



# IHE-HL7 Gemini SES+MDI – *From Use Cases to Test Reports –* 2022 RI+MC+RR Strategy

Updated: 2022.05.13



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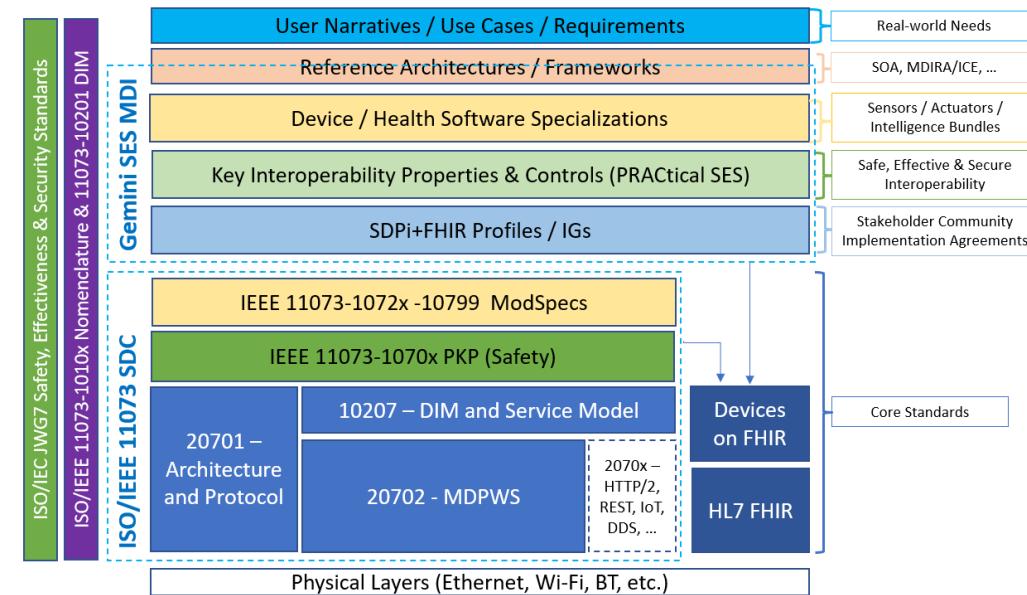
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# Gemini SES+MDI

## From Use Cases to Test Reports

## 2022 RI+MC+RR Strategy



**Landscape Outlook for SDPi Specification & Testing in 2022**

**SDPi 1.0 – RI+MC – Basic Support**

**SDPi 1.0 – Testing & CA & Tooling – Basic Support**

**Possibilities but not Probabilities but .. *Opportunities?*!**

# Gemini SES+MDI – 2022 RI+MC+RR Strategy –

## *Landscape Outlook for SDPi Specification & Testing in 2022*

With a goal of publishing the SDPi 1.0 in 2022-Q2 and achieving first IHE CAT testing before the end of 2022 ... and given the *realities of what we have NOW* vs. our long-term vision for RI+MC+RR ... **what's the near-term strategy?**

# SDPi 1.0 Spec-to-Test – ‘22 Landscape Realities

## 2022 Landscape realities ...

- ✓ Gemini SES+MDI *Vision is solid*
- ✓ Requirements Interoperability + Model Centric + Regulatory Ready Aspirations ... *are solid*
- ✓ Increased testing rigor from messages to semantics to clinical context/function ... *is solid*
- ✓ 3-Year Roadmap & SDPi 1.0 “Basic” Capabilities + Testing Targets are settled ... *clock is ticking!*
- ✓ Gazelle is what it is ... today ... *Cannot wait for evolution to NextGen platform for SDPi 1.0*
- ✓ IHE Test Plan / Case formalization & script automation ... *remain mostly undefined*
- ✓ Support for HL7 FHIR-based IHE Profiles & Testing ... *has “taken the oxygen out of the room”*
- ✓ MedTech community of interest – esp. SES ... *just starting to get momentum*
- ✓ Work teams are established – SDPi Tech, Ecosystem Pathway, CA & Tooling ... *we are it!*
- ✓ MS Word based specifications remain the best path forward ... *but “toward MC” can be started*

# SDPi 1.0 Spec-to-Test – ‘22 Landscape Realities

**Good News!!!**

Working within these landscape realities...

**‘22 Gemini SES+MDI Roadmap  
“Basic” SDPi 1.0 can be  
successfully achieved**

# Gemini SES+MDI – 2022 RI+MC+RR Strategy –

## *SDPi 1.0 – RI+MC – Basic Support*

Given the landscape before us at the start of 2022, what can we *realistically* achieve for advancing the requirements interoperability and model centric initiatives? *What does “basic support” look like?*

# SDPi 1.0 & RI+MC – “Basic” Support

## What does SDPi 1.0 “Basic” Support look like?

- ✓ SDPi 1.0 Specification –
  - ❖ Word-based – > 200 page supplement “skeleton” already crafted
  - ❖ Publish as PDF (traditional) – *optionally* HTML via NIST V2plus Tooling (*adapted*)
  - ❖ 2022 Capabilities identified in the roadmap are detailed in the TF supplement
- ✓ Requirements Interoperability –
  - ❖ RI UML Model linked to Word constructs (Styles / Bookmarks / Links)
  - ❖ Requirements sources modeled: Use Cases + Ref'd Standards + SES/RM + Tech Specific
  - ❖ Requirements flow established: TF-1 Appendix B & C to TF-1, TF-2 & TF-3 elements
- ✓ Model Centric –
  - ❖ Basic UML Model for RI + Testing Elements ... *perhaps incl. modeled IHE TF elements*
  - ❖ NIST tooling (for V2plus) leveraged to create initial “single source of truth” database

# SDPi 1.0 & RI+MC – “Basic” Support

## What does SDPi 1.0 “Basic” Support look like?

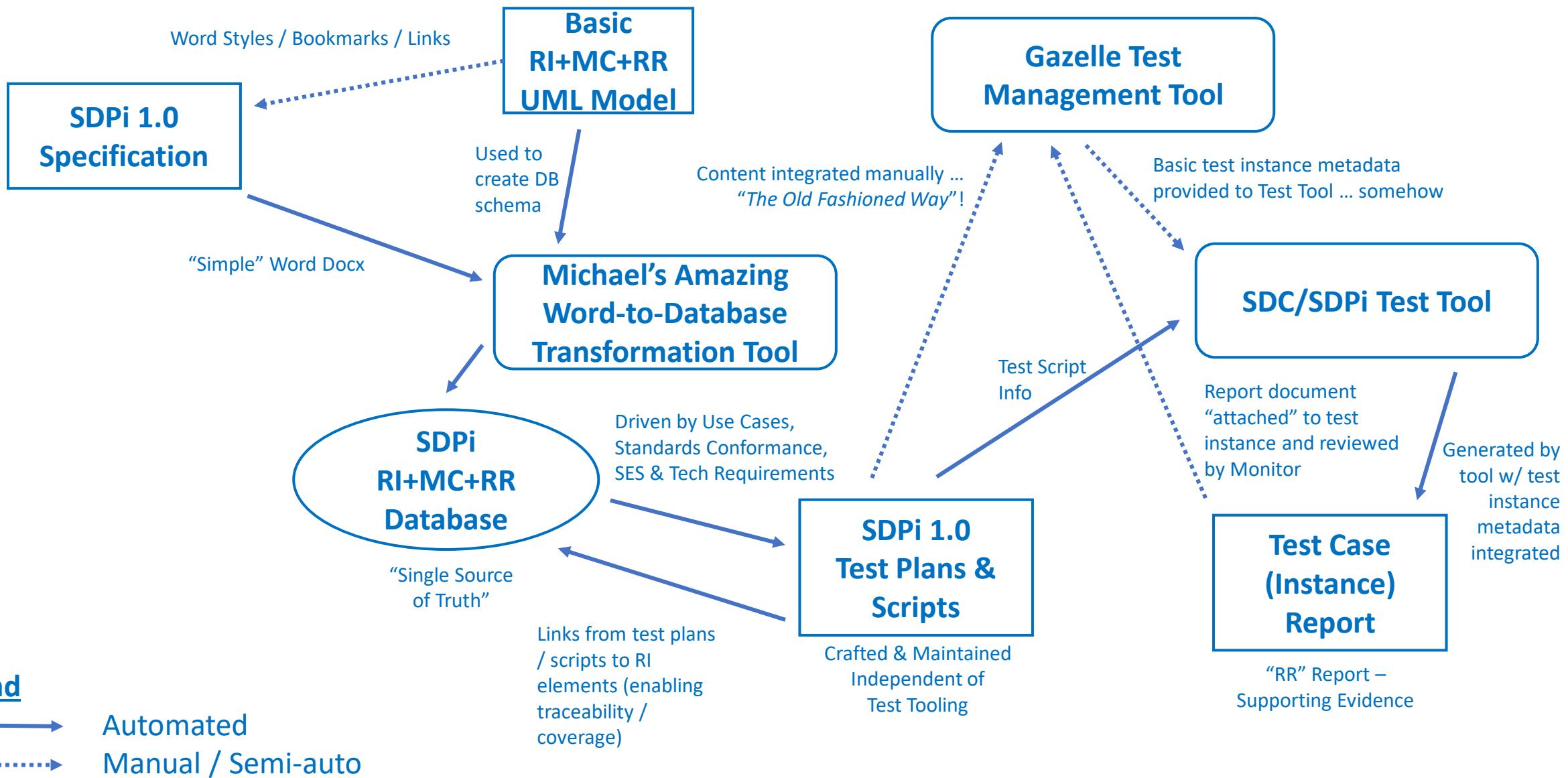
- ✓ Regulatory Ready / CA & Tooling –
  - ❖ Test plans / cases incl. content as for previous profiles ... *but maintained external to test tooling*
  - ❖ IHE PAT events leveraged to continue test tooling & test cases / scripts development
  - ❖ Manually integrate into Gazelle ... *as for previous profiles*
  - ❖ Test plan / case information and linkages integrated into SST Database for basic RI – traceability & coverage from test cases to requirement sources

# Gemini SES+MDI – 2022 RI+MC+RR Strategy –

## *SDPi 1.0 – Testing & CA & Tooling – Basic Support*

With basic support for RI+MC in hand, how might we *advance “RR”* – regulatory submission ready – test reports? Given the early 2022 testing and tooling landscape, how can *test plans, scripts, Gazelle test management, SDC/SDPi tooling* be leveraged to provide basic support for IHE Connectathon events ... in 2022?

# From Specs to Test Reports – “Basic” Strategy

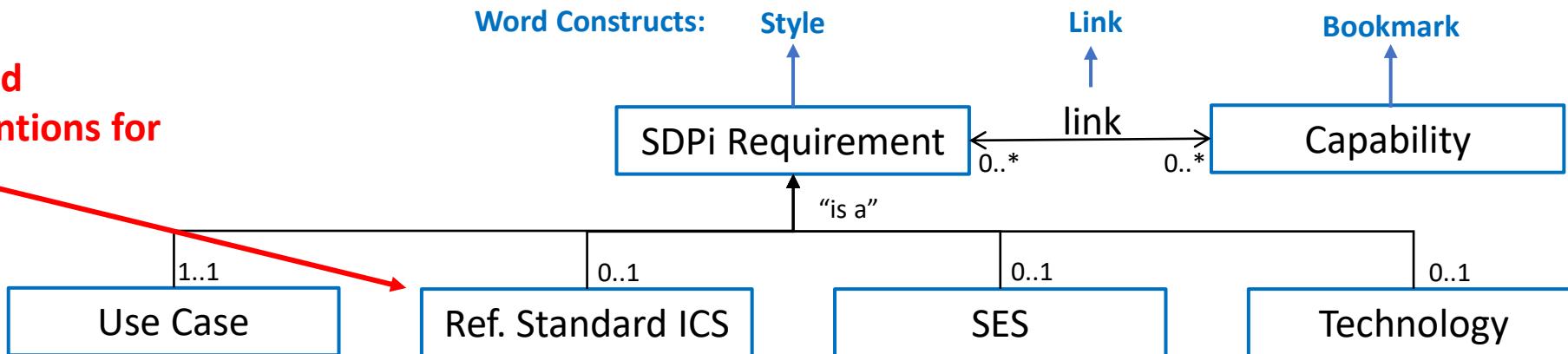


# Spec-to-Test Strategy – RI+MC+RR Model

Basic  
RI+MC+RR  
UML Model

## “Basic” Requirements Interoperability Model for SDPi 1.0 Document:

Need standardized language / conventions for “Requirement” specification



### Considerations / Homework:

Capability provides *implementation* for Requirements

- Word references / links require “bookmarks” – set places in the document (see also PKP examples)
- Word “styles” will require some naming method of each style / link / Bookmark to ensure continuity
- “Capability” Types needed?
- Identifiers / nomenclature required? SDPi Rxxxx? “Link” text?
- Create examples for each, including Text in Word + Word XML rendering
- Bidirectional navigation? Unidirectional (req to capability) sufficient? (Note: 0..\* simply indicates that each end can be linked to / from multiples on the other side of the relationship)

# Spec-to-Test Strategy – RI+MC+RR Model

Basic  
RI+MC+RR  
UML Model



IEEE p11073-10700  
(Draft 1 – Under the Hood)

## ReqIF Example: Requirement related to System Function Contribution

```
<w:p w14:paraId="5672C5E0" w14:textId="77777777" w:rsidR="00743536" w:rsidRDefault="000A5E66">
  <w:pPr> <w:pStyle w:val="IEEEStdParagraph"/> <w:jc w:val="left"/> </w:pPr>
  <w:bookmarkStart w:id="123" w:name="Requirement:R0062"/>
    <w:r> <w:rPr> <w:b/> </w:rPr> <w:t>R0062</w:t> </w:r>
  <w:bookmarkEnd w:id="123"/>
  <w:r> <w:rPr> <w:b/> </w:rPr>
    <w:t> If an SDC PARTICIPANT produces EXCESSIVE LOAD CONDITIONS, each SDC PARTICIPANT that is affected by these conditions SHALL maintain its SYSTEM FUNCTION CONTRIBUTIONS for other SDC PARTICIPANTS.</w:t>
  </w:r>
</w:p>
```

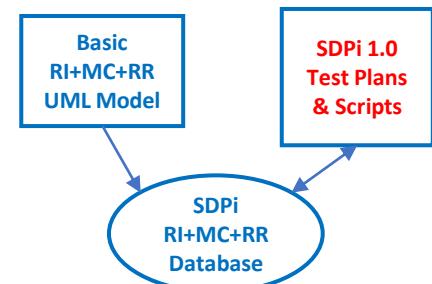


IEEE p11073-10700  
(Draft 1)

- 19    R0062: If an SDC PARTICIPANT produces EXCESSIVE LOAD CONDITIONS, each SDC PARTICIPANT that is affected by these conditions SHALL maintain its SYSTEM FUNCTION CONTRIBUTIONS for other SDC PARTICIPANTS.
- 20
- 21

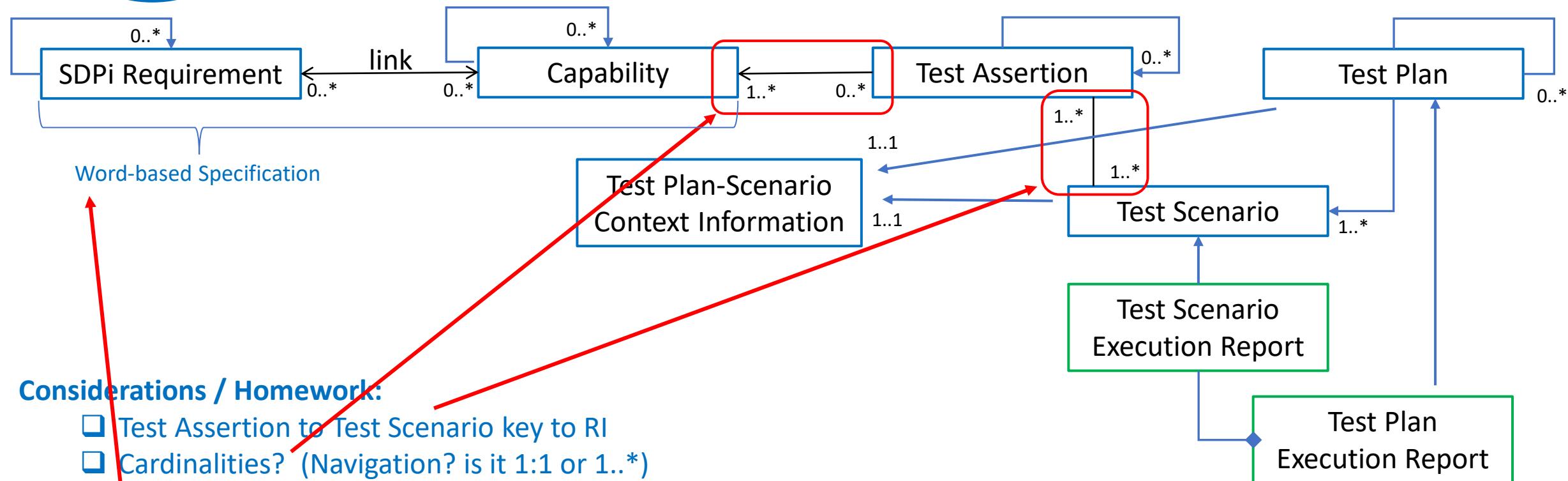
**Observation: ReqIF Used for Document Creation –**  
***Not requirements formalization!***

# Spec-to-Test Strategy – RI+MC+RR Model



## “Basic” Requirements Interoperability Model for *Test Plans/Cases*:

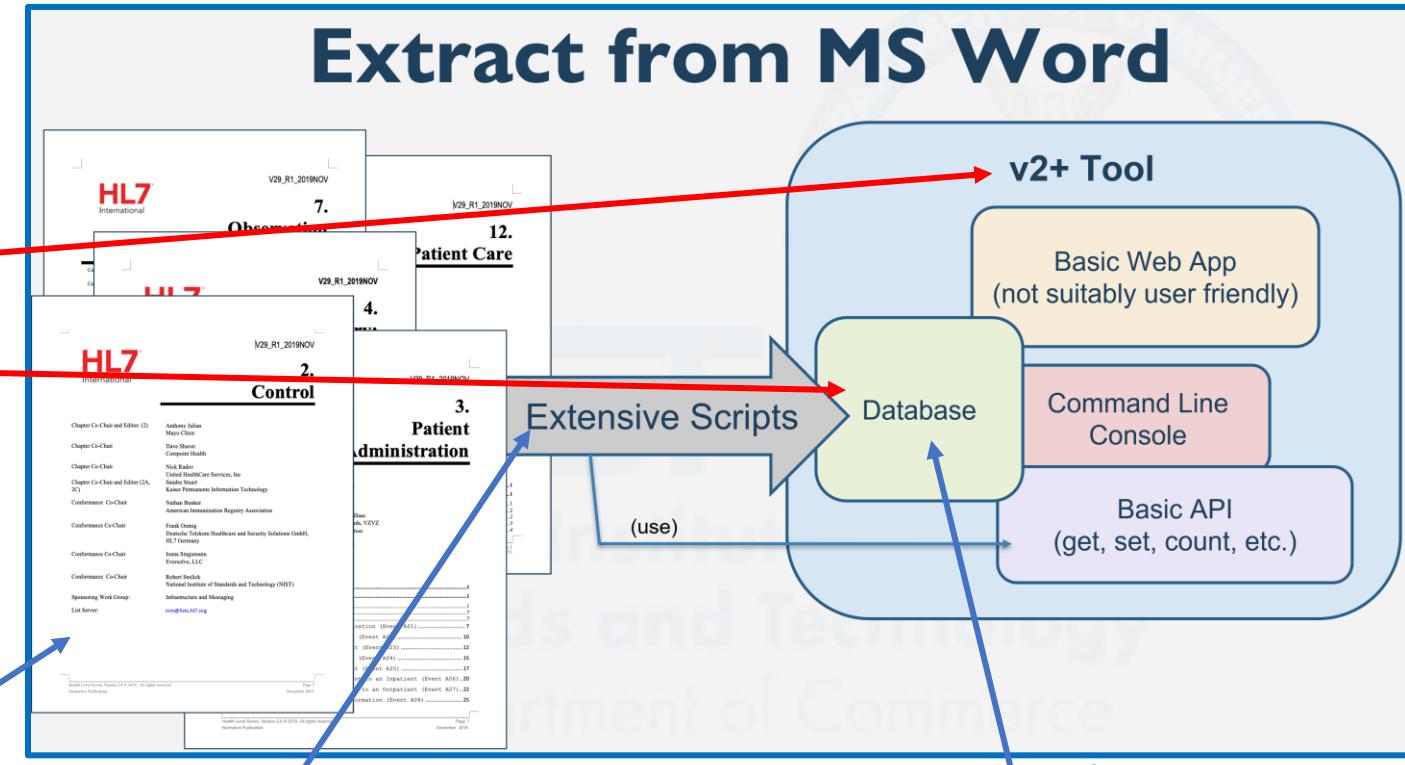
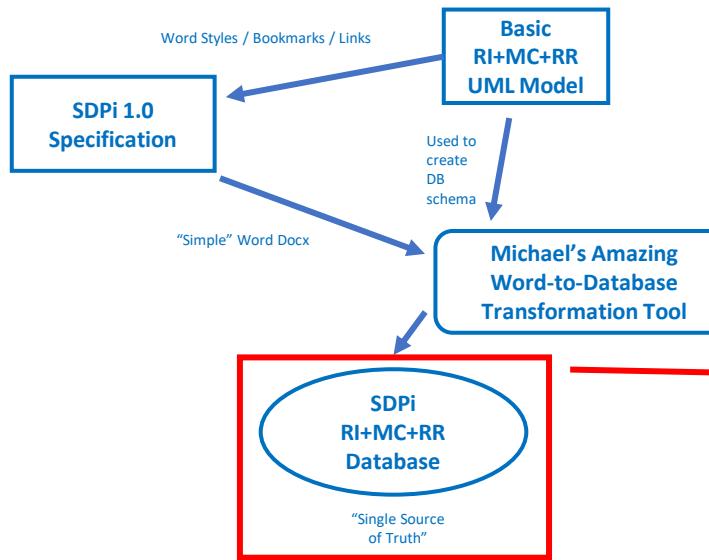
Note: Model for early discussion purposes only (not formal UML!)



### Considerations / Homework:

- Test Assertion to Test Scenario key to RI
- Cardinalities? (Navigation? is it 1:1 or 1..\*)
- Test Assertions are *external* to Word spec. – SST DB or Separate File?
- ...

# Spec-to-Test Strategy – To a SST Database

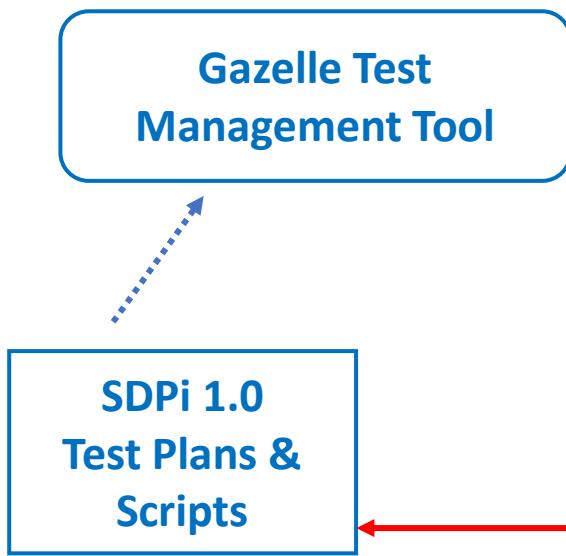


## Road to an SDPi 1.0 Single Source of Truth Database:

- ❖ Build SDPi 1.0 Word document w/ content aligned to *basic* RI+MC(+RR) UML model
- ❖ Utilize “Extensive Scripts” to extract content from Word documents to Database

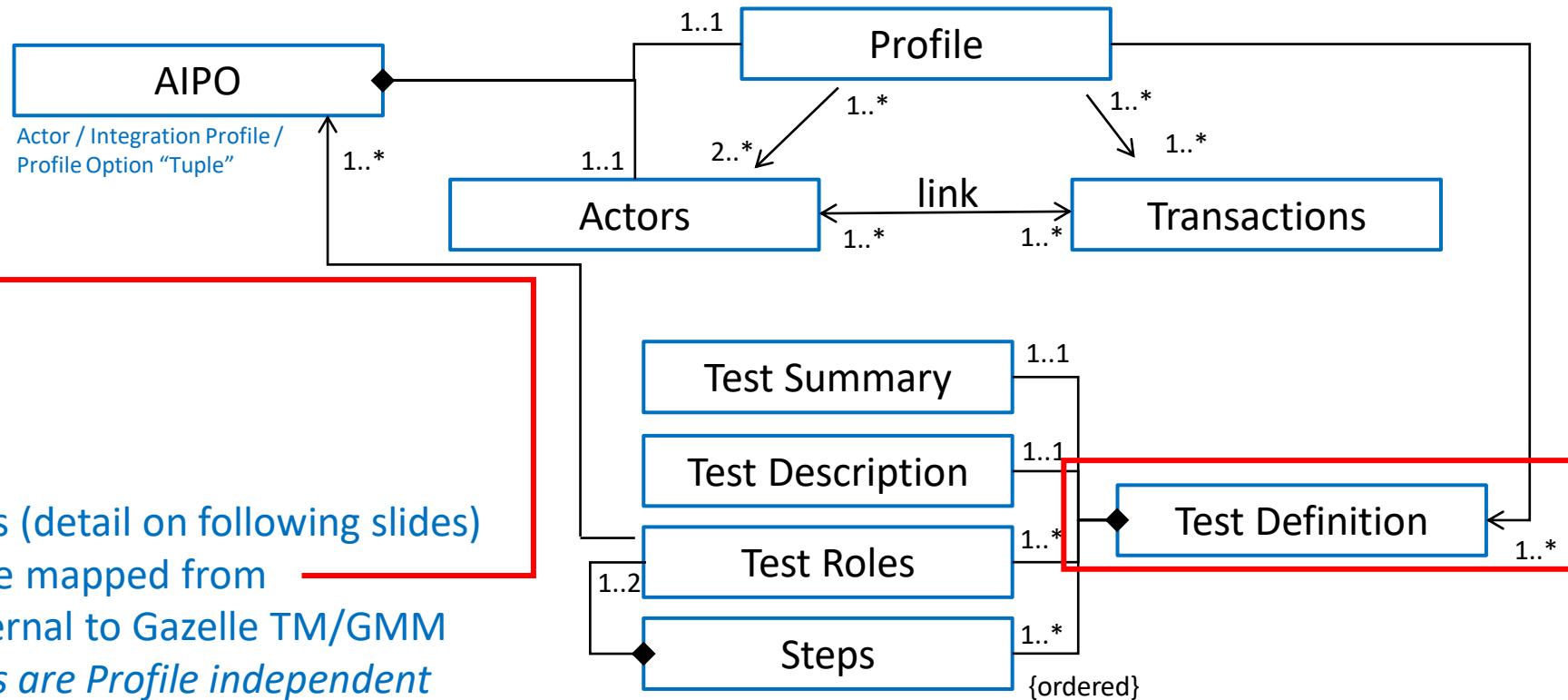
- ❖ Utilize UML Model to create database schema

# Spec-to-Test Strategy – To Gazelle Integration



## Gazelle Master Model (GMM) –

- ❖ GMM content leveraged by all instances of the test management tool
- ❖ All profile & test information entered manually via GMM UX



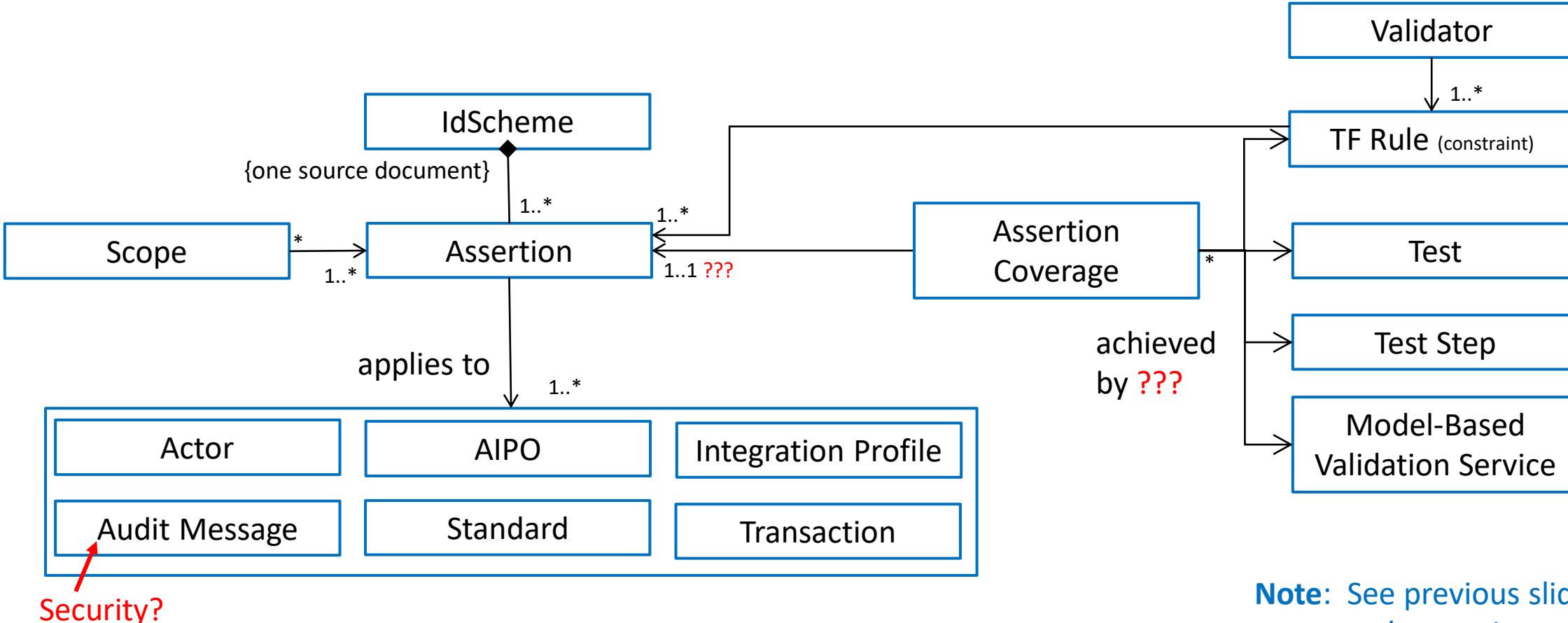
## Gazelle Test Definitions –

- ❖ Consists of four components (detail on following slides)
- ❖ GMM Test elements must be mapped from **Test Definition**
- ❖ Test automation mostly external to Gazelle TM/GMM
- ❖ Note: *Actors & Transactions are Profile independent*
- ❖ Question: “link” cardinality 2..2 or 1..\* or ... ???
- ❖ Question: “links” are also “initiator” & “consumer”

# Spec-to-Test Strategy – *Gazelle Assertion Manager*

## Gazelle Assertion Manager Tool –

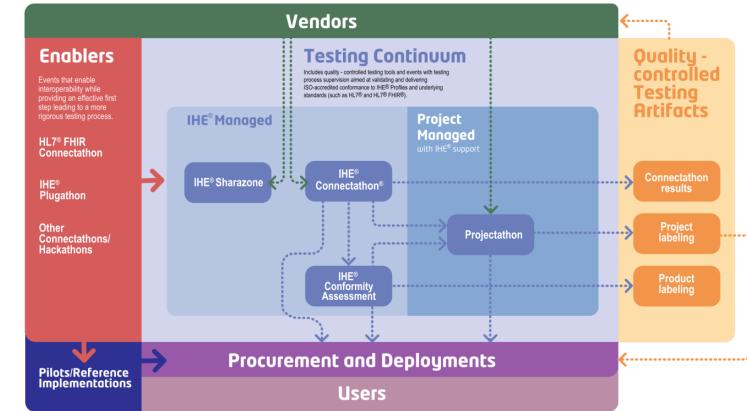
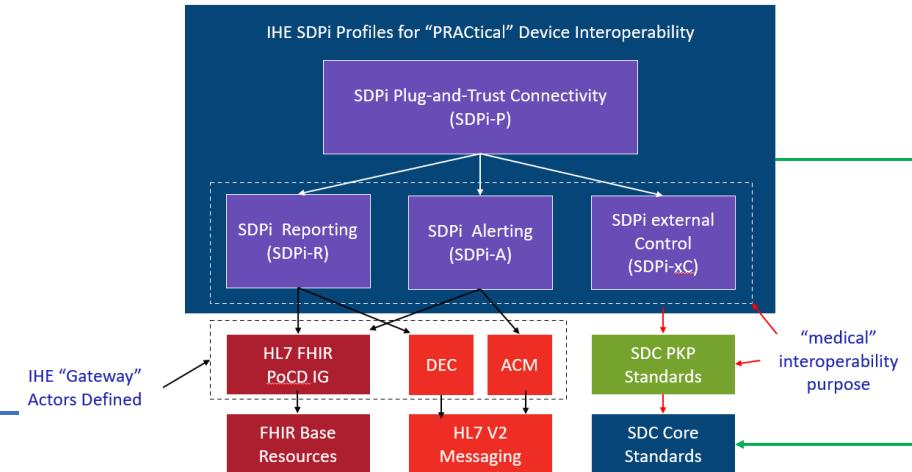
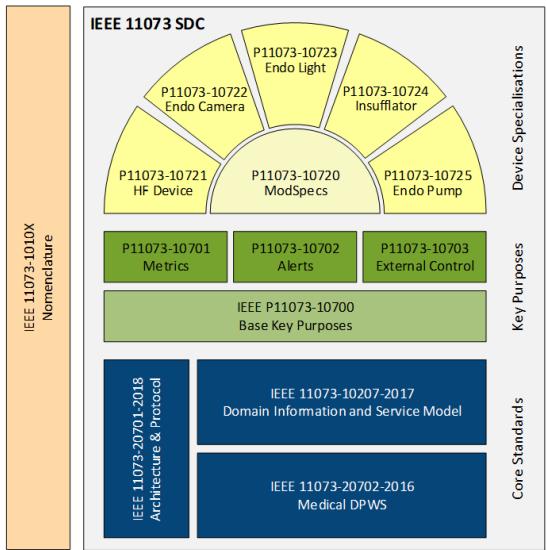
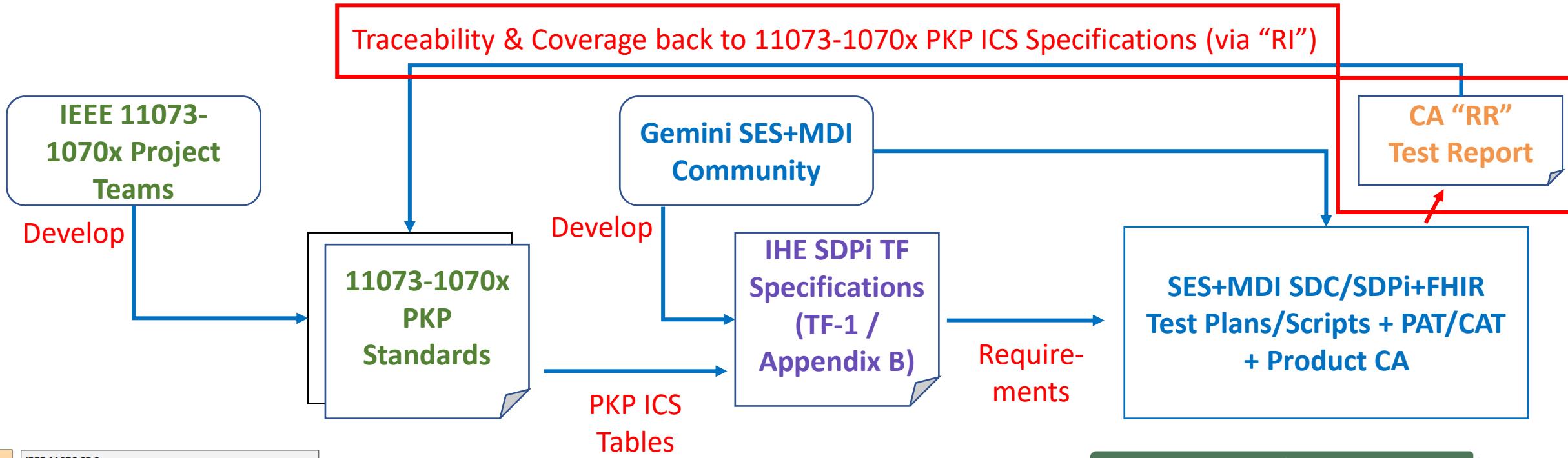
Source: [Gazelle X](#)  
[Validator Rule Editor](#)



**AIPO** = Actor / Integration Profile / Profile Option tuple

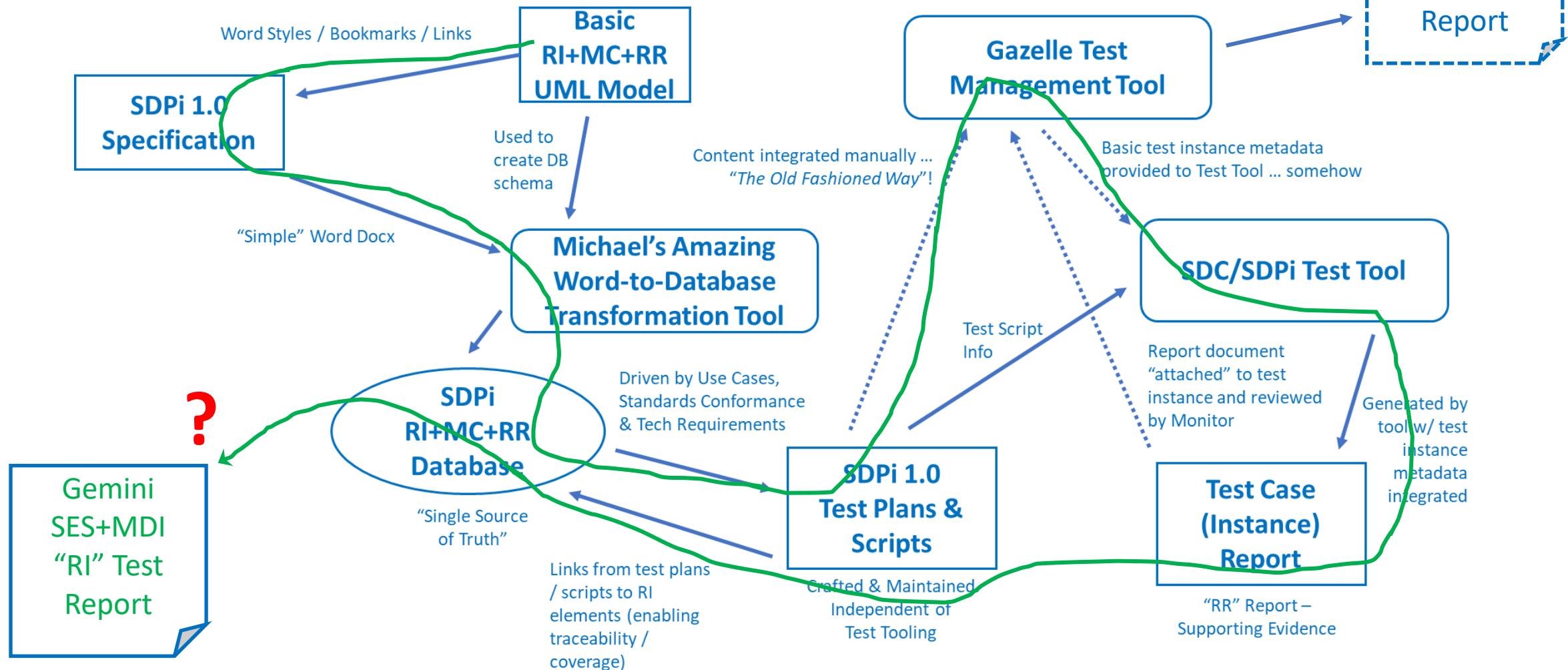
**Note:** See previous slides for GMM TF / Tests elements + “Assertions in Test Steps?”

# Spec-to-Test Strategy – *Closing the Loop / EP Style*

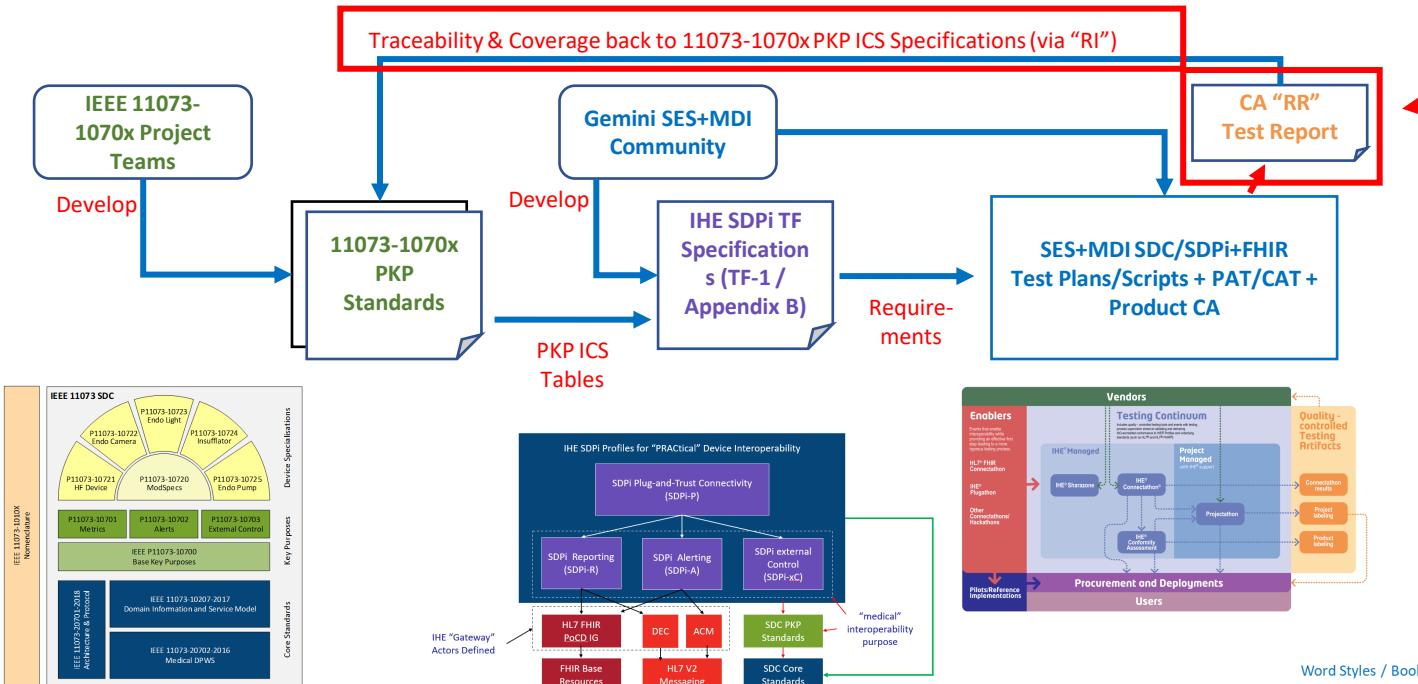


# Spec-to-Test Strategy – *Closing the Loop?*

*Pathway with RI+MC+RR Support ...*



# Spec-to-Test Strategy – “RR” Test Reports?



What is the strategy for getting to a “regulatory submission ready” product CA test report?

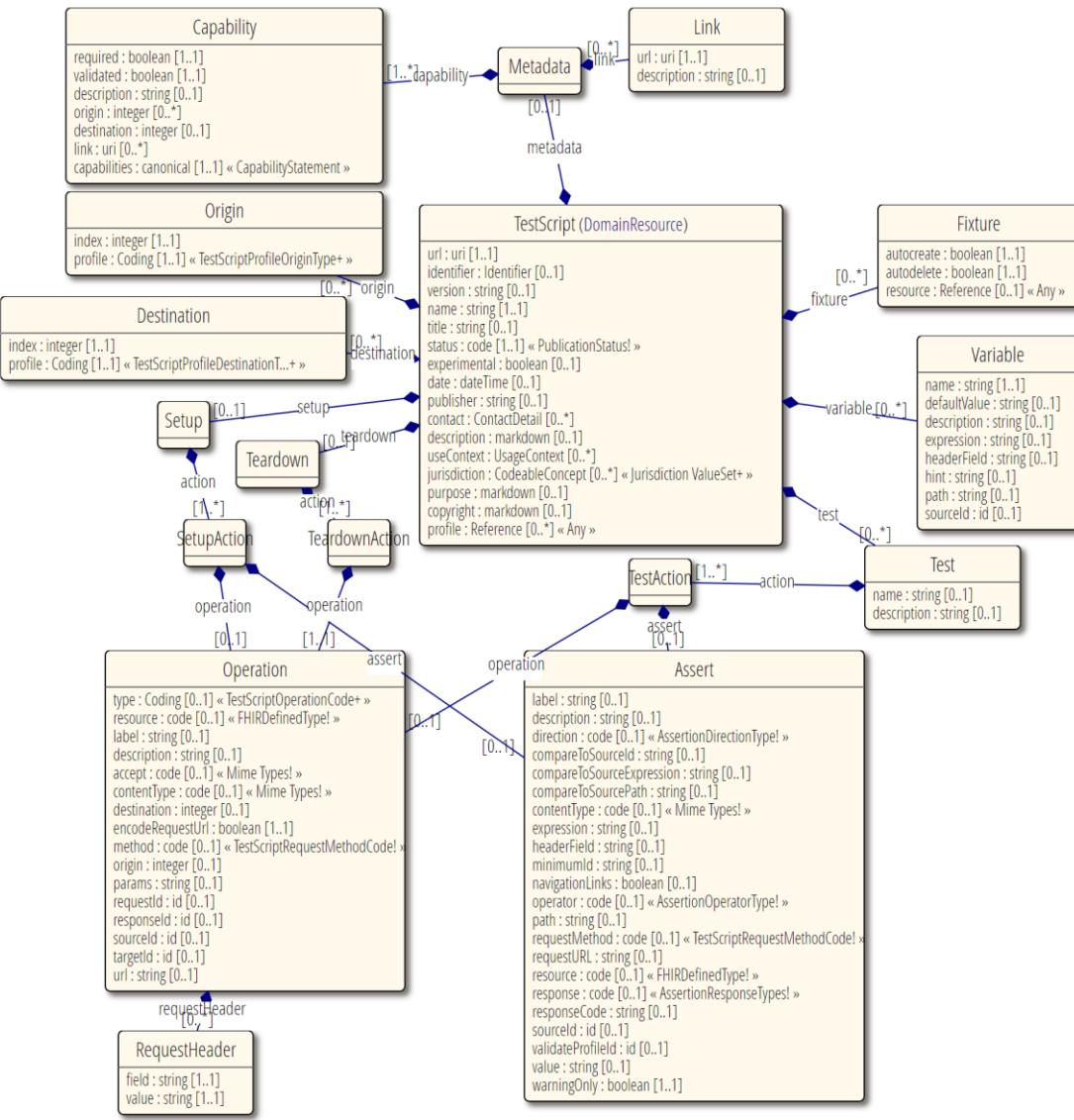
Test results currently are persisted in the Gazelle testing / CA database ...

Should SDPi 1.0 test report results be incorporated into the SST database to link with RI-to-Test Case information?

Should a separate test results database be created? + A tool that can combine the multi-database content to create a RR CA report?

How are CA test reports created today? Historically?  
Separate tool from Gazelle? Extended Gazelle instance?

# Spec-to-Test Strategy – FHIR TestScript “Friendly”



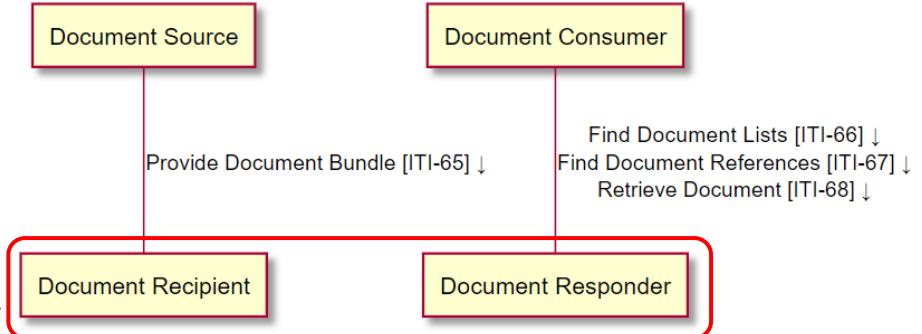
- ❖ <do the analysis (see slide #36)>
- ❖ <normalize with MODEL of TESTING>

## 7.2 Assertions

Assertion	Valid operator values	Description
compareToSourcePath	equals   notEquals	Asserts that compareToSourcePath against the response body of compareToSourceId fixture evaluates to a value that is equal or notEqual to the evaluated value of path which must be present also.
contentType	equals   notEquals   contains   notContains	Asserts that the "Content-Type" in response header is or is not the specified value for contentType element depending on the operator used.
headerField	equals   notEquals   in   notIn   greaterThan   lessThan   empty   notEmpty   contains   notContains	Asserts that the header specified for headerField element in the response contains, not contains, is equal, not equal, in, not in, greater than, or less than the value specified for value element if present. If the operator is "empty" or "notEmpty" then value will be ignored. If sourceId is not specified, then headerField will be evaluated against the last operation's response headers.
minimumId	N/A	Asserts that the response contains all the element/content in another fixture pointed to by minimumId element. This can be a statically defined fixture or one that is dynamically set via respondId.
navigationLinks	N/A	Asserts that the response Bundle contains or does NOT contain first, last, and next links depending on whether or not navigationLinks element is set to true or false.
path	equals   notEquals   in   notIn   greaterThan   lessThan   empty   notEmpty   contains   notContains	Asserts that path against the response body evaluates to a value that contains, not contains, is equal, not equal, in, not in, greater than, or less than the value specified for value element if present. If the operator is "empty" or "notEmpty" then value will be ignored. If sourceId is not specified, then path will be evaluated against the last operation's response body.
resource	equals   notEquals	Asserts that the resource returned in the response body is or is not of the specified value for resource element.
response	equals   notEquals	Asserts that status code in the response is or is not one of the enumerated values in response abbreviations.
responseCode	equals   notEquals   in   notIn   greaterThan   lessThan	Asserts that status code in the response is equal, notEqual, in, not in, greater than, or less than the specified value(s) for responseCode element
validateProfileId	N/A	Asserts that the response is valid according to the profile specified by validateProfileId element.

# Spec-to-Test Strategy – MHD & FHIR Test Plans

The screenshot shows the 'Mobile access to Health Documents (MHD)' test plan page. At the top left are the IHE International and ITI logos. The title 'Mobile access to Health Documents (MHD)' and subtitle '4.1.0 - Trial-Implementation' are centered above a purple header bar. Below the header is a navigation menu with links for 'MHD Home', 'Volume 1', 'Volume 2', 'Volume 3', 'Test Plan', and 'Artifact Index'. A red dotted arrow points from the 'Test Plan' link in the menu to the 'Test Plan' link in the breadcrumb trail below. The breadcrumb trail reads 'Table of Contents > Test Plan'. On the right side of the page are '<prev | bottom | next>' navigation links. A yellow banner at the bottom of the page states: 'This page is part of the IHE Mobile Access to Health Documents (v4.1.0: Trial Implementation) based on FHIR R4. This is the current published version. For a full list of available versions, see the Directory of published versions.' A red dotted arrow points from the 'Test Plan' link in the banner back to the 'Test Plan' link in the menu. The main content area contains several sections of text.



## MHD Test Plan

- ❖ Focus: Server-side actors – Document Recipient & Responder
- ❖ Tests support MHD infrastructure (incl. XDS on FHIR) options and variations
- ❖ Unit Test Procedures (Conformance Testing) per MHD Actor utilize Simulators / Validators
- ❖ Unit Test Tools include: NIST Asbestos (Simulator & Validator) + KEREVAL Gazelle EVS Client (V only)
- ❖ Integration Test Procedures (Interoperability Testing) build on unit conformance testing (pre-CAT)
- ❖ All Actors & Transactions include StructureDefinition & CapabilityStatement profile artifacts (see [ITI Appx. Z](#))
- ❖ MHD Tests are defined in the Gazelle Master Model
- ❖ MHD FHIR TestScript Usage? Enter: *NIST “Asbestos” Toolkit!*

# Gemini SES+MDI – 2022 RI+MC+RR Strategy –

## *NIST “Asbestos” Tool for IHE Testing*

Given the landscape evaluation, the IHE test artifacts (tests, assertions, Gazelle), the current focus on FHIR even for infrastructure / automated test tooling (FHIR TestScript, TestReport) and the work NIST is advancing for IHE FHIR-based profile testing with MHD and “XDS on FHIR” ... *could this be the best approach forward?*

# Test Tool Strategy – Why NIST Asbestos?

## Landscape Realities

- ❖ As stated above, current landscape “reality” can be summarized as: FHIR FHIR FHIR!
- ❖ IHE Gazelle / NIST tooling / other tooling leverages FHIR TestScript, TestReport, ... today
- ❖ Non-device verification & CAT & product CA are increasingly using FHIR-based tooling infrastructure
- ❖ NIST Asbestos was intentionally architected to support multiple protocols and “gateway” functions
- ❖ NIST Asbestos already supports FHIR extensions to enable needed capabilities (e.g., modularity)

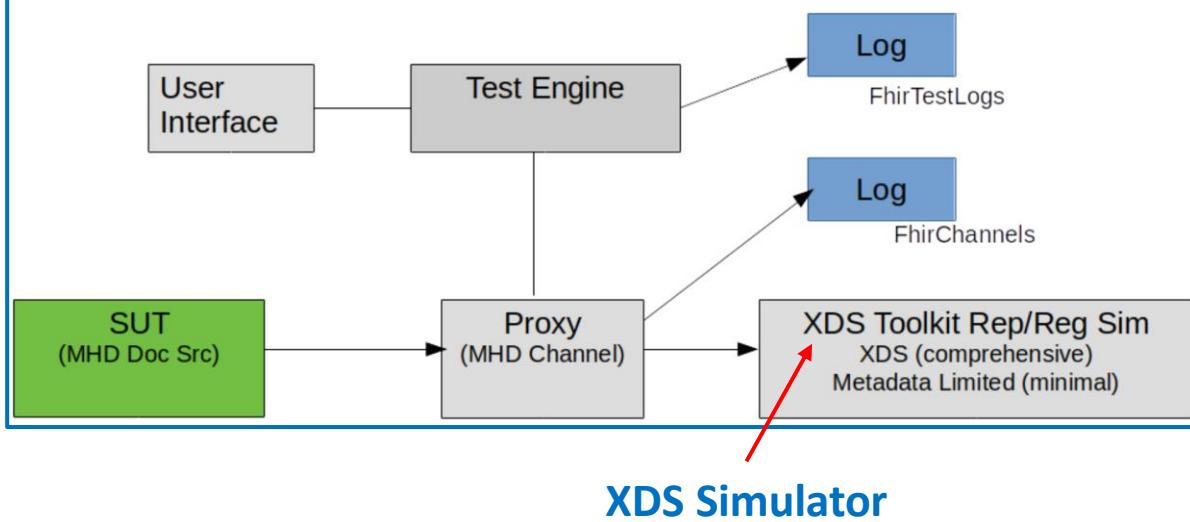
## Asbestos Value Proposition

- ❖ Do not reinvent the wheel: SDC tooling has to be built anyway – Asbestos reduces the work load
- ❖ Artifact authoring & management (test plans / scripts, assertions, tracing) exists separately and can be leveraged by vendor tool chains
- ❖ Testing that includes not only SDC-to-SDC but also SDC-to-FHIR & V2 will be a near future need
- ❖ An SDC/SDPi “Reference Implementation” built for NIST Tooling? ... no brainer!

# Test Tool Strategy –NIST Asbestos Architecture

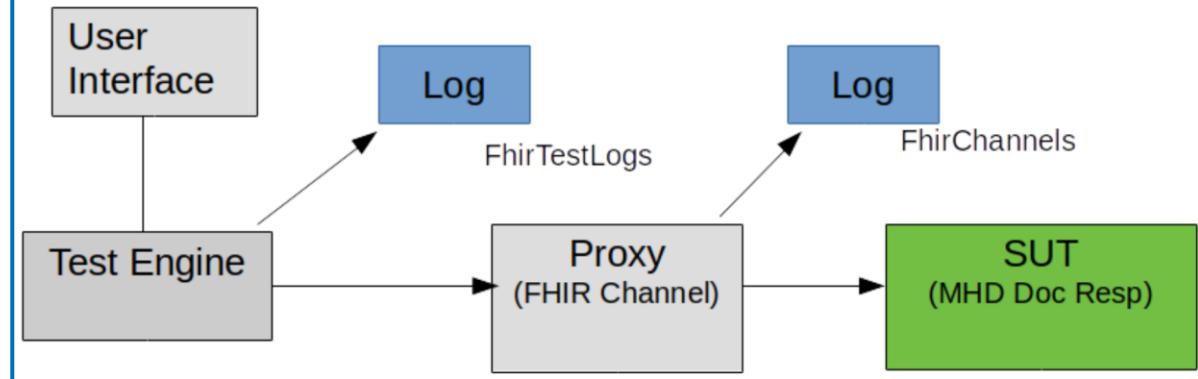
## Client testing

System Under Test initiates the message.



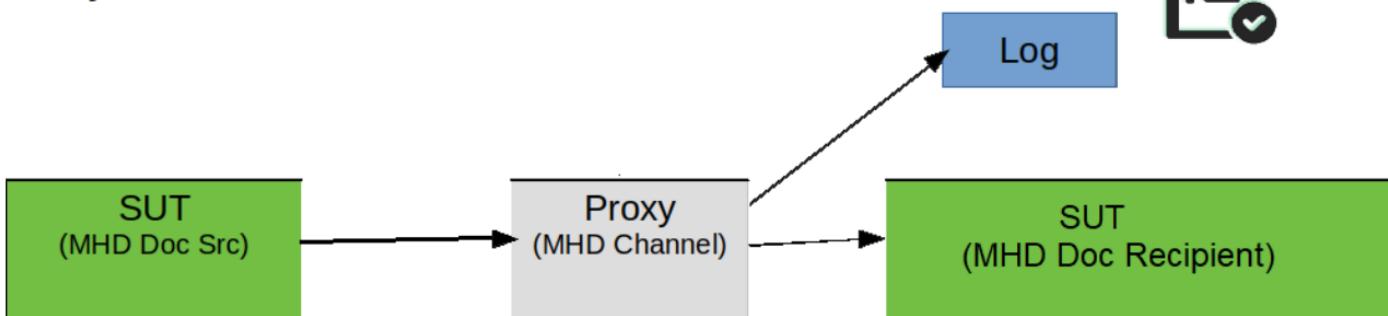
## Server testing

System Under Test receives the message.



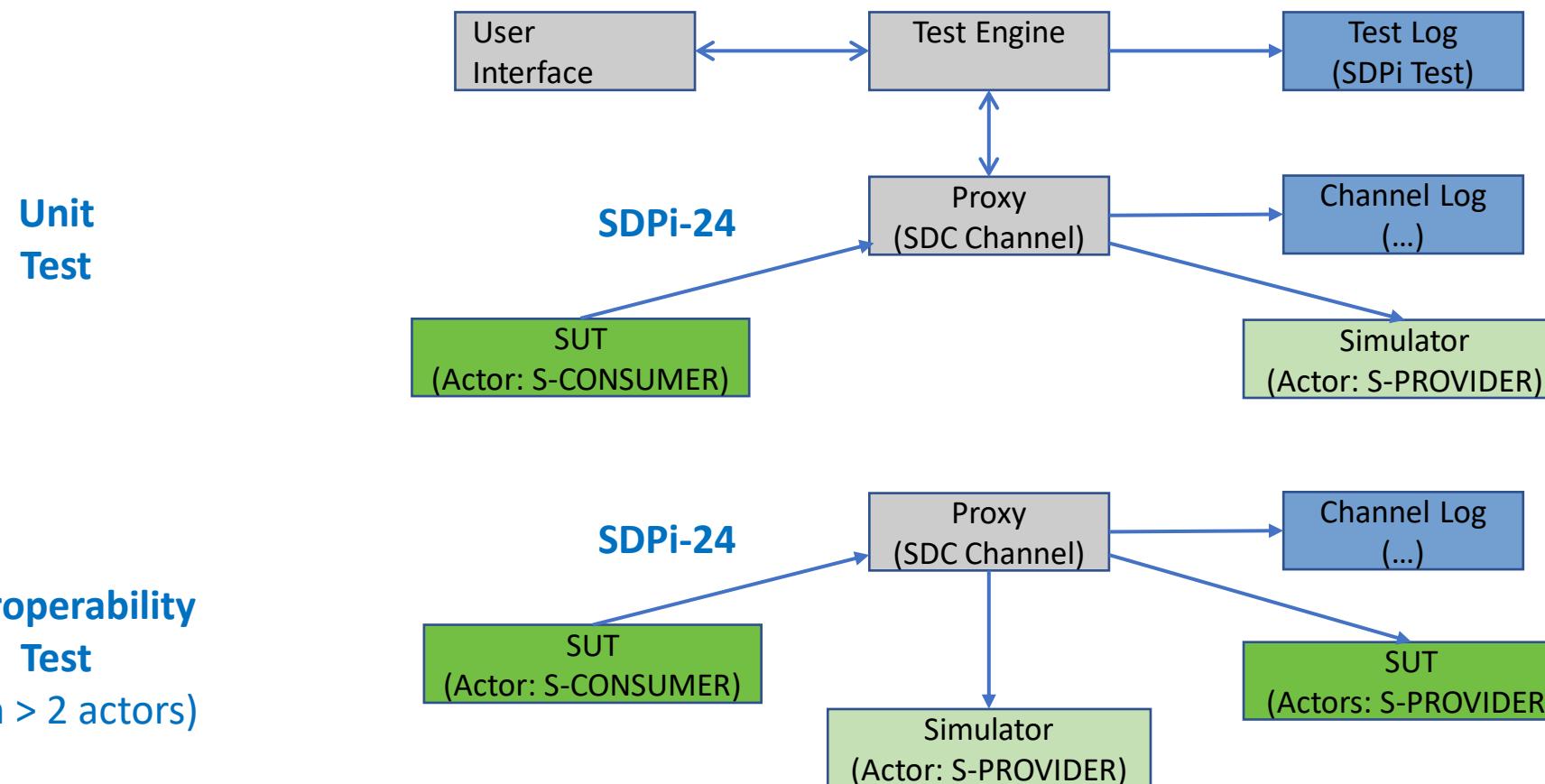
**Interoperability Test:**  
FHIR Toolkit acts as a proxy between Systems Under Test.

Logs are analyzed for results.



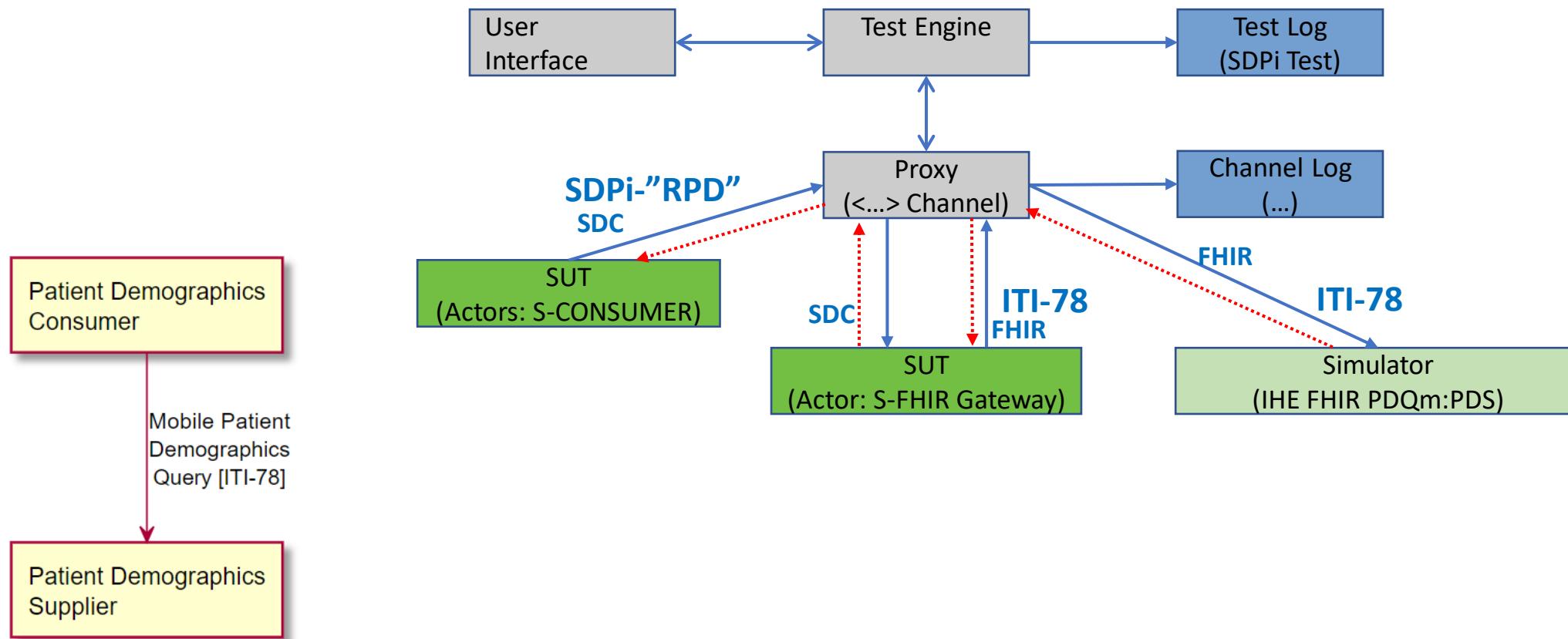
# Test Tool Strategy –NIST Asbestos for SDC/SDPi

## Test Scenario: SDPi-24 Discover Network Topology (Part of Test Step #1)



# Test Tool Strategy –NIST Asbestos for SDC/SDPi+FHIR

## Test Scenario: SDPi-xyz Retrieve Patient Demographics Information (PDQm)

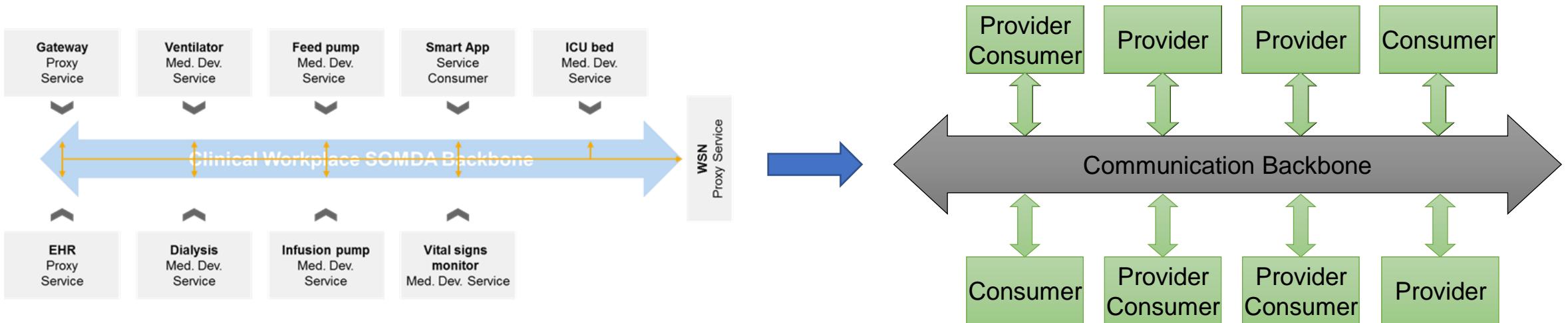


# Gemini SES+MDI – 2022 RI+MC+RR Strategy –

*IHE DE PAT Testing – May 2022*

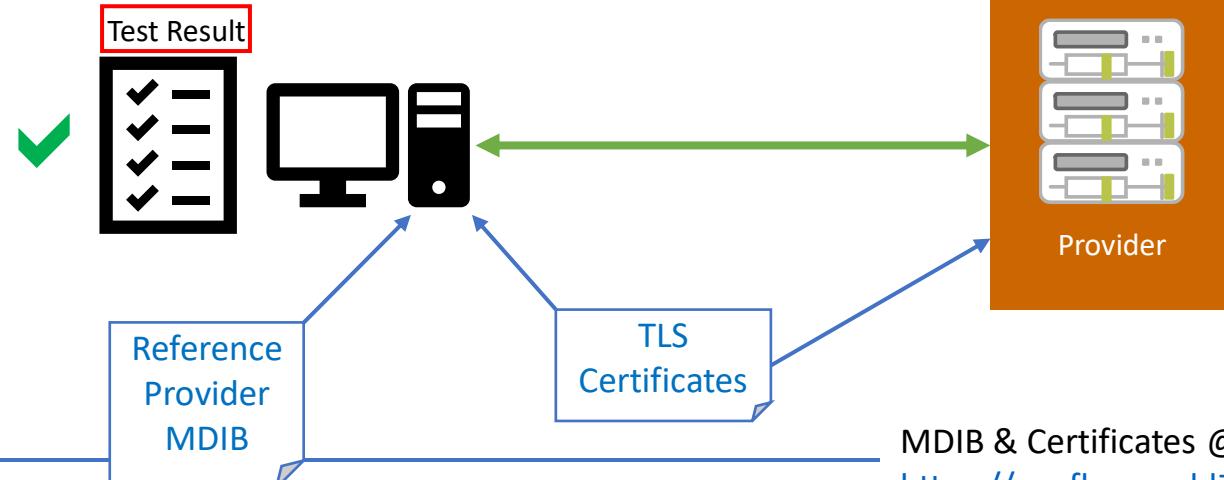
Starting point for the 2022 testing strategy includes what has been progressed as part of the IHE Germany Plugathon (PAT) testing events, and ... *how much of this approach and tooling can be leveraged going forward?*

# Test Tool Strategy – IHE DE PAT ‘22 Testing

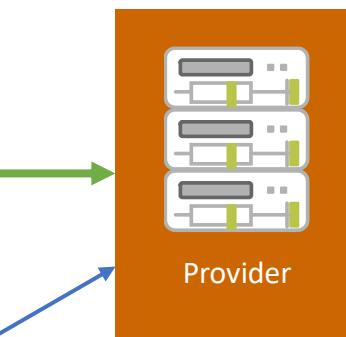


Compares actual exchanges  
(from PROVIDER SUT) with  
Reference MDIB

Test app (consumer)



Device under test (provider)



# Test Tool Strategy – IHE DE PAT #7 '22 Testing

See [PAT #7 Test Matrix for Example Results](#)

What does a PAT testing event look like?

1. Configure & connect systems [per network settings \(e.g., #7\)](#)
2. SDC PROVIDER systems tested w/ **Reference Consumer App** (akin to Pre-CAT ... or *Pre-PAT testing*)
3. SDC PROVIDER & CONSUMER systems work through the test sequences for *interoperability* testing

What current PAT testing does *not* include:

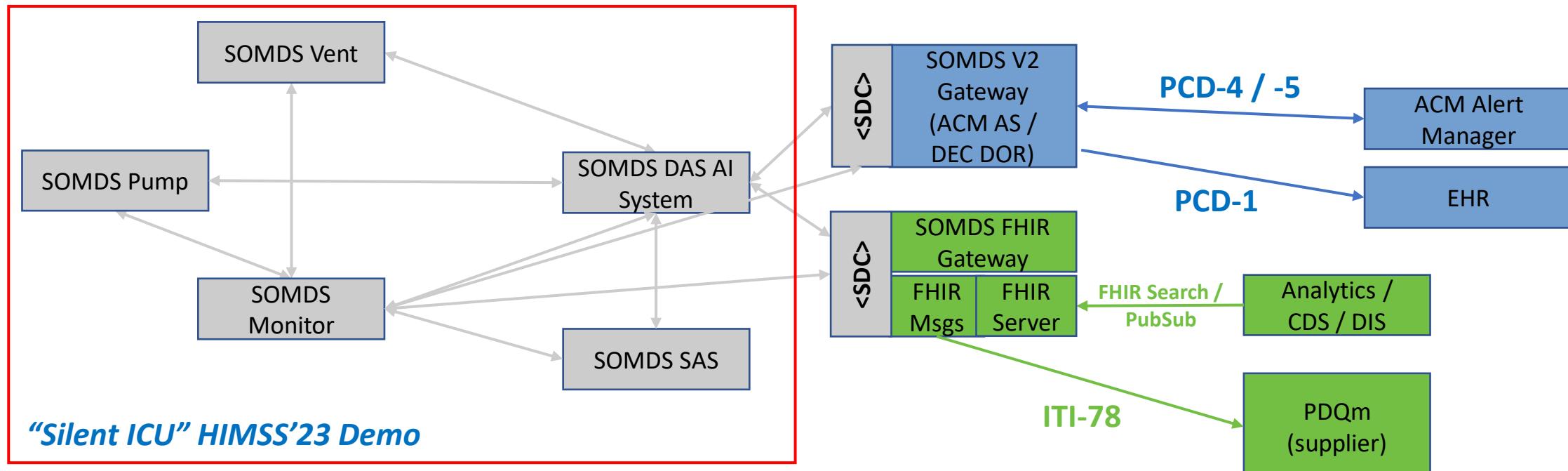
1. Unit Testing (automation)
2. Consumer SUT Testing (unit)
3. Proxy (with security)
4. Test “Engine” w/ scripts & reports & configuration ...  
(see sdcTest in [github sdpi-fhir github repo](#))

Step	Description	Transaction covered
1	Discovery of a provider with a specific endpoint reference address  1. See that Probe is answered 2. See that Resolve is answered	DEV-23, DEV-24
2	Connect to the provider with specific endpoint, i.e. establish TCP connection(s) and retrieve endpoint metadata	DEV-25
3	Read MDIB of the provider	DEV-26
4	Subscribe at least metrics, alerts, waveforms and operation invoked reports of the provider	DEV-27
5	Check that least one patient context exists	DEV-26, DEV-27
6	Check that at least one location context exists	DEV-26, DEV-27
7	Check that metric updates for one metric arrive at least 5 times in 30 seconds	DEV-35, DEV-36, DEV-29
8	Check that alert updates of one alert condition arrive at least 5 times in 30 seconds	DEV-38, DEV-39
9	Execute external control operations (any operation that exists in the containment tree, if none exist: skip test) by checking the ultimate transaction result is "finished"  a. Any Activate b. Any SetString c. Any SetValue	DEV-31, (DEV-44, DEV-45)
10	Shutdown connection (cancel subscription, close connection)	DEV-34

Source: <https://confluence.hl7.org/x/LZLGBg>

# Test Tool Strategy – Testing for HIMSS'23 & Beyond

## HIMSS'23 Interoperability Showcase Demo: *Silent ICU (incl. DAS / DIS Support)*



SAS = Smart Alert System

DAS AI = Distributed Alarm System / Alarm Integrator

<SDC>

<FHIR>

<V2>

See detailed scenarios posted at [Gemini Topic of Interest DAS + Smart Alerting Challenges](#)

### Notes:

- ✓ PDQm & EHR & ACM included for illustrative purposes; may not be in '23 demo
- ✓ SOMDS Gateway actors are specialized – not shown here - for each of the (4) profiles
- ✓ SOMDS systems can integrate both Service Provider & Consumer actors
- ✓ Gateways can be bi-directional (both Service Provider & Consumer actors)

# Gemini SES+MDI – 2022 RI+MC+RR Strategy –

*Possibilities but not Probabilities but ..  
Opportunities?!*

“Basic Support” focuses on what we can do NOW with what we have in hand NOW, but in parallel there are activities that could provide additional opportunities for achieving RI+MC+RR support ... *beyond basic!*



# IHE-HL7 Gemini SES+MDI – *From Use Cases to Test Reports –* 2022 RI+MC+RR Strategy



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# Additional Materials

# Orientation Tour: IHE TF & SDPi Profiles

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

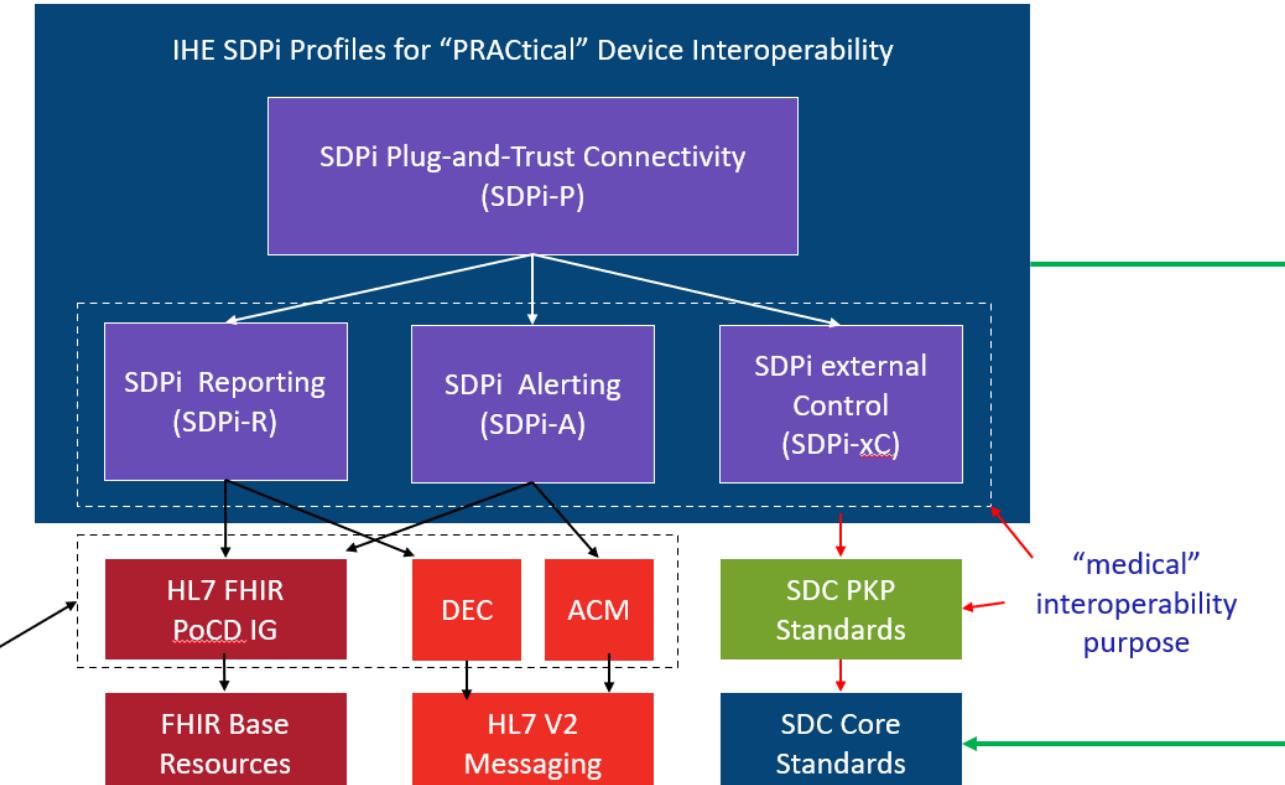
### ✓ Four profile specifications:

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

### ✓ Three IHE DEV TF Volumes:

- TF-1 Profiles / use cases / actors / ...
- TF-2 Transactions / MDPWS messaging
- TF-3 BICEPS content modules / device specializations

IHE "Gateway" Actors Defined



See draft SDPi Supplement Word Document for additional content detail & outline

(<https://github.com/IHE/sdpi-fhir/tree/master/SDPi%20Supplement/SDPi%20Rev%201.0>)

# Orientation Tour: From Volume 1 to 2 to 3

## SDPi TF Supplement Vol.1 Integration Profiles

### *SDPi-P Profile*

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

### *SDPi-Reporting Profile ...*

### *SDPi-Alerting Profile ...*

### *SDPi-xControl Profile ...*

M:N Profiles &  
Transactions

## SDPi TF Supplement Vol.2 Transactions

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

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

**MDPWS Message  
Detail in Appendix**

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

...

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

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

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

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

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

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

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

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

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

# Orientation Tour: From Volume 1 to 2 to 3

## SDPi TF Supplement Vol.1 Integration Profiles

### ***SDPi-P Profile***

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

### ***SDPi-Reporting Profile ...***

## SDPi TF Supplement Vol.2 Transactions

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

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

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

...

## Bindings – General & Specific

## SDPi TF Supplement Vol.3 Content Modules

### ***DEV Semantic Content Modules***

- General Device Content Considerations
- ...

### *SDC / BICEPS Semantic Content*

### ***DEV Specialization Content Modules***

- Device: *Infusion Pump*

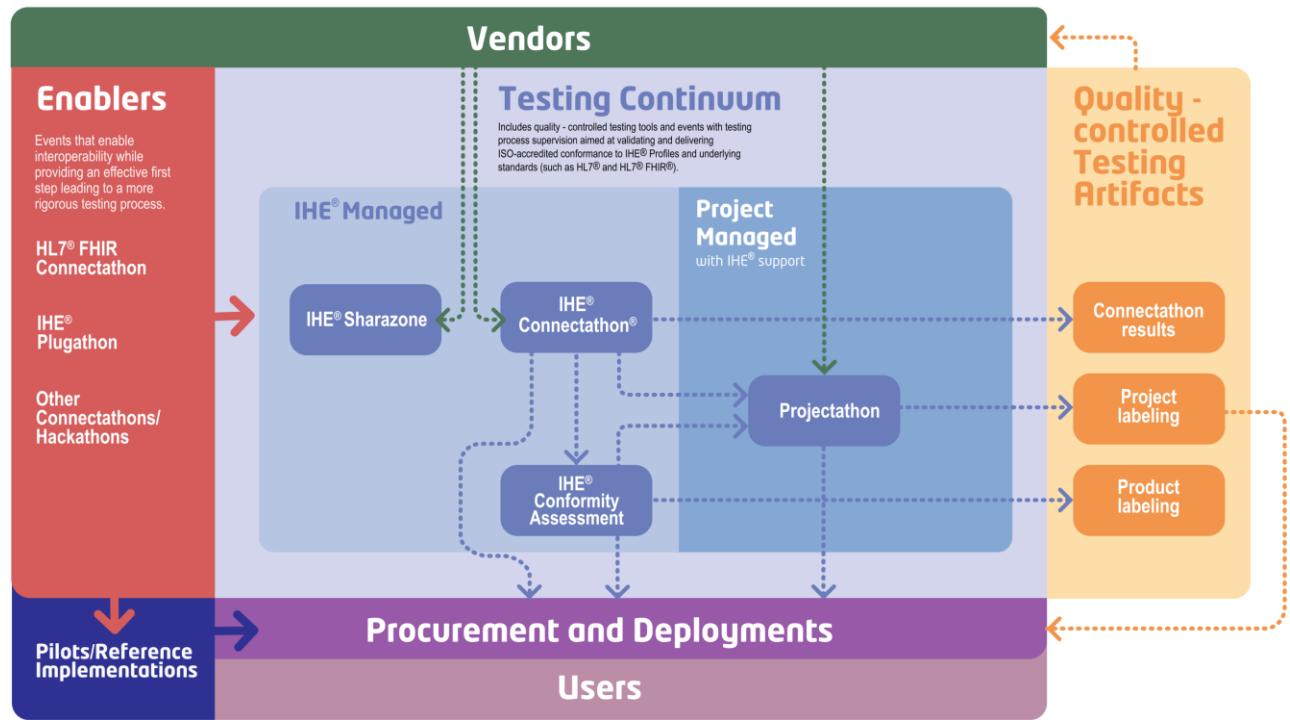
### *SDC / BICEPS Content Module*

- Device: *Ventilator ...*
- Device: *Physiologic Monitor ...*
- Devices: *Surgery ... (new)*
- Devices: *Anesthesia ... (new)*
- Devices: *Dialysis ... (new)*

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

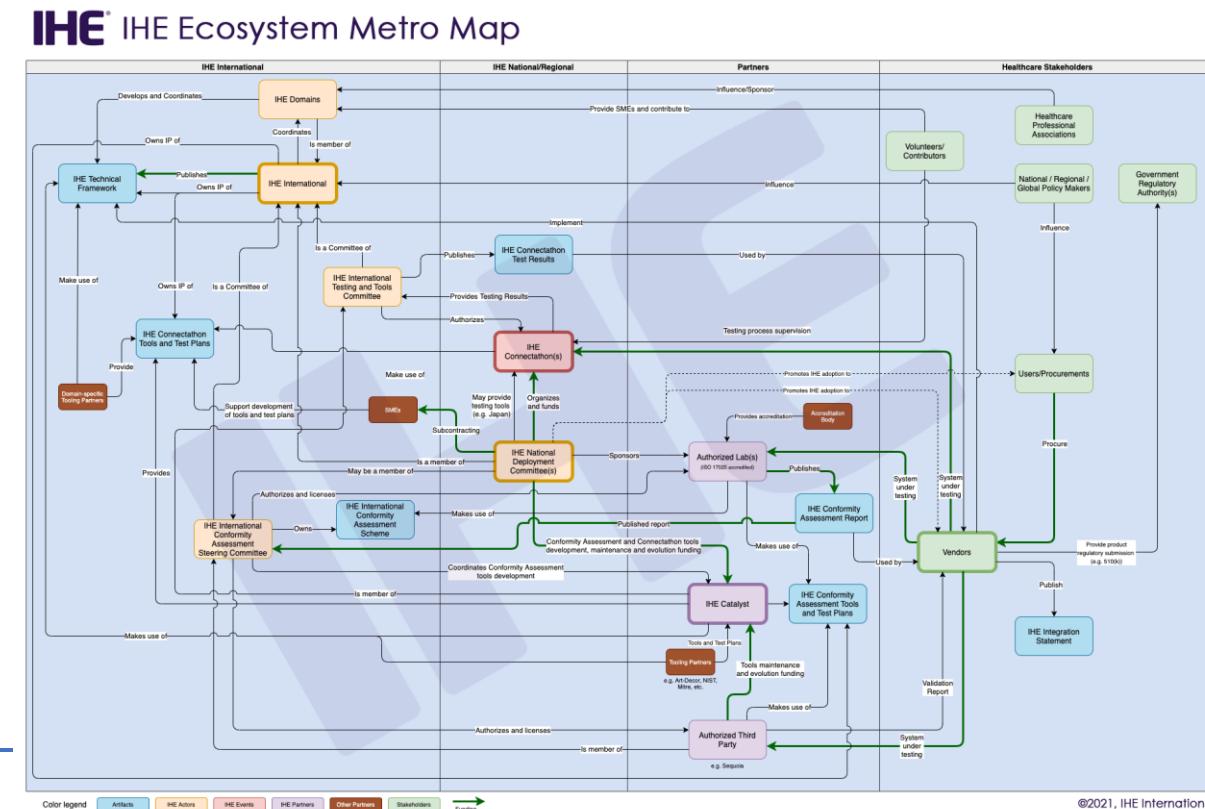
# IHE Catalyst (formerly IHE EU/IHE Services)

## *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/>

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# More detail is provided in ...



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20<sup>TH</sup>  
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## IHE & IHE Catalyst: Advancing Interoperable MedTec Solutions with "Regulatory Submission Ready" Conformity Assessment



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

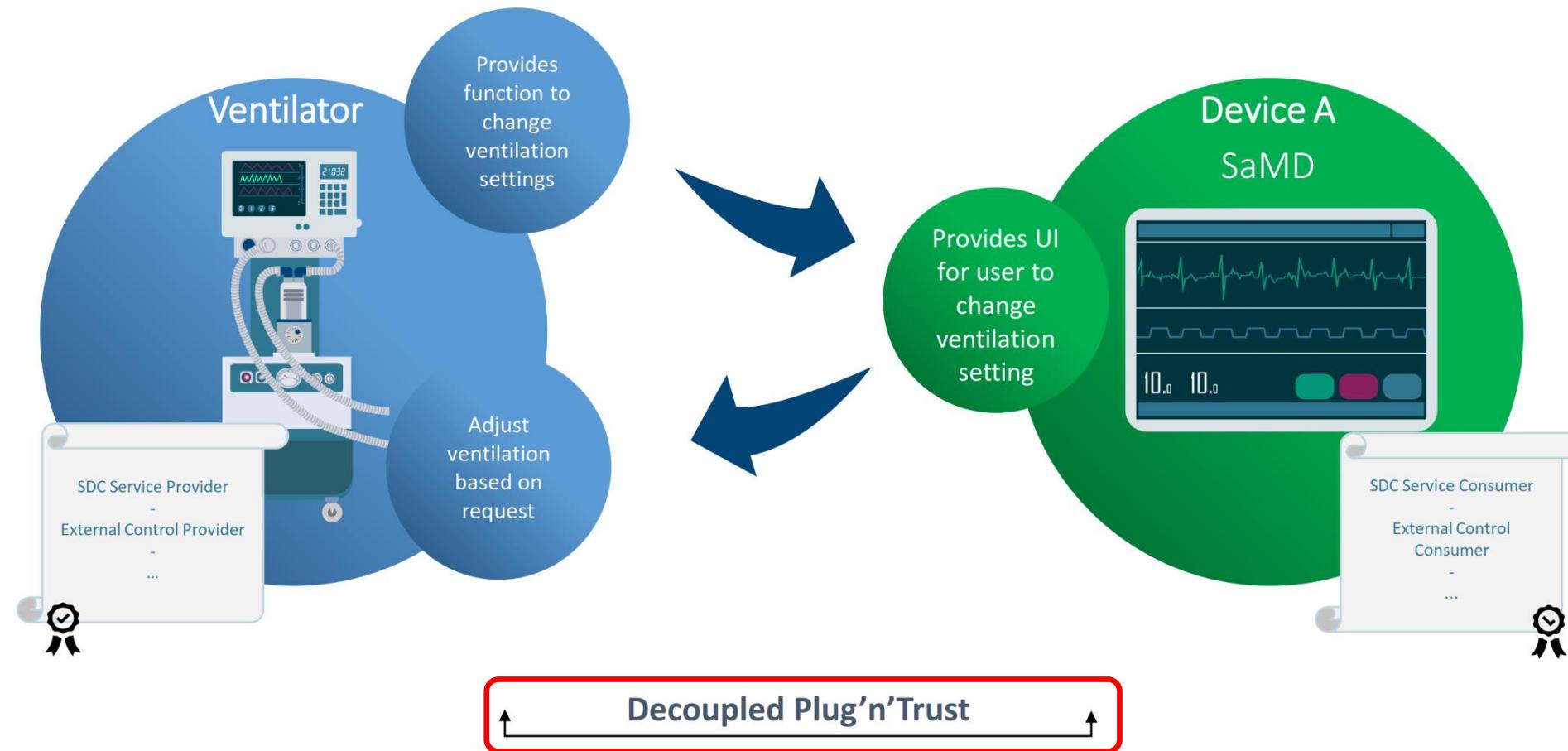


**Todd Cooper**  
Lead, IHE-HL7 Gemini Device Interoperability Program  
Board, IHE International  
Executive Director, Trusted Solutions Foundry

16/06/2021

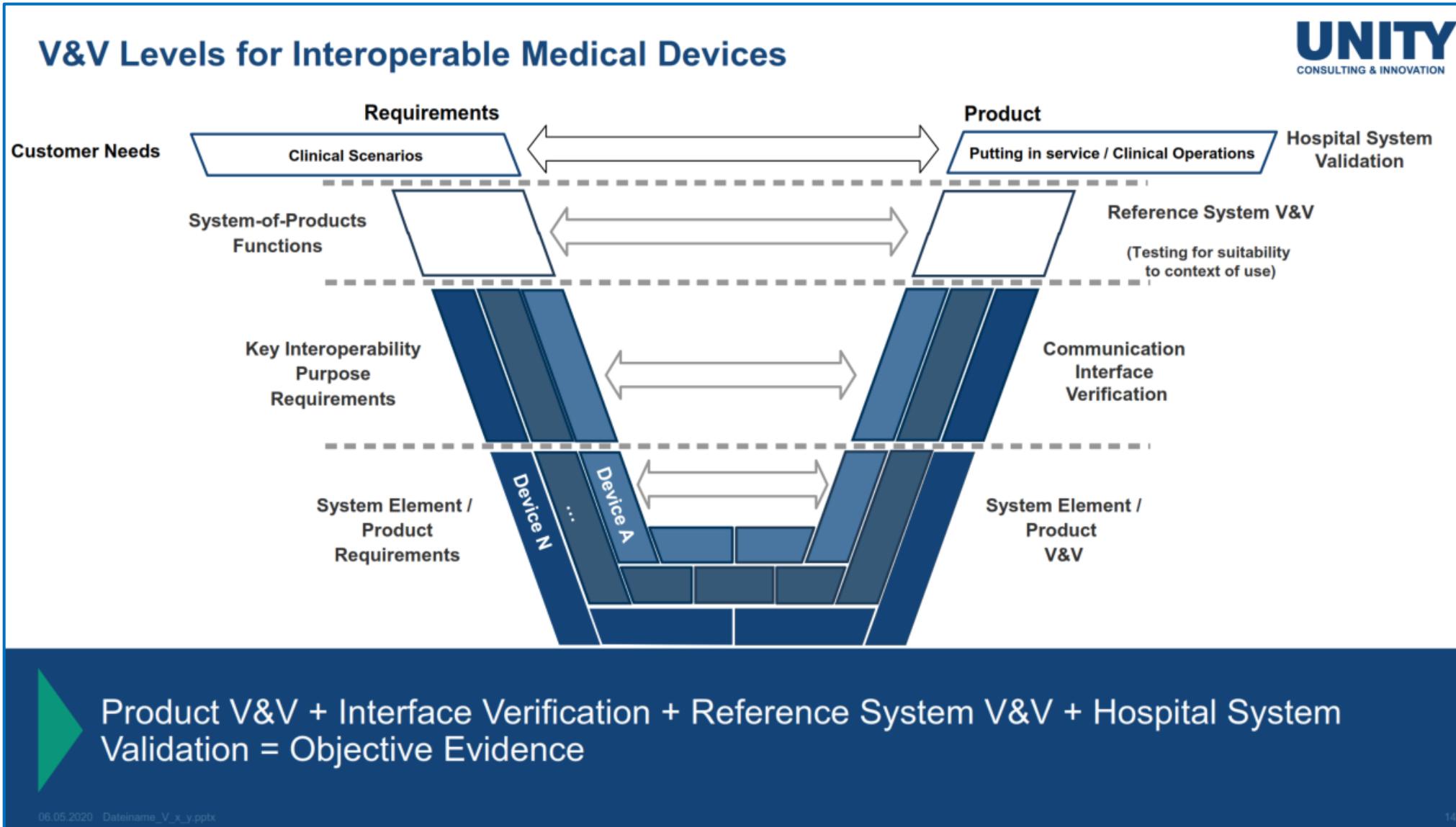
1

## Example: External Control of Ventilator using Device A



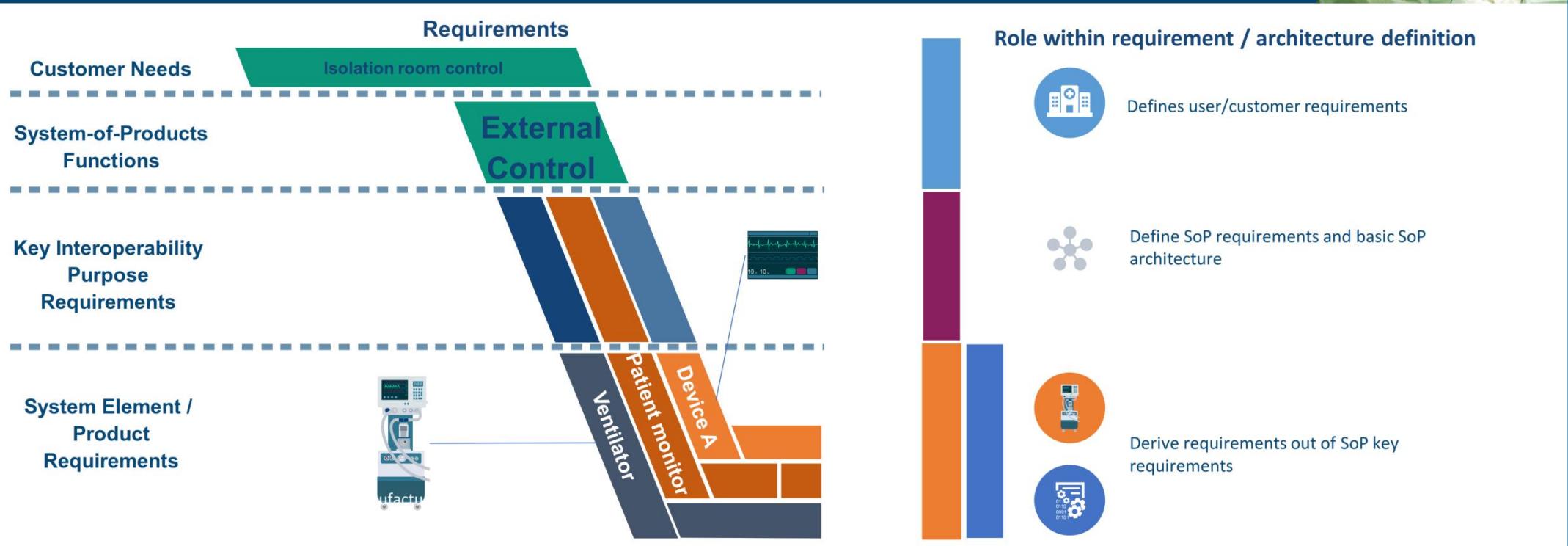
# V-Model for Systems of MedTech Products

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



## Implication of interoperable SoP on Requirement / Architecture

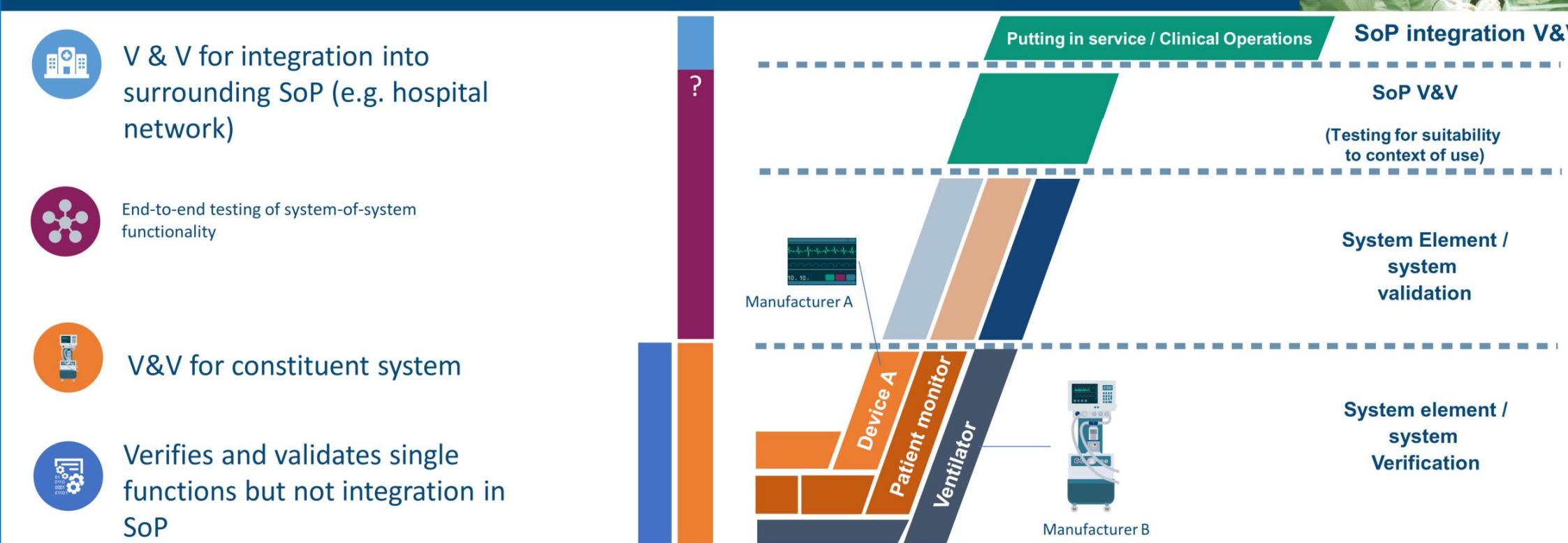
Traditional SE approach cannot fulfill the requirements



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

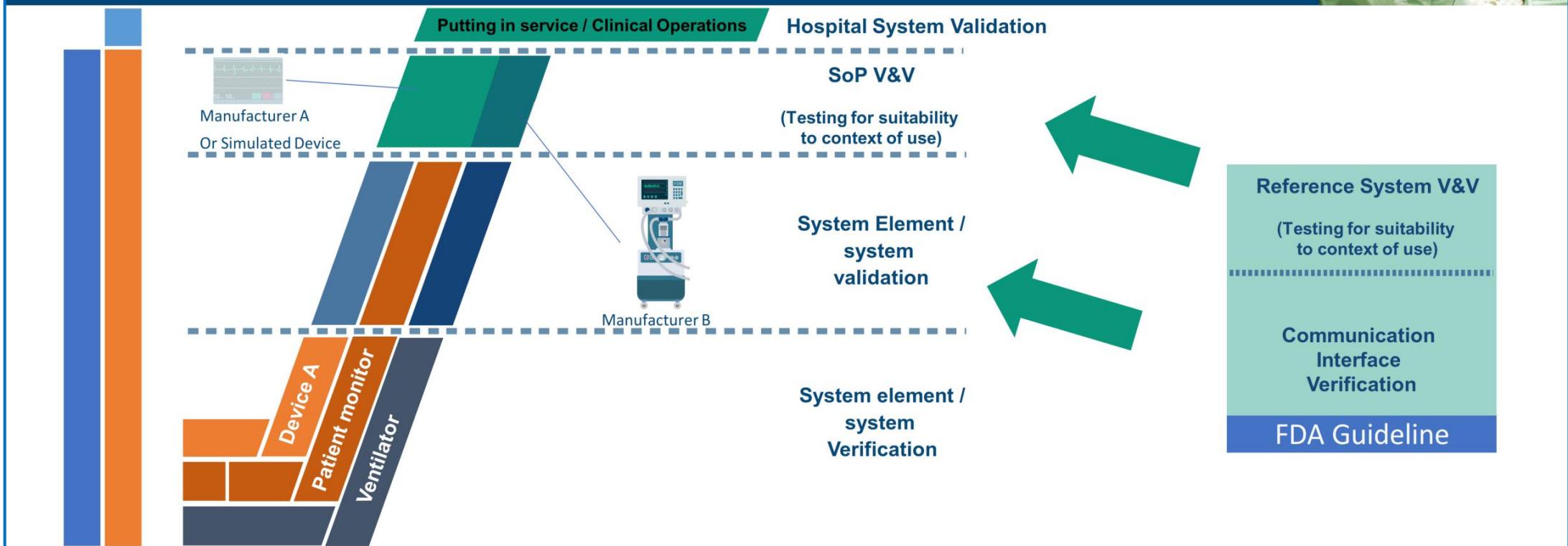
## Responsibility and Validation Challenges

Verification and validation responsibilities



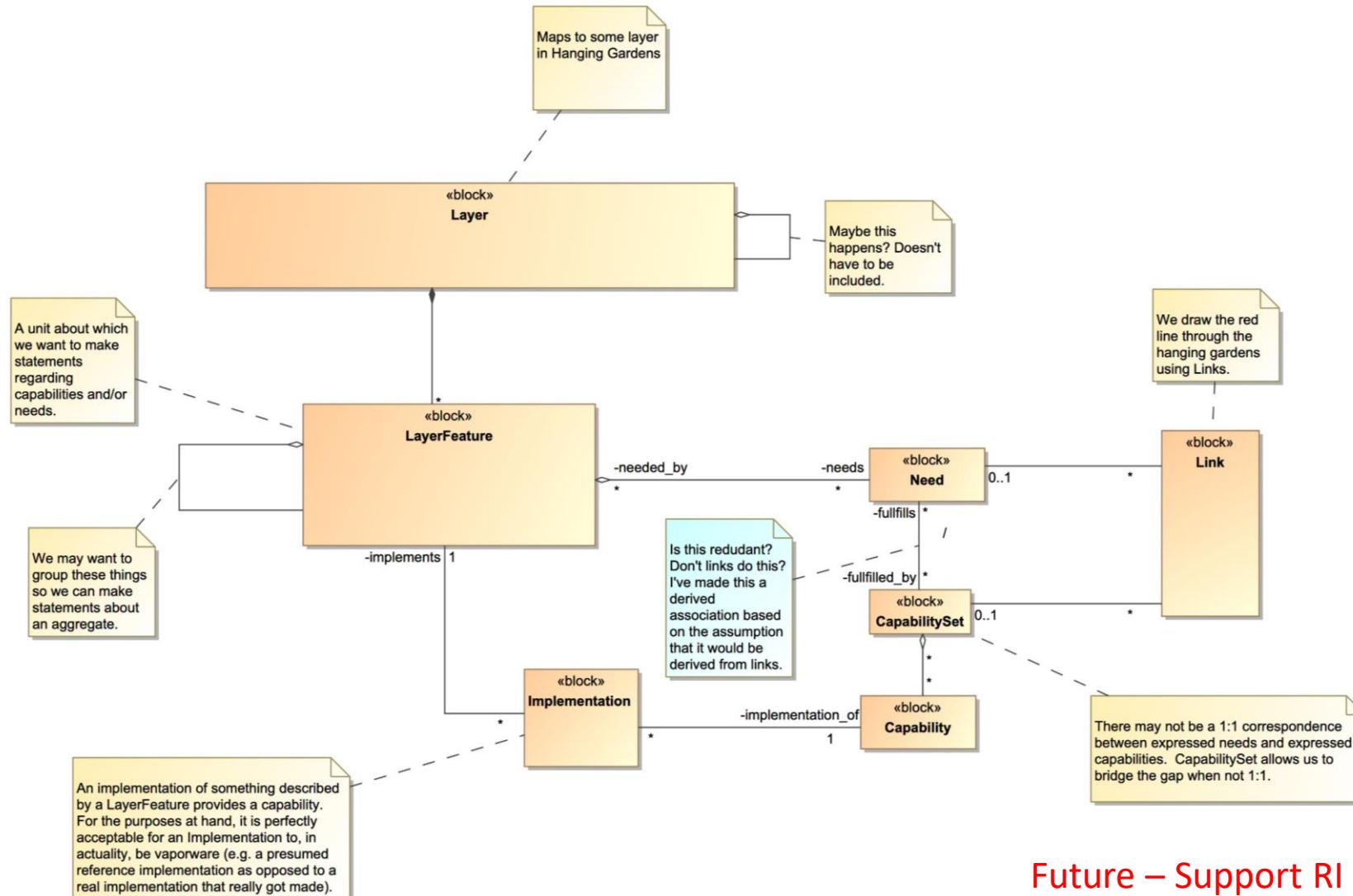
A lack of end-to-end testing responsibility is observed in traditional SE

## Verification and validation responsibilities Example Medical Device



FDA Guideline also applicable for CE market?

# MF's musings ... toward a layer model



1<sup>st</sup> – Human  
crafted (this  
need met by  
this  
capability) /  
consensus  
approved

Future – Support RI Component  
“assembly” automation