IHE® EUROPE | EXPERIENCE SESSIONS 15-17 JUNE 2021

IHE EUROPE 20TH 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

Session Presenters

Dr.-Ing. Stefan Schlichting

IHE Devices Co-Chair

Expert, Unity Consulting & Innovation

Over 10 years of experience with innovation, technology & product development & systems engineering

UNITY
CONSULTING & INNOVATION

Todd Cooper

Lead, IHE-HL7 Gemini Device Interoperability Program

Board, IHE International

Executive Director, Trusted Solutions Foundry

Over 30 years experience in open standards-based medical device interoperability

Trusted Solutions Foundry

OR.NET e.V.

IHE International sponsor of the IHE Devices Domain / Device Point-of-care Interoperability (DPI) Program

A non-profit organization with more than 50 international partners.

Session Overview

IHE International & IHE Catalyst:

Advancing Interoperable MedTec Solutions with *"Regulatory Submission Ready" Conformity Assessment*

- The MedTech Device Interoperability Challenge
- New Generation of MDI Standards & Profiles + Communities
- Addressing MedTech Regulatory Realities
- Big Ideas! enabling “Regulatory Submission Ready” IHE CA

The MedTech Device Interoperability Challenge

For some the challenge is “We’ve heard about this for decades! Why should we think that history will NOT repeat itself … again?!”

For others, “Medical device interoperability? What’s the ‘big deal’ … we’ve solved device interoperability challenges in many other industries?!”

Medical Device Interoperability Journey

40+ Year *Promise* of Medical Device Interoperability:

As we ponder the NEXT 40 …

Why do we think it will be any different?!

Medical Device Interoperability Journey

Does it have to be this hard?

Life-critical MedTech is HARD!

Is it a technology problem?

Not in the last 40 years!

Why such a challege?

#1 Misaligned Business Drivers

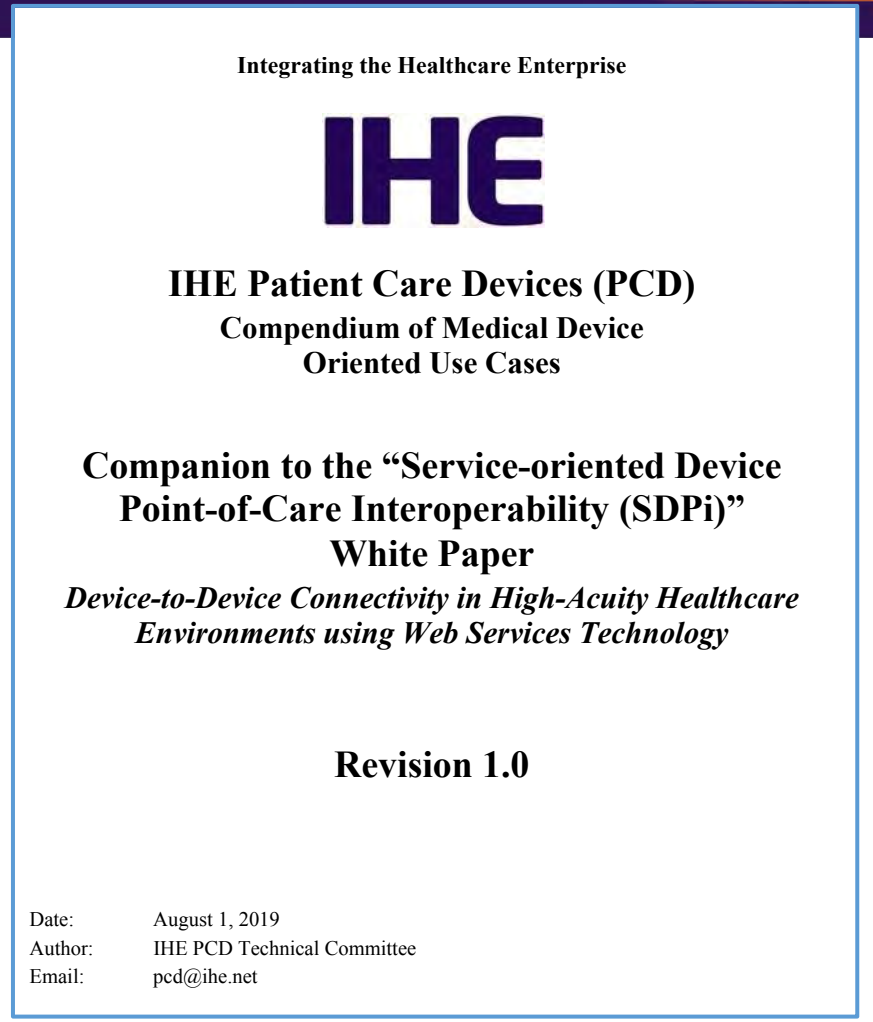
#2 Incomplete Standards Solutions

MedTech Use Cases & Contexts

Consider some exemplary MDI use cases:

- **Endoscopic/Laparoscopic Surgery** (OR focused)
- **Silent Bed** (ICU/ER focused)
- **Isolation Point-of-Care** (from Hospital to Home!)
- **MDIRA / Autonomous Medical Systems** (from OR to trauma site)

Compendium of MDI Oriented Use Cases
compiled by IHE Devices co-Chair Ken Fuchs …



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

MedTech Customer Need: Surgery Augmented Reality

The Customer Need – Information Availability

The ability to view settings of surgical devices like HF surgical devices or laparoscopic light sources as overlay on the laparoscopic view.

HF Device

Light Source

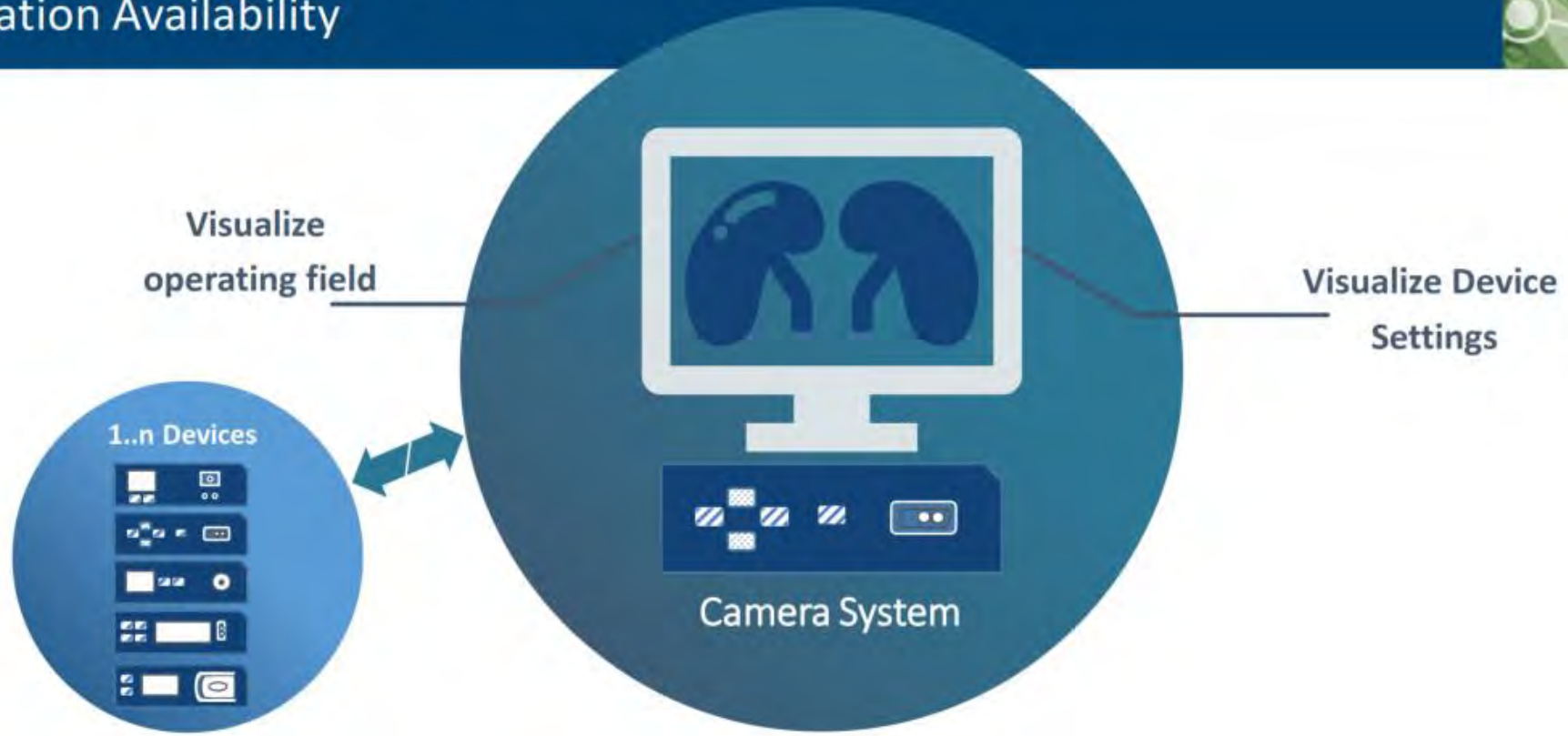
Camera System

Source: https://www.drbillhefley.com/the-importance-of-minimally-invasive-surgery/

Interoperable Medical Device System for information awareness without distracting the surgeon from the procedure.

MedTech Customer Need: Surgery Augmented Reality

Addressing the Customer Need
Information Availability



Laparoscopic camera system to visualize the operating field with overlaid device settings information of connected surgical equipment.

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MedTech Customer Need: Isolation Room Remote Control

The Customer Need – Isolation Room Remote Control

„Ingenuity.. this is one of MANY things that make me proud to be part of a great group of Respiratory Therapists! Removing the control monitor of Hamilton G5 ventilator and linking outside a closed door. RTs effectively limiting exposure and conservation of PPE!" – A. Smith BS, RRT-ACCS on LinkedIn

The ability to view patient data as well as device settings and control devices from outside the patient´s room, as well as be informed about the alarm status.

Ventilators

Infusion Pumps

Patient Monitor

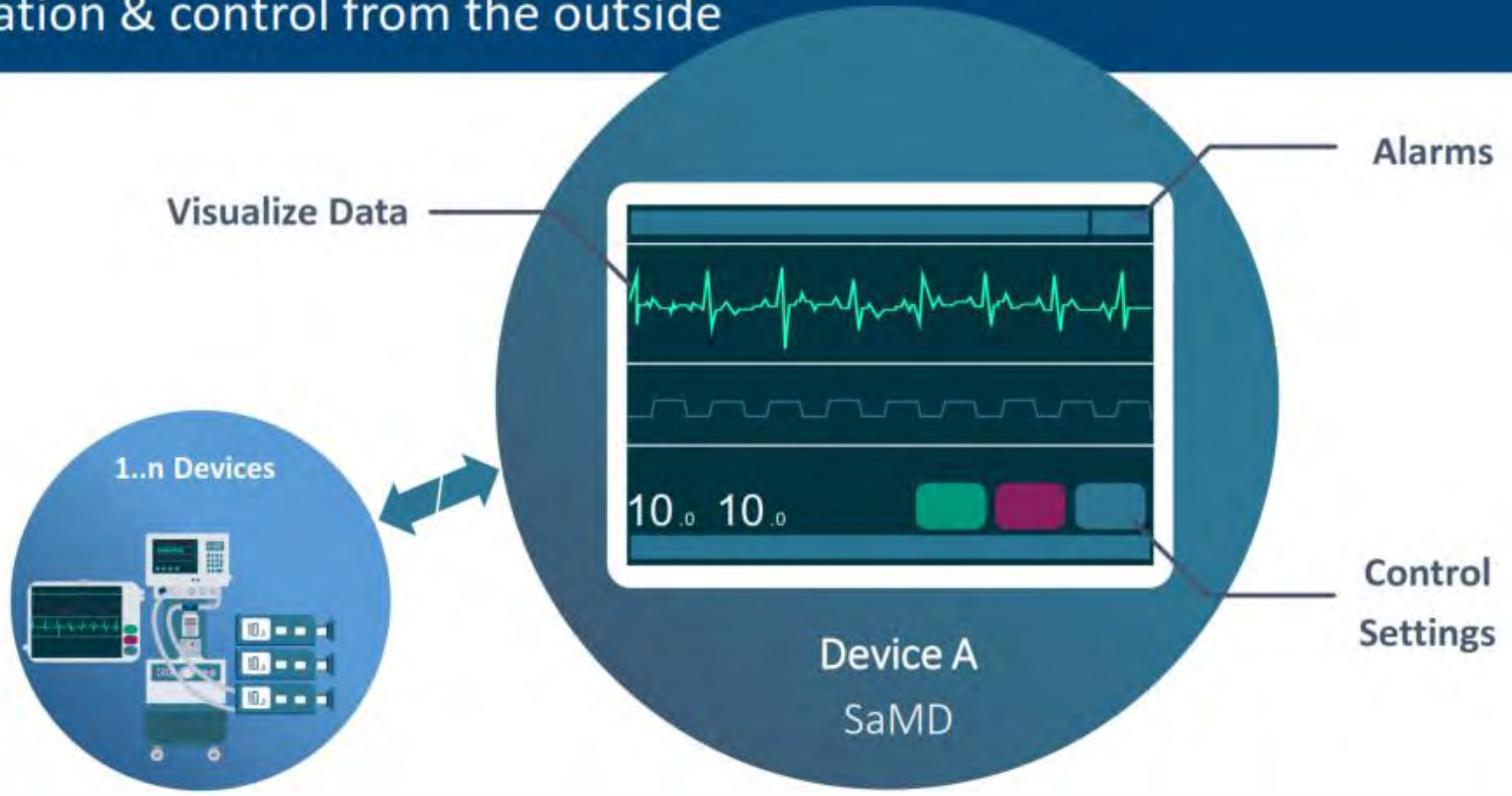
Isolation Room Controller

Interoperable Medical Device System for information awareness and control that **limits staff exposure.**

MedTech Customer Need: Isolation Room Remote Control

Addressing the Customer Need

Information & control from the outside



Limiting staff exposure by a Software as a Medical Device allows the medical staff to view the aggregated patient´s status, alarms and to control the patient´s devices.

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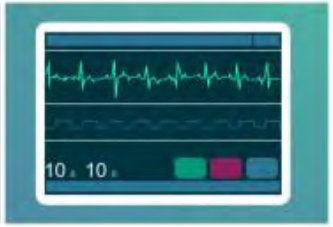
MedTech Customer Need: Health Software / Medical “Apps” Enabled by Interoperability

Interoperability Applications

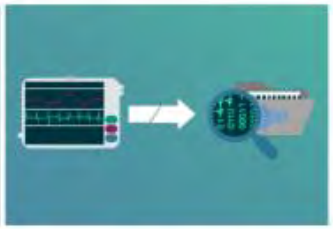
Data-Driven Clinical Application

… “Real-time” patient status, Remote supervisor support, Remote Control, Isolation Rooms



Automated Documentation

… for Data Analytics, Forensic Documentation, Reimbursement



Care Automation

…OR Planning, OR Setup Assistance, Device Setting Recommender, Physiological Closed-Loop Controller

There exists a customer need for applications that would benefit from interoperability!

MedTech Interoperability Reality: Virtually "Nonexistent"

Interoperability Challenges

Conventional Medical Devices
Generate a lot of data about the patient, the current workflow, and about their configuration.

Limited Data Availability
Devices have either no digital export interface or proprietary protocols that have to be manually integrated.

Limited External Control
Devices have either no or limited external control interface.

„Interoperability[1] is an almost nonexistent feature of medical devices"
- Lesh et al 2007

[1]Based on FDA Interoperability Guidance (2017) see

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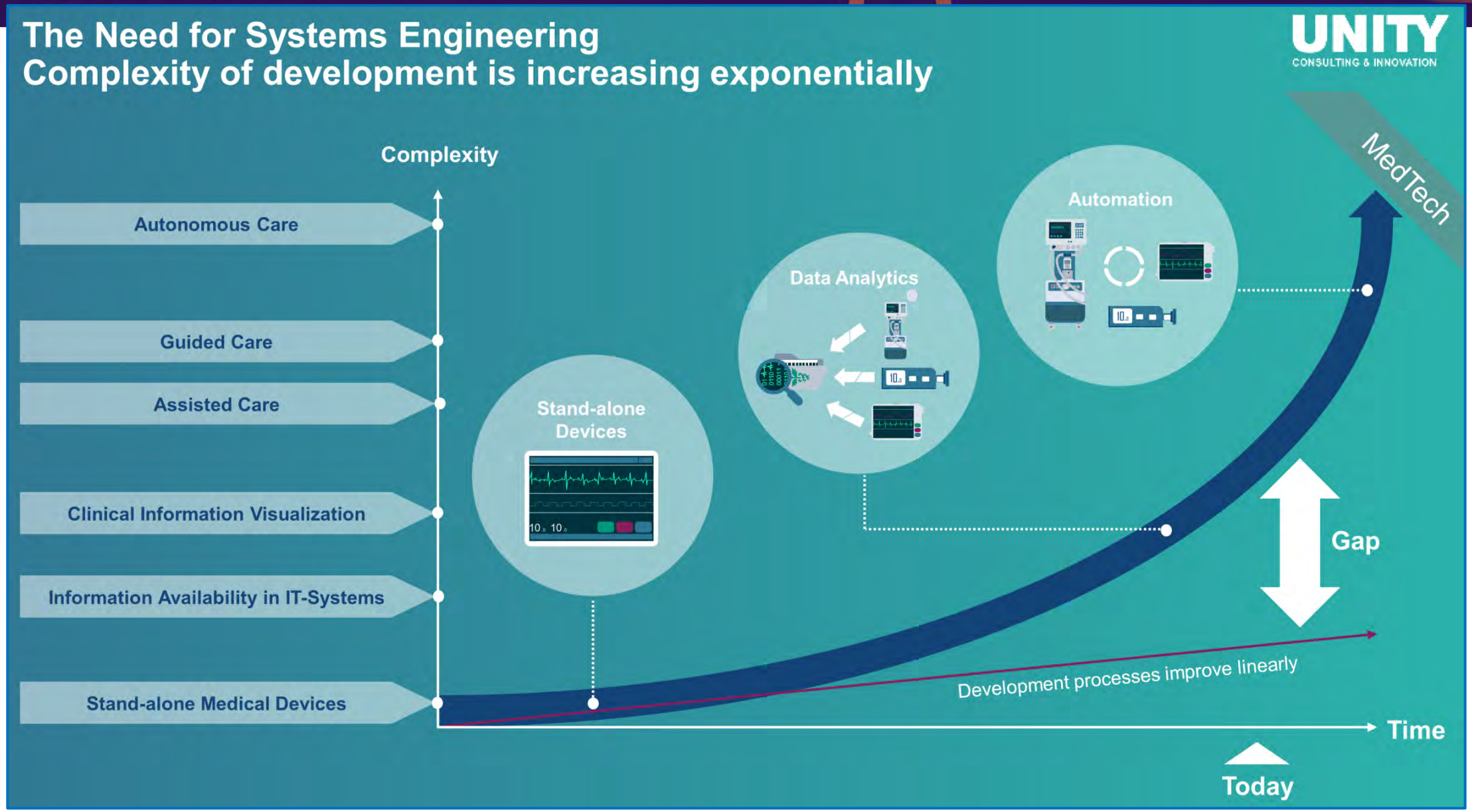
MedTech Challenges – Complexity!



MedTech Challenges – Total Product Lifecycle Cost

Defined Costs vs. Incurring Costs during the Life Cycle

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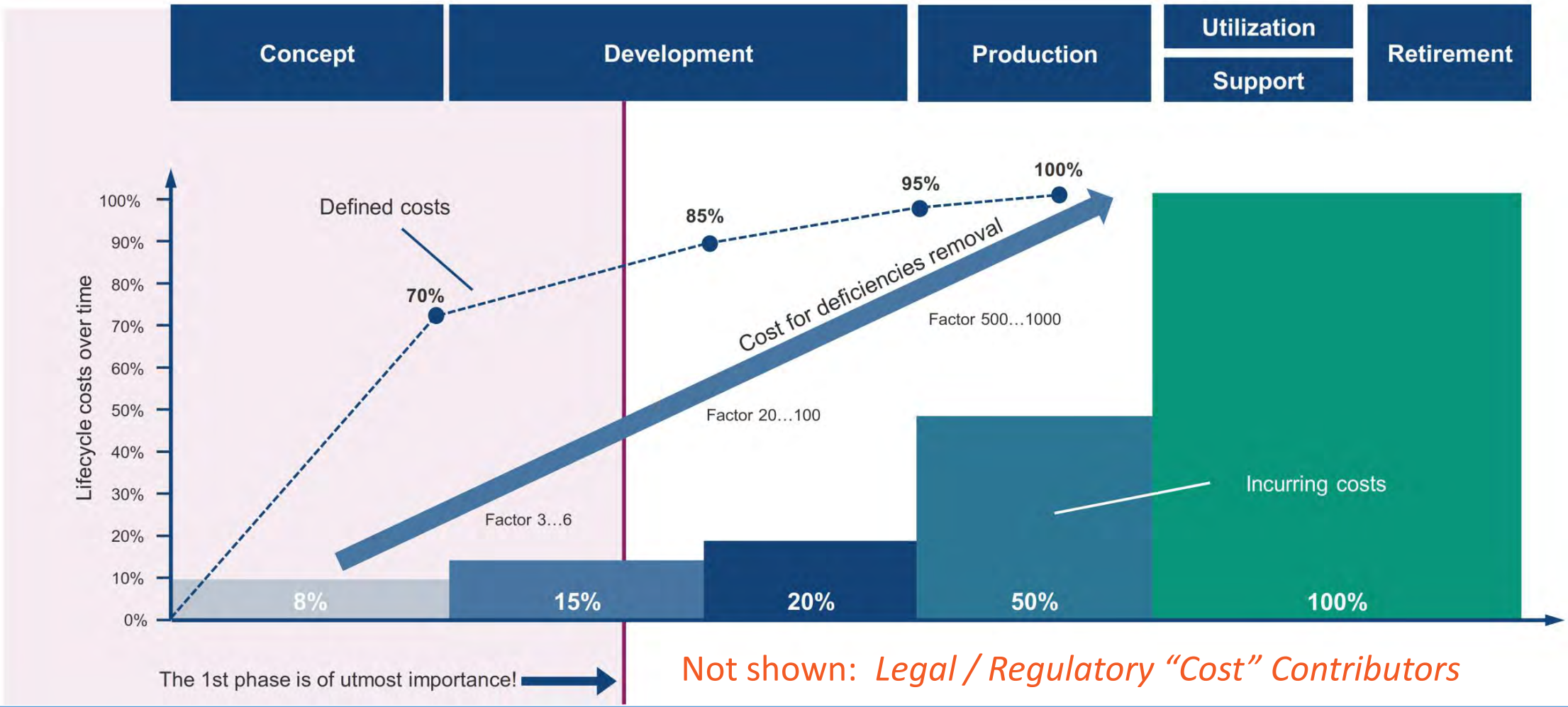


Not shown: *Legal / Regulatory "Cost" Contributors*

MedTech Interoperability – Open ?'s

MedTech Interoperability Challenges and Open Questions abound …

- Technology constantly evolves but *MedTech product life cycles are looooooong*!
- What is a medical device? "SaMD" and *Medical "Apps"?!*
- Implementing mostly non-regulated health ICT in a *regulated device ecosystem*
- *Risk management* of "component products" in a *decoupled ecosystem*
- Integrating standards-based requirements and specifications in a *MedTech product development management tool chain*
- …

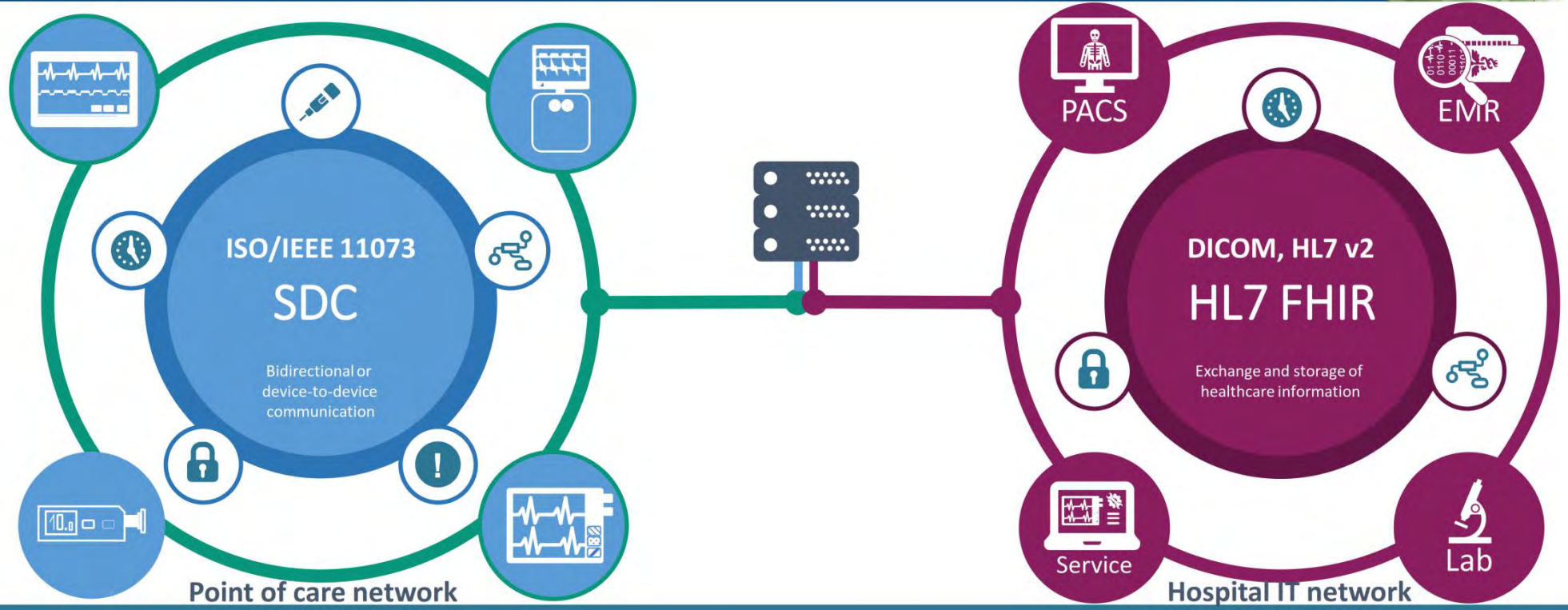
Conclusion: *To break out of the "40 year wander" cycle, we have to* ***do differently*** *and* ***do better –*** *enabling* ***significant implementer value chain improvements***

New Generation of MDI Standards & Profiles + Communities

The stage is set for finally breaking through to realizing open standards-based medical device interoperability due to a new generation of ISO/IEEE 11073 standards, IHE profiles of those standards and a broad international community that has embraced and is advancing real-world implementations …

Medical Device Interoperability – Enterprise & PoC Networks … with a Gateway Inbetween!

The Interoperability Standards Landscape



IEEE 11073 SDC & HL7 FHIR – **Complementing Standards**

Medical Device Interoperability – ISO/IEC 11073 SDC "From the Device Interface"

Interoperable Medical Device System Functions

International standard for safe, secure and dynamic interoperability of medical devices for enabling clinical applications in highly acute environments

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Concept and development of the standard driven by the non-profit organization, OR.NET, with more than 50 international partners.

* Typically with SDC-FHIR Gateway

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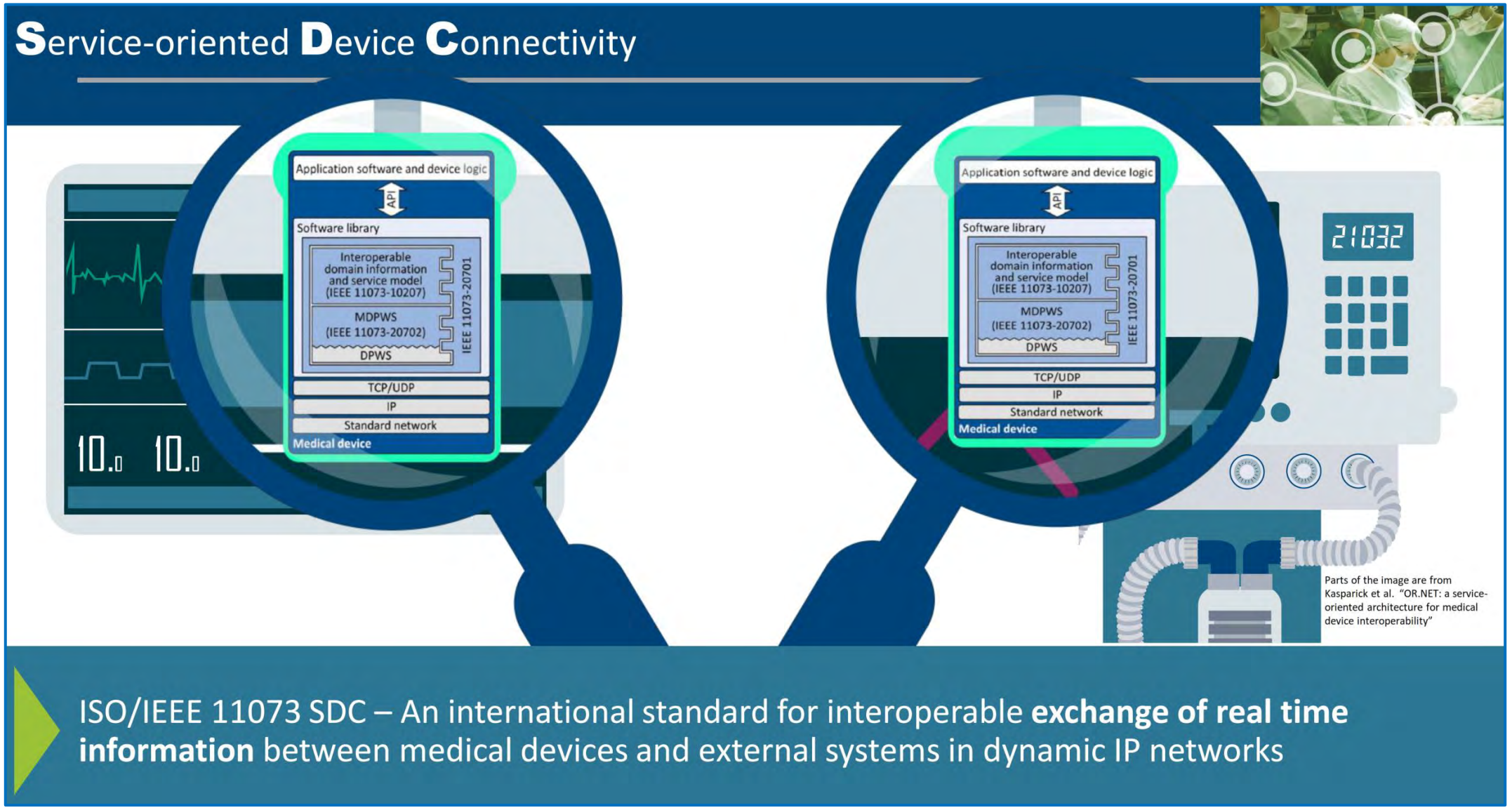
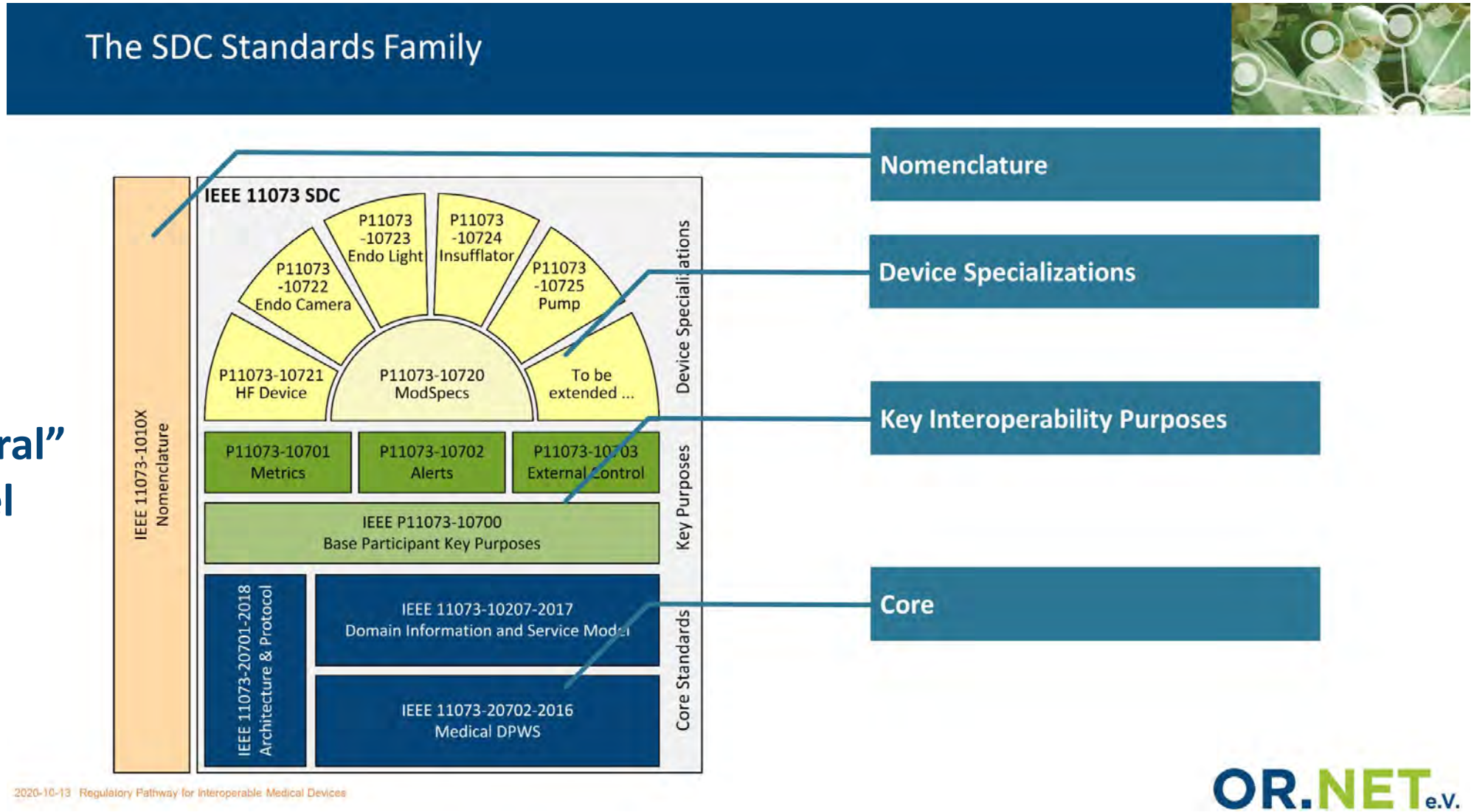
Medical Device Interoperability – ISO/IEC 11073 SDC "From the Device Interface"



Medical Device Interoperability – ISO/IEC 11073 SDC "From the Device Interface"

"Cathedral" Model



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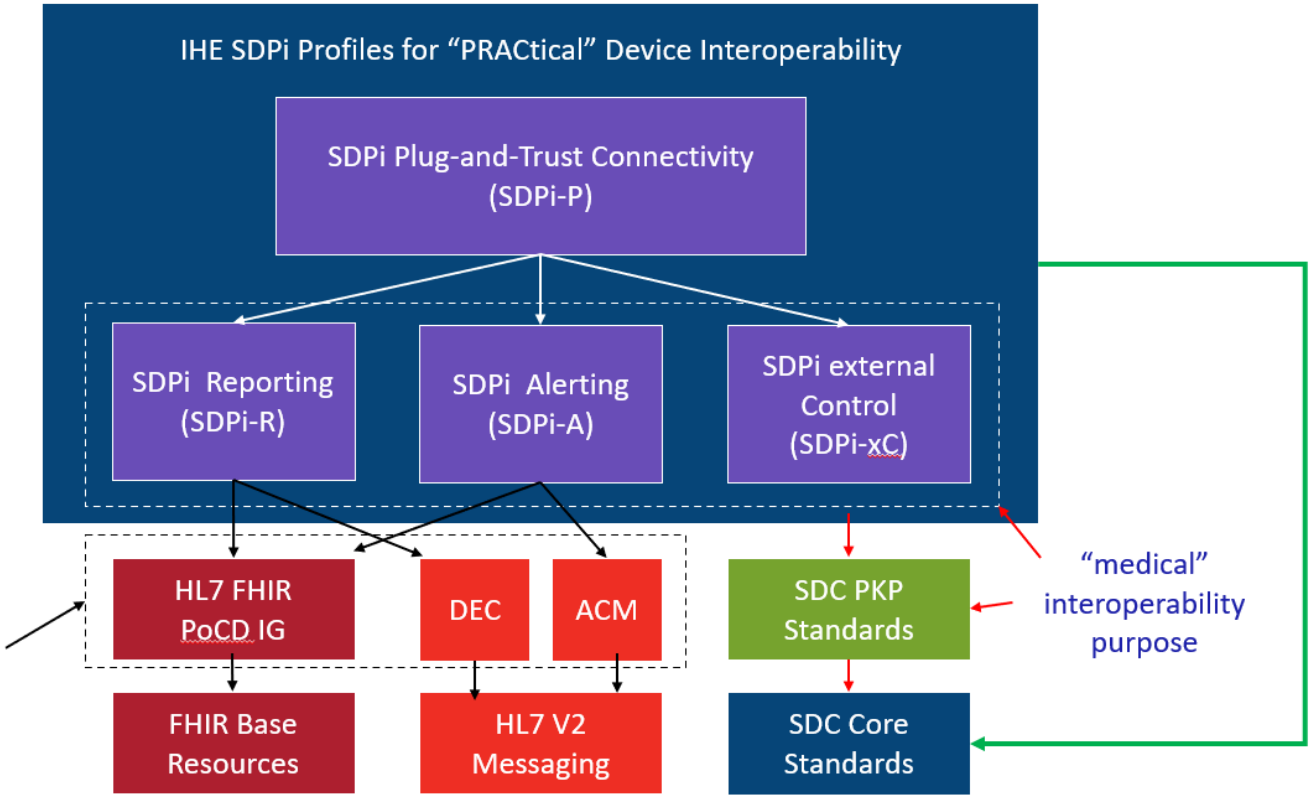
IHE Devices Technical Framework: SDPi Profiles Supplement

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
- ✓ **Three IHE DEV TF Volumes:**
  - TF-1 Profiles / use cases / actors / …
  - TF-2 Transactions / MDPWS messaging
  - TF-3 BICEPS content modules / device specializations



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

HL7 FHIR

IHE DEVICES Making Healthcare Interoperable

SDC SERVICE-ORIENTED DEVICE CONNECTIVITY

IHE-HL7 Gemini MDI SDPi+FHIR – *Project Update*

for

Joint IEEE / HL7 / IHE Working Group Meetings

2021.01.27 (Finalized 2021.02.19)

Year 3 Update @ https://confluence.hl7.org/x/Xzf9Aw

IEEE Advancing Technology for Humanity

ISO HEALTH INFORMATICS TC 215

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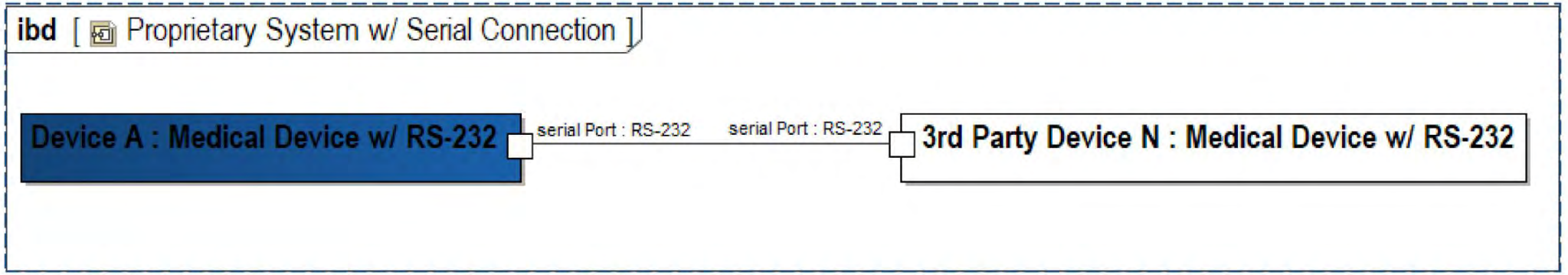
Addressing MedTech Regulatory Realities

For all MedTech products, getting to the market includes having to navigate regulatory requirements and challenges – interoperability standards communities have not provided a cohesive, integrated approach for applying their standards, leaving the burden largely on the backs of product developers – we must do better!

MedTech Regulatory Pathway – Core to SDC/SDPi Specifications

Established approach today

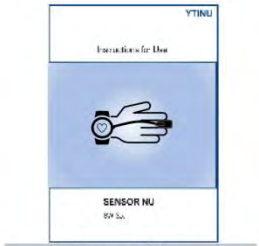


Risk Management	Verification	Validation	Labelling
Responsibility for risk management for claimed system function for specific devices	System functions with specific device combinations 1:n (100%) but only a	New relevant risks out of the system functionality	Additional information for system functionality

Manufacturer of “Device A” performs Risk Management, V&V and Labelling for the System Function of the combined proprietary system.

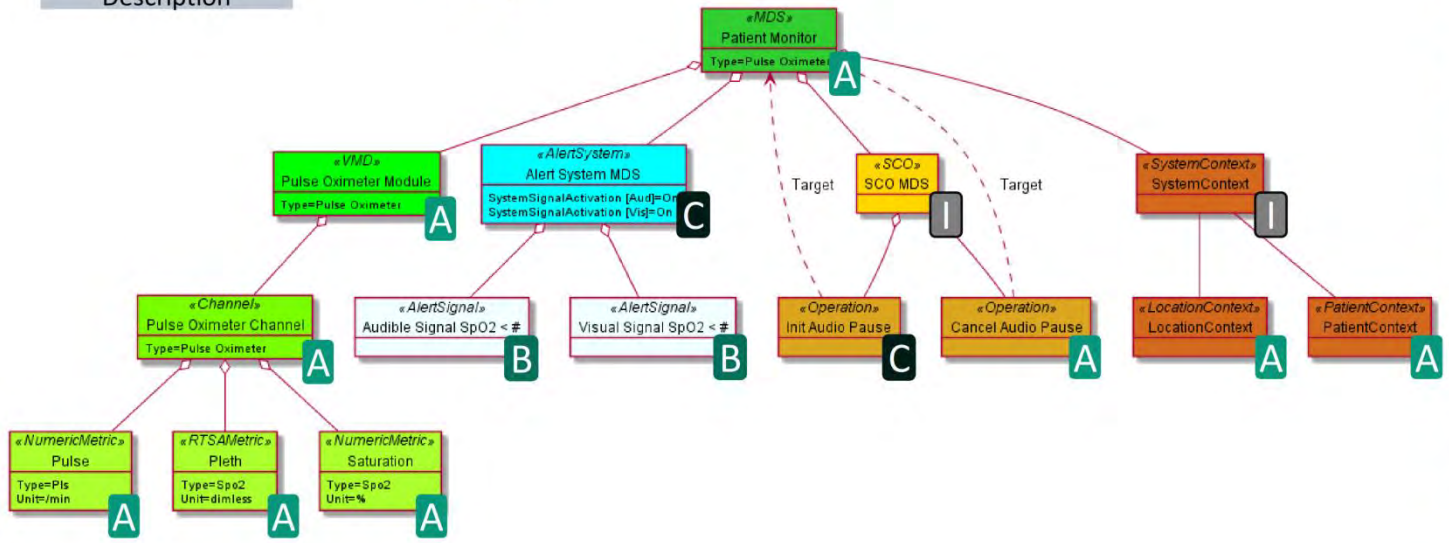
MedTech Regulatory Pathway – Core to SDC/SDPi Specifications

Safety Classification Concept



Capability Description

ISO/IEEE 11073-10207
Information Model integrates Safety Classification Semantics



I Informational A Med A B Med B C Med C

Safety Classification

The **Capability Description** of an SDC Service Provider comprises a Safety Classification attribute.

Indicator from the SDC Service Provider to the SDC Service Consumer on how the Manufacturer of the SDC Service Provider has considered the intended use of the Containment Tree Entry in its Risk Management.

4 Safety Classes exist:
- Informational,
- Medical Class A, Medical Class B, Medical Class C

It should be noted that the classes are not equal to the safety classes from IEC 62304.

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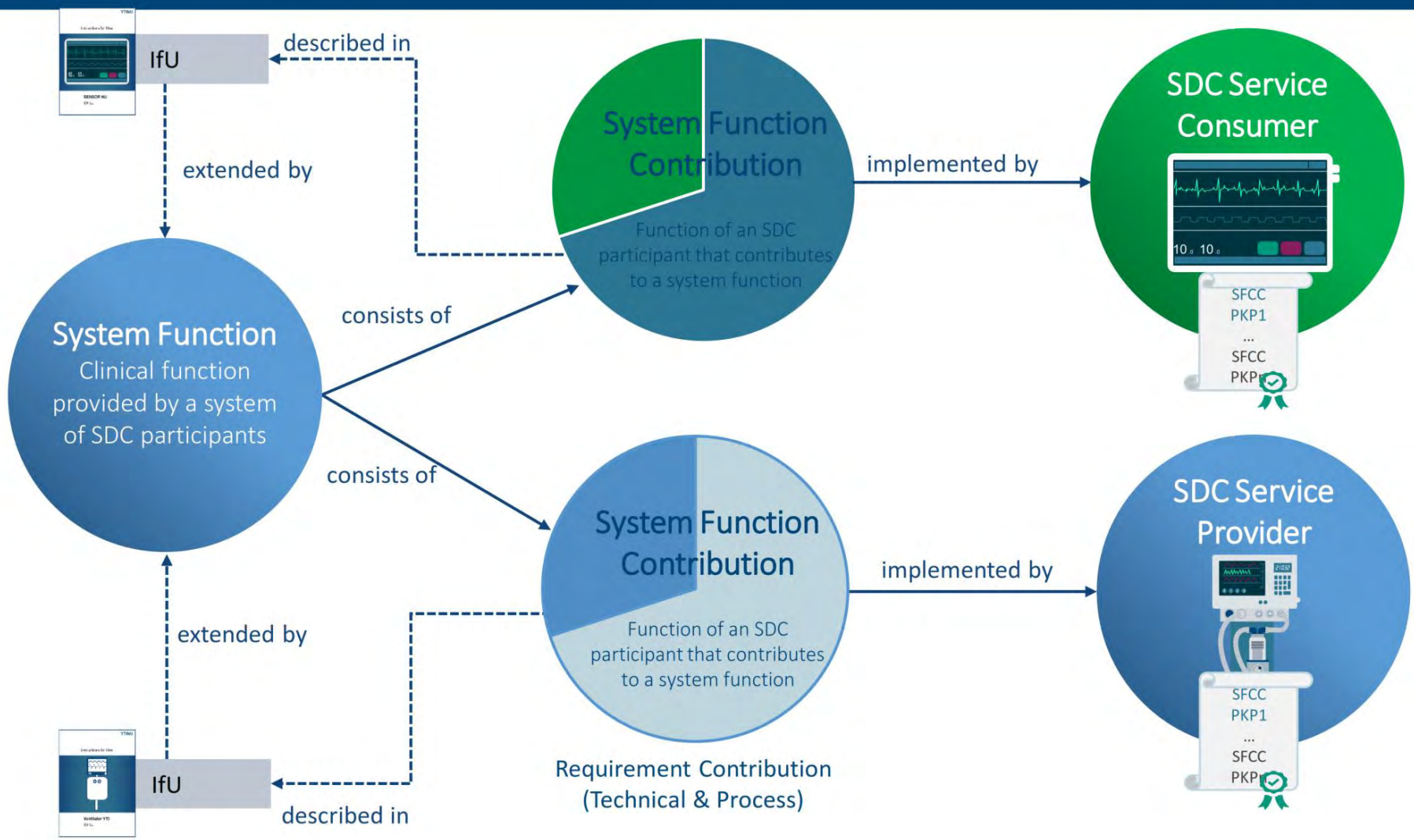
MedTech Regulatory Pathway – Core to SDC/SDPi Specifications

System Functions & System Function Contributions



See ornet.org/en/download/ for *"SDC Conformance Principles" & Approval* documents

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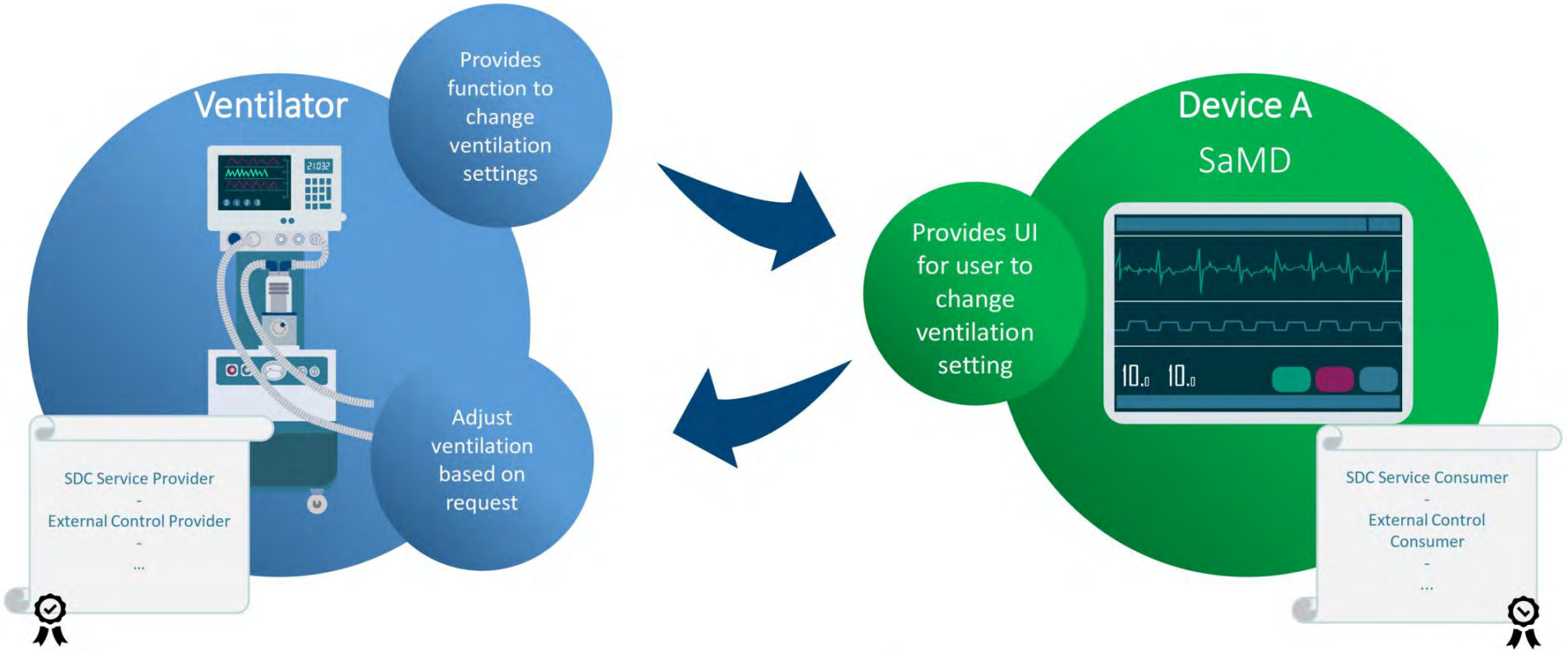
MedTech Regulatory Pathway – Core to SDC/SDPi Specifications

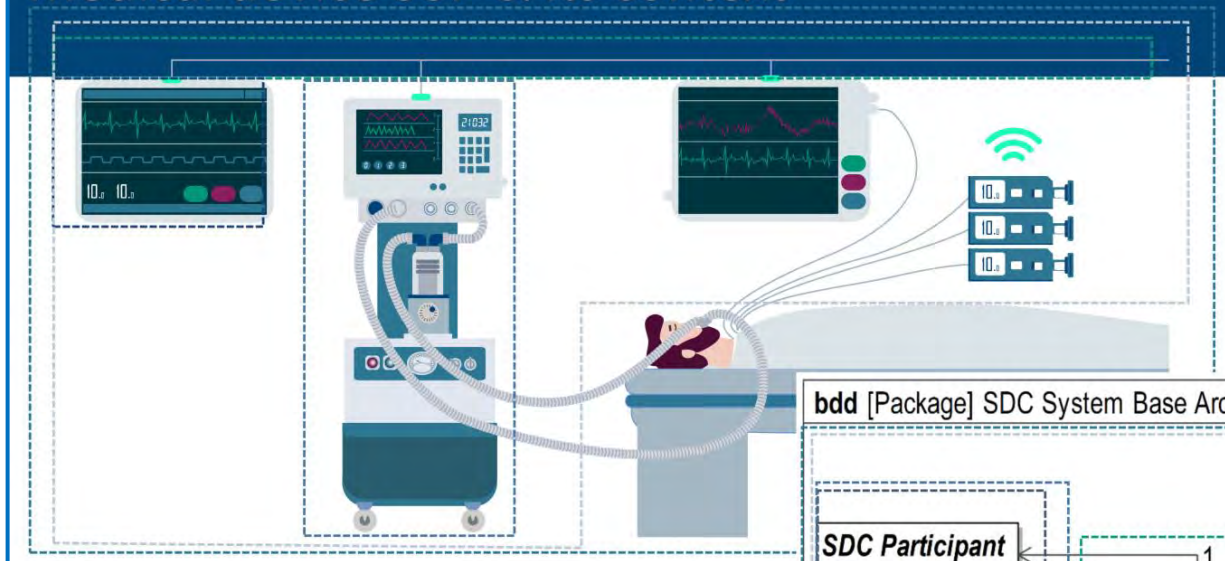
Example: External Control of Ventilator using Device A



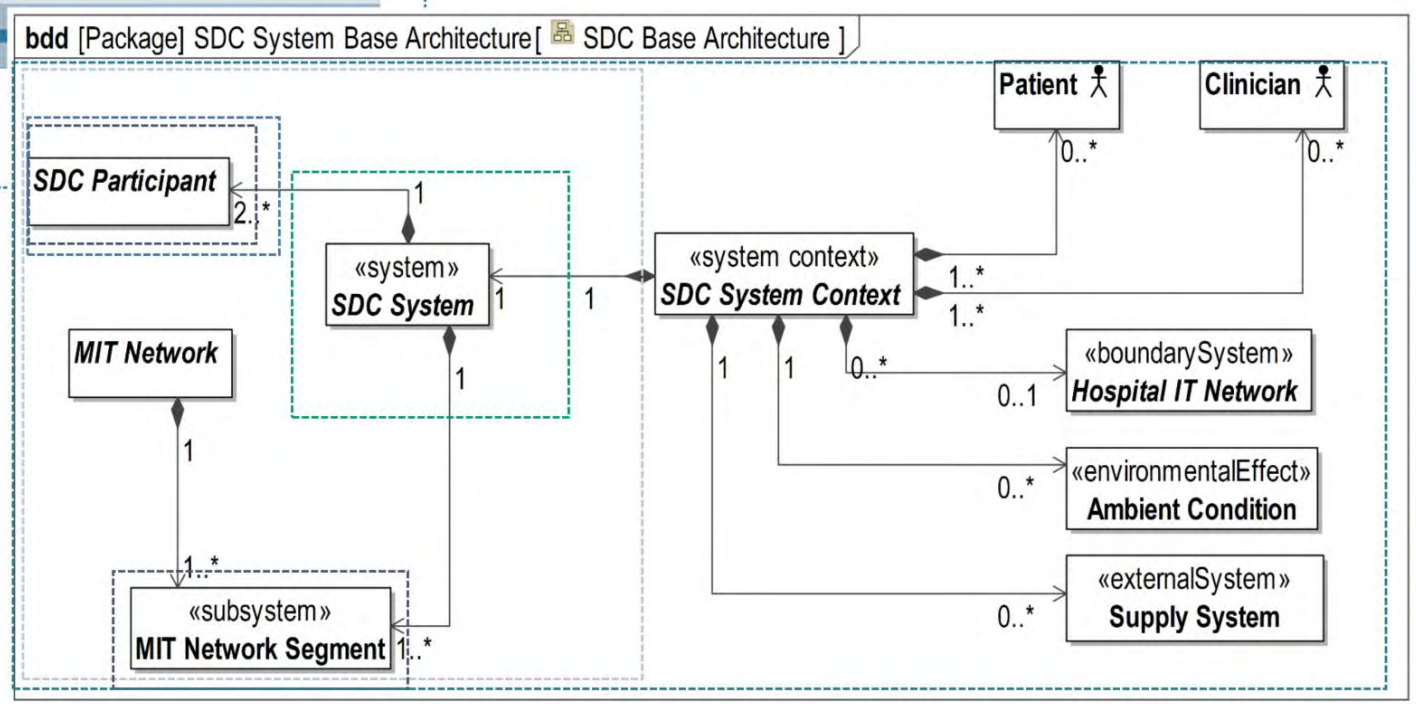
Decoupled Plug'n'Trust

MedTech Regulatory Pathway – Core to SDC/SDPi Specifications

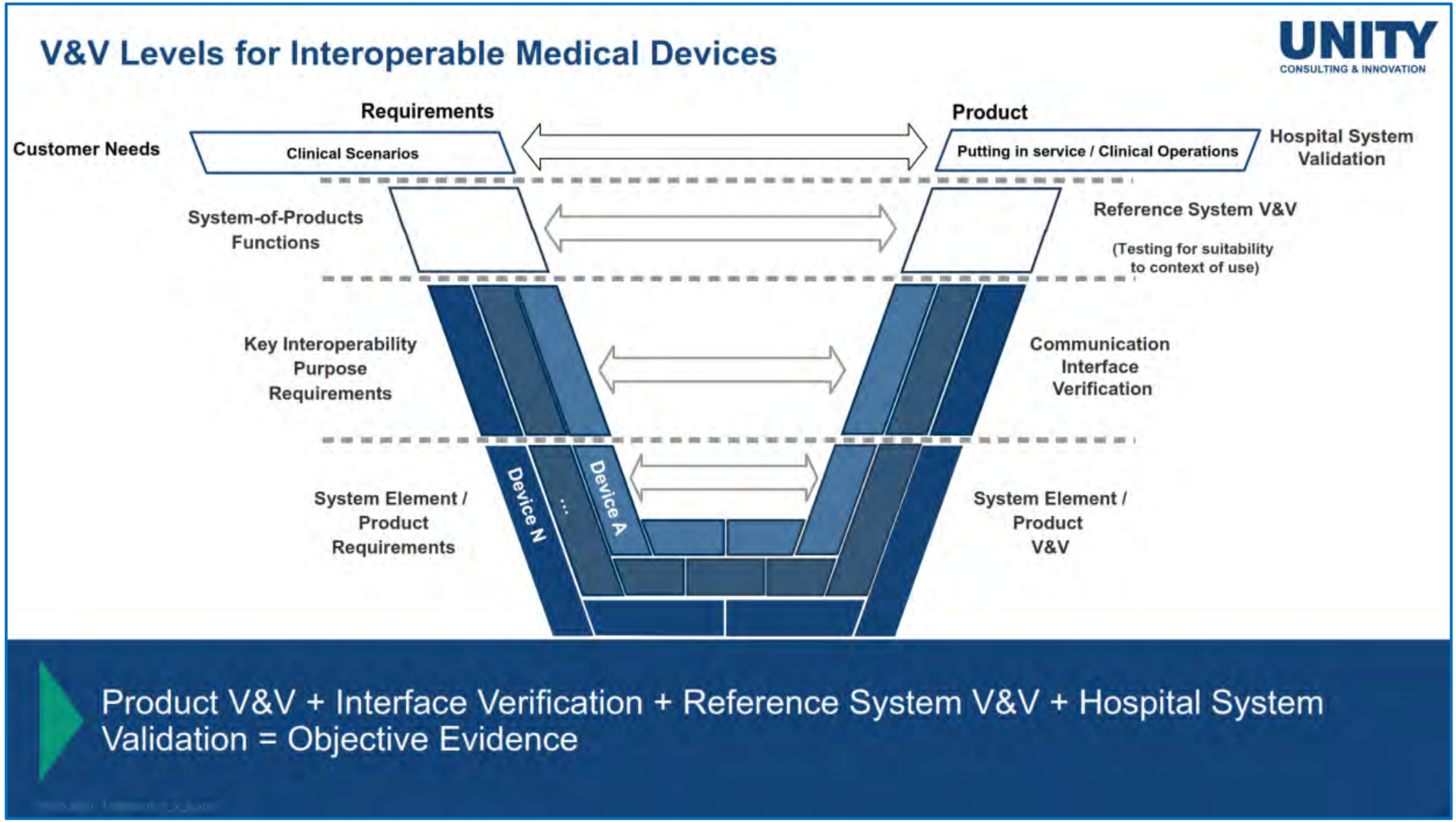
Medical device SoP & its context



- System Function Provider
- Constituent System Provider
- System Integrator
- SoP manufacturer
- SoP Operator



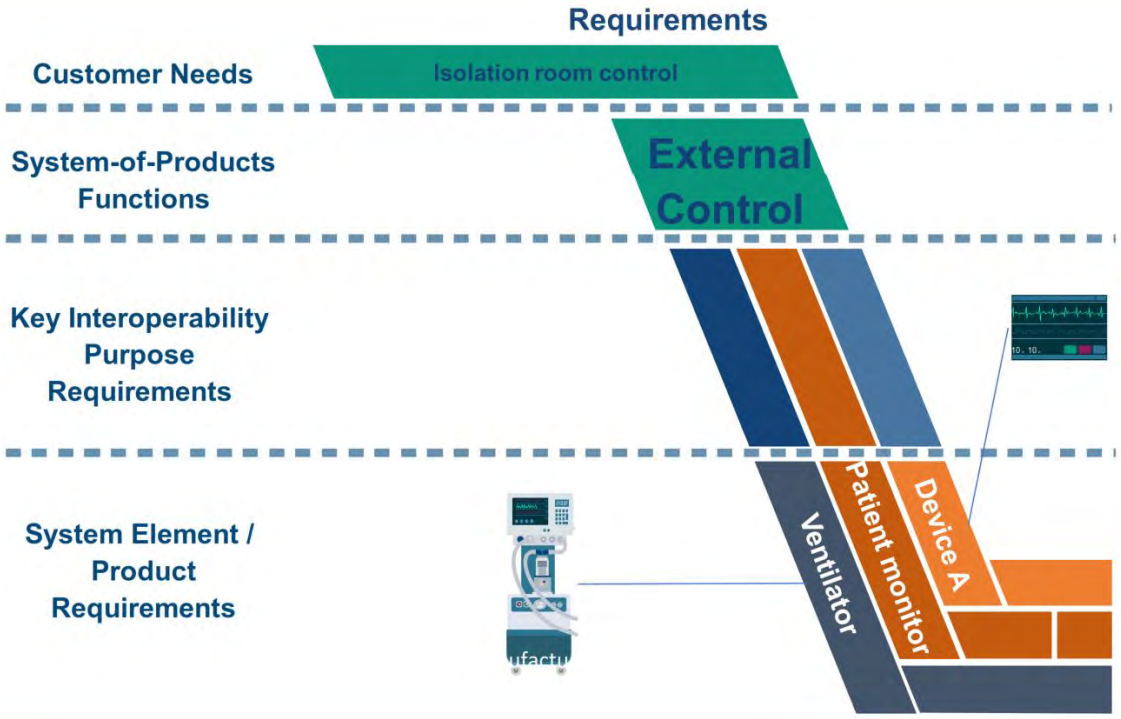
MedTech Regulatory Pathway – Core to SDC/SDPi Specifications

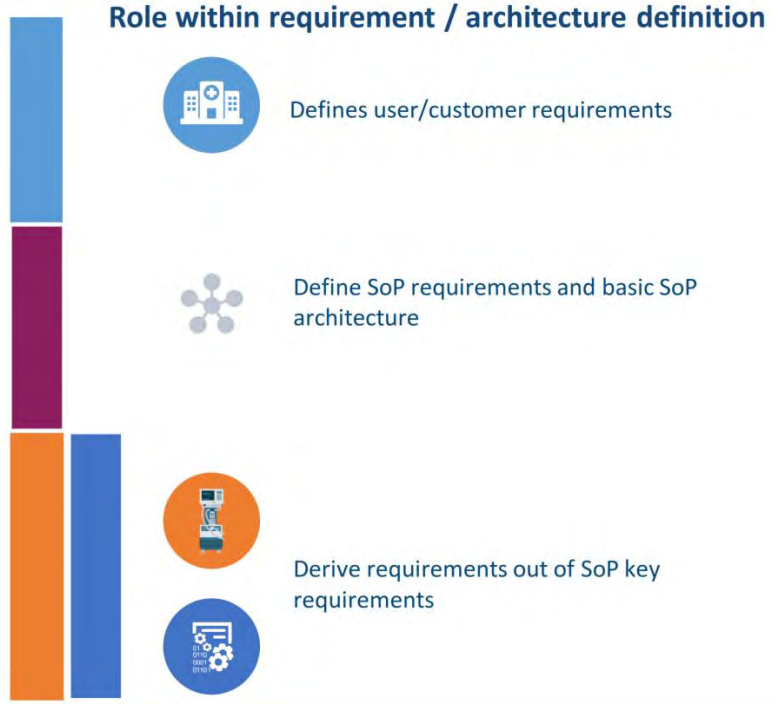


MedTech Regulatory Pathway – Core to SDC/SDPi Specifications

Implication of interoperable SoP on Requirement / Architecture

Traditional SE approach cannot fulfill the requriements





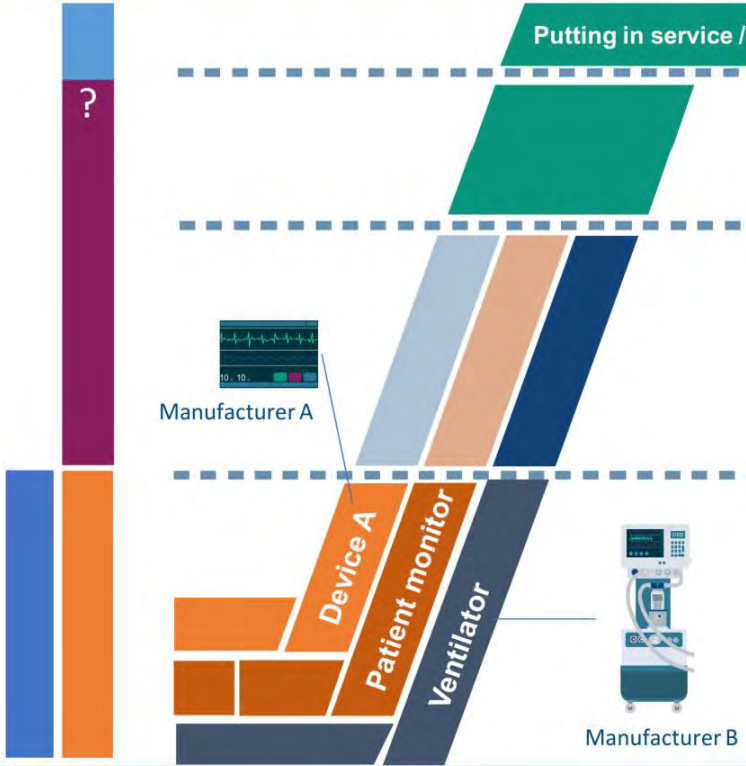
Using the traditional SE approach leads to a lack of responsibility between the User requirements of the system-of-product and the system requirements / architecture of the constituent systems and functions

MedTech Regulatory Pathway – Core to SDC/SDPi Specifications

Responsibility and Validation Challenges

Verification and validation responsibilities

- V & V for integration into surrounding SoP (e.g. hospital network)
- End-to-end testing of system-of-system functionality
- V&V for constituent system
- Verifies and validates single functions but not integration in SoP



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

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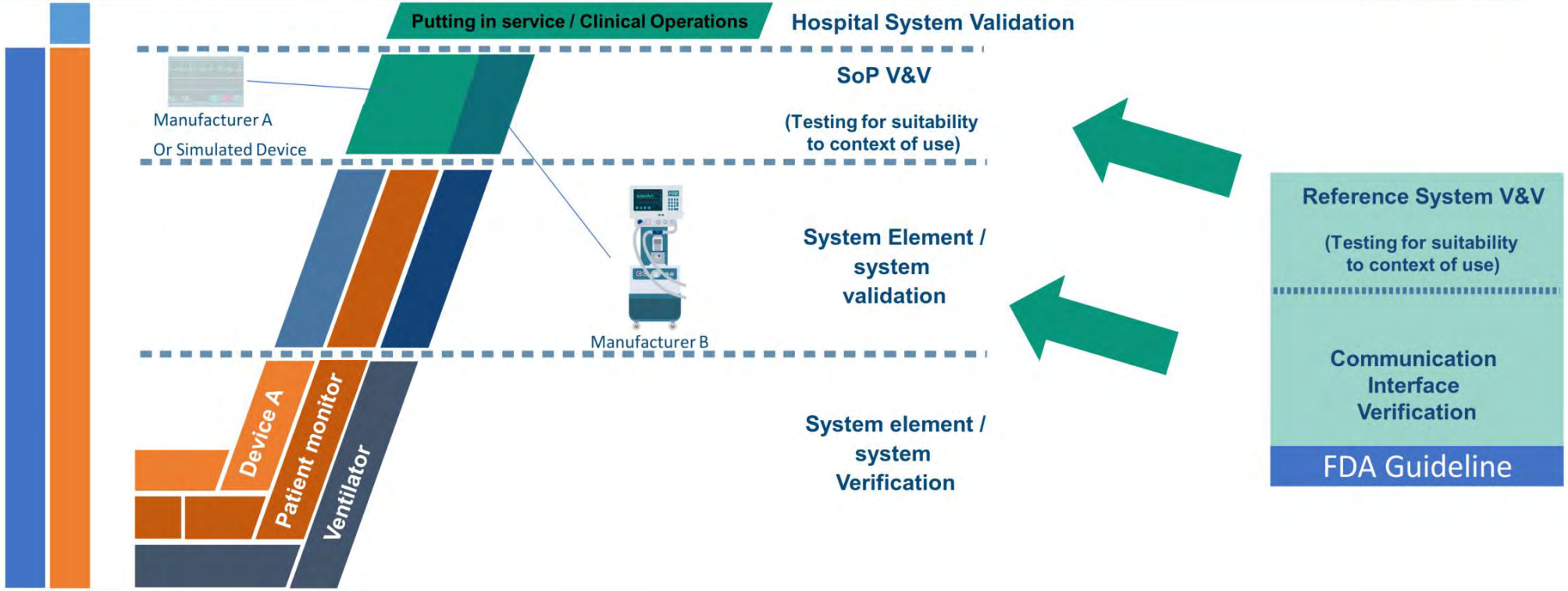
MedTech Regulatory Pathway – Core to SDC/SDPi Specifications

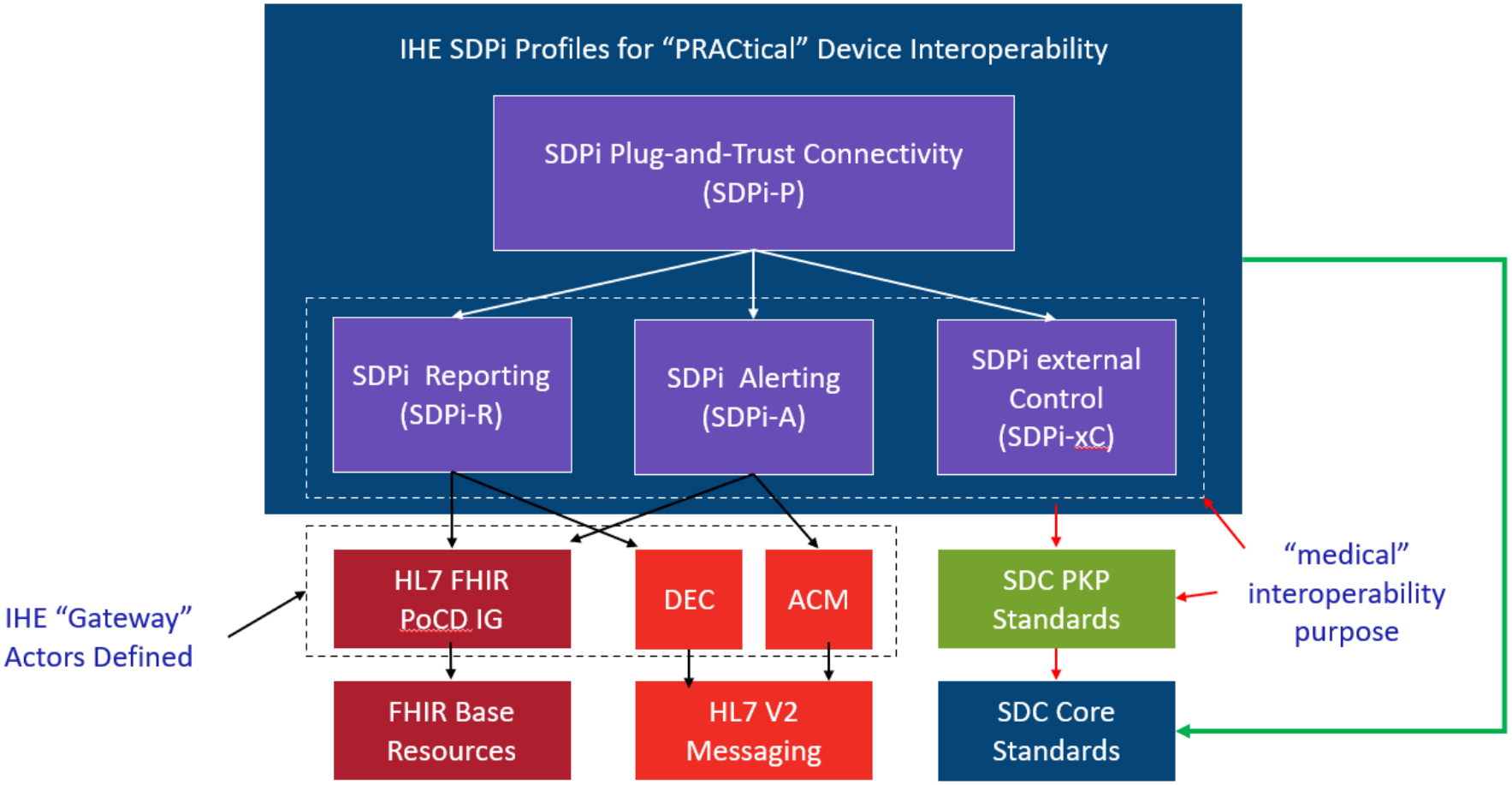
Verification and validation responsibilities

Example Medical Device



FDA Guideline also applicable for CE market?

MedTech Regulatory Pathway – Core to SDC/SDPi Specifications



Integrating the PKP Requirements – across the (4) Interoperability Key Purposes – into the (4) IHE SDPi specifications …

Enables IHE Conformity Assessment to ensure that the "decoupled" system has implemented the required quality/regulatory risk control measures

Addressing the EU Medical Device Regulation (MDR:2017)

European MedTech industry must support the latest EU MDR requirements, including:

- ✓ "*Regulations*" vs. Directives ("MDD" previously)
- ✓ *Increased evidence* supporting ALL intended use "purposes"
- ✓ *Increased post-market surveillance* (esp. for intelligent tech)
- ✓ *Product registration database* – euroUDI? SaMD / Med "Apps"?
- ✓ New cohort of "*recognized standards*" (100's!) proposed
- ✓ …

Source: **eumdr.com**

May 2021:

- Notice to stakeholders: Status of EU-Switzerland mutual recognition agreement on medical devices.
- **Press release 26 May 2021:** announcing **Stronger rules on medical devices** (EU MDR) have entered into application.
- Publication of MDCG 2021-8 Clinical investigation application/notification documents.
- The UDI Helpdesk is live. Click here. The UDI Helpdesk is intended to help economic operators implement the requirements of the new UDI system.

April 2021:

- Publication of MDCG 2021-6 Questions & Answers regarding clinical investigation.
- Publication of MDCG 2021-5 Guidance on standardisation for medical devices.
- Publication of MDCG 2021-4 Application of transitional provisions for certification of class D in vitro diagnostic medical devices (according to Regulation (EU) 2017/746).
- Update to MDCG 2018-1 Rev 4 Guidance on basic UDI-DI and changes to UDI-DI.
- Publication of a Factsheet on Class 1 Medical Devices.

March 2021:

- Publication of MDCG 2021-3 Questions and Answers on Custom-Made Devices.
- Publication of MDCG 2021-2 Guidance on state of the art of COVID-19 rapid antibody tests.
- Publication of an Infographic "Is your software a Medical Device?"

February 2021:

- Publication of MDCG 2021-1 Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional.

Big Ideas! enabling “Regulatory Submission Ready” IHE CA

Premise is simple: Can we craft IHE profiles and testing such that IHE conformity assessment (CA) test reports can be directly included in regulatory submissions?

Answer: Yes! But it will take some innovative thinking and a few: Big Ideas!

Big Idea: Safe, Effective, Secure + Medical Device Interoperability (SES+MDI)

SES+MDI – *Parallel Universe Problem*

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

MDI: ISO/IEEE 11073 ***SDC***, IHE ***SDPi*** & HL7 ***FHIR Interoperability Standards***

+

SES: ISO/IEC ***JWG7 Safety, Effectiveness & Security Standards***?

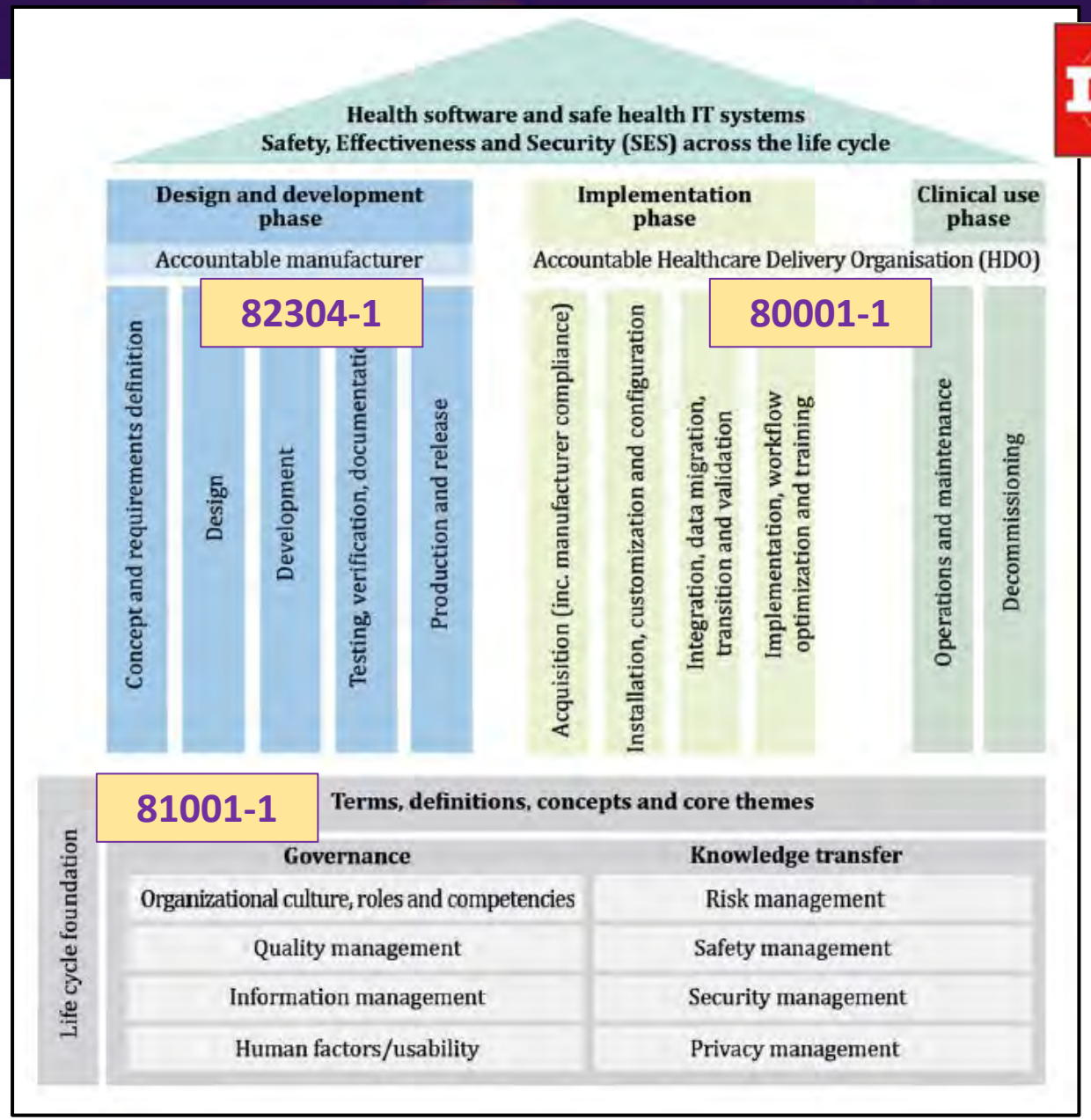
Big Idea: Leveraging the SES "Temple" Model

The JWG7 SES "***Temple Diagram***" identifies core topic / subject areas …

… standardized in ***81001-1*** …

… over which you can "make sense of" ***specific standards*** …

… all with a process / quality / regulatory / legal ***"SES" community*** subject focus



ISO HEALTH INFORMATICS TC 215

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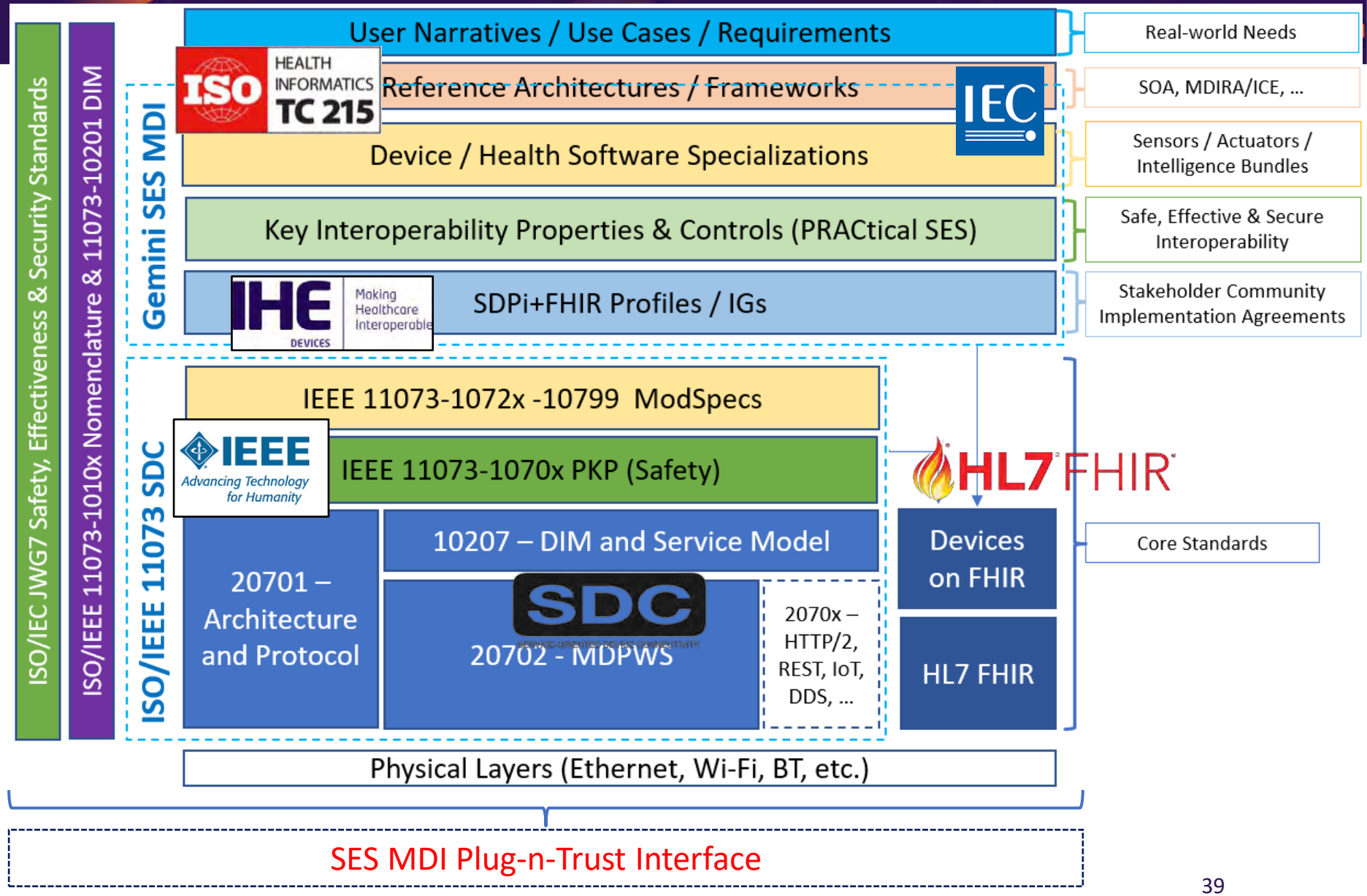
Big Idea: SES+MDI Hanging Gardens Framework

Consider the ***SES MDI "Hanging Gardens" Framework*** …



(More @ https://confluence.hl7.org/x/4ijxB)

Big Idea: Establishing an SES+MDI Framework for Trusted Interoperable Product Decoupling

Addressing the SES MDI Ecosystem *"Trust Gap"* …

ISO/IEC JWG7 Safety, Effectiveness & Security Standards

ISO/IEEE 11073-1010x Nomenclature & 11073-10201 DIM

Gemini SES MDI

- User Narratives / Use Cases / Requirements
- Reference Architectures / Frameworks
- Device / Health Software Specializations
- Key Interoperability Purposes (PRACtical KIP)
- SDPi+FHIR Profiles / IGs

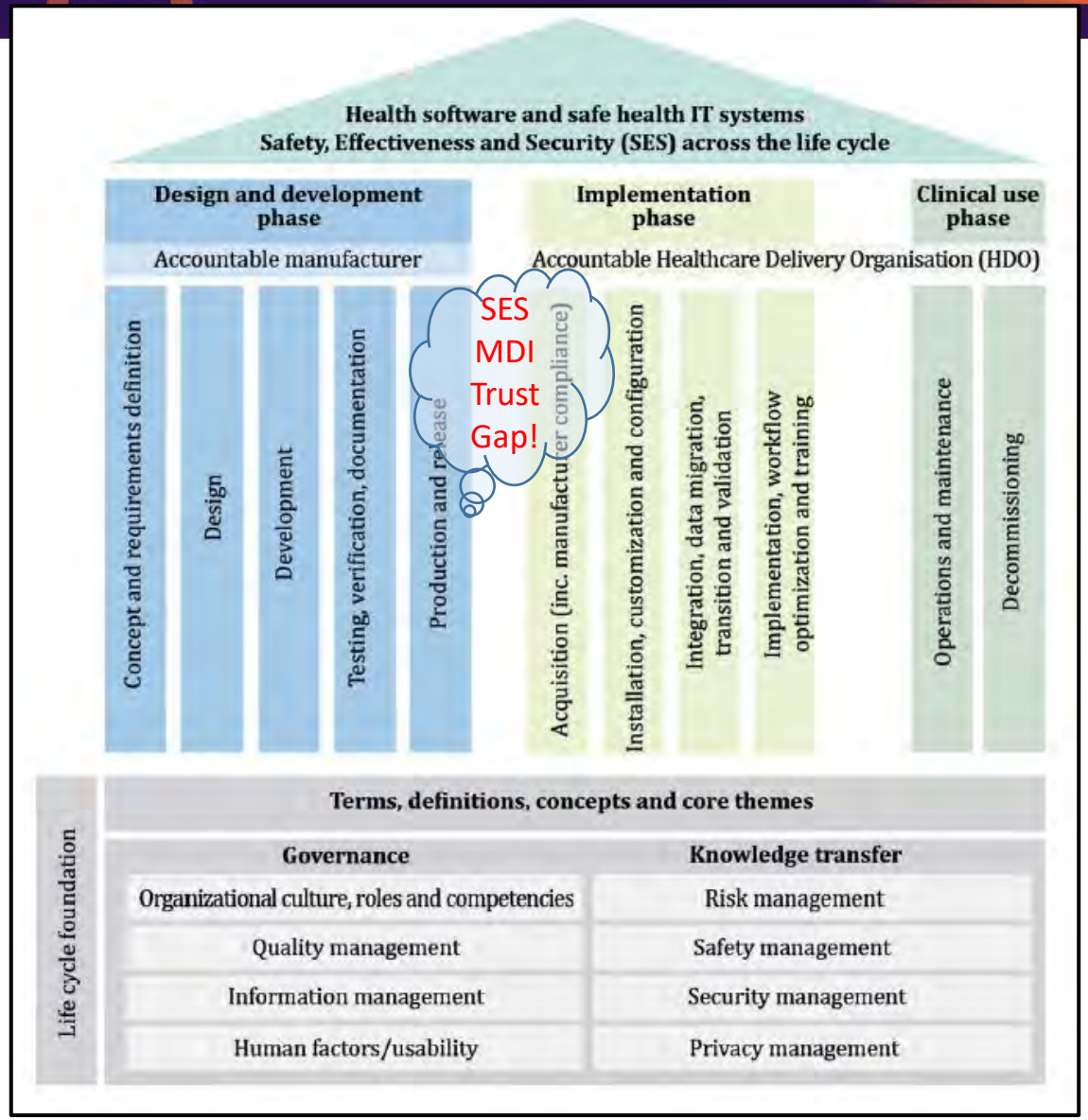
ISO/IEEE 11073 SDC

- IEEE 11073-1072x -10799 ModSpecs
- IEEE 11073-1070x PKP
- 20701 – Architecture and Protocol
- 10207 – DIM and Service Model
- 20702 - MDPWS
- 2070x – REST, IoT, DDS, …

Devices on FHIR

HL7 FHIR

Physical Layers (Ethernet, Wi-Fi, BT, etc.)



Big Idea: Requirements Interoperability + Model-Centric + Regulatory Ready (RI+MC+RR)

Pragmatic "Big Idea!" initiatives to realize SES+MDI – RI+MC+RR

- **Requirements Interoperability** (RI)
  Establishing traceability, test coverage & conformity from the device interface to multiple standards (1:m)
- **Model-Centric** (MC)
  Establishing a computable, model based "single source of truth" specification that supports all stakeholders' needs
- **Regulatory Ready** (RR)
  IHE Conformity Assessment (CA) that provides "regulatory submission ready" test reports

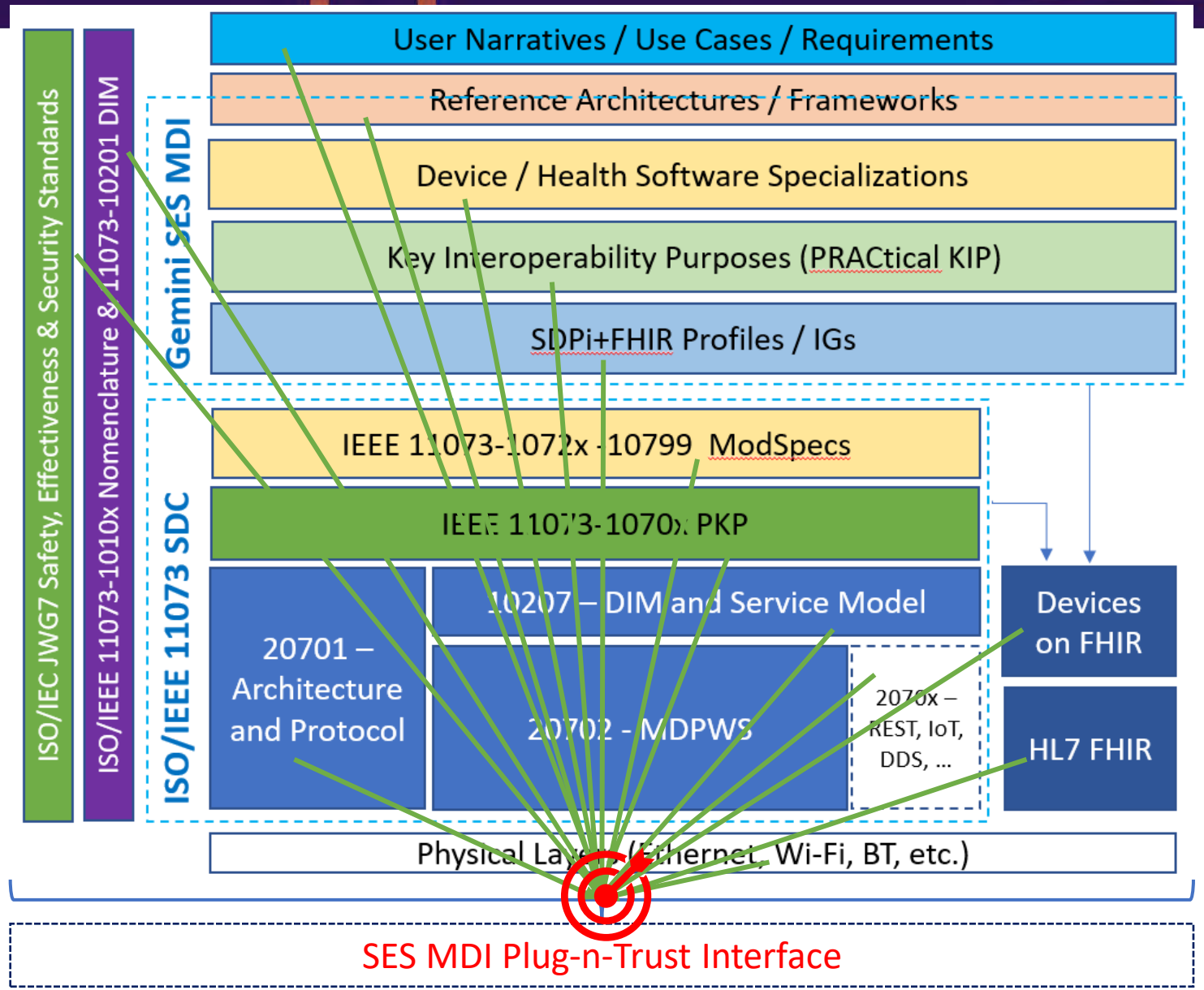
Big Idea: Requirements Interoperability

Innovators Challenge:

One Interface / <X> Standards

The Hanging Gardens framework provide a perspective on the various standards and specifications that are ***integrated into each individual product's interface*** …

One Layer & One Standard at a Time!



Big Idea: Requirements Interoperability

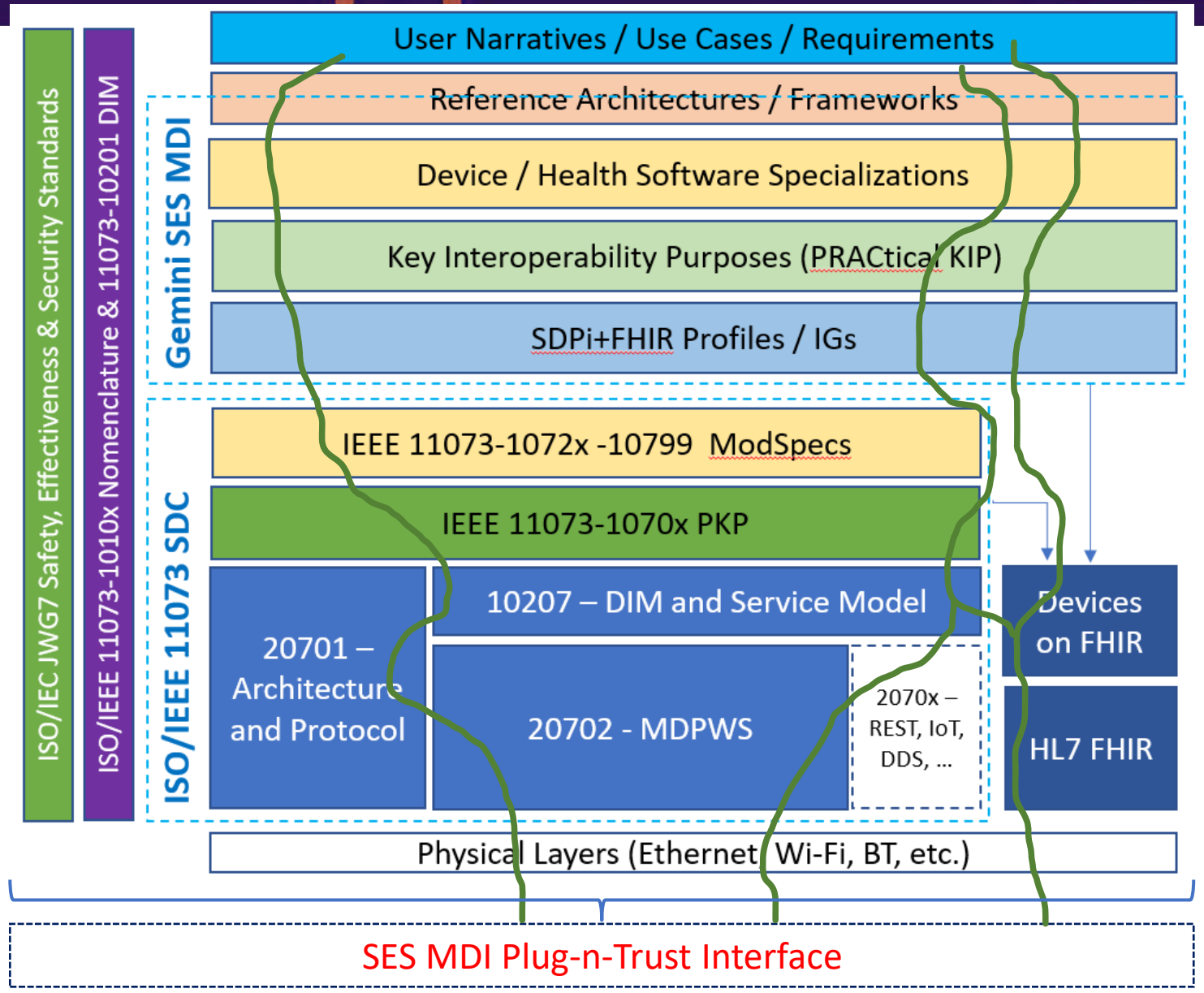
Innovators Hope:

Requirements Interoperability

The Hanging Gardens framework can also enable a much simpler, streamlined requirements pathway through ***through each standard's needs & capabilities*** …

… the ***Happy Path*** charts ***traceability*** from the interface back to each standard specification and their ***requirements***

How hard can it be?!



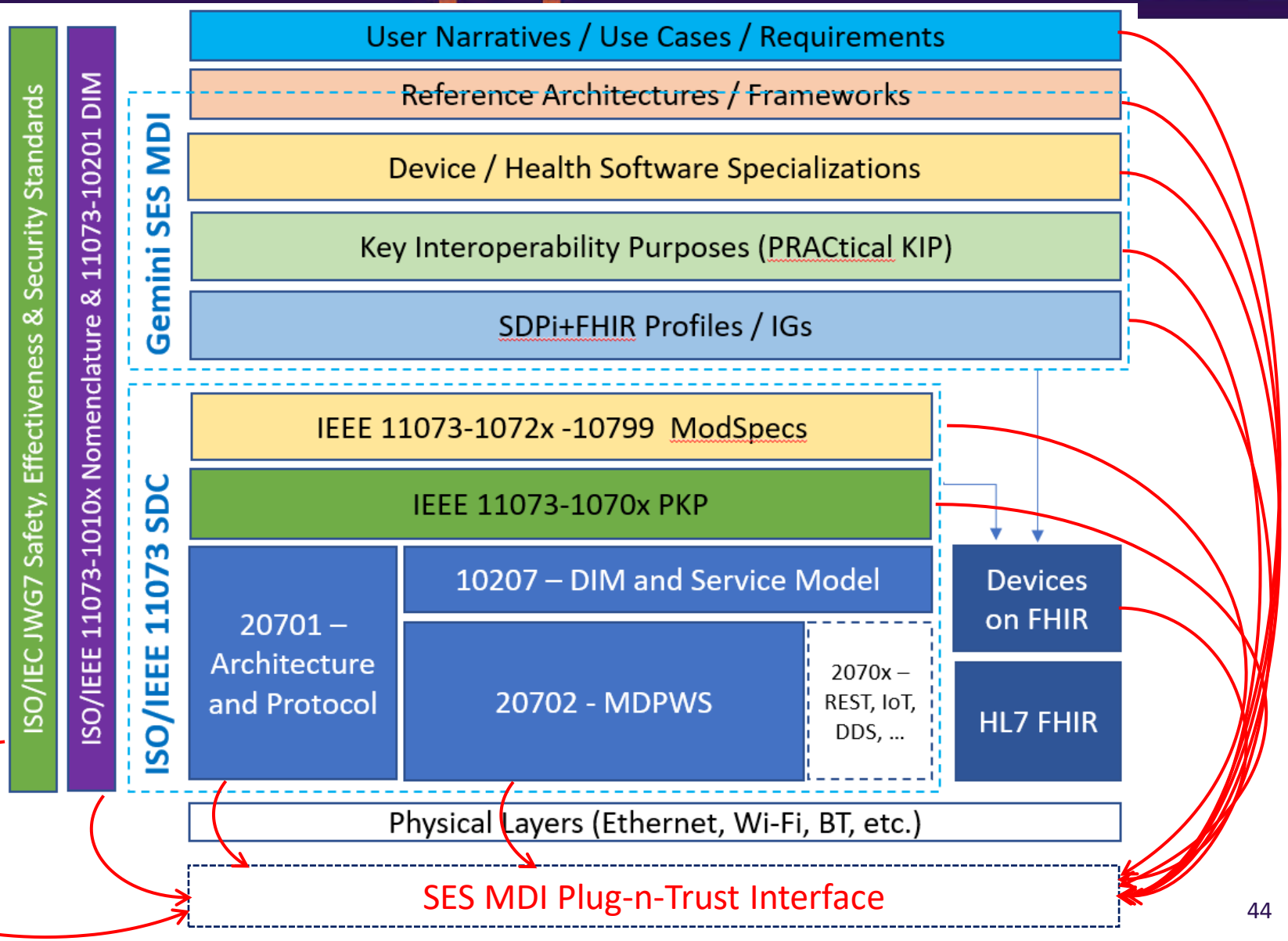
Big Idea: Requirements Interoperability

In the absence of a clearly defined ***Requirements Interoperability model*** to enable connection between standards …

How hard can it be?

PRETTY HARD!!!

(via **Ad Hoc Requirements *Integration***)



Big Idea: Requirements Interoperability + Model-Centric "Single Source of Truth" Computable Specifications!

Question: How are MedTech developers managing the complexity and cost of next generation solutions?

Answer:

- **MBSE** Model-based Systems Engineering (methodology)
- **SysML** OMG Systems Modeling Language (UML profile)
- **Tooling** Automation tool chains supporting

Question: Can standards specification move from document-centric to model-centric to support these complex next generation technologies?

Answer:

#1 MBSE / SysML / Tooling has advanced to make this 100% viable

#2 *Without transitioning* from document-centric *to computable, model-centric "single source of truth" specifications … standards adoption will continue to be **abysmal**!*

Big Idea: Requirements Interoperability + Model-Centric "Single Source of Truth" Computable Specifications!

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Definition
"Model Based Systems Engineering"

The formalized application of modeling to support ..

…system requirements, architecture, design, analysis, verification and validation activities

…beginning in the conceptual design phase and continuing throughout development and later life cycle phases

INCOSE Systems Engineering Vision 2020 (2007)

Big Idea: Requirements Interoperability + Model-Centric "Single Source of Truth" Computable Specifications!

Document-based vs. Model-based approach

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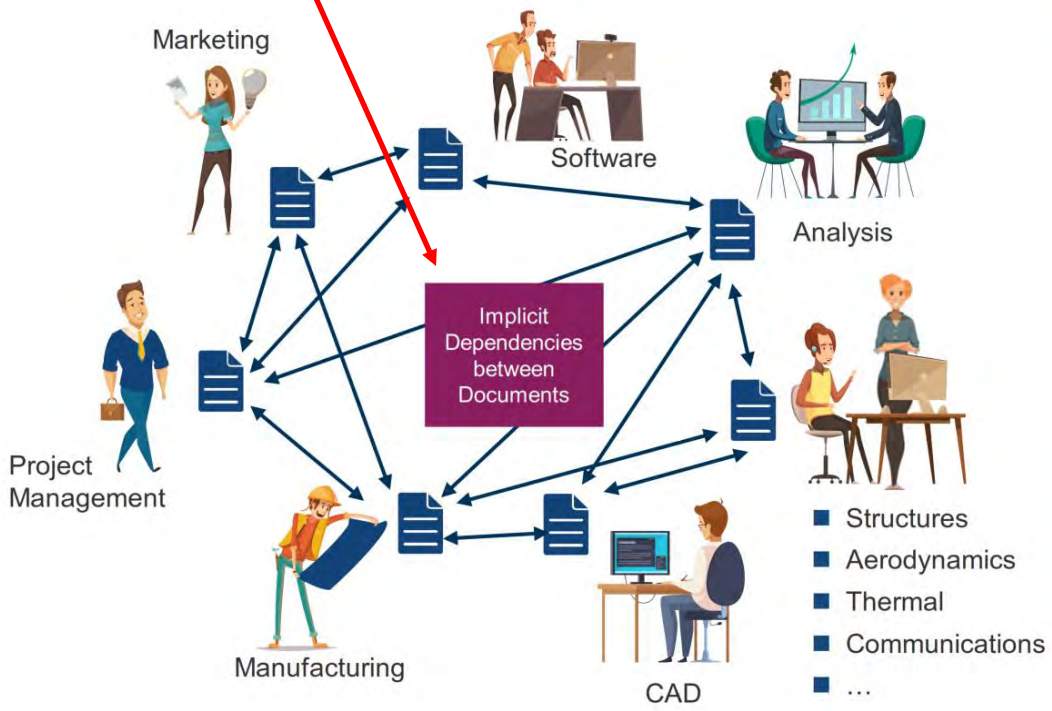
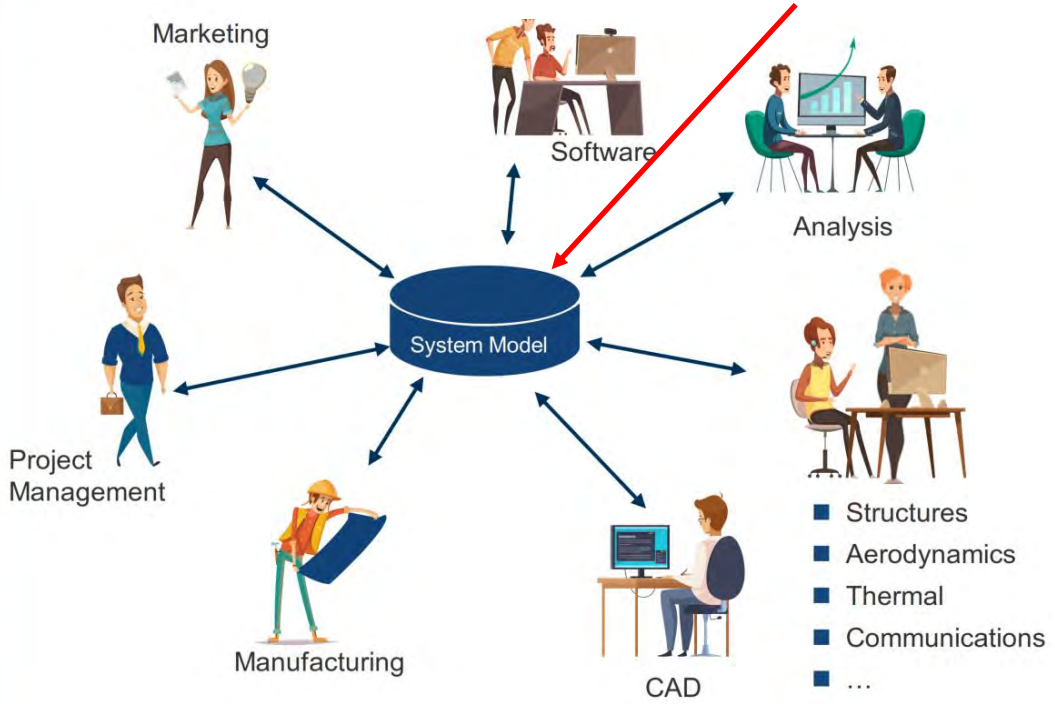
Standards remain document-centric



Traditional systems engineering

Gemini SDPi+FHIR must transition to model-centric



Model-based systems engineering

Madni et.al. 2019

Big Idea: Requirements Interoperability + Model-Centric "Single Source of Truth" Computable Specifications!

Aspects of Practical MBSE Application: Publishing & Reviewing

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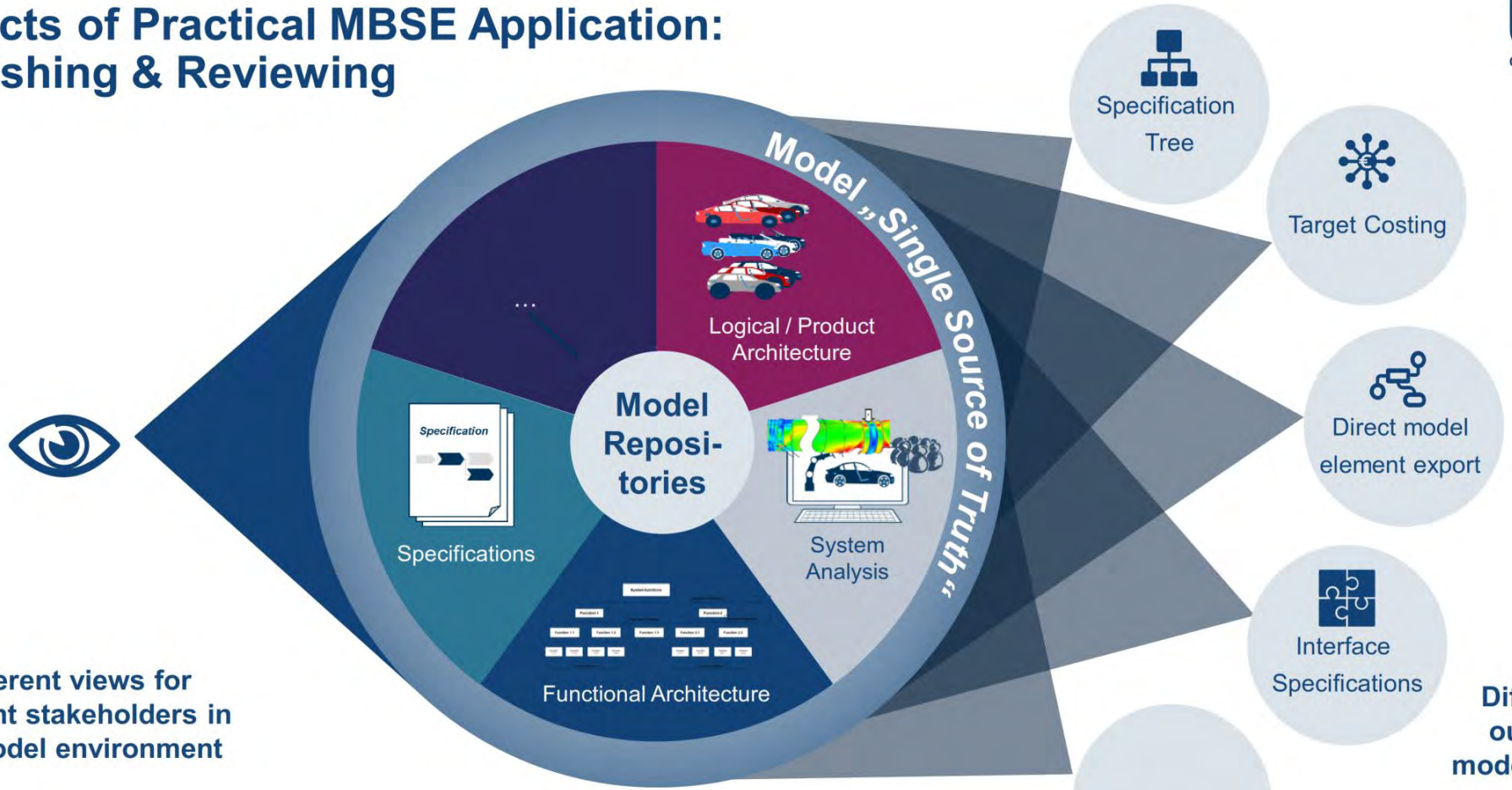
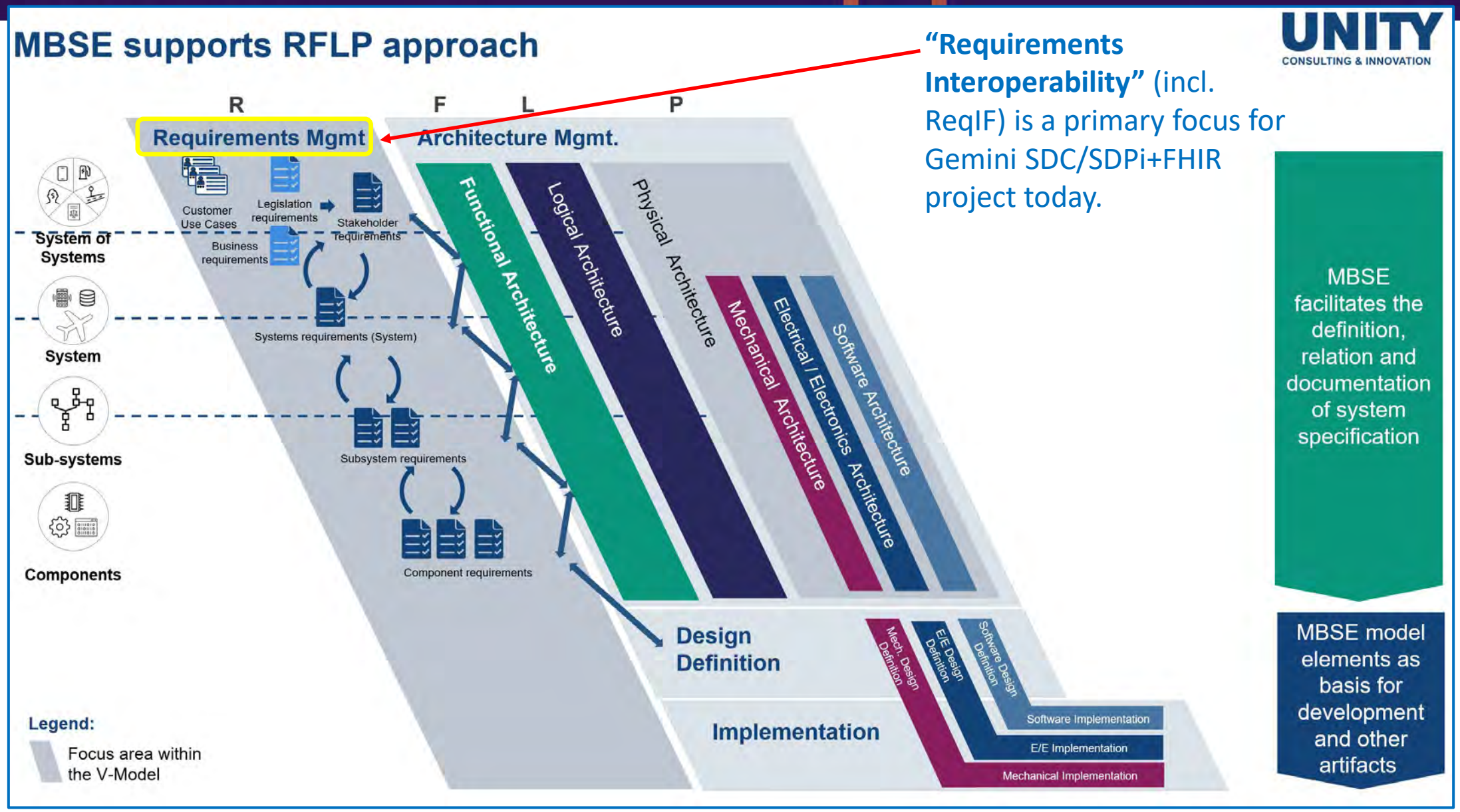


Different views for different stakeholders in the model environment

Different views outside of the model environment

The MBSE approach interfaces well even with traditional information structures. It's a question of customization.

Big Idea: Requirements Interoperability + Model-Centric "Single Source of Truth" Computable Specifications!



Big Idea: Requirements Interoperability + Model-Centric + Regulatory Ready

Question: Can IHE Conformity Assessment of SDC/SDPi+FHIR specifications provide test reports that can be directly included in regulatory submissions?

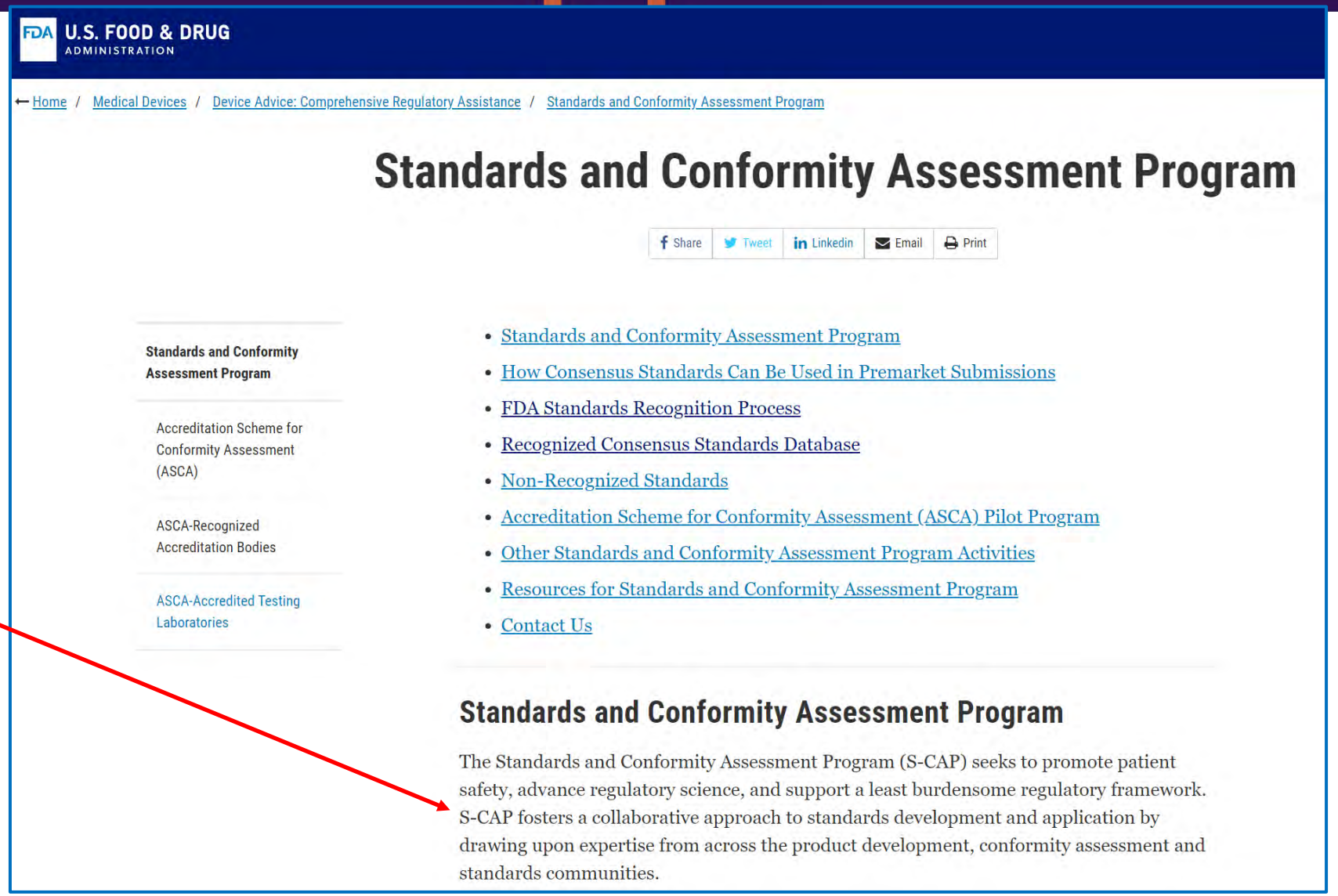
Answer:

- 11073 SDC has a comprehensive integrated SES MDI regulatory pathway
- IHE SDPi+FHIR profiles fully integrate the foundational
- Requirements Interoperability provides the traceability and coverage required to claim conformity to key SES standards and the MDI risk mitigations
- MBSE / SysML not only increases overall quality across ALL implementers, but enables simulation and other Systems of Products validation techniques

Question: But what is the basis for confidence that a regulatory agency will *recognize* and *accept* **IHE SDPi CA Test Reports** in submissions as *"sufficient" evidence of SES MDI*?

Big Idea: Requirements Interoperability + Model-Centric + Regulatory Ready

U.S. FDA S-CAP program lays the foundations for determing if and how SES MDI CA test reports could be used in regulatory submissions …



FDA U.S. FOOD & DRUG ADMINISTRATION

← Home / Medical Devices / Device Advice: Comprehensive Regulatory Assistance / Standards and Conformity Assessment Program

Standards and Conformity Assessment Program

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Standards and Conformity Assessment Program

Accreditation Scheme for Conformity Assessment (ASCA)

ASCA-Recognized Accreditation Bodies

ASCA-Accredited Testing Laboratories

- Standards and Conformity Assessment Program
- How Consensus Standards Can Be Used in Premarket Submissions
- FDA Standards Recognition Process
- Recognized Consensus Standards Database
- Non-Recognized Standards
- Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program
- Other Standards and Conformity Assessment Program Activities
- Resources for Standards and Conformity Assessment Program
- Contact Us

Standards and Conformity Assessment Program

The Standards and Conformity Assessment Program (S-CAP) seeks to promote patient safety, advance regulatory science, and support a least burdensome regulatory framework. S-CAP fosters a collaborative approach to standards development and application by drawing upon expertise from across the product development, conformity assessment and standards communities.

Source: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program

Big Idea: Requirements Interoperability + Model-Centric + Regulatory Ready

U.S. FDA ASCA Pilot Program leverages the same **NIST Expertise** and **ISO 17000 CA "pedigree"** as the **IHE CA program!**

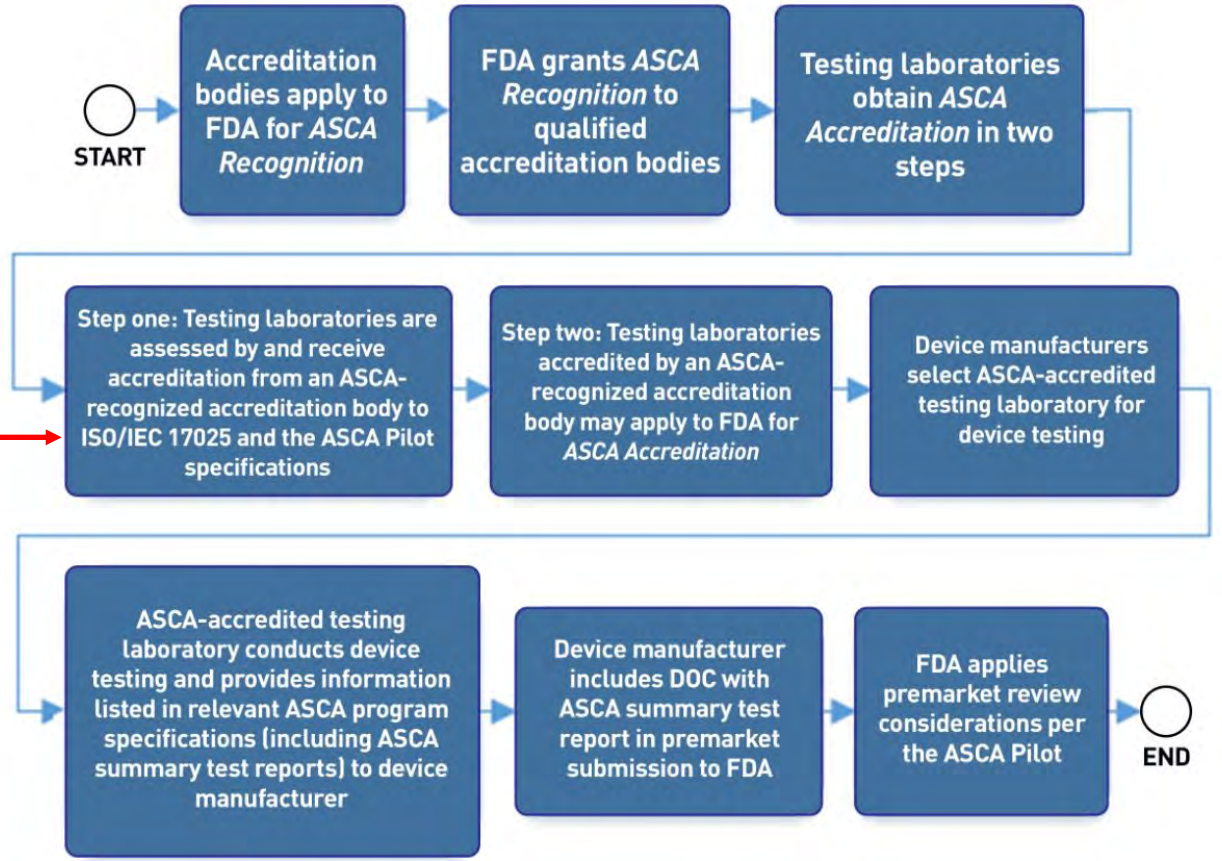

Figure: Process flow for the ASCA Pilot

See April 2021 FDA Webinar for more complete information @

https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-asca-pilot-streamlining-conformity-assessment-device-submissions#materials

Source: https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

Conclusion: *"Are we there yet?"*

Arguably, no BUT we are closer than ever before and are closing fast on the long sought-after goal of "Plug-and-Trust" Safe, Effective & Secure (SES) Medical Device Interoperability (MDI) …

Conclusions

IHE International & IHE Catalyst:

Advancing Interoperable MedTec Solutions with *"Regulatory Submission Ready" Conformity Assessment*

- ISO/CEN/*IEEE 11073 SDC Standards* provide true ***Plug-and-Trust*** *Interoperability*
- *IHE-HL7* **Gemini** *Device Interoperability using SDC/***SDPi+FHIR** will deliver the profiles needed to advance *interoperable* **MedTech** *product* implementation and deployment
- "**SES MDI**" closes the "*interoperability trust gap*" between tech & quality standards
- **RI+MC+RR** – Requirements Interoperability + Model-Centric + Regulatory Ready provide new value for all implementers
- Integration of a *regulatory pathway* into the standards & profiles + engagement with *notified bodies* + pilot projects such as the **FDA ASCA** set stage for decoupled products
- Integration with *total product lifecycle* management *automation tool chains*
- **IHE Conformity Assessment** + **IHE Catalyst** support add the last pieces of the puzzle!

Connect to Other IHE Europe Experience Sessions

Tomorrow's IHE Europe Experience Sessions will fill in the rest of the picture for:

- ***IHE Catalyst***
- ***IHE Testing (CA) Continuum***

Experience Sessions Thursday, 17 June

The IHE-Europe Experience Programme is online! Register now for the sessions of your interest.

IHE EUROPE EXPERIENCE SESSIONS 17 JUNE

14:00 - 15:00	**IHE Catalyst: Its value for users, governments and vendors** *Claudio Saccavini, IHE Catalyst* *Lapo Bertini, IHE Catalyst* *Register here*
16:00 - 16:30	**All you want to know on the IHE Testing Continuum** *Lapo Bertini, IHE-Services* *Alexander Berler, IHE-Services* *Register here*

IHE EUROPE EXPERIENCE SESSIONS 15-17 JUNE 2021

Questions & Answers

IHE International & IHE Catalyst:

Advancing Interoperable MedTec Solutions with

"Regulatory Submission Ready" Conformity Assessment

OR.NET e.V.

IHE International sponsor of the
IHE Devices Domain / Device Point-of-care
Interoperability (DPI) Program

Dr.-Ing. Stefan Schlichting

OR.NET: stefan.schlichting@ORNET.org
Unity: Stefan.Schlichting@unity.de
+49 162 2465894
Lübeck, Germany

UNITY CONSULTING & INNOVATION

Todd Cooper

OR.NET: Todd@ORNET.org
TSF: Todd@TrustedSolutionsFoundry.com
+1 858.442.9200
San Diego – ***«America's Finest City!»***

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