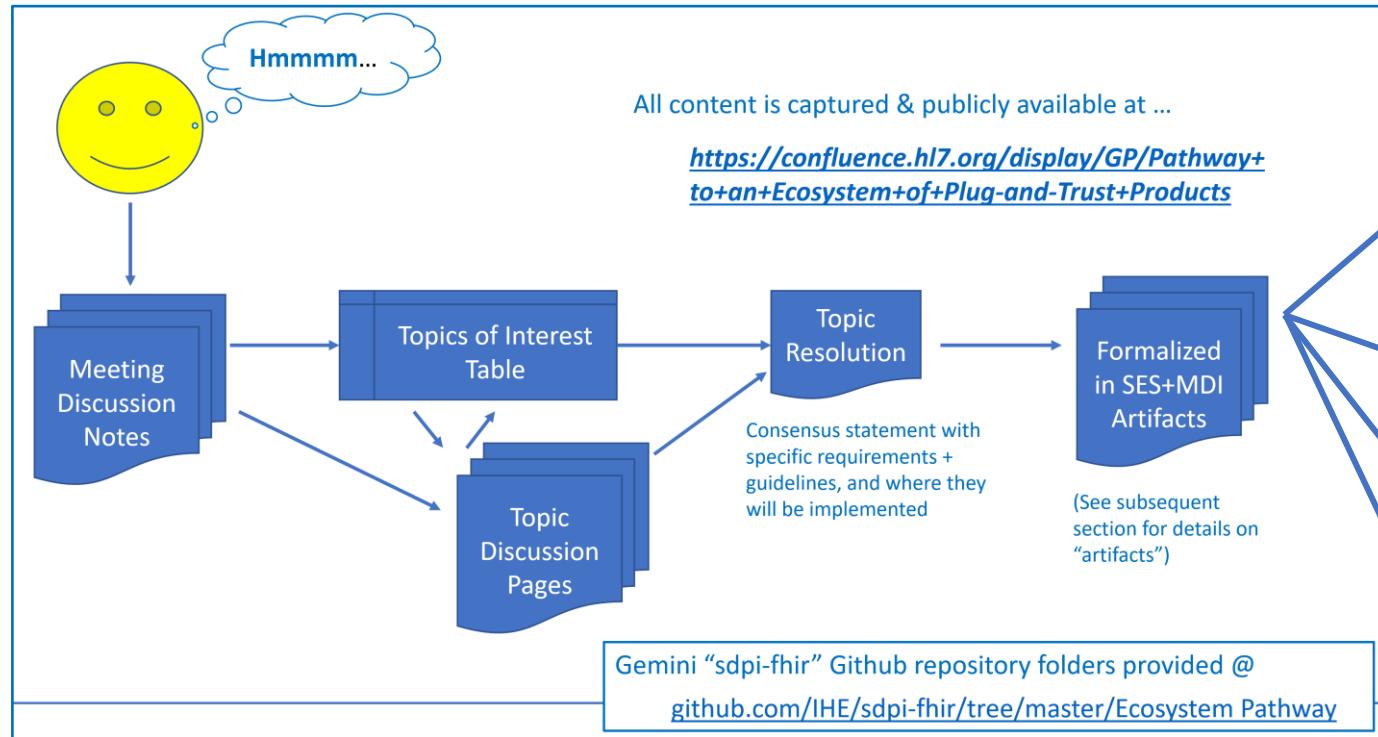
1. *Identify* existing SES standards relevant to establishing Plug-n-Trust product ecosystem  
(along with the scope and rationale for their use)
2. Determine *how* the requirements from each standard should be applied  
(both in principle and specifically / concretely)
3. Integrate *SES requirements* / principles / guidelines with *MDI SDC/SDPi+FHIR technology*  
(SES requirement <X> is addressed by MDI <xyz> requirements / capabilities)
4. Specify *how* standards-specific *conformity* will be *determined* and by whom  
(IHE CAT/CA vs. company-product-specific V&V)
5. Provide *feedback* as appropriate to standards developers regarding *gaps & issues*  
(recognizing that SES+MDI may include near term “workarounds”)

**Note:** Not detailed here, but wholly applicable, is the EP role in advancing “requirements interoperability” (e.g., 80001-1 with PKPs) and “regulatory submission ready” test reports with traceability and coverage.

# Gemini SES+MDI / Ecosystem Pathway – *Formalizing Requirements & Guidance*

As the EP group works through its issues and tasks, **WHAT** will they do with the requirements & guidance that is developed? What documents will be created or updated? What artifacts for conformity assessment and testing are created to ensure that at the end of the day, *implementers* following the *product ecosystem pathway*, can *trust* that *everyone* got to the same place without leaving out any steps?

# Gemini EP Formalizing Requirements & Guidance



## Ecosystem Pathway Guidance document

- ✓ “Start here...” source for all EP community discussions & deliverables
- ✓ EP “Cookbook” approach
- ✓ PnT Ecosystem IFU Template
- ✓ See [EP confluence page home](#)

## IHE SDPi Supplement document

- ✓ “SES” section content
- ✓ SES standard conformity sections + principles & guidelines
- ✓ Use Case SES requirements

## Testing & Conformity Assessment artifacts

- ✓ V&V Process for PnT Ecosystem
- ✓ Test plans & protocols
- ✓ Test Report Template (for “RR”)

## Educational Materials

# IHE Devices Technical Framework: SDPi Profiles Supplement

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

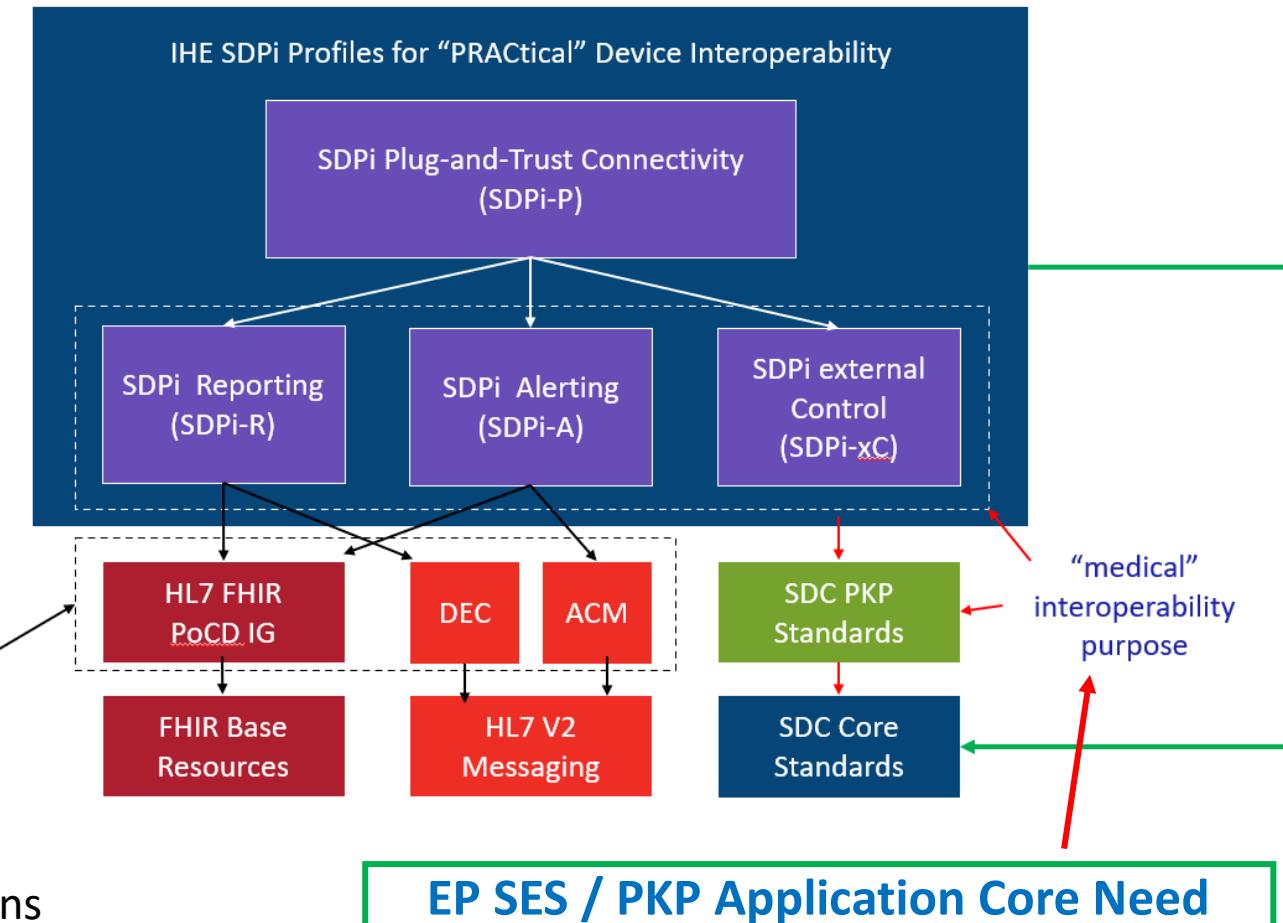
### ✓ Four profile specifications:

- SDPi-P for Plug-and-Trust Interoperability
- SDPi-R for Reporting Medical Information
- SDPi-A for Alerting
- SDPi-xC for External Controlling

IHE "Gateway"  
Actors Defined

### ✓ 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/sdipi-fhir/tree/master/SDPi%20Supplement/SDPi%20Rev%201.0>)

# SDPi Tour: From Volume 1 to 2 to 3

EP SES Content Fully Integrated

## 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 ...

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

## Appendix B: Referenced Standards Requirements Coverage

<including ISO/IEEE 11073 SDC PKP tables>

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

<including Gherkin detail & SES Considerations 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

### DEV-24 Discover Network Participants

...

### DEV-44 Invoke Medical Control Services

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

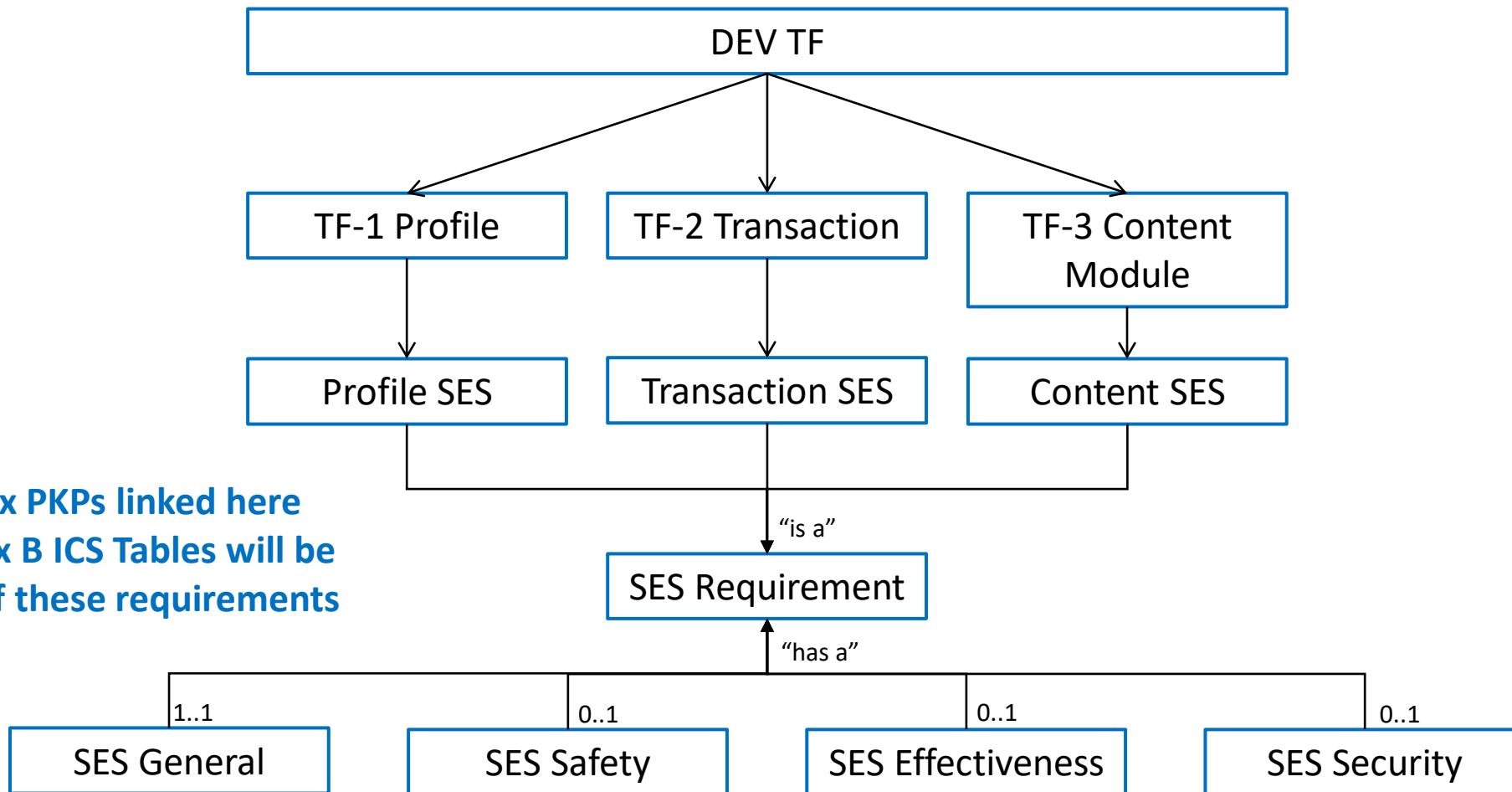
SDC/BICEPS to SDC/MDPWS Message Specifications

Messages for BICEPS Discovery Model

<specific MDPWS message links>

<example exchanges & library calls>

# SDPi “RI” – Starter Model @ SES



# Next Step: Requirements Interoperability Pilot

## Hanging Gardens Layer

User Narratives / Use Cases / Requirements	
Reference Architectures / Frameworks	
Device / Health Software Specializations	
Key Interoperability Properties & Controls (PRACTical SES)	(Null layer)
ISO/IEC JWG7 Safety, Effectiveness & Security Standards	<b>80001-1 (2<sup>nd</sup> Ed.), Annex A</b>
SDPi+FHIR Profiles / IGs	(opt) PIXm / PDQm
IEEE 11073-1072x -10799 ModSpecs	(Null layer)
IEEE 11073-1070x PKP (Safety)	<b>11073-1070x ICS + R's?</b>
ISO/IEEE 11073-1010x Nomenclature & 11073-10201 DIM	<b>RTMMS + DIM ICS Tables?</b>
10207 – DIM and Service Model	<b>ICS Tables + Rxxxx's?</b>
20701 – Architecture and Protocol	<b>ICS Tables + Rxxxx's?</b>
20702 - MDPWS	<b>ICS Tables + Rxxxx's?</b>

## SDPi 1.0 – Basic RI

### STANDARDS

SORD & SPoC & SICU

MD-SOA (SDC Core)

IHE TF-3 & X73 Stds.

(Null layer)

**80001-1 (2<sup>nd</sup> Ed.), Annex A**

(opt) PIXm / PDQm

(Null layer)

**11073-1070x ICS + R's?**

**RTMMS + DIM ICS Tables?**

**ICS Tables + Rxxxx's?**

**ICS Tables + Rxxxx's?**

**ICS Tables + Rxxxx's?**

### SDPi TF Sections

TF-1 Apdx. C + Profile Specific Map.

TF-1 SDPi Profiles Overview

TF-3 BICEPS sections

TF-1 Apdx. A “SES MDI” Section

TF-1 Apdx. B + TF SES Sections

TF-1 SDPi-P FHIR (in) Gateway

TF-1/-2/-3 SDPi SES Sections

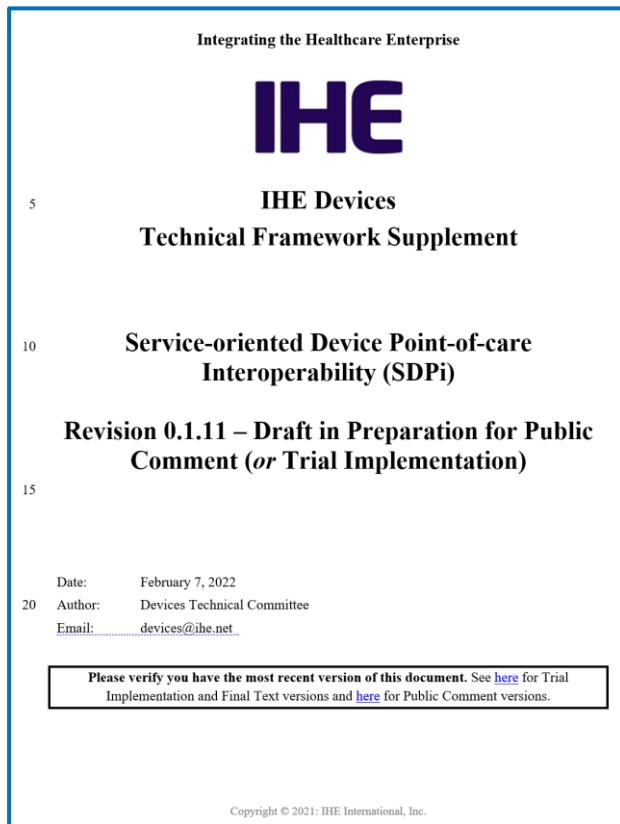
TF-3 + TF-1 “Content Profiles” Sections

TF-1 Apdx. B + Profile Mappings

TF-1 Apdx.B + TF-1 & TF-2 Trans.

TF-1 Apdx. B+TF-2 Apdx. A+Trans

# Gemini EP – Application of SES Standards



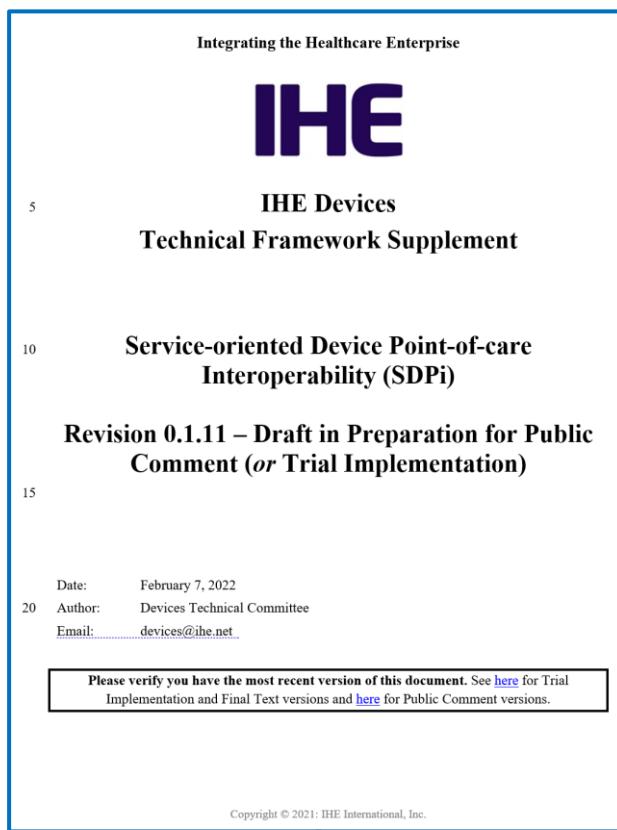
Draft 11073-10700  
Implementation Conformance  
Statement (ICS) Table

## B.5.2 General ICSs applicable to SDC PARTICIPANTS

General Base PKP requirements for all SDC PARTICIPANT systems. For the SDPi profiles, this is represented as the SDPi-P “SOMDS Participant” actor.

Index	Reference	Status	Requirement Text	SDPi Support
ICS-1285	RR1285	m	Where there is potential of injury or death resulting from the use of an SDC PARTICIPANT, the MANUFACTURER SHALL use a risk management process and a usability engineering process conforming to recognized standards.	<link to the SES section for SDC Participant>
ICS-1005	RR1005	m	When the MANUFACTURER of an SDC PARTICIPANT reveals deficiencies of another SDC PARTICIPANT, the MANUFACTURER SHALL provide information about the deficiency to the MANUFACTURER of the other SDC PARTICIPANT, unless the deficiency is already disclosed in the MEDICAL DEVICE's list of non-conformities.	<out-of-scope for SDPi?>
ICS-1241	RR1241	m	The MANUFACTURER of an SDC PARTICIPANT SHALL provide a list of OIDs in the accompanying documentation to express which sets of requirements the SDC PARTICIPANT satisfies.	<is this “CA by inspection” + linkage to OIDs list in this document & how discovered dynamically; see Note under requirement that this is to help RO’s identify potential incompatibilities>

# Gemini EP – Application of SES Standards



ISO/IEC 80001-1:2021,  
Appendix A

Note: 80001-1 referenced  
informatively from 11073-10700

## B.6.2 Support for specific requirements

The following requirements from the 80001-1:2021 standard are from the informative Annex A, Table A.1 that identifies requirements based on the sections of the standard in which they appear. Note that many requirements of this standard are completely out-of-scope for this specification, such as those that pertain to organizational management. When that is the case, the requirement scope is appropriately indicated. In other cases, the risk mitigation requirement may be reflected in a specific SDPi specification element, or may be verified based on capabilities contained in the specification.

Section	Requirement	SDPi Support
6.1.2.3 HAZARD identification	<p><b>The ORGANIZATION shall:</b></p> <ul style="list-style-type: none"><li>a) identify and document known, and foreseeable HAZARDS associated with deployment of the HEALTH IT SYSTEM and its use under both normal and foreseeable operating conditions;</li><li>b) review HAZARDS identified in any ACCOMPANYING DOCUMENTS supplied by the HEALTH SOFTWARE or MEDICAL DEVICE MANUFACTURER for applicability in the context of deployment, use or decommissioning of the HEALTH IT SYSTEM; and</li><li>c) where no HAZARDS are identified, record the justification for this conclusion within the RISK MANAGEMENT FILE.</li></ul>	<support in SDPi for identifying HAZARDS and their mitigations? Support for ACCCOMPANYING DOCUMENTS ... info that RO needs for RM?>  Links from 80001-1 requirements to PKP ICS table entries to SDPi risk management SES constructs?>
6.1.4.3 VERIFICATION of RISK CONTROL measures	<p><b>The ORGANIZATION shall:</b></p> <ul style="list-style-type: none"><li>a) implement the RISK CONTROL measures identified in accordance with 6.1.4.1;</li><li>b) verify the EFFECTIVENESS of each RISK CONTROL measure; and</li><li>c) incorporate the results of the RISK MANAGEMENT activities undertaken through the requirements in this subclause in the ASSURANCE CASE and record them in the RISK MANAGEMENT FILE.</li></ul>	<how does a connected system support verification of RCM effectiveness – both during initial implementation and during use?>  How can SDPi + IHE CA support both verification & ASSURANCE CASE content (evidence)? See TF-1 Appendix A section above>

# Gemini EP Deliverables & Artifacts

## Ecosystem Pathway will create ...

1. *Multi-year (3+)* **EP Roadmap** leading to a point where an ecosystem PnT products can be assessed for conformity, placed into use, and monitored for SES+MDI
2. **Guidance document** that will serve as the primary resource for the principles, requirements and guidelines for achieving SES+MDI across the product ecosystem
3. **SES content** in the SDC/SDPi+FHIR specification documents (w/ requirements interoperability)
4. **Test** and **Conformity Acceptance** requirements, principles, guidelines (incl. test cases, scripts, etc.)
5. **Test Report template** (in support of “regulatory submission ready”)
6. **Educational materials** + workshops, roundtables, etc.

**Note:** Formal “deliverables” governance (approval / balloting) and publication will be under the auspices of IHE and HL7; however, the specific details have yet to be finalized.

# Gemini SES+MDI / Ecosystem Pathway – Role of the IEEE 11073-1070x PKP's

One key focus of the EP discussions will be to effectively integrate the requirements of the IEEE 11073-1070x Participant Key Purposes (PKP) standards, which will provide a core *consensus* set of risk mitigations within the ISO/IEEE 11073 Service-oriented Device Connectivity (SDC) family of interoperability standards.

# Gemini EP Role of 11073 PKP Standards

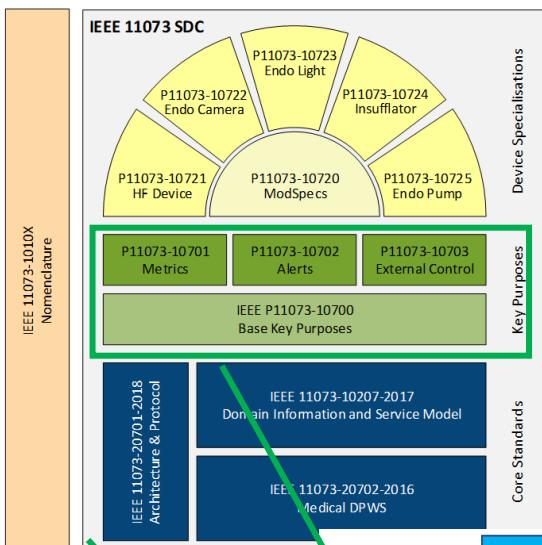
**Challenge:** Achieving an SES+MDI ecosystem of *Plug-and-Trust component products includes multi-vendor shared risk and requires ...*

- ✓ *All stakeholders contribute to and have confidence in the pathway elements that lay the basis for SES+MDI trustworthiness*
- ✓ *Each product (manufacturer) fully adheres to SES pathway requirements & guidelines – verified by product CA & discoverable at run-time*
- ✓ *Each product (manufacturer) can “trust but verify” in real-time that the other products are operating in a trustworthy way*
- ✓ *Systems of products can be monitored and managed in real-time to ensure SES+MDI is achieved and maintained*

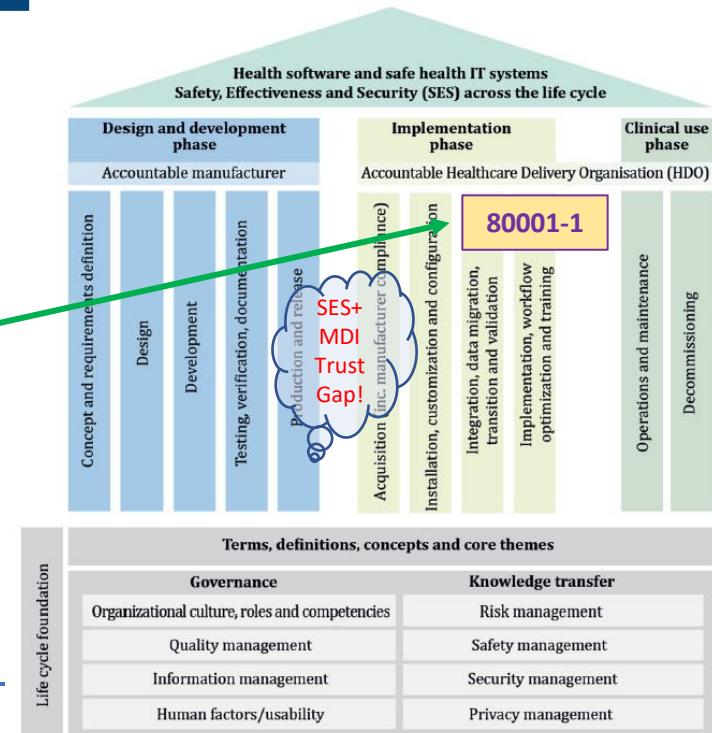
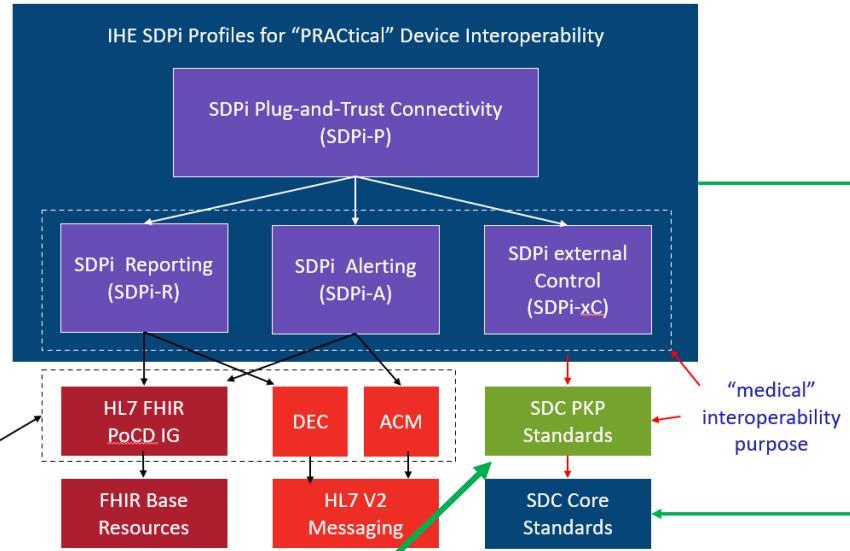
**Objective:** *Ecosystem Product Pathway must integrate an open consensus risk management process, including implementation of the IEEE 11073-1070x Participant Key Purposes (draft) standards*

# Gemini EP Role of 11073 PKP Standards

*EP Managed*

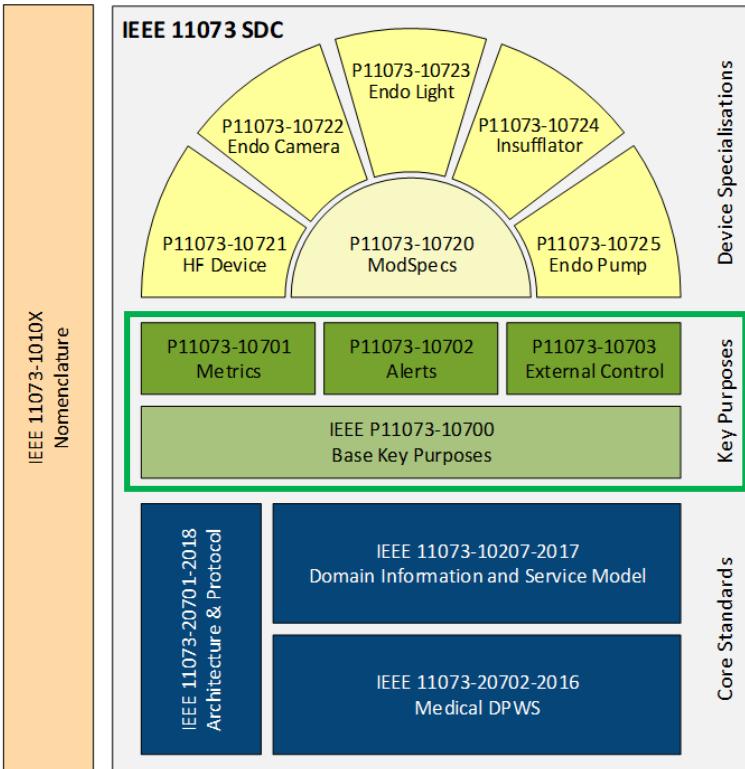


Fully integrated  
into the Gemini  
SES+MDI standards  
landscape!



# Gemini EP Role of 11073 PKP Standards

EP Managed



**IEEE 11073-1070x Participant Key Purposes standards provide ...**

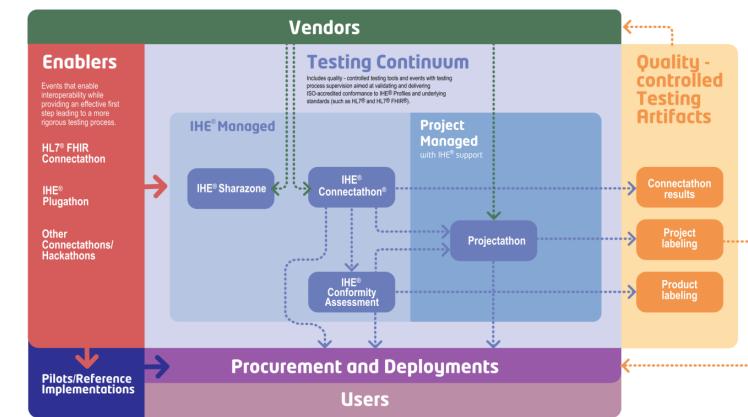
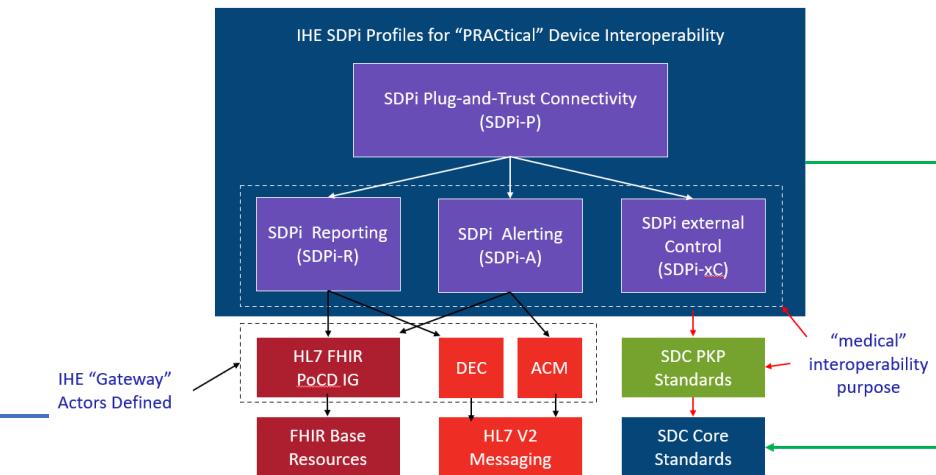
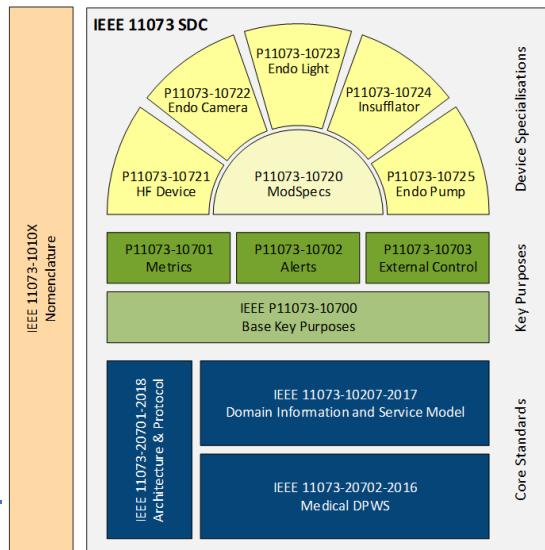
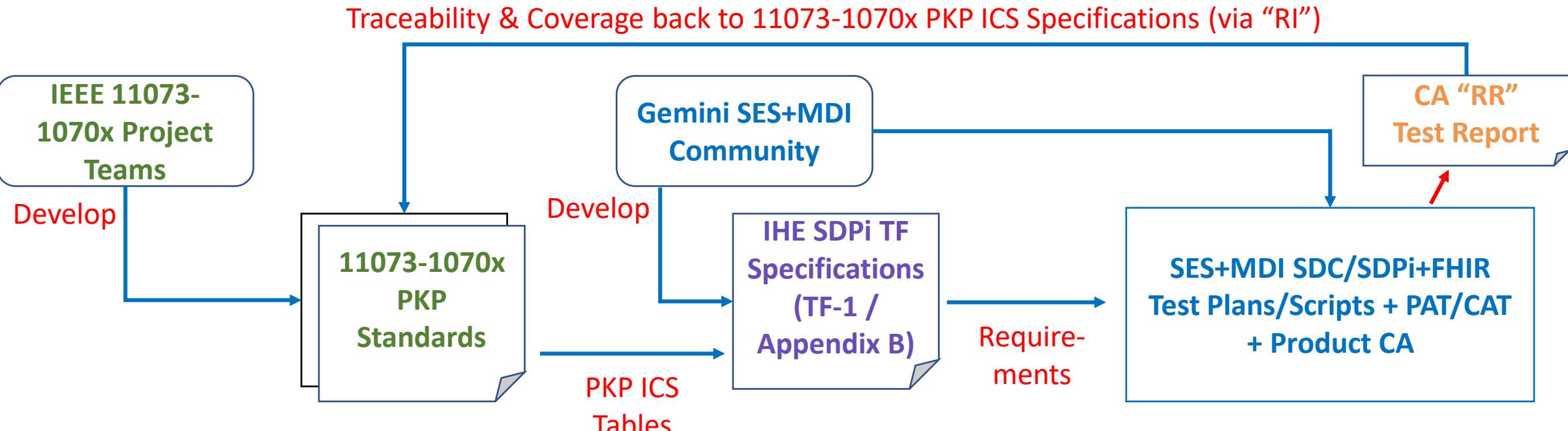
- ✓ *Shared / consensus risk management*
- ✓ *Safety, Security & Interoperability focused*
- ✓ *Scoped to 11073 SDC Plug-and-Trust MDI*
- ✓ *Risks, Controls, IFU, etc.*

**For an Ecosystem of *SDC/SDPi+FHIR* Plug-and-Trust Component Products!**

Note: See [overview](#) and [status update](#) presentations in [Ecosystem Pathway / Reference Materials](#) confluence page

# Gemini EP From PKPs to Product CA

*EP Managed*



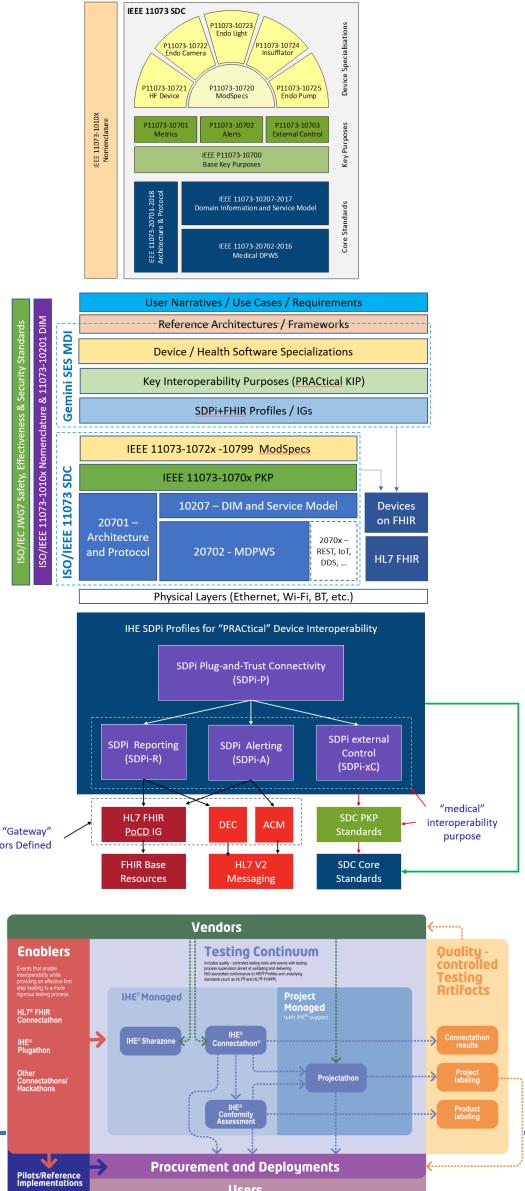
# Gemini EP Role of 11073 PKP Standards

EP Managed

And there's more ...

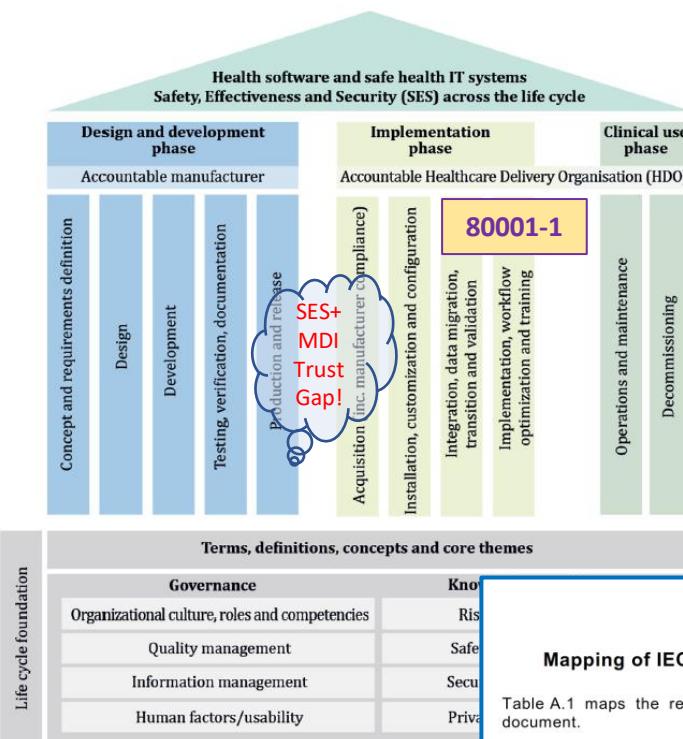
- ✓ SES of “gateway” actors (FHIR & V2)?
- ✓ MDIRA profile role in SDPi SES+MDI?
- ✓ Runtime computable “IFU” for SoP operational health?
- ✓ CA programs like FDA ASCA Pilot?
- ✓ Composable / computable SES+MDI Assurance Cases?
- ✓ Simulation enabled by “model centric” use of MBSE / SysML2.0?

Note: See PKP [overview](#) and [status update](#) presentations in [Ecosystem Pathway / Reference Materials confluence page](#)



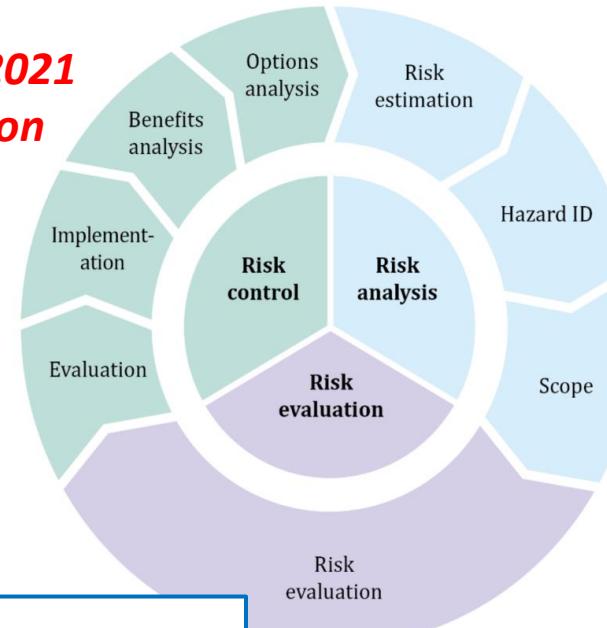
# Gemini EP – SES+MDI Trust Gap?

*EP Managed*



80001-1:2021

2<sup>nd</sup> Edition



Risk Management  
in a multi-vendor  
“decoupled” plug-  
and-trust product  
ecosystem?

**Annex A**  
(informative)

**Mapping of IEC 80001-1 text to reorganized document (by section)**

Table A.1 maps the requirement in this edition of IEC 80001-1 to the subclauses of the document.

**Table A.1 – IEC 80001-1 requirements table**

Subclause	Requirement
5.2 Leadership and commitment	<b>The ORGANIZATION shall:</b> <ul style="list-style-type: none"> <li>a) establish and adhere to a defined PROCESS for RISK MANAGEMENT</li> </ul>
5.4.1 General	<b>The ORGANIZATION shall:</b> <ul style="list-style-type: none"> <li>a) establish, at the start of a project, a <b>HEALTH IT SYSTEM RISK MANAGEMENT FILE</b></li> <li>b) maintain the RISK MANAGEMENT FILE throughout the lifecycle of the HEALTH IT SYSTEM; and</li> <li>c) ensure that the RISK MANAGEMENT FILE is recoverable in the event of failure.</li> </ul>
5.4.2 Understanding the ORGANIZATION and the SOCIOTECHNICAL ECOSYSTEM	<b>The ORGANIZATION shall:</b> <ul style="list-style-type: none"> <li>a) establish and maintain a defined list of ASSETS that interface with or constitute part of a HEALTH IT SYSTEM;</li> </ul>
5.4.3 Articulating risk management commitment	<b>The ORGANIZATION'S TOP MANAGEMENT shall:</b> <ul style="list-style-type: none"> <li>a) be accountable for ensuring that the ORGANIZATION adheres to the <b>HEALTH IT SYSTEM RISK MANAGEMENT PLAN</b>;</li> <li>b) be accountable for ensuring that the organization achieves compliance with this document; and</li> <li>c) authorise the sale or deployment of the HEALTH IT SYSTEM.</li> </ul>

**RISK MANAGEMENT PROCESS**

Annex B  
(Informative)

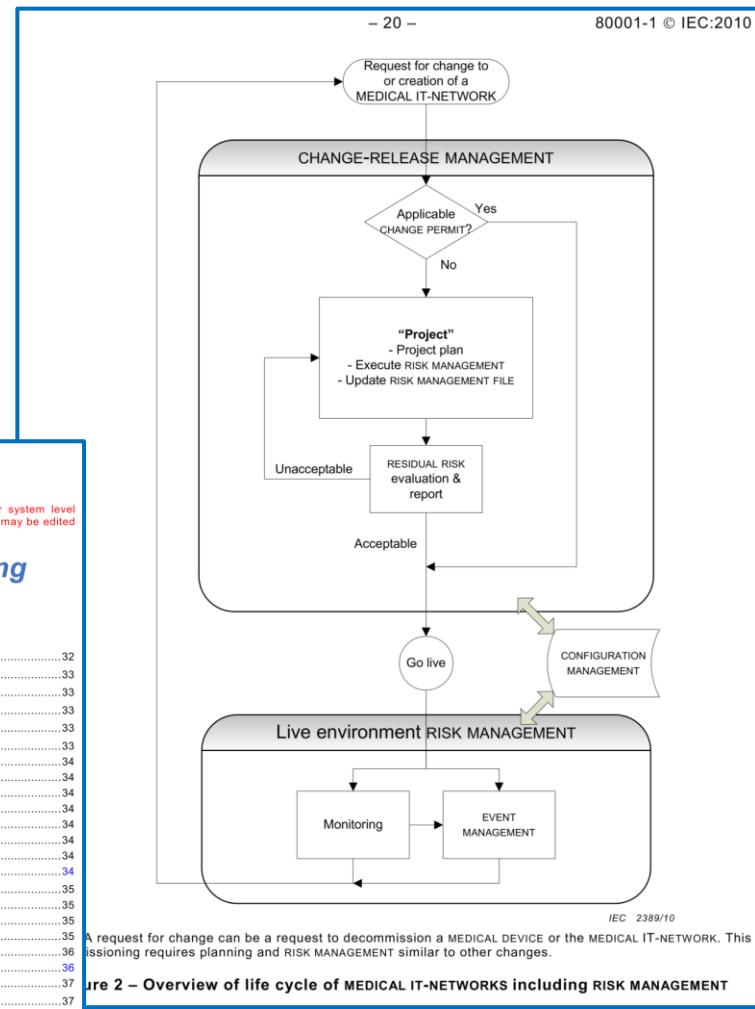
This annex is provided as a guidance document for ORGANIZATIONS to gather system level information from their medical device manufacturers. The sections and content may be edited or deleted at the discretion of the ORGANIZATION or medical device manufacturers.

**Guidance for Accompanying Document Information**

**Contents**

1 Foreword .....	32
2 Information System Categorization .....	33
3 Introduction / Title .....	33
4 Reference Documents .....	33
5 System Level Description .....	33
5.1 Environment Description .....	33
5.2 Network Ports, Protocols and Services .....	34
5.3 Purpose of connection to the health IT infrastructure .....	34
5.4 Networking Requirements .....	34
5.5 Required IT-network services .....	34
5.6 Data Flow and Protocols .....	34
5.6.1 Clinical information flow .....	34
5.6.2 Operational information flow .....	34
6 Security and User Access .....	35
6.1 Malware / Antivirus / White-Listing .....	35
6.2 Security exclusions .....	35
6.3 System Access .....	35
6.3.1 Types of Users .....	35
6.3.2 Remote Access and Maintenance .....	36
6.3.3 Patch Management .....	36
7 Risk Management .....	37
7.1 Hazardous situations resulting from health IT infrastructure failure .....	37

80001-1:2010 Edition  
“Life cycle” Model





# IHE-HL7 Gemini SES+MDI – *Ecosystem Pathway –* Foundations & Operationalization



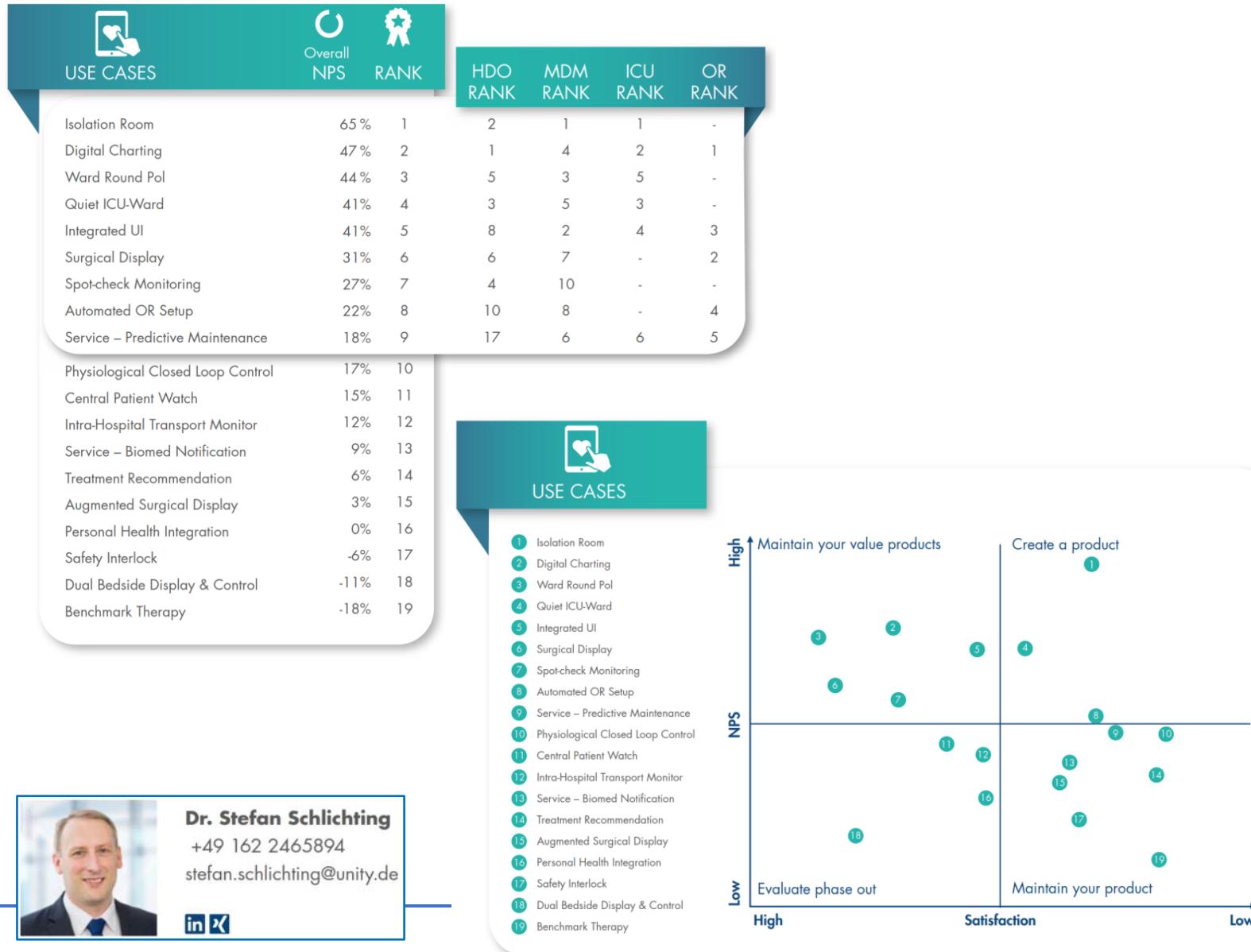
FHIR is a trademark of Health Level 7, International.

SDC is a registered trademark of OR.NET

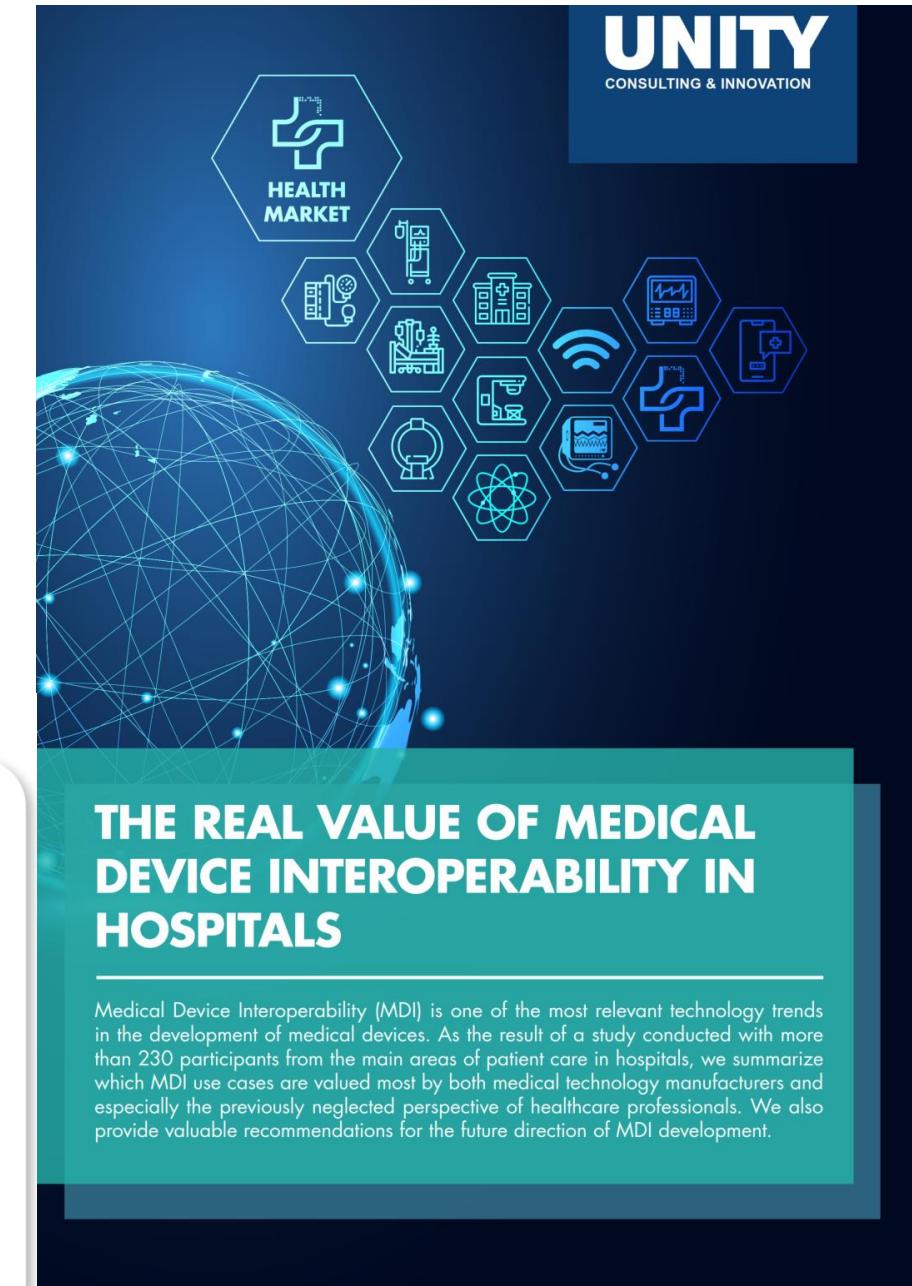
**OR.NET**  
e.v.

# Additional Materials

# Updated Value of MDI Study



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stefan.schlichting@unity.de



# Gemini SES MDI – SES Ecosystem Pathway Launch

Proposed September 2021, this new group will focus on the “SES” challenges for developing products along a pathway that includes ensuring system quality and risk management, along with regulatory affairs.

# Gemini SES MDI – SES Ecosystem Pathway

Recognizing the need to advance the non-MDI tech ... SES issues discussion, a new initiative was proposed during the 2021-09 WGM ...

BUT

- ✓ The “R” word was challenging!
- ✓ The need was clear but the formal scope and ToR were challenging

SO

- ✓ A group of key leaders met in October - December
- ✓ Issues were discussed ... at length! ... and progress made!

## Gemini SES MDI – Regulatory Initiative

“Regulatory Submission Ready” CA test reports is easy to say ...

Challenges on the road to RR and an ecosystem of PnT products :

- ✓ Engaging those whose “day job” is quality & regulatory affairs (IOW ... SES)
- ✓ Plug-and-Trust component products that are developed “regulatorily decoupled” ... is new!
- ✓ How to build understanding and confidence that a “shared risk” product ecosystem is ... trustworthy?
- ✓ In an increasingly virtualized world – how much virtual testing (vCAT’s) can be used vs. in-person device-connected-directly-to-device testing to build confidence in the SES community?
- ✓ How will post market surveillance be achieved & what role might MDIRA profile actors play?
- ✓ What about the addition of clinical / therapeutic / Dx & DTx “apps” (SaMD) to the ecosystem?
- ✓ How can the regulatory “burden” be reduced for all stakeholders, balancing between safety & innovation for these new technologies?

Proposal: Create a Gemini SES/Regulatory Initiative

18

Source: 2021-09 Gemini SES MDI Update to HL7 WGM

2022 January Update to IEEE/HL7  
Working Group Meetings

# Gemini SES MDI – SES Ecosystem Pathway

## Announcing a new Gemini SES MDI Group:

**Participants:** SES Product Quality / Risk Management / Regulatory Affairs Stakeholders

**Work focus:** Issues related to decoupled product development & use ... see [EP Tol Table](#)

**Launch:**

- ✓ Google Group Formed
- ✓ Bi-weekly Zoom meetings (starting Feb 1<sup>st</sup>)
- ✓ [EP confluence home page](#) (in development)

**CALLING ALL SES EXPERTS!!!**

## Ecosystem Pathway

(Pathway to an Ecosystem of Plug-and-Trust Products)

**2022 January Update to IEEE/HL7 Working Group Meetings**

## Gemini SES MDI – ~~Regulatory Initiative~~ Ecosystem Pathway Initiative

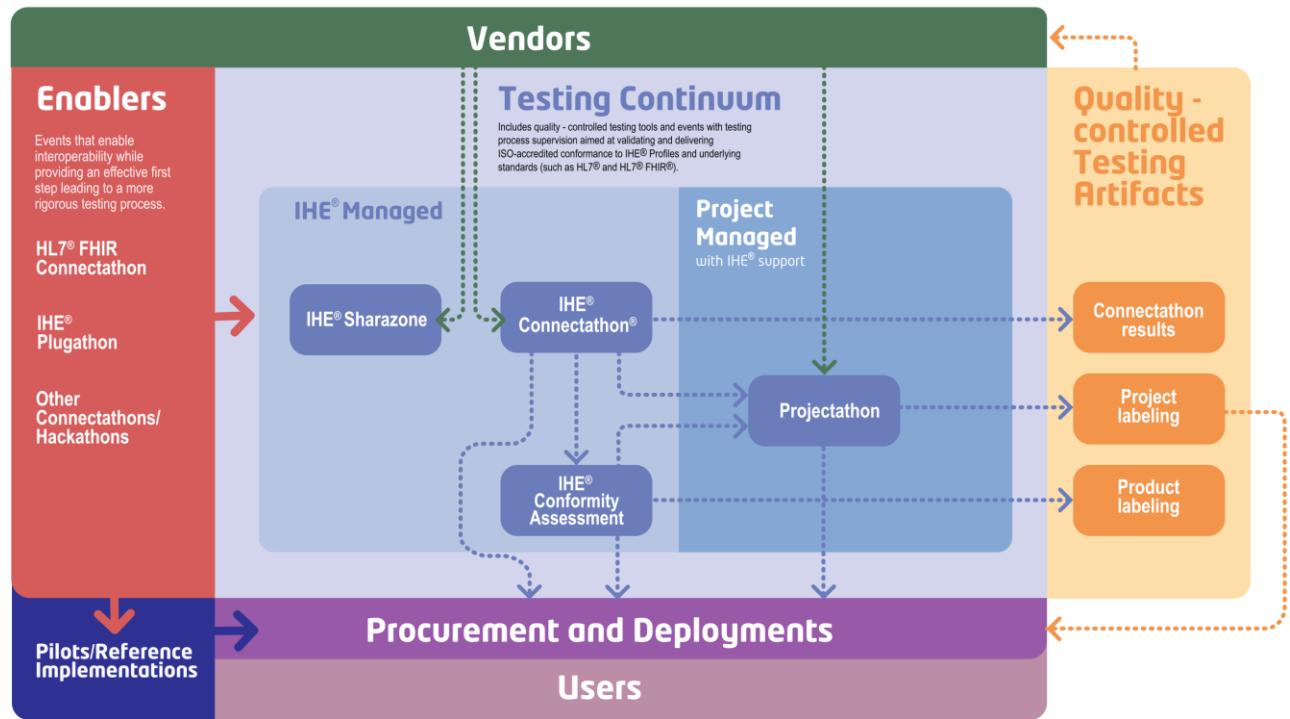
**Gemini SES / Regulatory Initiative proposal ...**

- ✓ *Open transparent public group* focused on the details of advancing SDC/SDPi-based products to patient use
- ✓ *Group leadership* would include representatives from *regulatory bodies, industry & standards*
- ✓ *Primary membership* would be *SES / quality & regulatory communities* ... MDI techies can “lurk”
- ✓ *Focus areas* would include ...
  - Establish the “*regulatory science*” for SDC/SDPi-based “regulatorily decoupled” Plug-n-Trust products
    - Starting with work done in OR.NET & IEEE PKP’s
    - *Shared risk management* from 80001-1 to PKPs to SDPi PnT interfaces to real-time monitoring
  - Establish *strategy for conformity assessment / testing* both virtually, and physically D2D
    - From prototype to product to market clearance to patient use & post-market surveillance
  - Integrate lessons from related programs such as the [FDA ASCA Pilot Project](#)
  - Build *guidance* and *educational materials* tailored for the SES/Quality & Regulatory community
  - *Convene workshops* and other educational events
  - Support *real-world pilot projects & demonstrations*
  - ...

✓ *Call for Participation* early October + *Biweekly WG meetings started by November 1st*

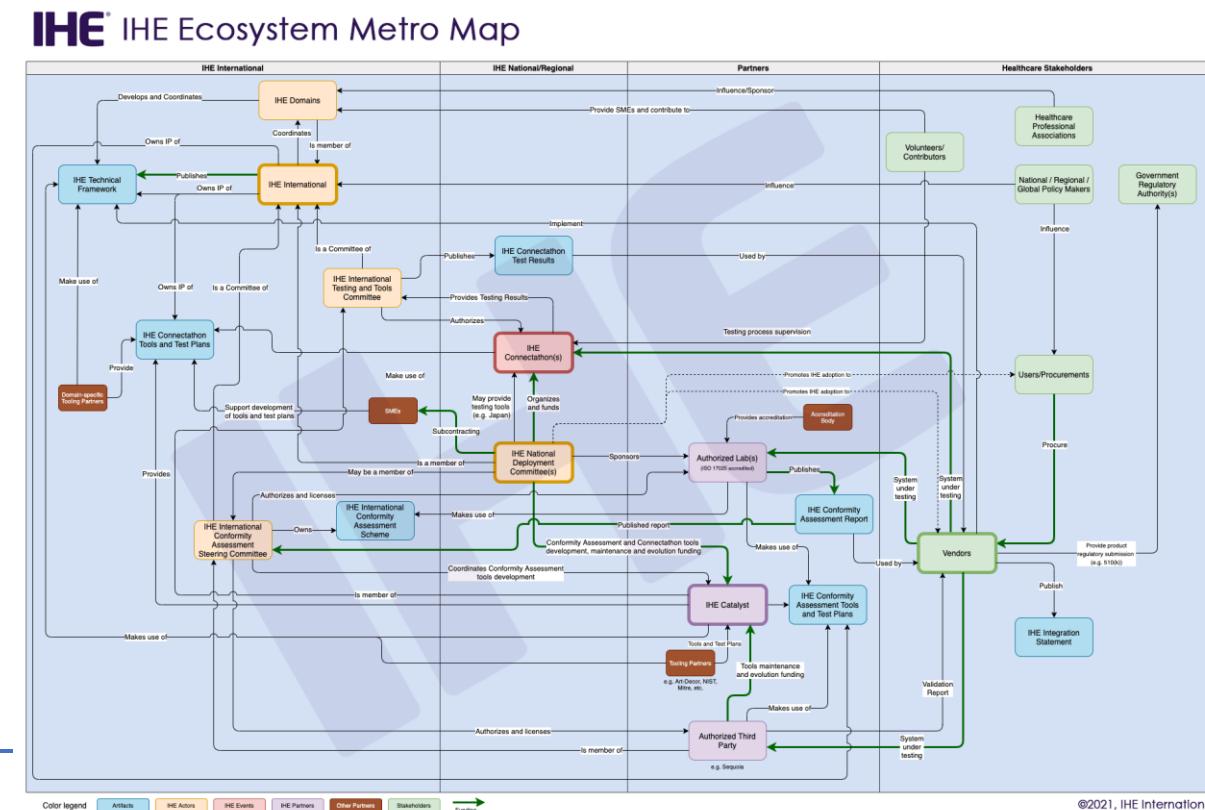
# IHE Catalyst (formerly IHE EU/IHE Services)

## *Factoring in the IHE Testing Continuum & Ecosystem ....*



- ✓ IHE Catalyst is central to all IHE based CA & Testing
- ✓ Gemini program “home” considered for Catalyst or HL7
- ✓ Study project (funded) being advanced with IHE Catalyst

**2021.09 Gemini Update  
to IEEE-HL7 WGM**



# SDC Conformance Principles

OR.NET  
e.V.

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.

IHE SDPi Supplement TF-1 annex includes a summary of Conformance Principles

Download @  
<https://ornet.org/en/download/>

## TABLE OF CONTENTS

1	Intent and Scope .....	9
1.1	Intended Readers of this document.....	9
2	System Architecture .....	10
2.1	System Configuration .....	10
2.2	Security .....	10
2.3	Types of Data Exchange .....	11
2.4	SDC Protocol Converters .....	11
3	Responsible Parties .....	12
4	Manufacturers Claims and Context of Use .....	13
4.1.1	Medical IT-Network .....	14
4.1.2	Other SDC Participants .....	14
5	Safety, Effectiveness, and Efficiency of SDC Systems .....	15
5.1	Requirements Allocation .....	16
5.1.1	User Experience .....	17
5.2	Key Purpose Concept .....	17
5.2.1	Metrics .....	19
5.2.2	Alerts .....	20
5.2.3	Operations .....	20
6	Product Lifecycle Processes .....	20
6.1	User and Customer Requirements .....	21
6.2	Documentation .....	21
6.3	Technical Design .....	21
6.4	Risk Management .....	22
6.5	Verification .....	22
6.6	Validation .....	24
6.7	Regulatory .....	24
6.8	Complaint Management / Post Market Surveillance .....	25
6.9	Change Management .....	25
6.9.1	Changes of the SDC System .....	25
6.9.2	Significant Changes of SDC Participants .....	25
7	SDC Conformance .....	26
7.1	Declaration of Conformance and System Governance .....	26
7.1.1	Conformance Documentation .....	26

# More detail is provided in ...



The logo features the IHE Europe Experience Sessions branding. The word "IHE" is in white with a registered trademark symbol, and "EUROPE" is in smaller white text below it. To the right, the words "EXPERIENCE SESSIONS" are in orange and white, with the date "15-17 JUNE 2021" in white below. A circular badge on the right says "IHE EUROPE 20<sup>TH</sup> ANNIVERSARY".

## IHE & IHE Catalyst: Advancing Interoperable MedTec Solutions with "Regulatory Submission Ready" Conformity Assessment



**Dr. Stefan Schlichting**  
IHE Devices Co-Chair  
Unity Consulting & Innovation

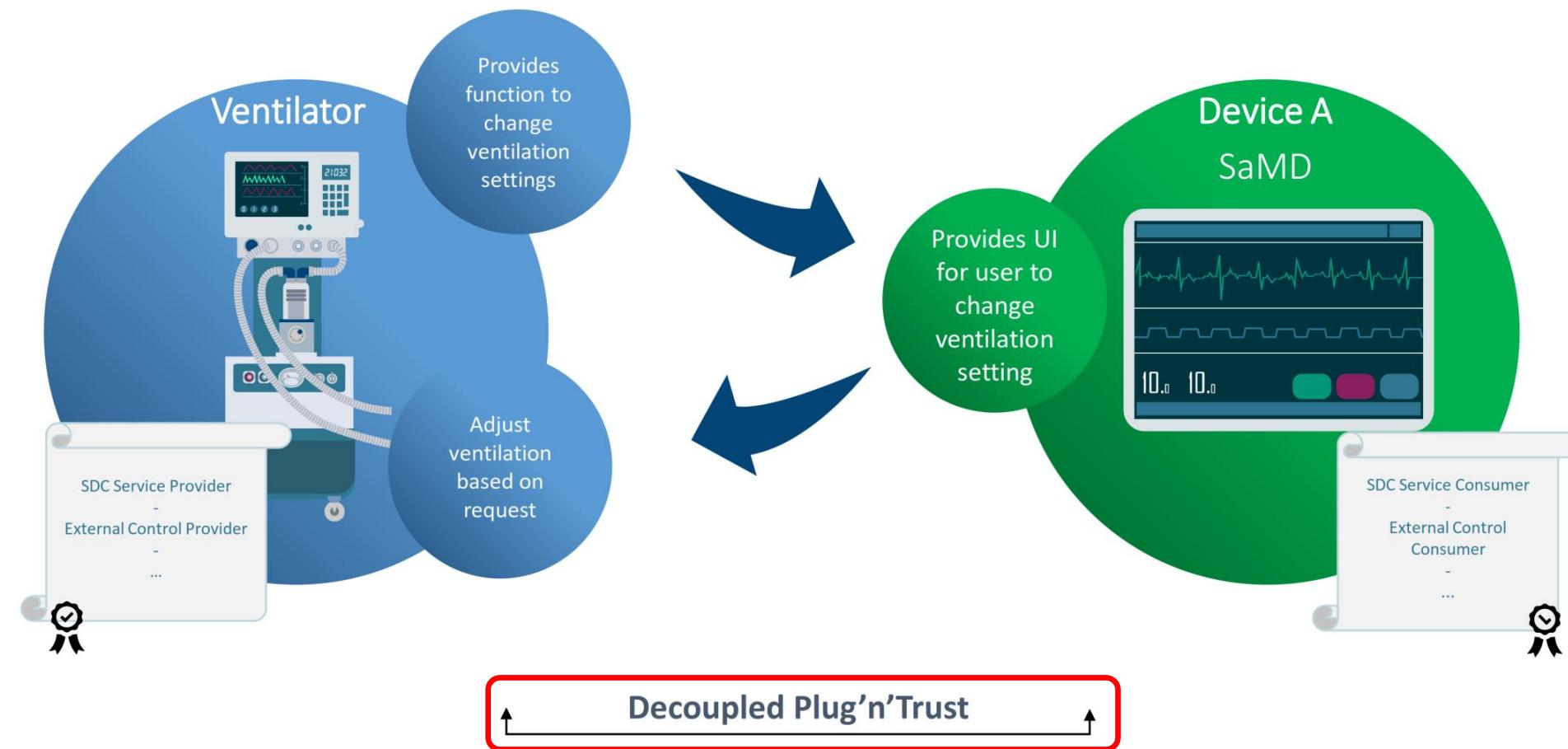


**Todd Cooper**  
Lead, IHE-HL7 Gemini Device Interoperability Program Board, IHE International Executive Director, Trusted Solutions Foundry

16/06/2021

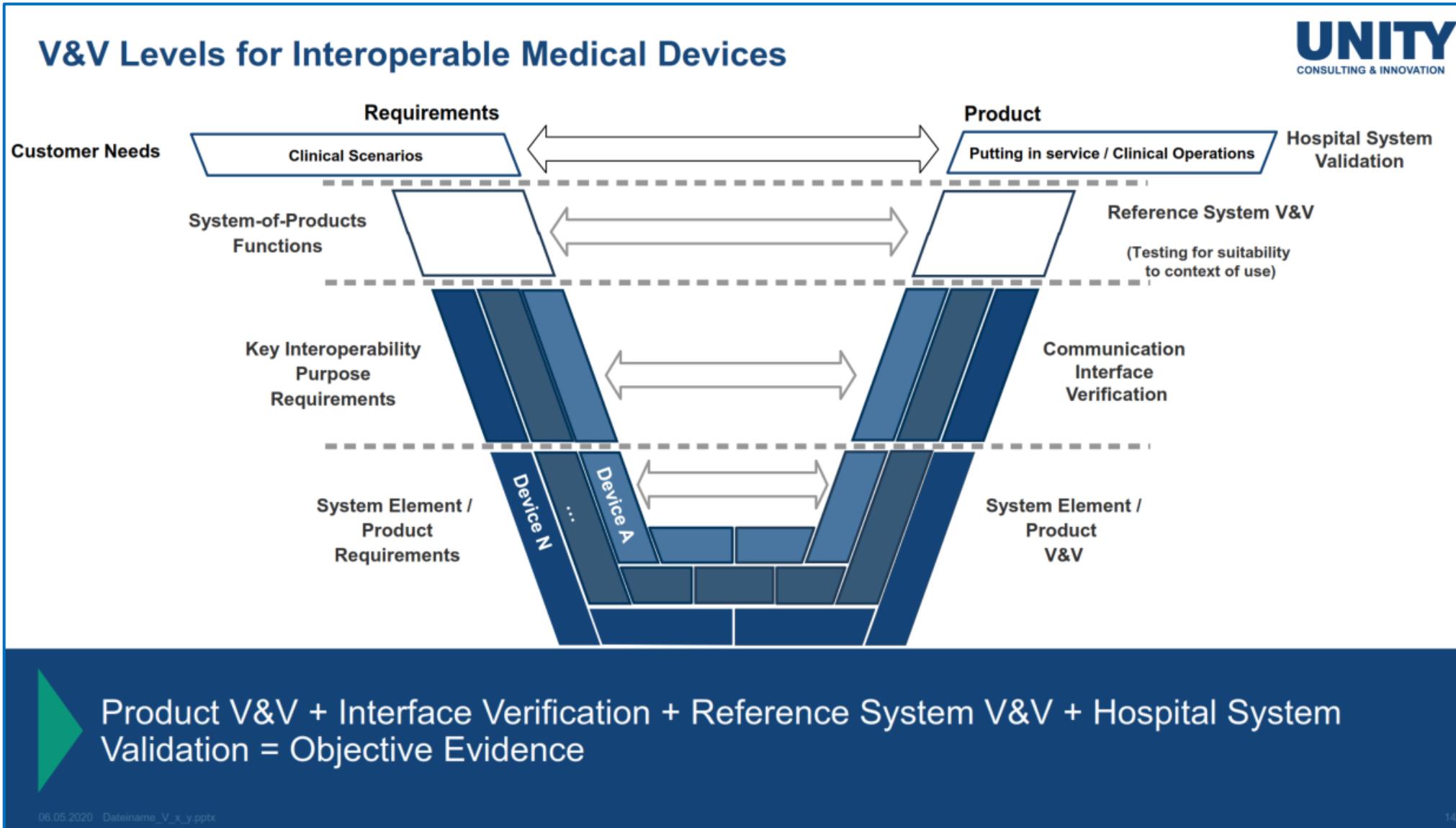
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## Example: External Control of Ventilator using Device A



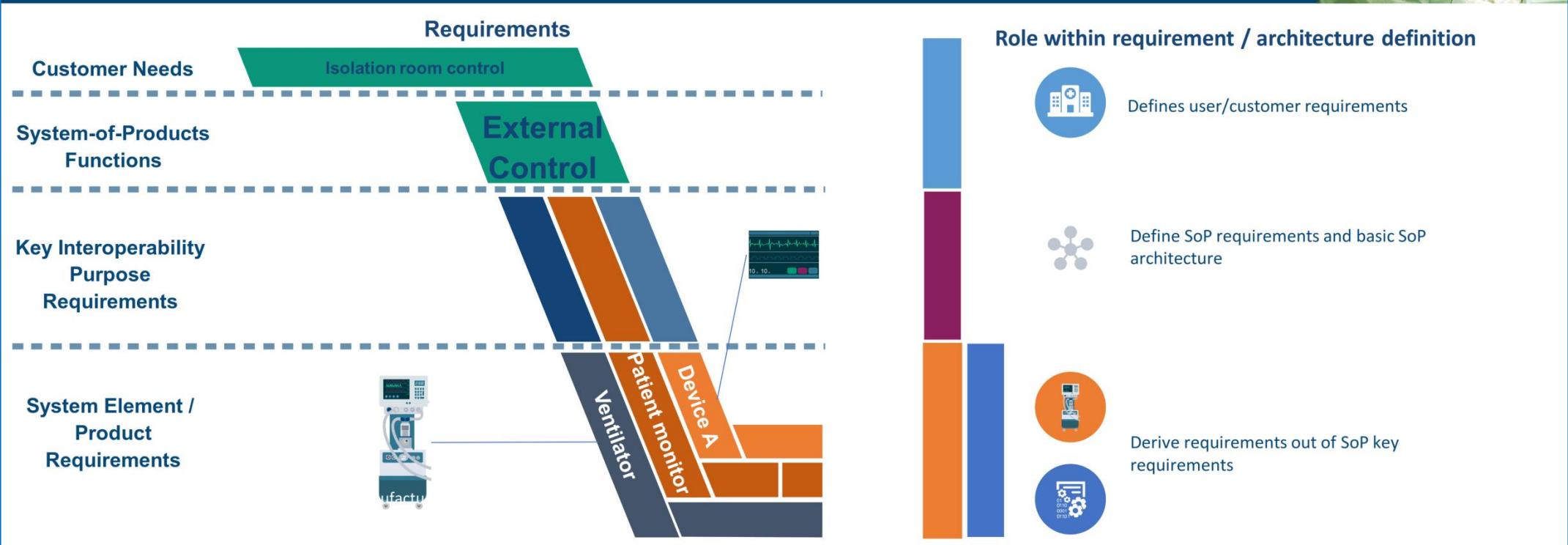
# V-Model for Systems of MedTech Products

See IHE EU Experience '21  
... "Regulatory Submission Ready" CA



## Implication of interoperable SoP on Requirement / Architecture

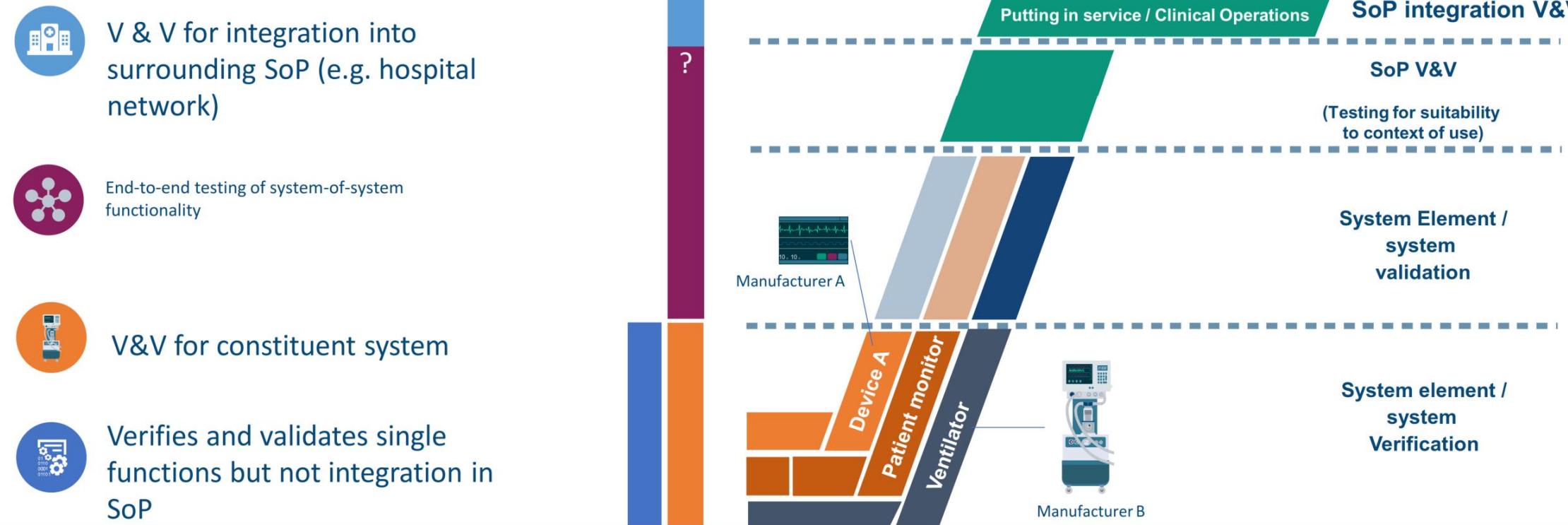
Traditional SE approach cannot fulfill the requirements



Using the traditional SE approach leads to a lack of responsibility between the User requirements of the system-of-product and the system requirements / architecture of the constituent systems and functions

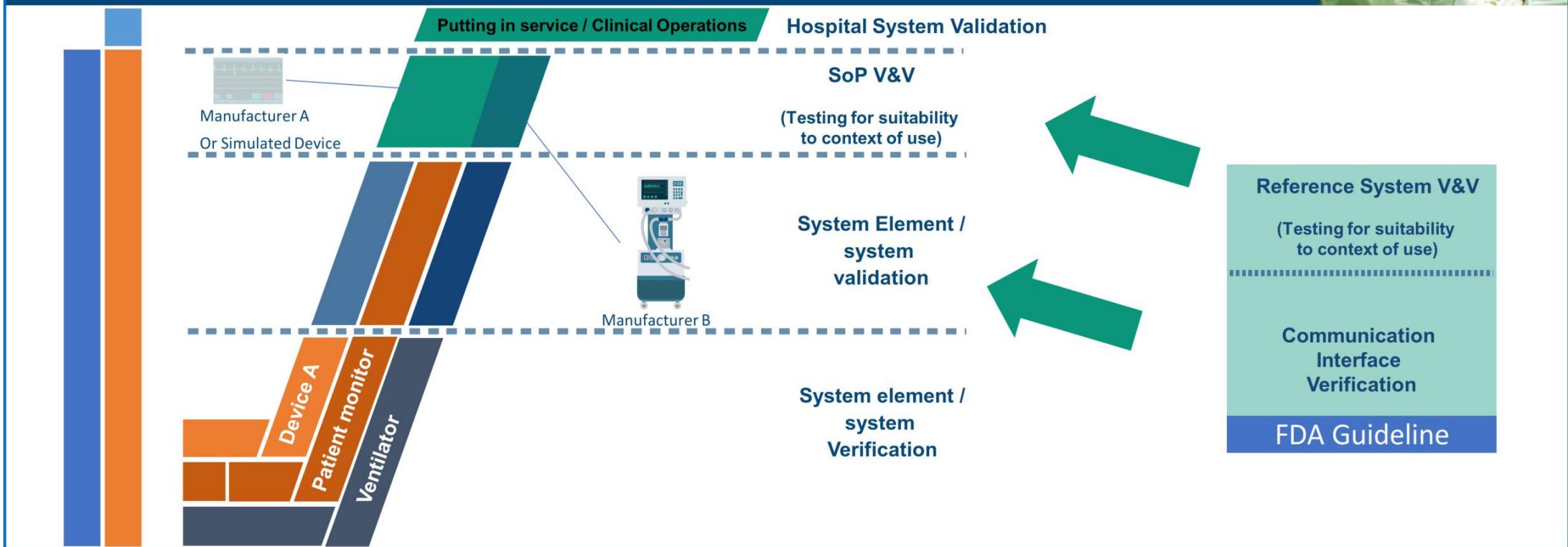
## Responsibility and Validation Challenges

Verification and validation responsibilities



A lack of end-to-end testing responsibility is observed in traditional SE

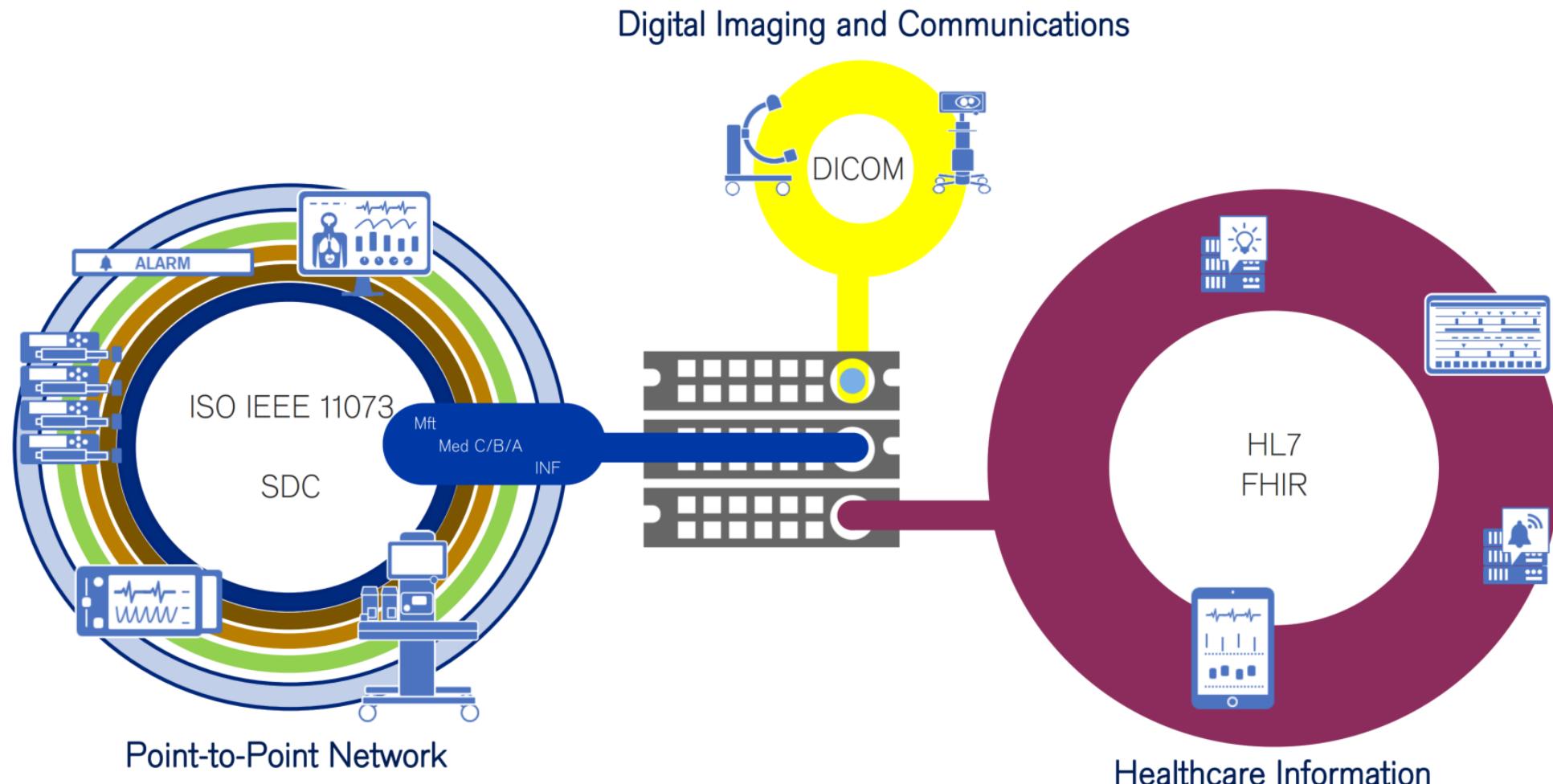
## Verification and validation responsibilities Example Medical Device



FDA Guideline also applicable for CE market?

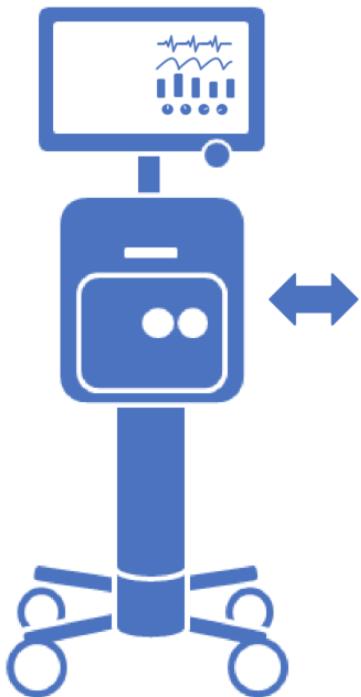
# AdvaMed Briefing 2021 (Marzenko)

## History / development of Interoperability



# AdvaMed Briefing 2021 (Marzenko)

## The next step ahead From standards to market



Safety and performance requirements for the medical device

+

System Functionality

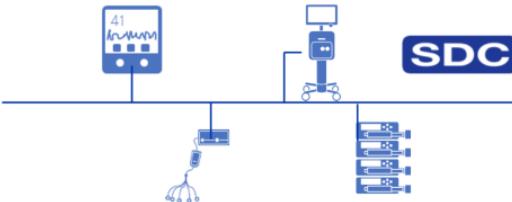
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Interoperability contributions

**Vision: Regulatory review convergence  
throughout different device sectors and  
globally harmonized**

# AdvaMed Briefing 2021 (Marzenko)

## Poster: Pathway to FDA pre-submission

Integration Roles, Responsibilities and Activities for Health Care Facilities		• AAMI / ANSI / IEC 80001-1	
	Integration: <ul style="list-style-type: none"><li>Typical functionality in reference System</li><li>Clinical evaluation</li></ul>	V: Design Considerations for Interoperable Medical Devices	VI: Recommendations for Contents of Pre-market Submissions
	Domain Specific standardized Information models (PKP)	Validation: <ul style="list-style-type: none"><li>PKB IEEE P11073-xxx</li><li>RM ISO 14971</li><li>HF IEC 60601-1-6</li><li>TDoc ISO 20417</li></ul>	A Purpose C Risk Management B Anticipated Users D Validation E Labeling F Consensus standards
	Standardized Safe and Secure meshed network	Verification: <ul style="list-style-type: none"><li>Interfacetest IEEE P11073-10700</li><li>Cybersecurity IEC 60601-4-5</li><li>Authentication</li><li>Encryption IEC 60601-xxx</li></ul>	D Verification F Consensus standards
	Device submission Core documentation	IEC 60601-2-xx	A Device Description