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

for

Joint IEEE / HL7 / IHE Working Group Meetings

2021.01.27 (Finalized 2021.02.19)

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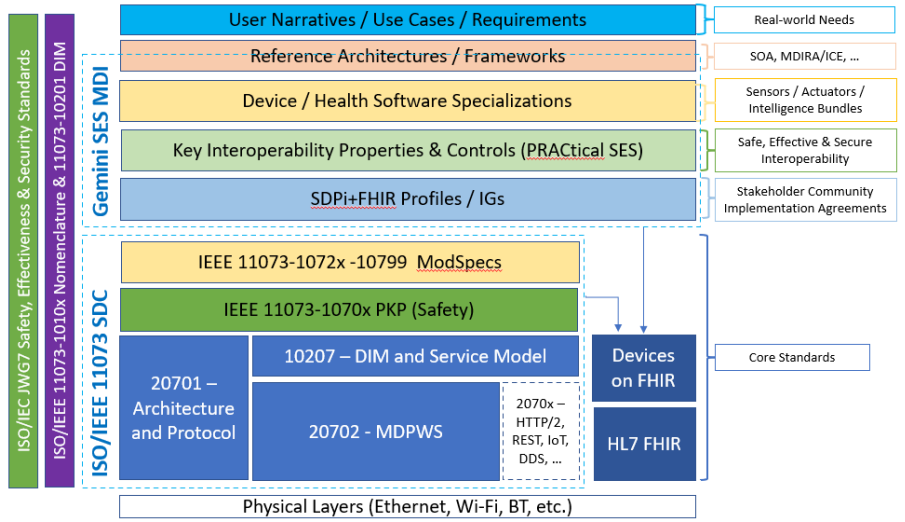
SDC is a registered trademark of OR.NET

Gemini SES MDI using SDPi+FHIR



Gemini SES MDI / SDPi+FHIR – Year 3 Update!

Focus Topic: Do all roads lead to … *Devices on FHIR Destination*?!

Focus Topic: IHE TF Publications – *Accelerating the Evolution*

Focus Topic: Is a strategy emerging for Traceability from Use Case Requirements to Conformity Assessment?

Gemini SES MDI / SDPi+FHIR – Year 3 Update

Actually, longer than that … and a quick look at recent years gives a very positive expectation for this 3rd year of SDPi+FHIR!

Prehistory: ISO/IEEE 11073 SDC – 15 Year Journey

2004

2004

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

2010

TekoMed
Feasibility study to prove the SOA approach for medical devices

2011

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

2013

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

2015

OR.NET e.V.

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

2016

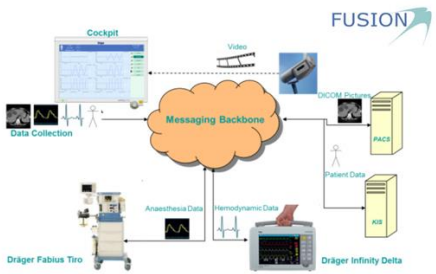
IEEE 11073-20702
Standard approved Medical Devices Communication Profile for Web Services

2017

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

2018

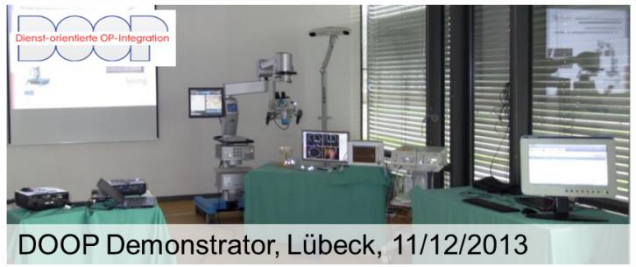
IEEE 11073-20701
Standard approved Service Oriented Medical Device Exchange Architecture & Protocol Binding



Demonstrator, 2009

Demonstrator, 2011

OR.NET, Berlin, 15/04/2015



DOOP Demonstrator, Lübeck, 11/12/2013

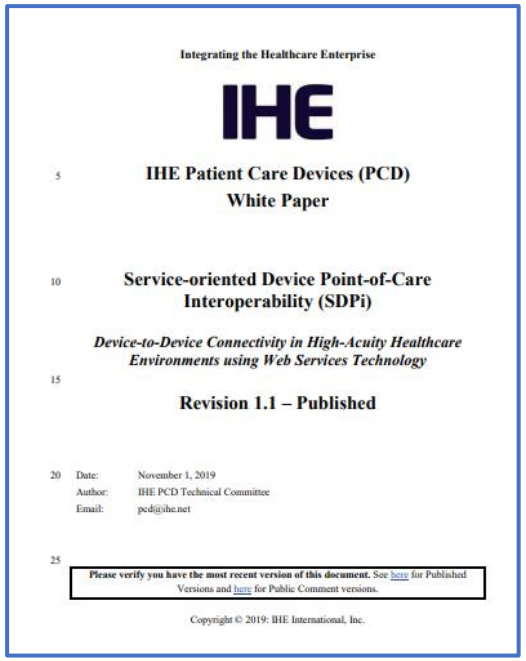
NOTE: This roughly parallels the timelines for IHE Devices Domain & HL7 Devices WG

SDC
IEEE 11073 Series
IEEE

SDC/SDPi+FHIR: Year 1 (2019) Visioneering

Year 1 Milestones

- ✓ Published SDPi White Paper & Use Case Compendium
- ✓ Conference briefings from Germany to North America to Australia & Asia
- ✓ IHE SDPi Supplement development approved and initiated
- ✓ IHE Devices rebranding / reorganization initiated (at the 15-year anniversary mark!)



Integrating the Healthcare Enterprise

IHE

IHE Patient Care Devices (PCD)
White Paper

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

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

Revision 1.1 – Published

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

Please verify you have the most recent version of this document. See here for Published Versions and here for Public Comment versions.

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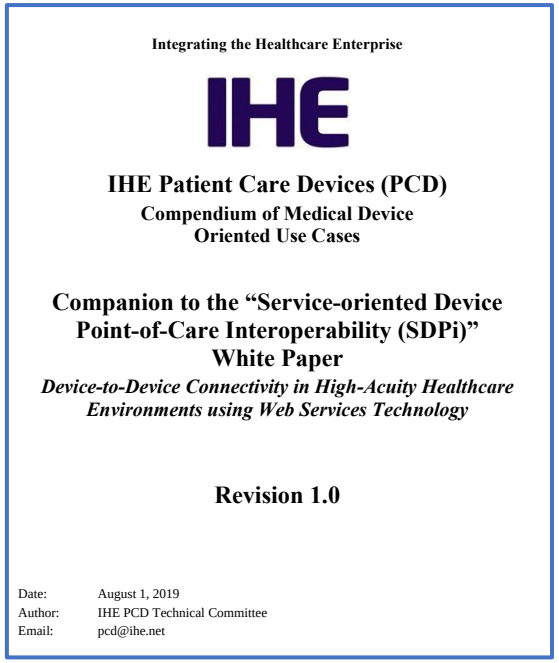
https://www.ihe.net/uploadedFiles/Documents/PCD/IHE_PCD_WP_SDPi_Rev1-1_Pub_2019-11-01.pdf



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

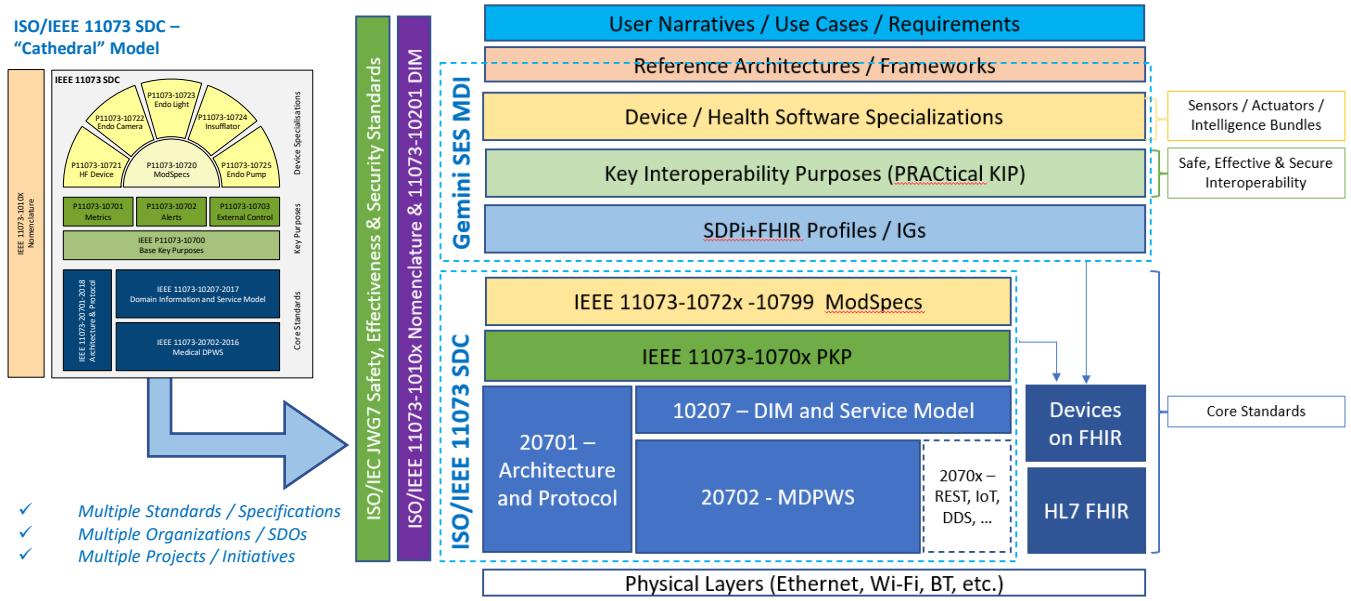
https://wiki.ihe.net/index.php/SDC@IHE_White_Paper

SDC/SDPi+FHIR: Year 2 (2020) The Journey Begins

What didn't exist before 2020.01.01!

Year 2 Milestones

- ✓ Health Challenges … Everywhere & Everyone
- ✓ Tobias & Todd @ HIMSS'20!
- ✓ "Layers" Model => Hanging Gardens Model
- ✓ Joint HL7-IHE Governance Established in Gemini SES MDI!
- ✓ IHE DEV/DPI operationalized / HL7 DEV Rebranded
- ✓ ISO/IEC Coordination via TR's for SES MDI & SES RCC/MH



HL7 FHIR IHE SDC

Device Interoperability using Service-oriented SDPi + FHIR™

A Joint HL7-IHE Gemini Program Proposal

2020.04.21

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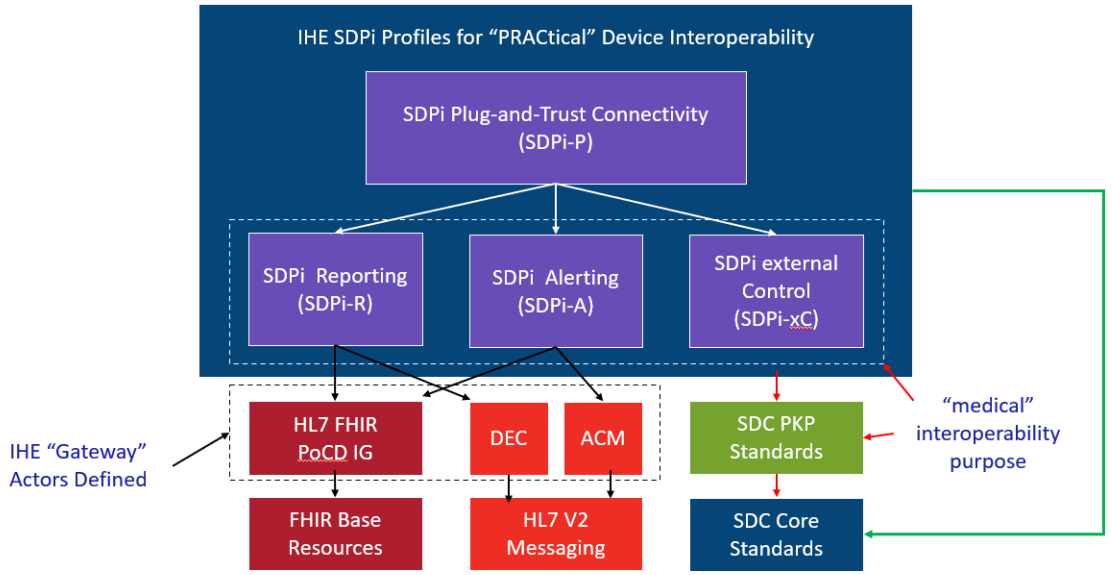
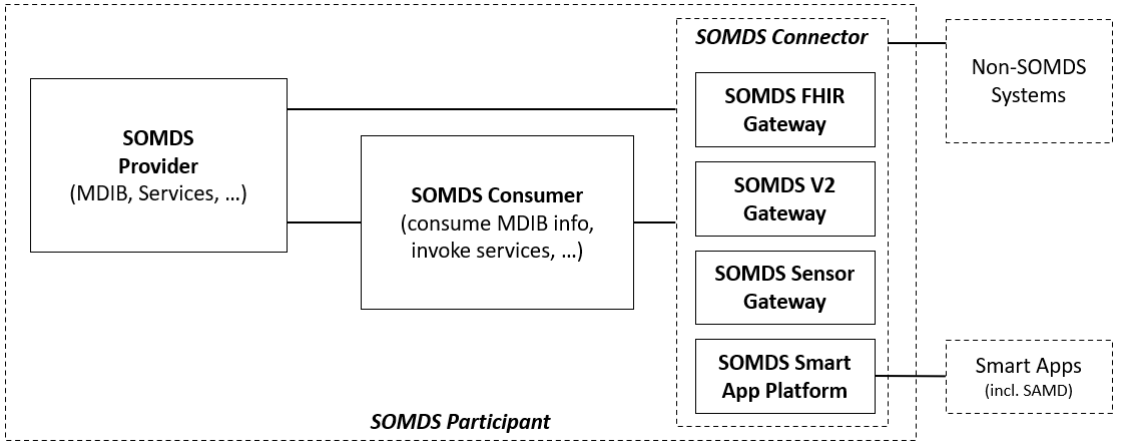
SDC/SDPi+FHIR: Year 2 (2020) The Journey Begins

Year 2 Milestones

- ✓ SDPi Supplement Crafting begun in earnest … starting with the profiles framework
- ✓ Gemini MDI Community formed
- ✓ Coordinated use of HL7 Confluence & IHE Github
- ✓ Initial Actors & Transactions defined
- ✓ Enhanced Use Case specificity & TF integration + "Silent PoC" detailed
- ✓ Initial SDC/BICEPS reporting & alerting mappings for DoF PoCD IG crafted
- ✓ MDI SDC Security approach advanced
- ✓ 1st IHE DE SDC/SDPi Plug-a-thon!



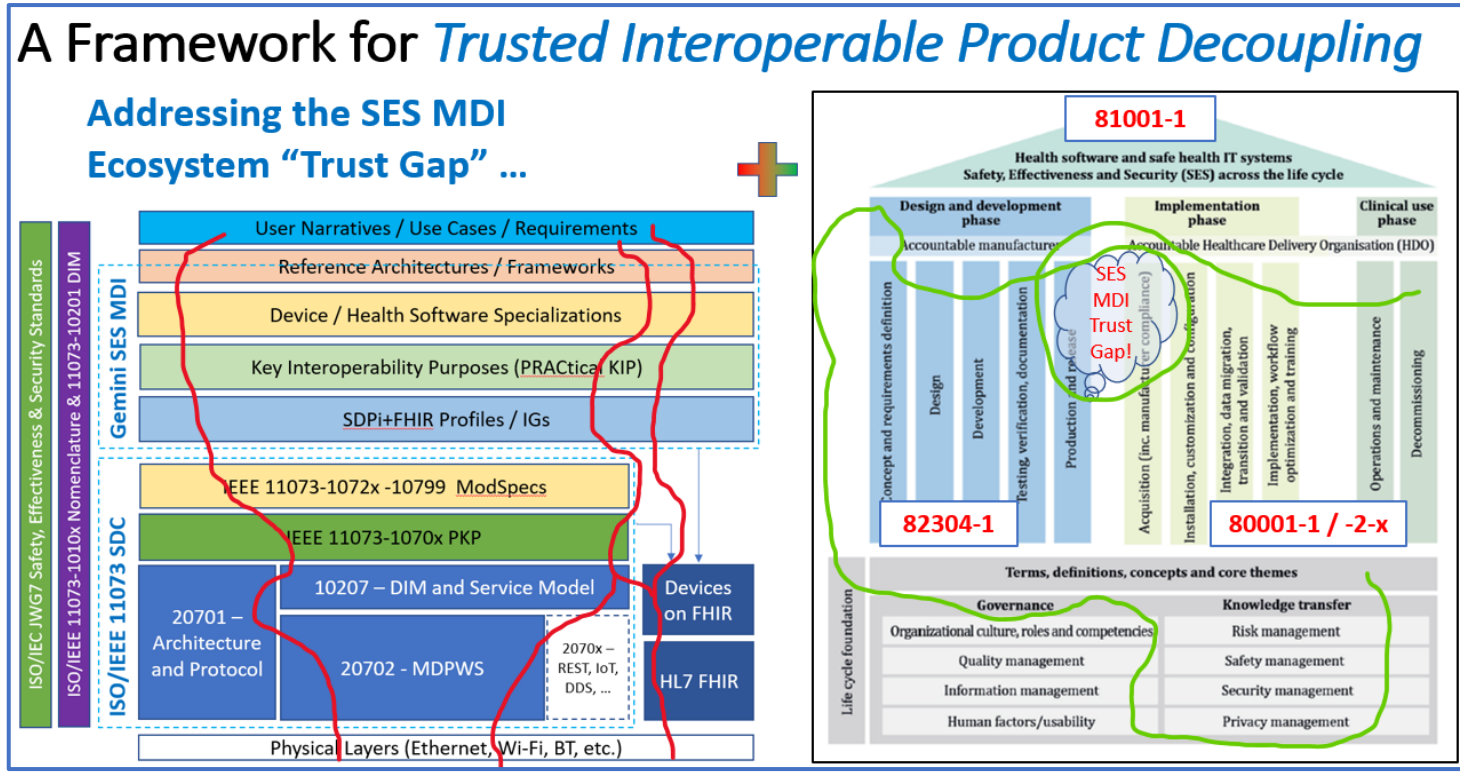


Source: SDPi-P Actor Diagram

SDC/SDPi+FHIR: Year 2 (2020) The Journey Begins

Year 2 Milestones

- ✓ "SES MDI" identified as a foundational concept …
- ✓ Integration of MDI technical standards w/ SES Quality & Regulatory process standards …
- ✓ Like real-world products do!
- ✓ EU "Notified Bodies" discussions advanced & OR.NET position paper published & initial IEEE 11073-10700 PKP standard draft out for review

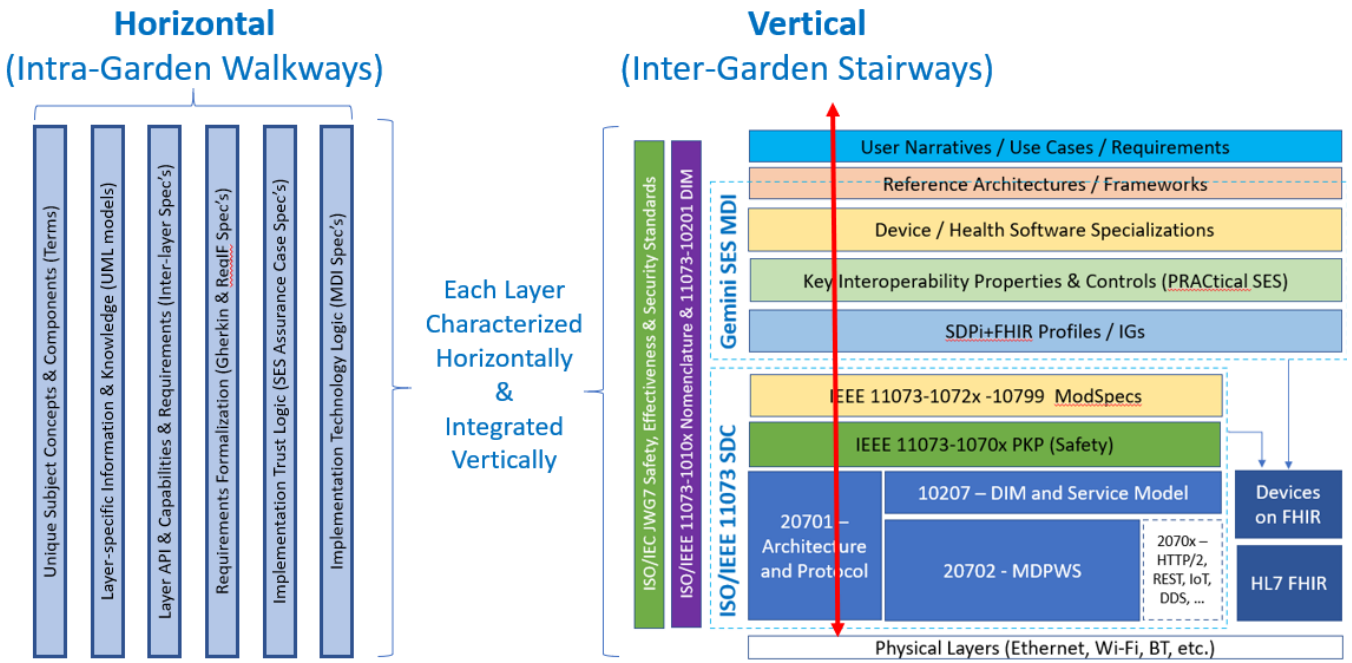


See OR.NET downloads for papers @ https://ornet.org/en/download/

SDC/SDPi+FHIR: Year 2 (2020) The Journey Begins

Year 2 Milestones

- ✓ New level of requirements management and Conformity Assessment (CA)
- ✓ Use of Gherkin & ReqIF evaluated to achieve traceability from use case narratives & scenarios to component product specification & testing
- ✓ Goal: CA test reports that can be directly used for regulatory submissions + certification of Plug-and-Trust products



SDC/SDPi+FHIR: Year 2 (2020) The Journey Begins

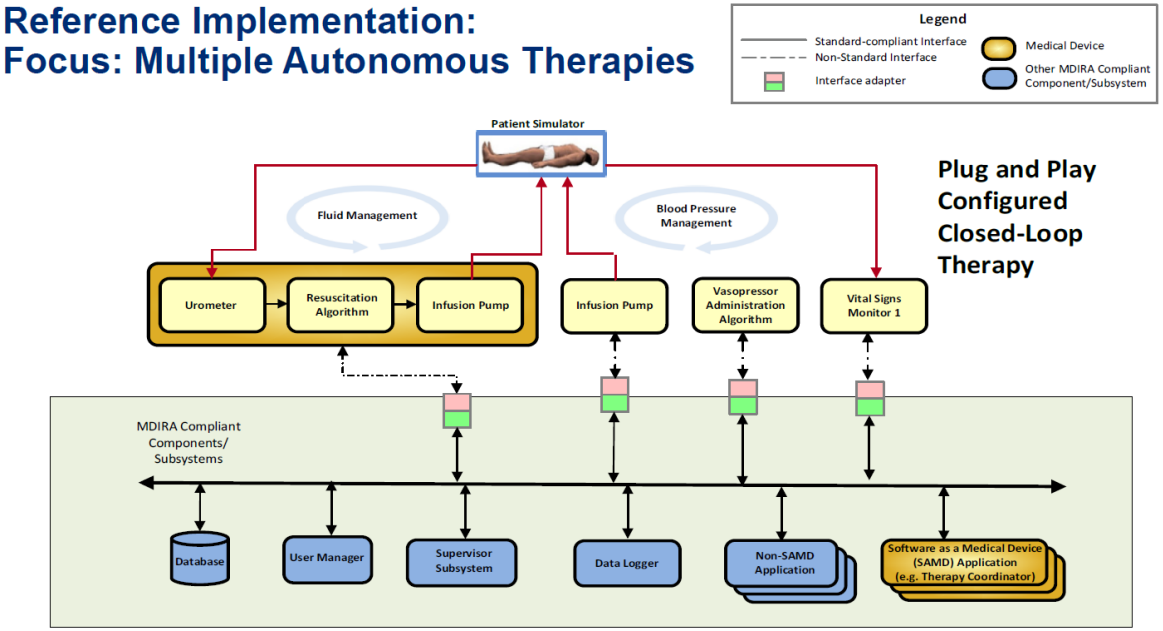
Year 2 Milestones

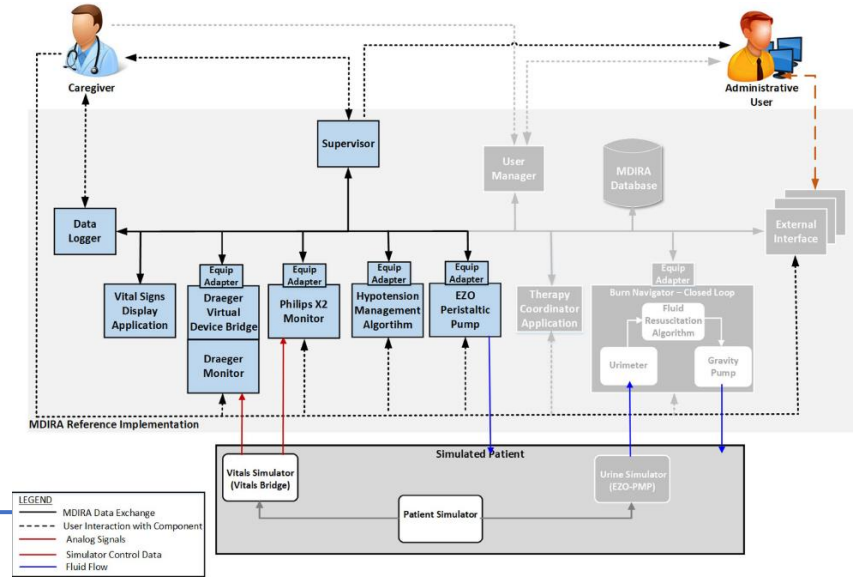
- ✓ JHU/APL MDIRA crafts an SDC-based reference implementation
- ✓ IHE DEV approves MDIRA Brief Profile Proposal for an SDPi+FHIR based specification
- ✓ NOTE: MDIRA motivated definition of Hanging Gardens Framework layer

And we survived 2020, but with close-to-home heart felt losses:

Christophe Fournier & Bill Majurski

Reference Implementation:
Focus: Multiple Autonomous Therapies



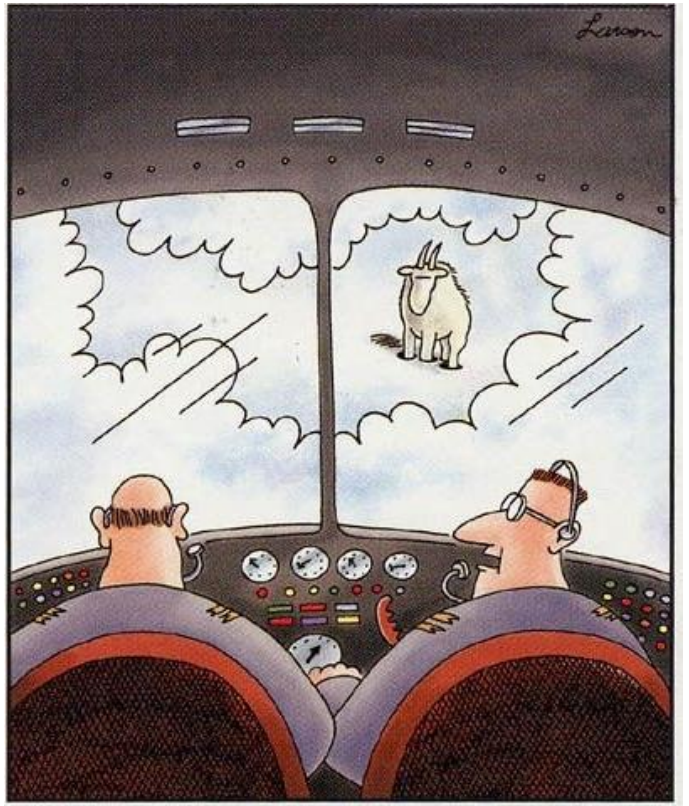


Source: JHU/APL MDIRA Update to IEEE/IHE/HL7 DEV WGM 2021.01.25

SDC/SDPi+FHIR: Year 3 (2021) 1st Summiting!

Year 3 Milestones

- ✓ Reach the first summits!
- ✓ Publish SDPi Supplement 1.0 (June '21), draft 2.0 (December '21)
- ✓ Publishing 1.0 using emerging IHE tooling (incl. Github repo => HTML)
  - Stretch Goal: IHE DEV TF 2021 Edition published from Github
- ✓ IHE & HL7 Plug-a-thongs & Connectathons
  - Tailored for emerging specifications (virtual & low budget!)
  - Regular cadence ~ monthly events
- ✓ Use Cases & Demonstrations, including focus on:
  - Silent Point of Care (SPoC) / Silent ICU
  - Isolation Point-of-Care (IPoC)
- ✓ Drafting MDIRA profile supplement
  - Initial (80%?) draft … requires coordination w/ SDPi TF



(View from an Isolation Point-of-Care Cockpit …)

SDC/SDPi+FHIR: Year 3 (2021) 1st Summiting!

Year 3 Milestones

- ✓ **Requirements Requirements Requirements**
  - *Integration (Gherkin->ReqIF) across Hanging Gardens Layers* (at least a few!)
- ✓ **Tooling Tooling Tooling**
  - *Leverage existing & emerging while advancing next generation support*
- ✓ **Education Education Education**
  - *Must be better at briefing SES MDI using SDC/SDPi+FHIR to all audiences*
- ✓ **Community Community Community**
  - *Must expand the developer/adopter community!*
  - *Must expand engagement of the SES Quality & Regulatory community*

Focus Topic: Do all roads lead to … *Devices on FHIR Destination*?!

Considerations in light of the HL7 V2-to-FHIR Project

Devices in FHIR – Multiple paths … Same Destination?

Since DoF launched in 2016 June …

Consider the current paths for device informatics in HL7 FHIR constructs:

- ✓ DoF PoCD IG – Maps ISO/IEEE 11073 PoCD (Classic & SDC) + IHE DEV/PCD V2 profiles

  (https://build.fhir.org/ig/HL7/uv-pocd/index.html)

- ✓ DoF PHD IG – Maps ISO/IEEE 11073 PHD + IHE DEV / PCH profiles

  (https://build.fhir.org/ig/HL7/PHD/TechnicalImplementationGuidance.html)

- ✓ V2-to-FHIR Project – Maps the HL7 V2 specification (across all uses) to FHIR constructs

Question: ***With these multiple paths … will we end up with a consistent integration of device informatics in HL7 FHIR ecosystems?***

Devices in FHIR – Multiple paths … Same Destination?

Emerging path: HL7 V2-to-FHIR Project

- ✓ Project (led by HL7 OO) is nearing in ‘21 ballot … it is real, here & now!
- ✓ Project maintained in Github repository: https://github.com/HL7/v2-to-fhir
- ✓ Published in HTML a la FHIR: https://build.fhir.org/ig/HL7/v2-to-fhir/
- ✓ Observations: Message Mappings VERY similar to DoF IG work
  (e.g., spreadsheets with 11073 PHD on the left, FHIR on the right)
- ✓ Status Notes:
  1. Limited number of messages (but ORU is included!)
  2. Pulled from January ‘21 Ballot due to the need to “bake” it some more

Devices in FHIR – Multiple paths … Same Destination?

At end of 2021 … will all paths lead to the same DoF destination?

- ✓ **Goal**: *Consistent integration of device informatics within FHIR-based ecosystems*
- ✓ HL7-IHE DEV support specifications using V2 messaging, 11073 PoCD & PHD semantics, SDC BICEPS & communications … and FHIR
- ✓ SDPi+FHIR includes "SOMDS Connector" bidirectional gateways … including for FHIR
- ✓ DoF Implementation guides consistently map 11073 semantics to FHIR resources
- ✓ V2-to-FHIR will be baked into products & open source tooling, etc.

Question: *Will the V2-to-FHIR message mappings (esp. for ORU profiles) be consistent with existing HL7-IHE DEV DoF specifications?*

Who / how / when … will this ***automagically*** happen?

(not a rhetorical question … time to engage is ***NOW***!)

Focus Topic: IHE TF Publications – *Accelerating the Evolution*

Oft heard:

- Do we have to keep these monolithic Word / PDF spec documents?
- Can't we become more like … HL7 FHIR publication in HTML?
- It's the 20's … can't we do better?!

IHE TF Publications – *Accelerating the Evolution*

Current state & challenges for IHE Technical Framework Publication

- ✓ Goals and Objectives of committee managing IHE use of HL7 IG publisher
- ✓ ITI TF Publication rolled out (https://profiles.ihe.net/index.html)
- ✓ IHE Publication Project (https://github.com/IHE/publications/)
- ✓ IHE "supplement template" project (https://github.com/IHE/supplement-template)
- ✓ Status of publishing @ ihe.github.io?

Publication at profiles.ihe.net represents a huge step forward … but …

Does this get us to where we really want to be? How does it compare to the V2+ work?

IHE TF Publications – *Accelerating the Evolution*

Consider the analogous HL7 V2+ project

- ✓ HL7 V2 is analogous: Word/PDF documents … pain pain pain
- ✓ V2+ Project aims to publish V2 in a way very similar to HL7 FHIR

And the Tooling is 1st Class, with our amazing Master Tool Builder: ***Michael Faughn***!

Project repository: https://github.com/HL7/v2-to-fhir

HTML Publication: https://v2plus.hl7.org/2021Jan/index.html

IHE TF Publications – *Accelerating the Evolution*

HL7 V2+ Project Review

MS Word

↓

Database + API
(based on v2+ & FHIR models)

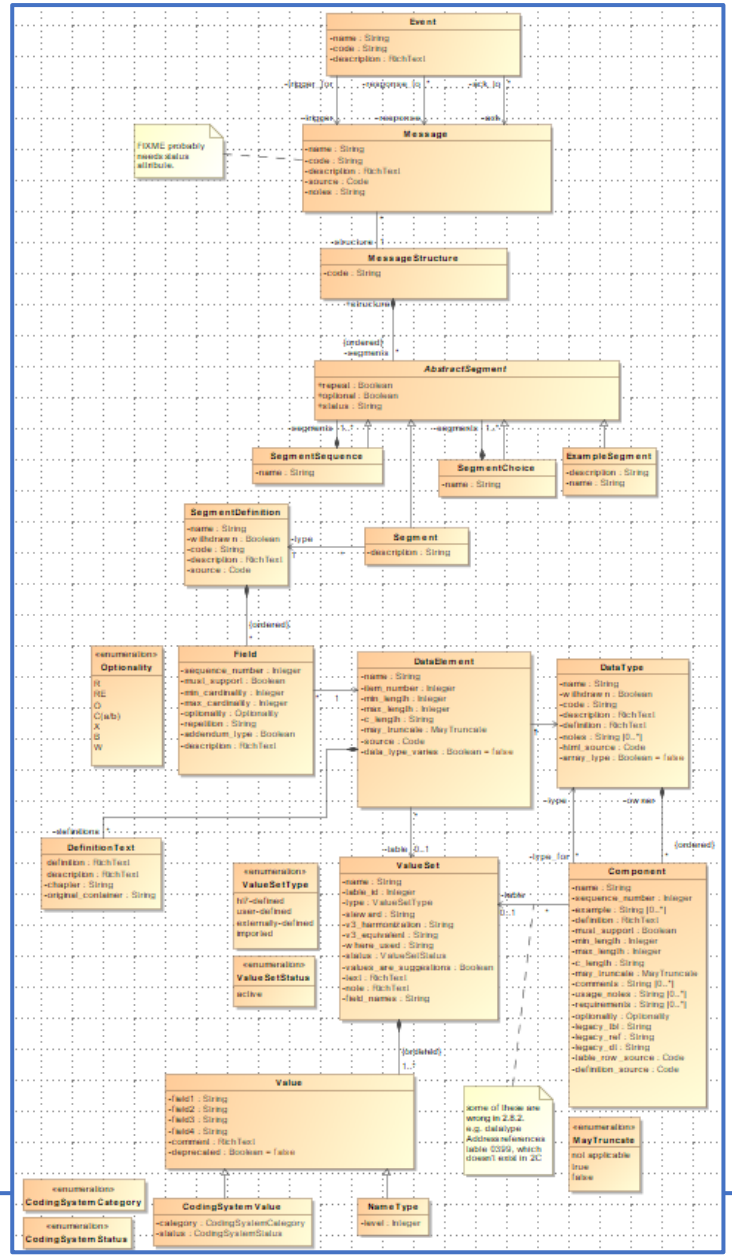
V2+ Editor 1.0

↓

FHIR Resources

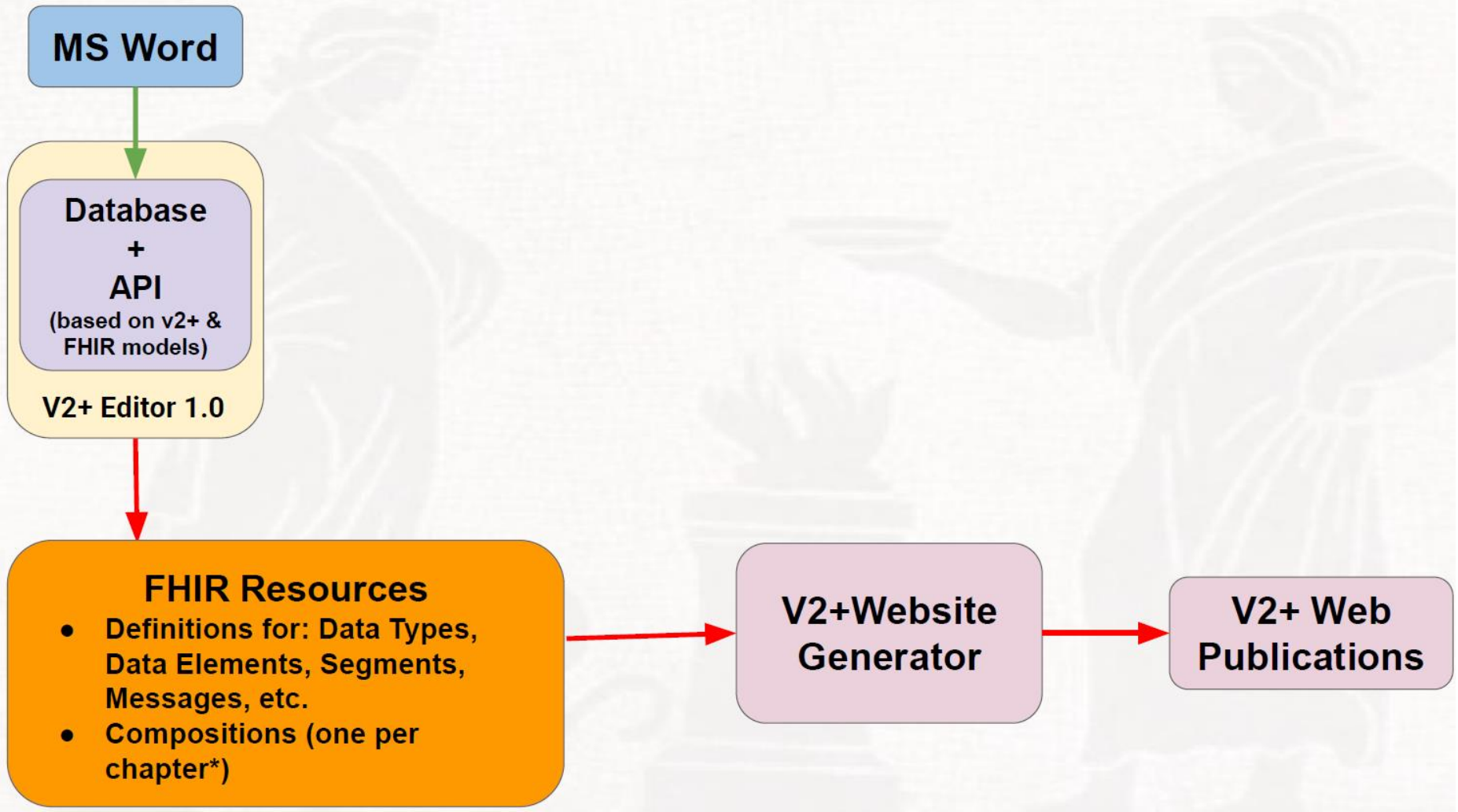
- Definitions for: Data Types, Data Elements, Segments, Messages, etc.
- Compositions (one per chapter*)

(note: Non-normative V2 UML model!)



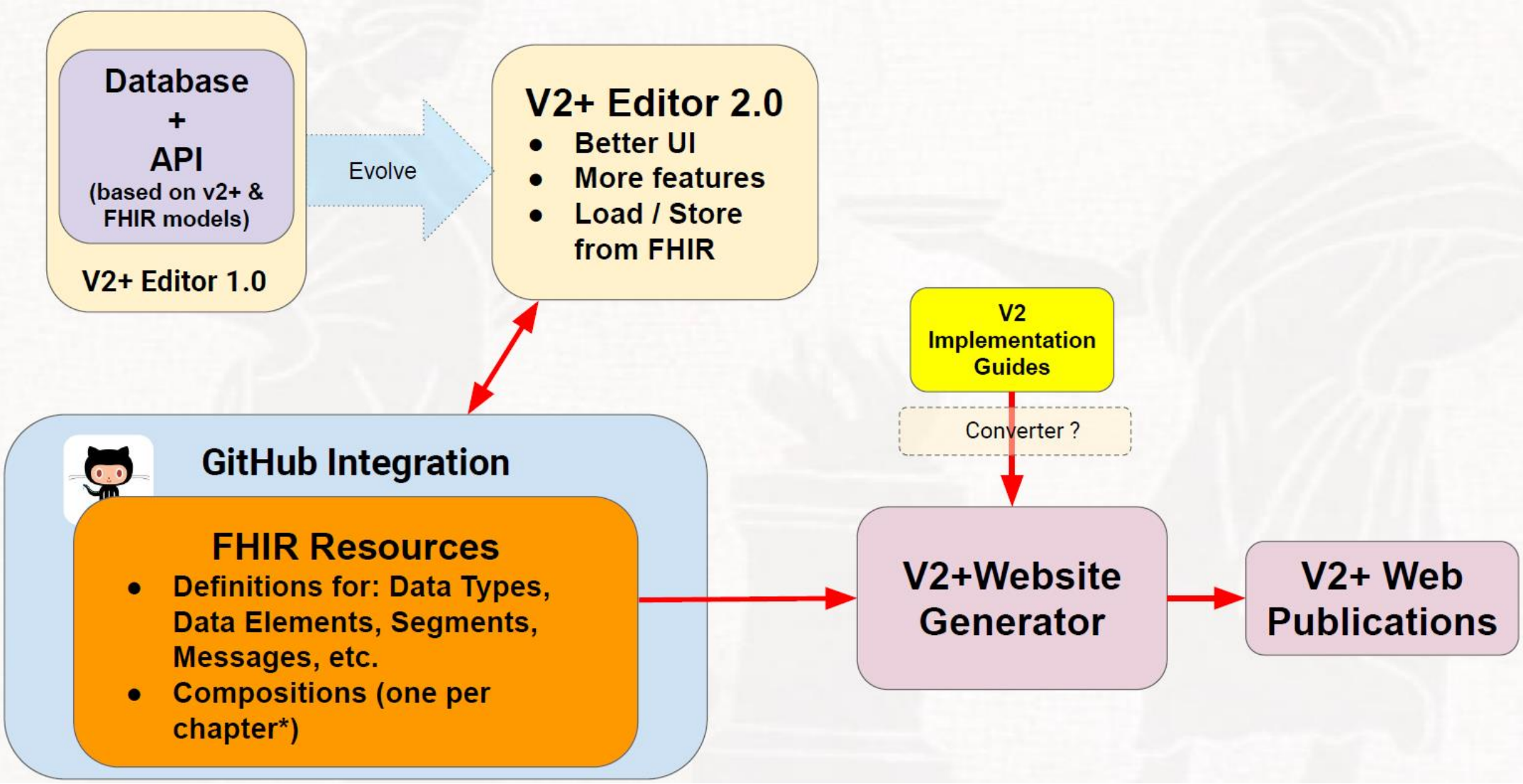
IHE TF Publications – *Accelerating the Evolution*

HL7 V2+ Project Review



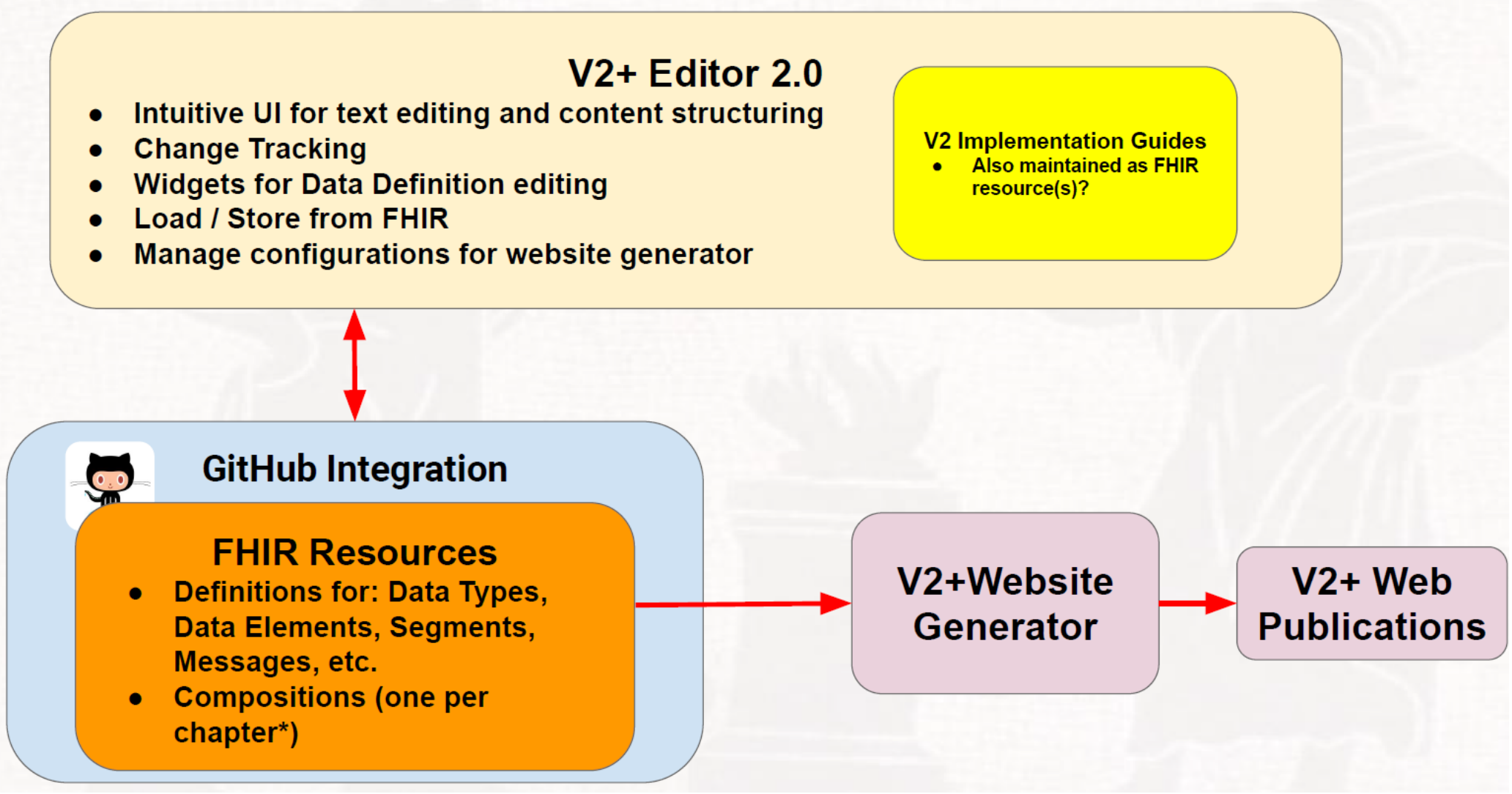
IHE TF Publications – *Accelerating the Evolution*

HL7 V2+ Project Review



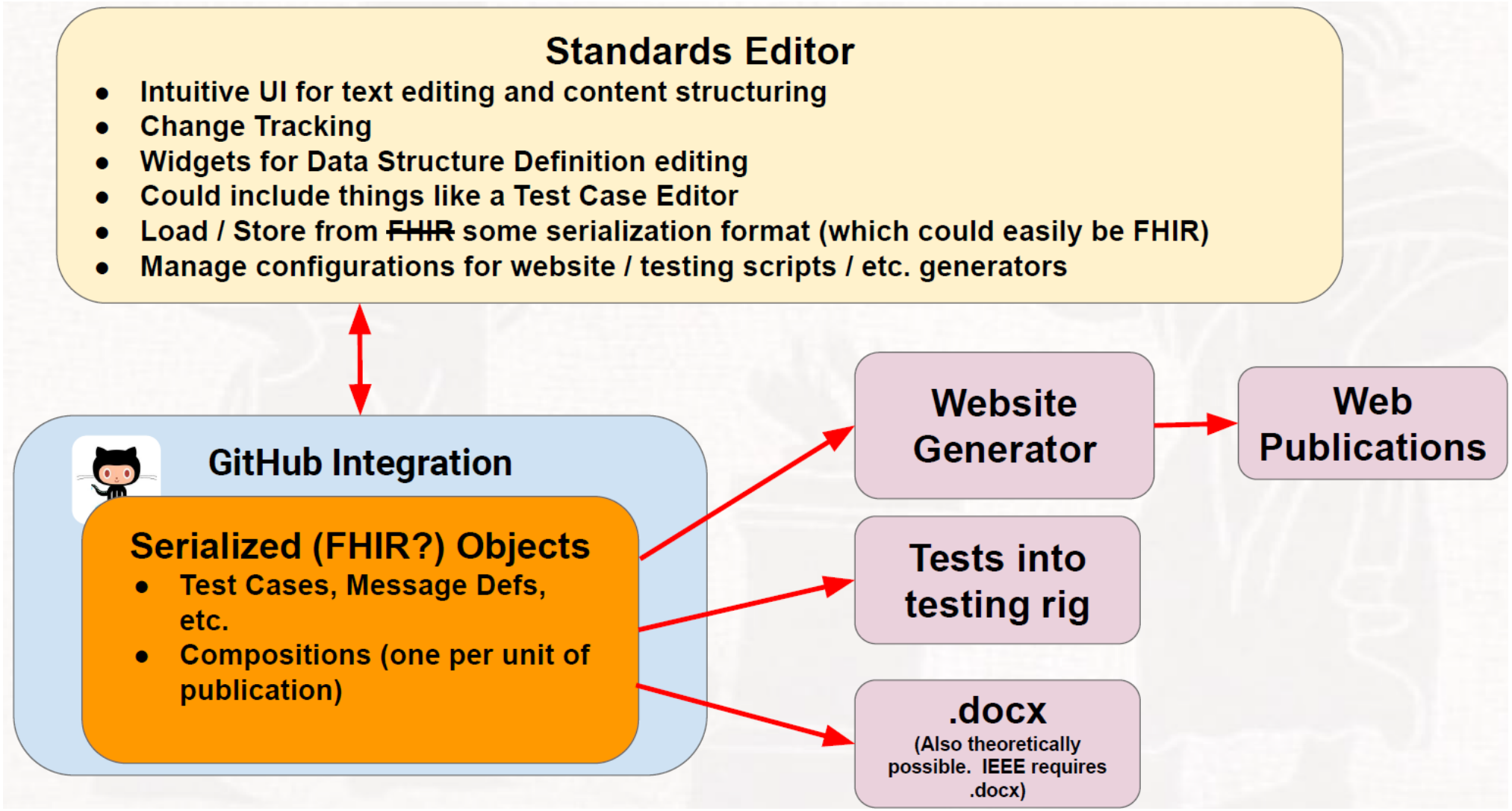
IHE TF Publications – *Accelerating the Evolution*

HL7 V2+ Project Review



IHE TF Publications – *Accelerating the Evolution*

HL7 V2+ Project Review



IHE TF Publications – *Accelerating the Evolution*

The 2021 Path Forward?

- ✓ Can we leverage the current ITI publication process (github => IG Builder => HTML)?
- ✓ Can we leverage the tooling approach crafted for HL7 V2+ Project? (V2+4IHE!)
- ✓ What is the role of tools like NIST IGAMPT? Usable for more than V2-based profiles? Integratable?
- ✓ Can we chart a path through 2021 to start with what we CAN do and move to a more robust – SME & User Friendly! – future state?

Discussion:

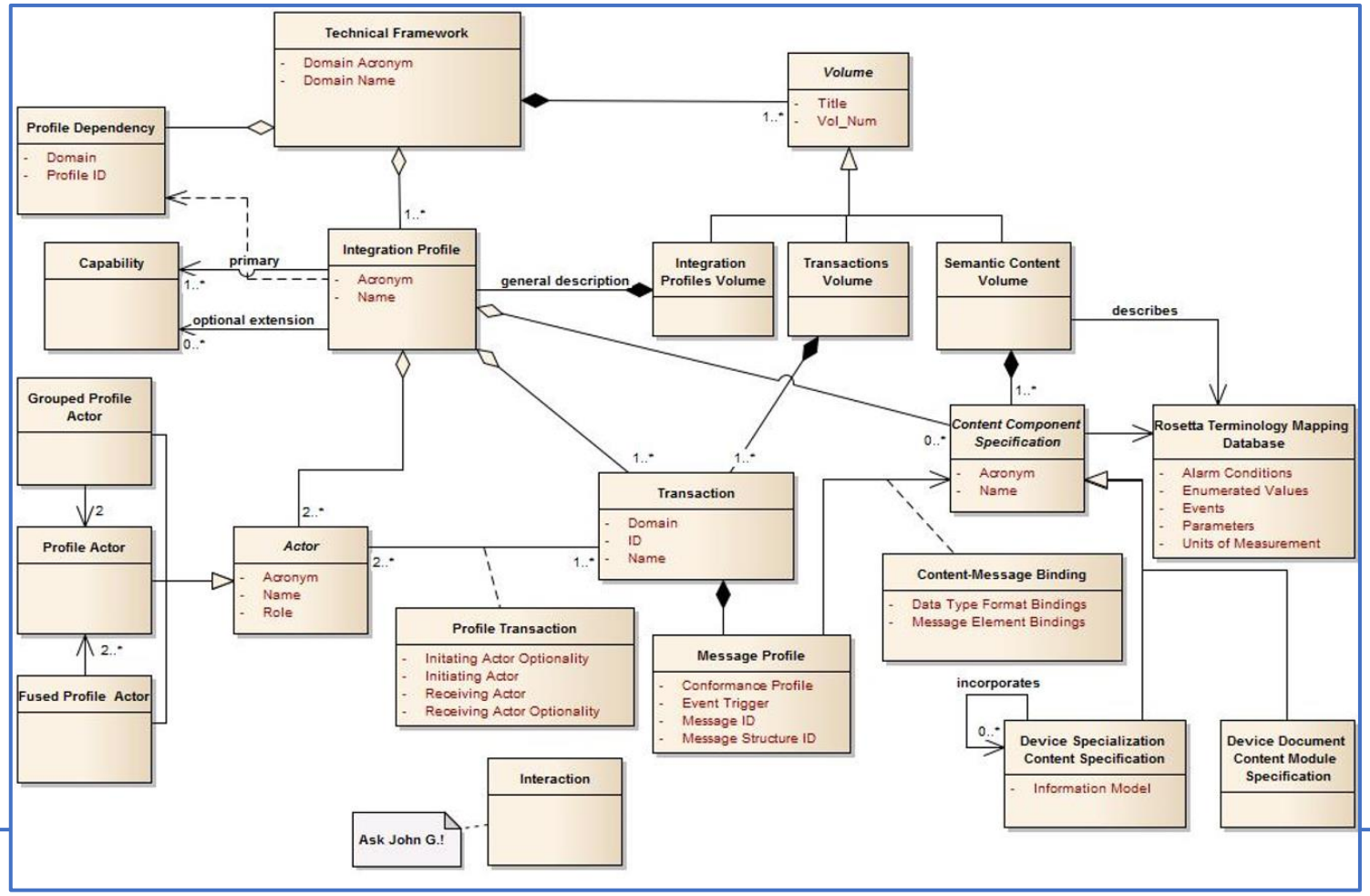
- ✓ See Michael Faughn's initial "feasibility" study (xml & HTML rendering)
- ✓ What would an IHE TF HTML "site" look like?
  - Refactoring of IHE TF pages (only dynamically published from github repo's)
  - Integrated specifications like HL7 FHIR (but without the messy IG Builder!)
- ✓ What additional markup would we want to include (e.g., ReqIF ready!)
- ✓ Include IHE DEV TF 2021 and integrate at https://profiles.ihe.net/index.html?

IHE TF Publications – *Accelerating the Evolution*

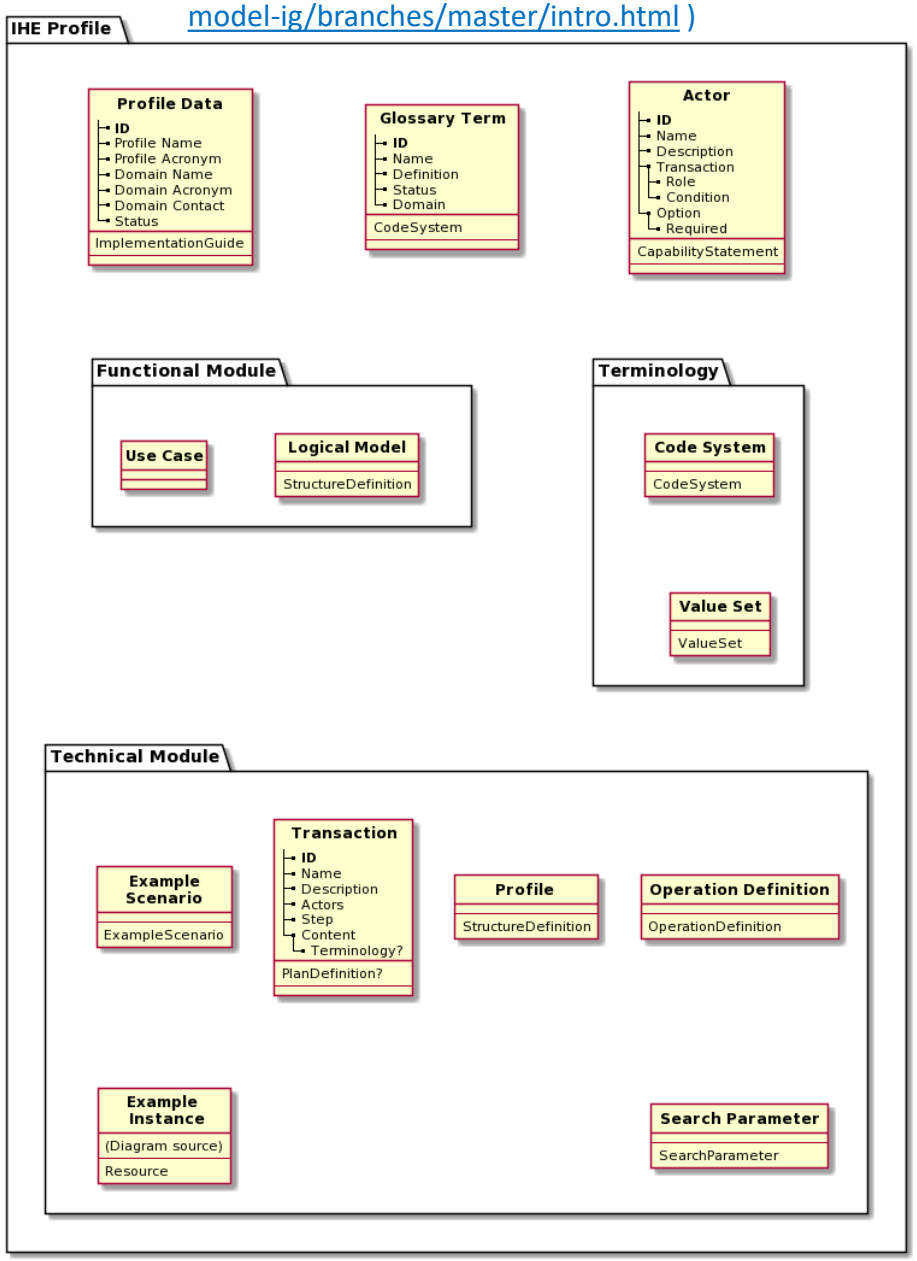
Discussion:

- ✓ Expand & update IHE TF Models to match current & future relationships?

Source: 2019 IHE SDPi White Paper



Source: IHE FHIR IG (http://build.fhir.org/ig/IHE/ihe-model-ig/branches/master/intro.html)



IHE TF Publications – *Accelerating the Evolution*

2021.02.10 Update (after ITI Publication Discussion w/ Moehrke)

- ✓ Discussion "Takeaways":
  - All efforts are in experiment stages … NOTHING is finalized as "The IHE Approach"
  - ITI has (4) Different HTML Publication Approaches: TF vs. White Paper vs. Supplement vs. FHIR-based IHE IG … and they are all "experimental"
  - *profiles.ihe.net* will be used long term for publication of IHE profiles
  - *ihe.github.io* used for "pre-staging" draft content incl. for group review & comment
  - "HIE White Paper" created in ***markdown*** but the ITI TF FT will be maintained & edited in ***HTML*** only
  - https://*github.com/IHE/publications* is where all published content is maintained and, in some cases, managed (e.g., vs. ITI TF FT but not FormatCode which has its own repo)
  - '22 on … no PDFs!
  - Used PanDoc for Word-to-Markdown … *OTHER TOOL for Word-to-HTML (ask Martin Smock)*
  - FSH / Sushi used (https://github.com/FHIR/sushi) for MHD integration with **IG Publisher**
  - See also "gen-html.bat" tool on IUA Supplement (https://github.com/IHE/ITI.IUA)
    - For example, may be a one liner script to call PanDoc

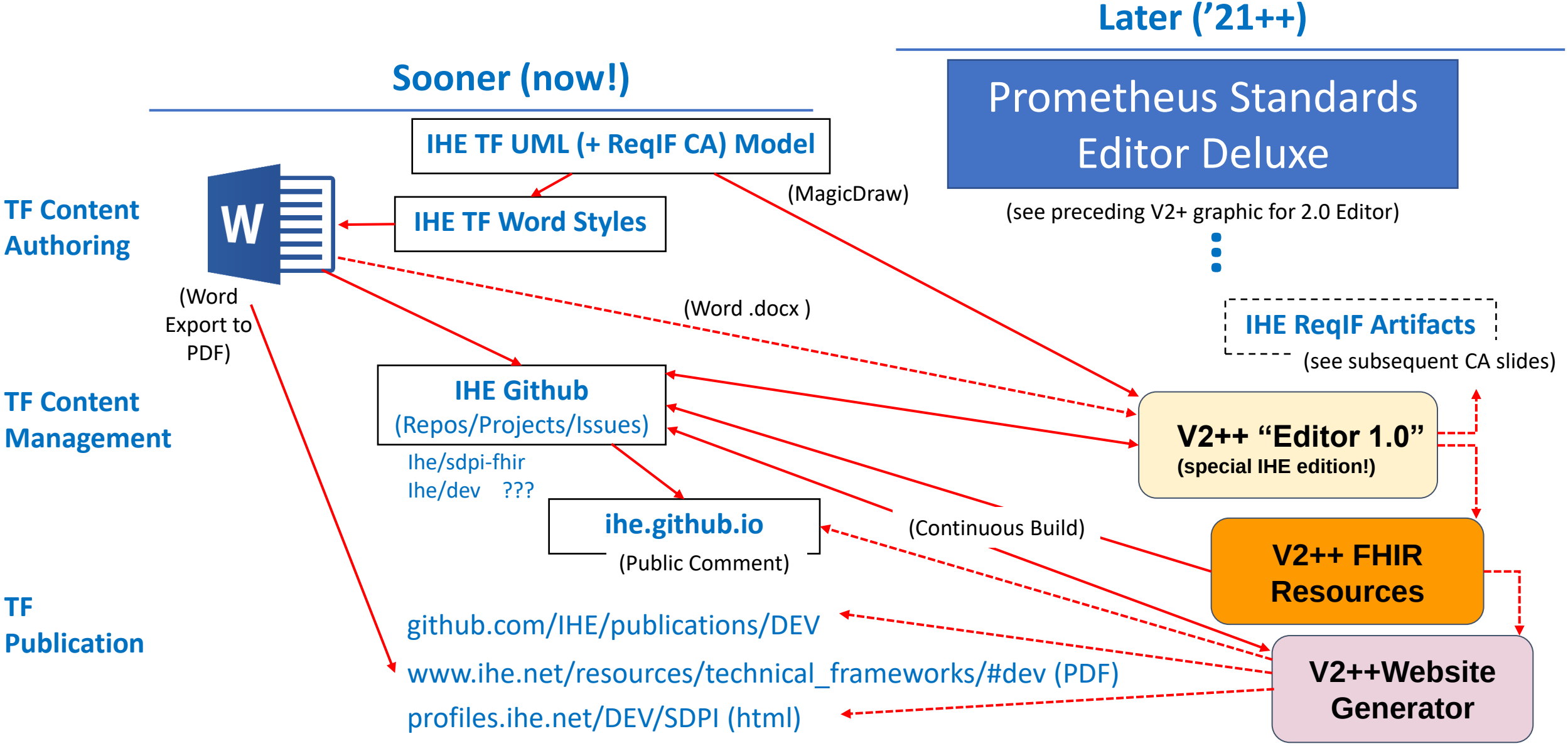
IHE TF Publications – *Accelerating the Evolution*

2021.02.10 Update (after ITI Publication Discussion w/ Moehrke

- ✓ SDPi Pilot Project Next Steps :
  - Craft updated IHE TF UML Model that integrates / supports the CA strategy below
  - Define a model-aligned set of Word styles that can be leveraged by the V2+ front end tool
  - Review the various IHE & V2+ HTML publications look-and-feel to craft a target for SDPi
    - IUA would be a preferred starting point (https://profiles.ihe.net/ITI/IUA/index.html)
    - ITI TF HTML at profiles.ihe.net
    - Consider MHD HTML also (http://build.fhir.org/ig/IHE/ITI.MHD/branches/master/index.html)
  - Near Term: Utilize the V2+ tooling for HTML publication
    - See gitlab.com/prometheuscomputing/v2fhir
  - Longer Term: Move toward the "Standards Editor" WYSIWYG vision for the project, informed by the UML model & SDPi Supplement development & publication
    - ***Word Free & FHIR IG Publisher Free & Markdown/HTML Editing Free … Future***

      Note*: "free" = Not required but can use if and when appropriate +*
      Users won't have to know what is "under the hood" !
  - **OPEN ISSUE**: *What to do / IF to do for the 2021 IHE Devices FT for HTML Publication … ??*
  - Schedule regular "IHE Publication Automation" meeting for those advancing pilot projects

IHE TF Publications – *Accelerating the Evolution*



Focus Topic: Is a strategy emerging for traceability from Use Case Requirements to Conformity Assessment?

Gemini SES MDI initiative looks to raise the bar for navigating from detailed use case requirements specifications to CA testing reports that can be used directly for regulatory purposes. Is there a clear strategic path to achieving this … in our lifetime?!

Use Cases to CA: From vision to reality?

Two key questions:

- ✓ Big Picture: Can a course be charted from where we are today … that's worth embarking on?

and

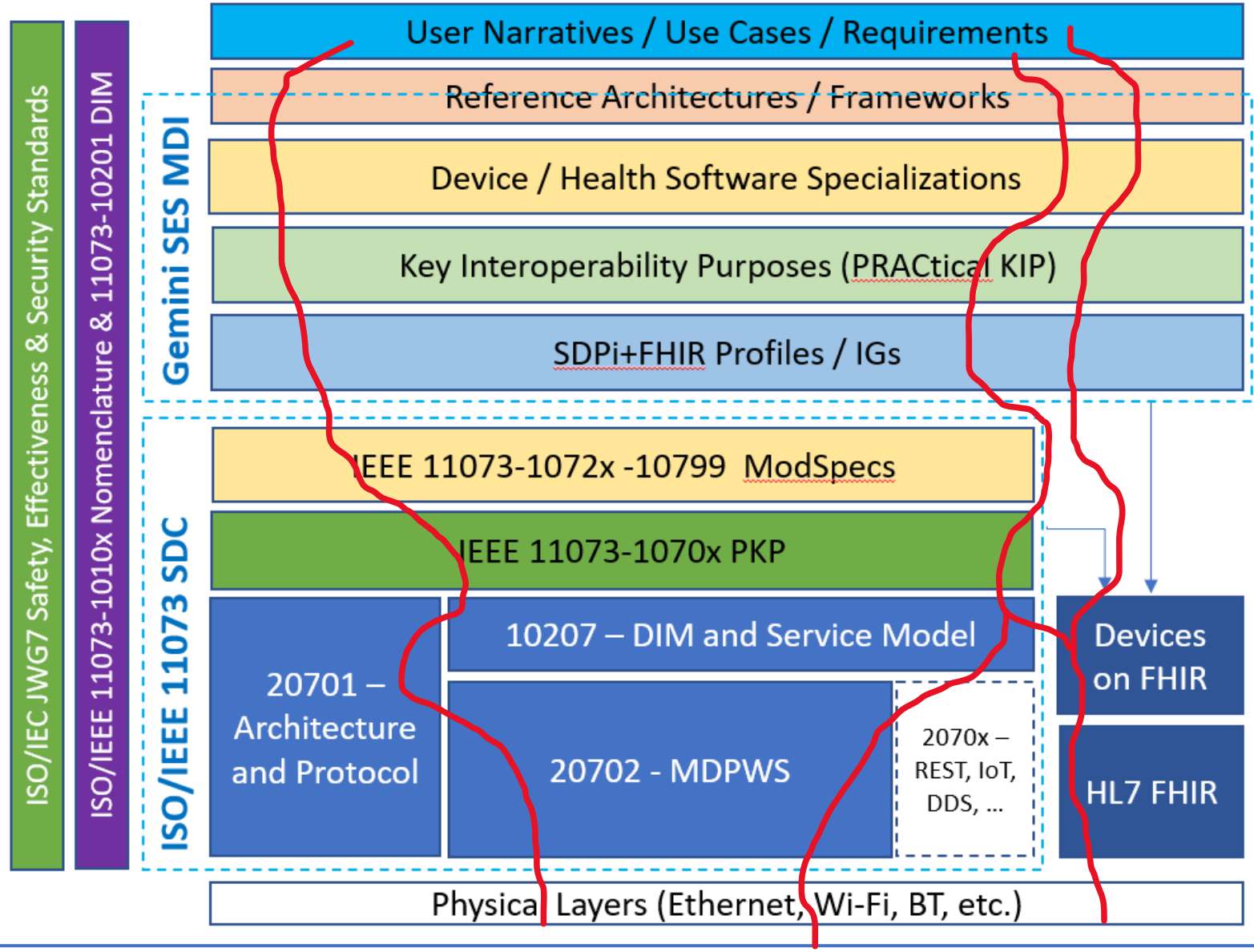
- ✓ Traceability: Can this be achieved in a Hanging Gardens world?

Charting the course from narratives to interfaces

SDPi+FHIR Grand Vision:
Traceability from Narrative/Use Cases to Plug-n-Trust Interfaces!

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

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



Comprehensive System Function Contribution (SFC) → Plug-n-Trust Interfaces / Ecosystem

Orientation Tour: From Volume 1 to 2 to 3

Remember the organization / integration of the SDPi Supplement …

SDPi TF Supplement Vol.1 Integration Profiles

SDPi-P Profile

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

SDPi-Reporting Profile …

SDPi-Alerting Profile …

SDPi-xControl Profile …

M:N Profiles & Transactions

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

Appendix B: ISO/IEEE 11073 SDC Requirements Coverage

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

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

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

SDPi TF Supplement Vol.2 Transactions

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

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

MDPWS Message Detail in Appendix

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

…

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

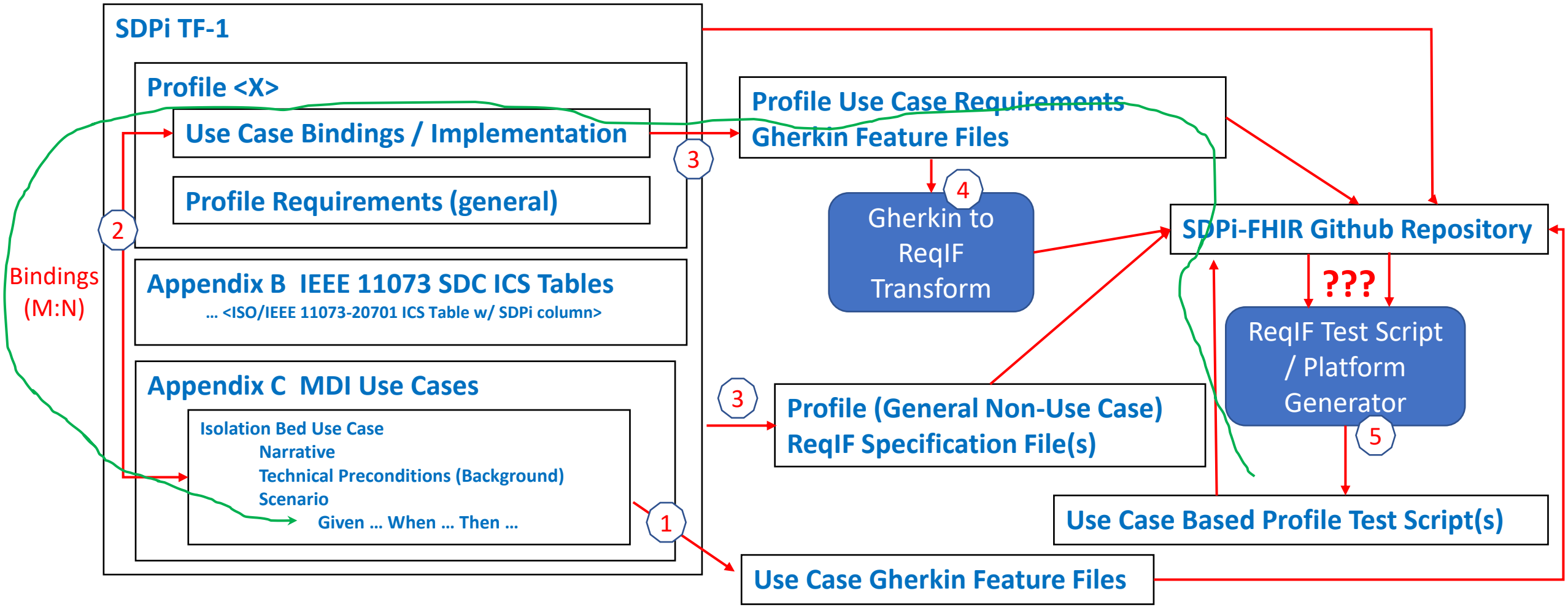
Appendix A: ISO/IEEE 11073 SDC / MDPWS Message Specifications (Normative)

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

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

Requirements: From Use Cases to CA Test Scripts

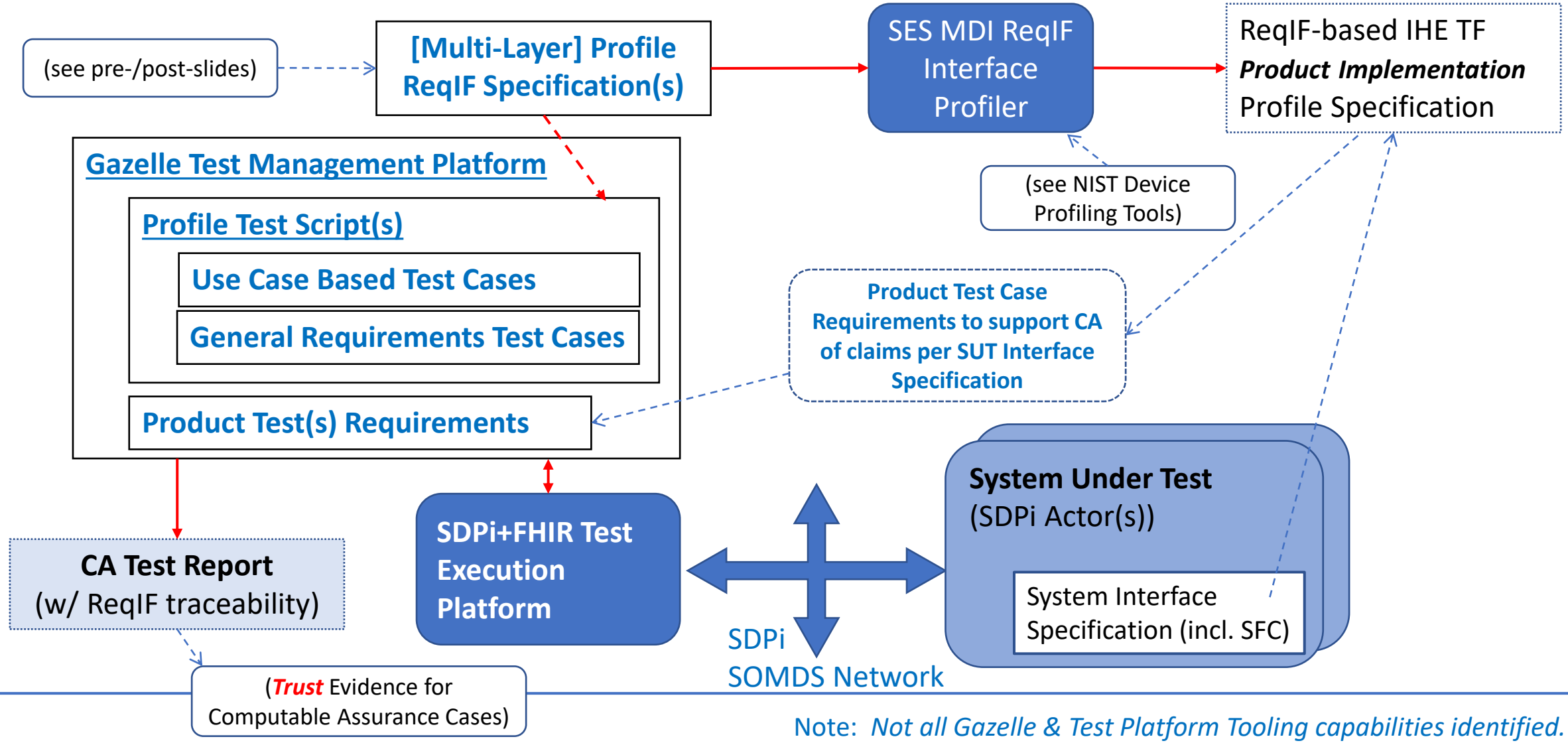
Consider the following … "From *Use Case* requirements"



NOTE: TF-2 & TF-3 requirements management not included but would leverage the same approach.

Requirements: From Use Cases to CA Test Scripts

Consider the following … "to Conformity Assessment"

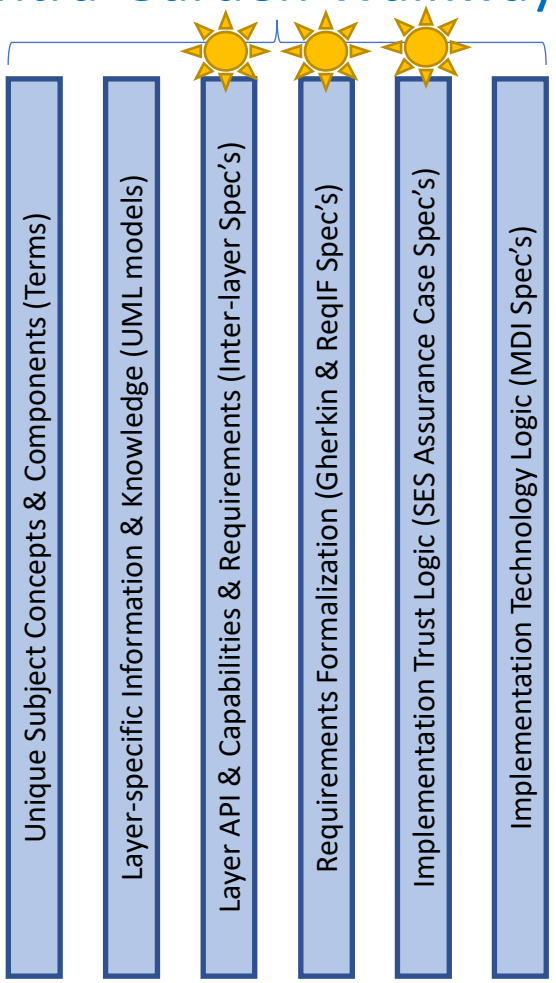


Note: *Not all Gazelle & Test Platform Tooling capabilities identified.*

Layer Characterization: *Horizontal & Vertical*

Remember from 2020 Hanging Gardens discussion …

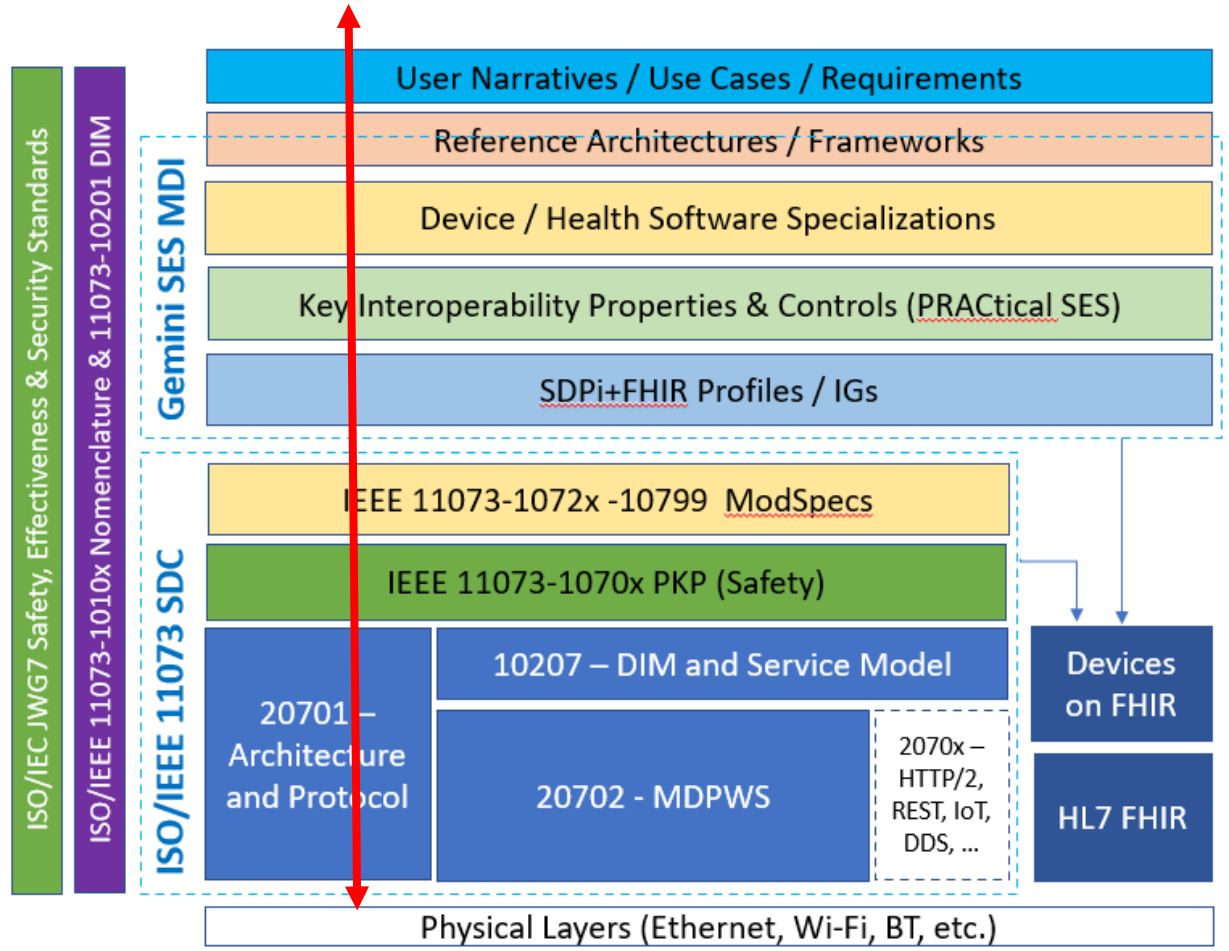
Horizontal
(Intra-Garden Walkways)



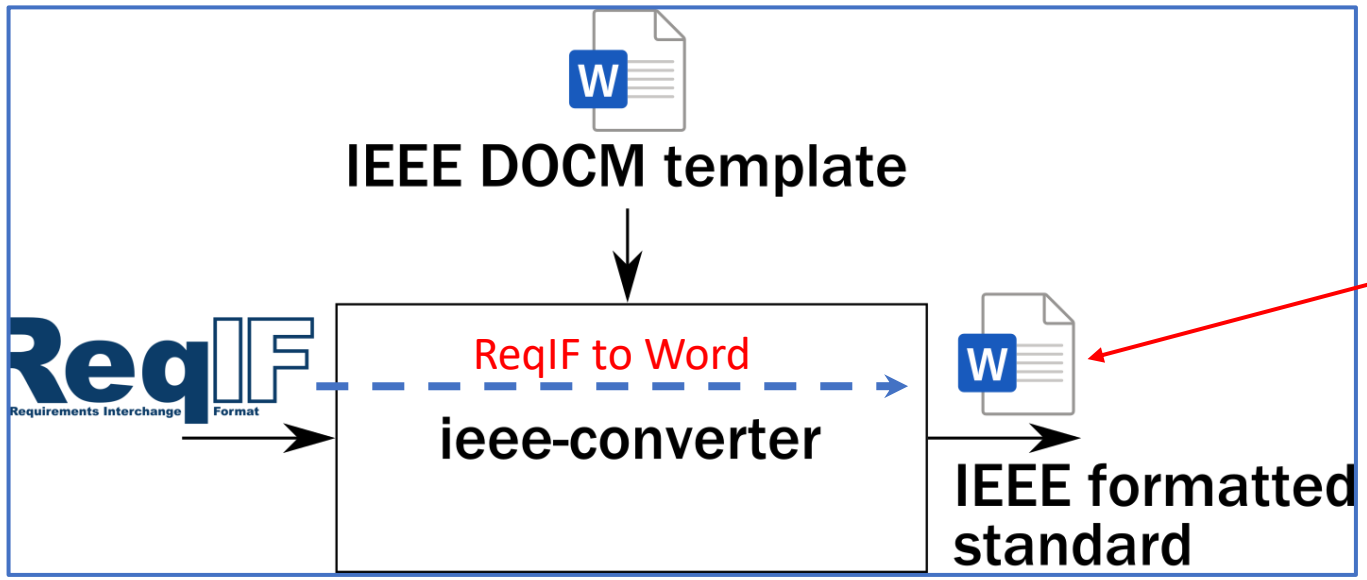
Each Layer Characterized Horizontally & Integrated Vertically

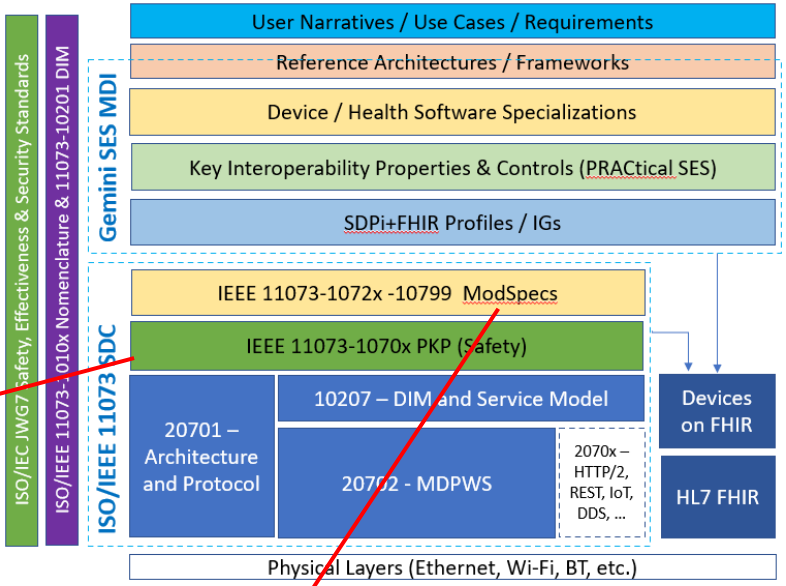
How?!

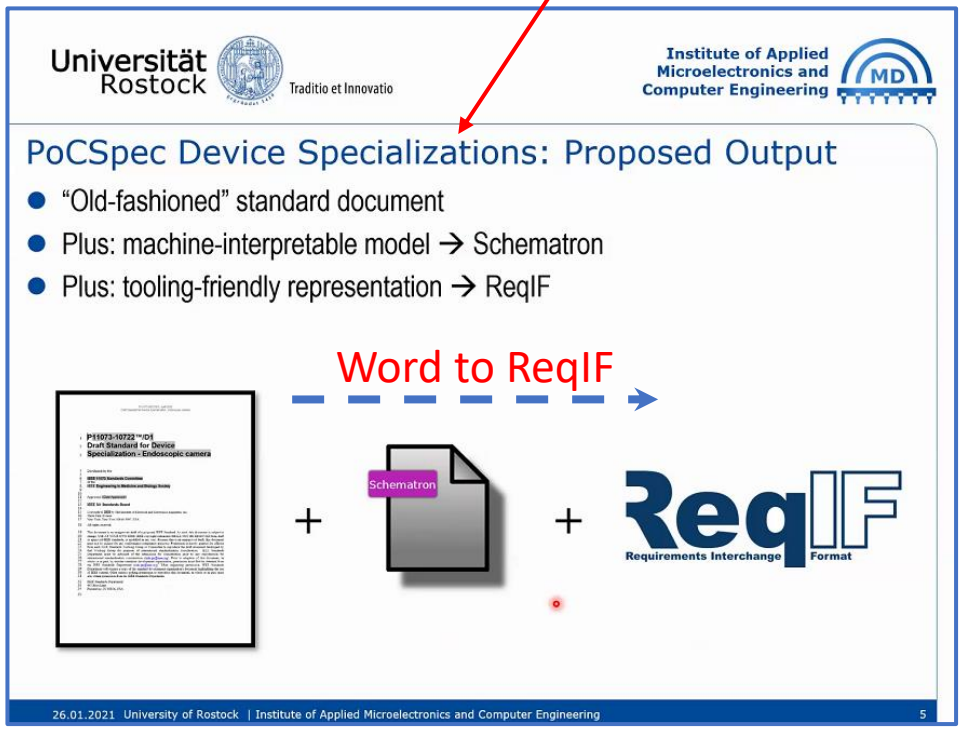
Vertical
(Inter-Garden Stairways)



ReqIF sightings in the gardens …



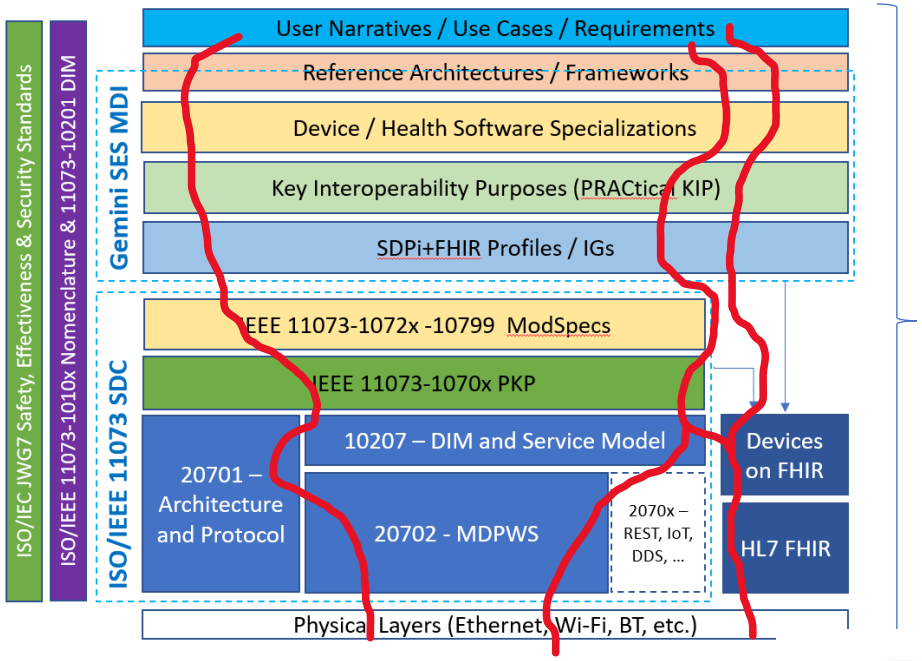




Note: Though Requirements Interchange Format (ReqIF) does not ensure inter-layer requirements integration out-of-the-box, it is increasingly used and as a result, found supported by many requirements management system tools.

Requirements: From Use Cases to CA Test Scripts

Consider the following … "*Traceability* in a Hanging Gardens World"



Layer ReqIF Meta-Model *

Layer Requirements Specifications

- **Layer Capabilities "API" Specification**
- **Implementation / Realization Req'ts**
- **Computable Assurance Case Specification(s)**

(see ReqIF SpecHierarchy Model)

ReqIF "Layer Mapping" Tool

Inter-Layer Mapping Specification(s)

Multi-Layer Profile ReqIF Specification(s)

(see preceding slide)

SDPi + MDIRA Pilots could include:

- ✓ General Use Cases (Appendix C)
- ✓ "MD-SOA" & MDIRA/ICE Architectures
- ✓ IEC 80001-1 2nd Edition
- ✓ SDPi+FHIR & MDIRA Profiles
- ✓ IEEE 11073-10700 PKP
- ✓ IEEE 11073 SDC Core Standards

Requirements Interoperability!

* "ReqIF Meta-Model" will include requirement classification "attributes" / SpecTypes for "user views" and grouping (e.g., func/non-func).

Requirements: From Use Cases to CA Test Scripts

The 2021 Path Forward?

- ✓ What is the best path forward for formalizing capture of these requirements? (one that can be expanded as additional profiles & standards & organizations are integrated)
- ✓ How can a "new" IHE TF approach incorporate this level of requirements specification and traceability?
- ✓ Should we even bother with a tool like Cucumber Studio? Is there an open source Cucumber/Gherkin "syntax" tool that would be better to use? **PROBABLY NOT**
  - ✓ NOTE: *Many IDE & editors support "syntax highlighting" for Gherkin*
- ✓ Is the ReqIF Studio tool needed? Sufficient? **PROBABLY NOT**
- ✓ …

Yes … there’s more!

Additional information … if the preceding didn’t quench your thirst!

OMG ReqIF: Base Model

See also: ISO/IEC/IEEE 29148:2011 Systems And Software Engineering - Life Cycle Processes - Requirements Engineering

Source: OMG Requirements Interchange Format (ReqIF) Standard

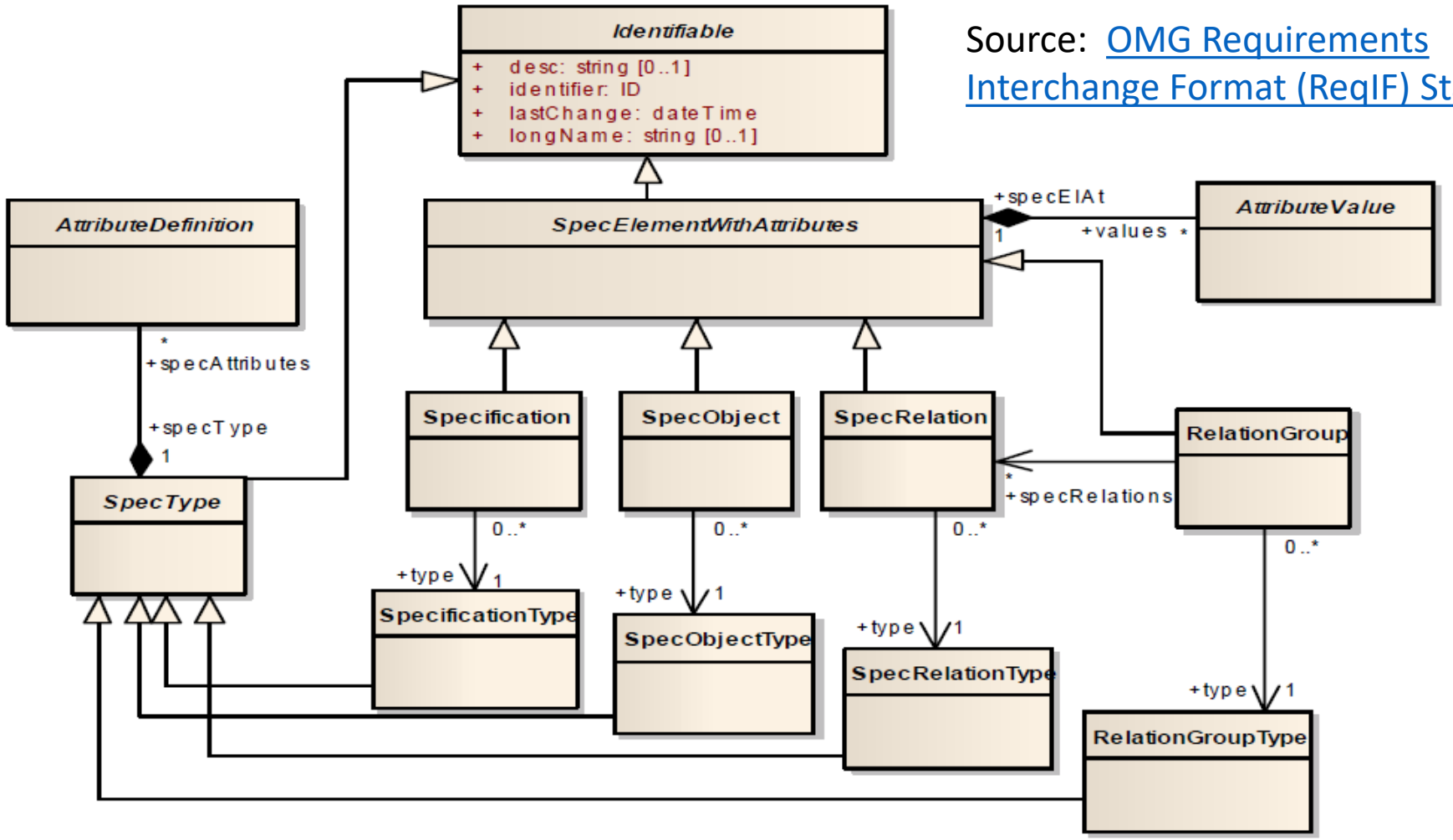


Figure 10.3 - Specification (Specificification), requirement (SpecObject), requirement relation (SpecRelation), relation group (RelationGroup) and associated attributes (AttributeDefinition, AttributeValue)

ReqIF: Requirement Hierarchies & Relationships

“mapping”
between
Source & Target Requirements

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

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

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

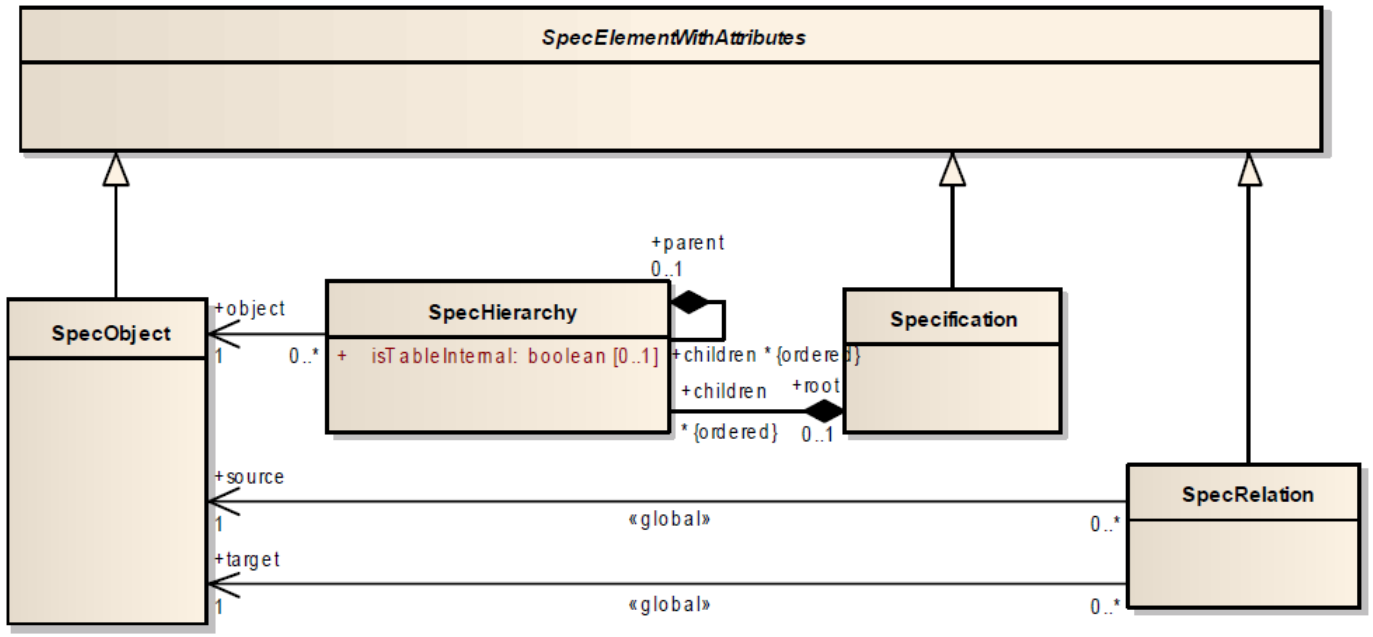
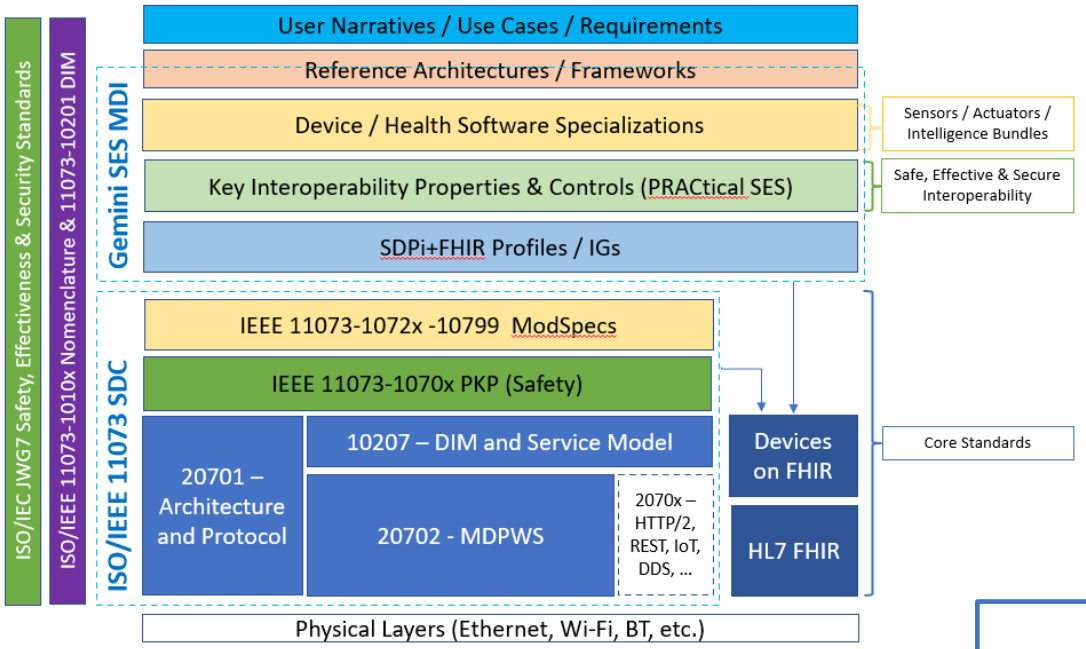


Figure 10.6 - Requirements, requirement relations and how requirements are structured hierarchically in a specification

Source: [OMG Requirements Interchange Format (ReqIF) Standard]

Hanging Gardens: *After SDPi 1.0 …*

NOTE: *Profile Titles are notional – hopefully useful too!*



Devices-In-Care (PDP) Profile

Device Specialization Profile

Surgery PoC Profile

ICU PoC Profile

MDIRA ICE Profile

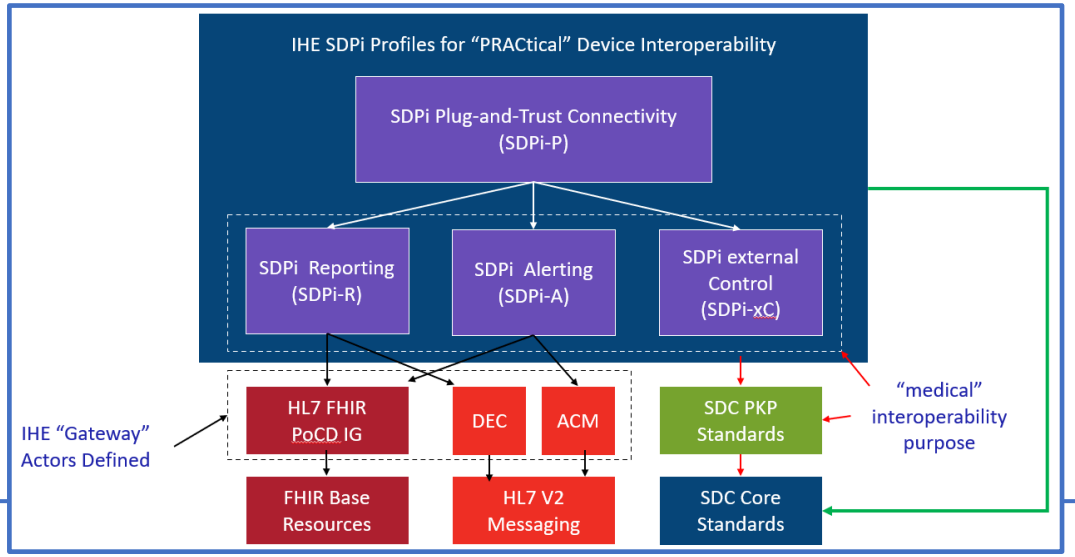
SOMDS@home Profile

IHE (Official) Profile Types:

Transport, Content, Workflow

Or a combination of all (3)

Other types?

Architecture (SOA, MDIRA, SDC, ….?

Single domain / multi-domain?