



IHE-HL7 Gemini SES+MDI – *Program Update*

for

IHE Devices “Spring” Meetings

2022.04.28 ~ San Diego “AFC!”

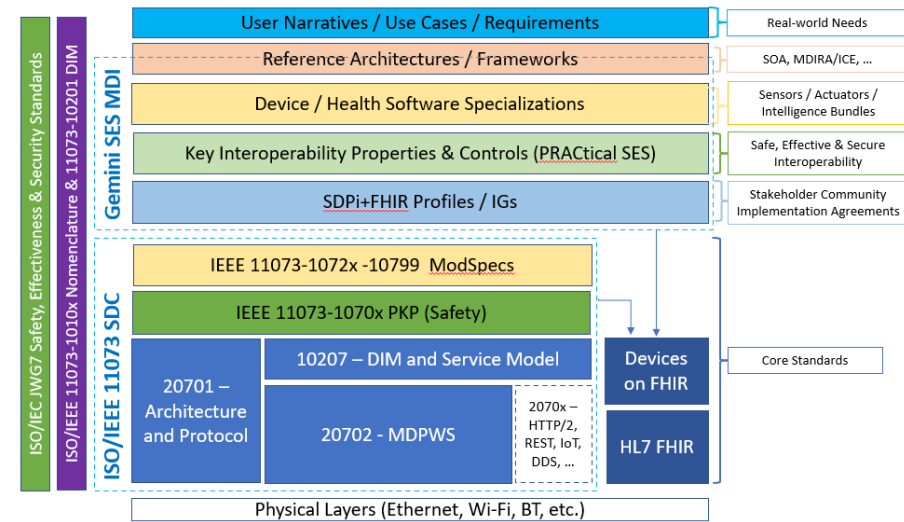


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Gemini SES+MDI using SDPi+FHIR



General Project Update – January to April 2022

RI+MC+RR Update – 2022 CA & Tooling Strategy Challenges

SES Ecosystem Pathway Update

Topics of Interest Review

Focus: Updating IHE DEV OIDs & Supporting SDPi Extensions

Focus: From github repo's to profiles.ihe.net/dev

Gemini SES+MDI – General Project Update 2022.01 - 04

What have been the primary activity threads since the January 2022 working group meetings?

Gemini SES+MDI Updates ...

Building on two years of updates ...



Making Healthcare Interoperable



SERVICE-ORIENTED DEVICE CONNECTIVITY

IHE-HL7 Gemini MDI SDPi+FHIR –
Hanging Gardens Guided Tour

for
Joint IEEE / HL7 / IHE Working Group Meetings
2020.09.23



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Program Update

for
Joint IEEE – HL7 Devices Working Group Meetings
2022.01.21



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2021.09.24



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Project Update

for
Joint IEEE / HL7 / IHE Working Group Meetings
2021.05.26



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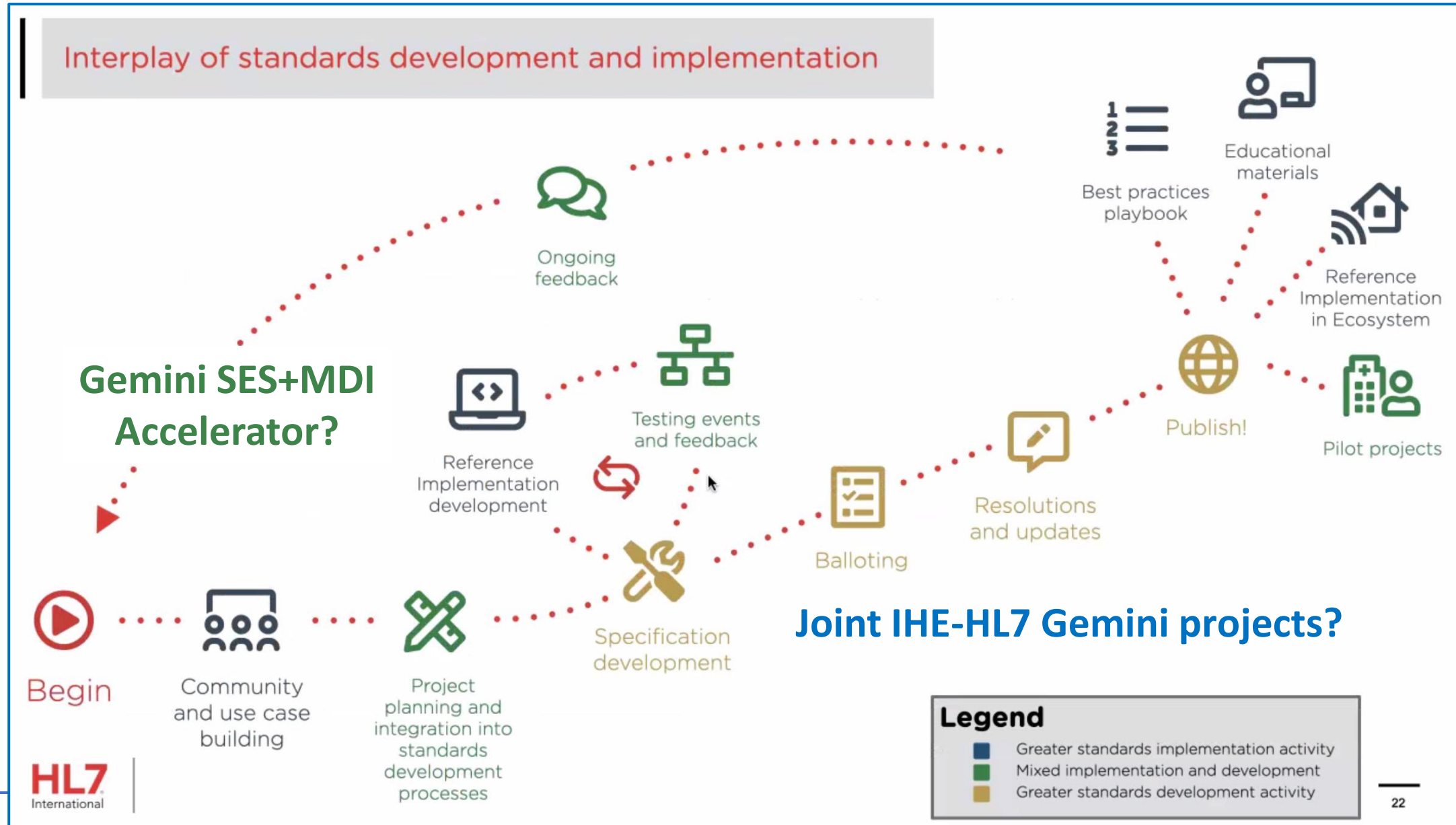


Gemini SES+MDI – Update January to April '22

Program highlights since January '22 WGM include ...

- ✓ *Primary focus has been on CA & Tooling '22 Strategy Development (see next sections)*
- ✓ *IHE DE Plugathon's (PAT) #7 successfully completed, #8 planned for 2022 May*
- ✓ *SDC/SDPi Demo's at HIMSS'22 Interoperability Showcase + DEMA'22 (Berlin, OR.NET booth) - IPoC*
- ✓ *HIMSS'23 Demo Focus: Silent Point-of-Care / ICU Use Case (see also DAS / SAS Topic)*
- ✓ *Sustainable business model “accelerator” options being evaluated for the Gemini SES+MDI program*
- ✓ *SDPi “Topics of Interest” list updated, prioritized & resolution work continued (See next sections)*
- ✓ *Focus on an SDC/SDPi PAT @ IHE Global CAT September '22 + Hybrid SDPi CAT late '22*
- ✓ *MDIRA Profile activity continued monthly discussions – especially relevant to EP SES Discussions*
- ✓ *IEEE 11073 Coordination – especially -1070x PKP implementation + fixes/extensions ... now!*
- ✓ *HL7 Coordination: PSS-1980 SES+MDI & PSS-2005 Device Alerting (DEVAL) (see next sections)*

Gemini SES+MDI Updates ... HL7 "Re-envisioning"



Gemini SES+MDI – RI+MC+RR Update – 2022 CA & Tooling Strategy Challenges

How can we advance from PATs to CATs using what we have “in hand” now but laying the foundations for 2023 and beyond?

Gemini SES+MDI Updates ... CA & Tooling Strategy

Since early February 2022 ... a key focus has been ...

(Over 100 slides now ... and still growing ...)



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

Updated: 2022.04.27



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Gemini SES+MDI SDPi+FHIR Project

Gemini SES MDI – SES Ecosystem Pathway Update

Proposed September 2021, this new group is fully operational and has a significant backlog to address.

Gemini SES+MDI Updates ... *Ecosystem Pathway*

Since early February 2022 EP group has been active ...

How-to articles

Documents

Projects

- Device Interoperability using SDPi+FHIR
 - Library with EVERYTHING you ever w
 - Glossary & Abbreviations Deobfusca
 - Community Engagement
 - Pathway to an Ecosystem of Plug-and-Trust Products**
 - EP Glossary
 - Gemini 2022 EP Discussion Notes
 - EP Topics of Interest
 - IHE CA Alignment with FDA ASCA
 - Hanging Gardens Framework
 - Topics of Interest
 - Stacks of Useful Stuff
 - Conformity Assessment & Tooling
 - Specifications: Device Specializations
 - Specifications: Devices on FHIR
 - Specifications: MDIRA / ICE Profile
 - Specifications: SDPi IHE Profiles
 - Narratives & Use Cases
 - Paper: What is a device?
 - Paper: SES MDI
 - Paper: SES Remote Connected Care a
 - Gemini SDPi+FHIR Technical Reports

Pages / ... / Device Interoperability using SDPi+FHIR

Pathway to an Ecosystem of Plug-and-Trust Products

Created by Todd Cooper, last modified on Apr 26, 2022

Ecosystem Pathway Workstream

The IHE-HL7 Gemini SES+MDI (*Safe, Effective, Secure Medical Device Interoperability*) program has primarily focused on the technical "MDI" aspects of the program, but not the "SES" aspects that are arguably as important – more important! – than the technical aspects: *Why bother coming up with a consensus technical solution if a clear parallel approach is not established that addresses the quality, risk management and public/private oversight (government/regulatory) - process aspects of product development?*

"Pathway to an ecosystem of Plug-and-Trust Products" (Ecosystem Pathway / EP) workstream evaluates those systems engineering lifecycle processes (Total Product Lifecycle) that will need to be applied consistently across the Gemini SES MDI implementation community to ensure that products that are developed independently ("decoupled") by different manufacturers are trustworthy and when they are connected "plugged" together, will interoperate effectively, safely and securely.

This is **not an abstract "what if" exercise, nor creation of yet more SES standards**. Rather, the EP group will *identify* and *apply specific standards* (e.g., 80001-1:2021) and *processes*, to *specific product implementations of the SDC/SDPi+FHIR technical interoperability specifications, for specific real-world acute care use cases* (e.g., *silent ICU or isolation point-of-care*).

NOTE: The joint IHE-HL7 Gemini SES+MDI program leverages *specific technical interoperability standards* including ISO/IEEE 11073 Service-oriented Device Connectivity (SDC), IHE Service-oriented Device Point-of-care Interoperability (SDPi) profile specifications, and HL7 Devices on FHIR (DoF) implementation guides. Thus "**SDC/SDPi+FHIR**" references the combined technical specifications context in which the EP group will apply the related **SES process standards and requirements**.

As is the case for the *foundational* technical MDI standards mentioned above (e.g., from ISO/IEEE or HL7), the EP work also leverages its own set of **foundational process / quality standards**, such as ISO/IEC 80001-1:2021 or 81001-1, and determines how to apply them to the technical implementations envisioned by the MDI SDC/SDPi+FHIR specifications. Similarly, there are Conformity Assessment (CA) processes and programs that the EP effort will integrate and adapt as needed.

Ecosystem Pathway stakeholders are primarily those SES quality, risk management, public (regulatory) & private governance affairs experts who are concerned with the product development, implementation and use aspects of establishing an ecosystem of trusted products. Open consensus will always be the goal for determining agreed guidance

What Lays Below ...

- Ecosystem Pathway Workstream
- Ecosystem of Plug-and-Trust Products - What's the big deal?
- Pathway Construction
- Real World "Concrete" Clinical System Functions
- CA for an Ecosystem of Plug-and-Trust Products
 - EP & Gemini Program CA & Tooling Workstream
 - "Regulatory Ready" Initiative
- Ecosystem Topics of Interest
- Team Collaboration
- Task report
- Pathway Guidance
- Reference Materials

Provide feedback

[Visit EP confluence home page ...](#)

Gemini SES MDI – Topics of Interest Review

Consider the “Topics of Interest” tables as a type of prioritized issue backlog that helps the group focus on solving the most important issues first ... but now we have (3) Tol tables ...

Gemini SES MDI – Topics of Interest x 3

From 2022 January Update

Topics of Interest (ToI) tables provide a simple way of prioritizing and resolving key issues ...

[Yes, we would have used JIRA if we could ... IEEE 11073 SDC uses sourceforge & github tickets]

Resolution process:

1. Capture & Prioritize in ToI
2. Discuss & resolve in referenced page
3. Create github Issue w/ link to resolution
4. Add to SDPi Supplement Issues & Content

MDIRA Profile ToI takes the same approach

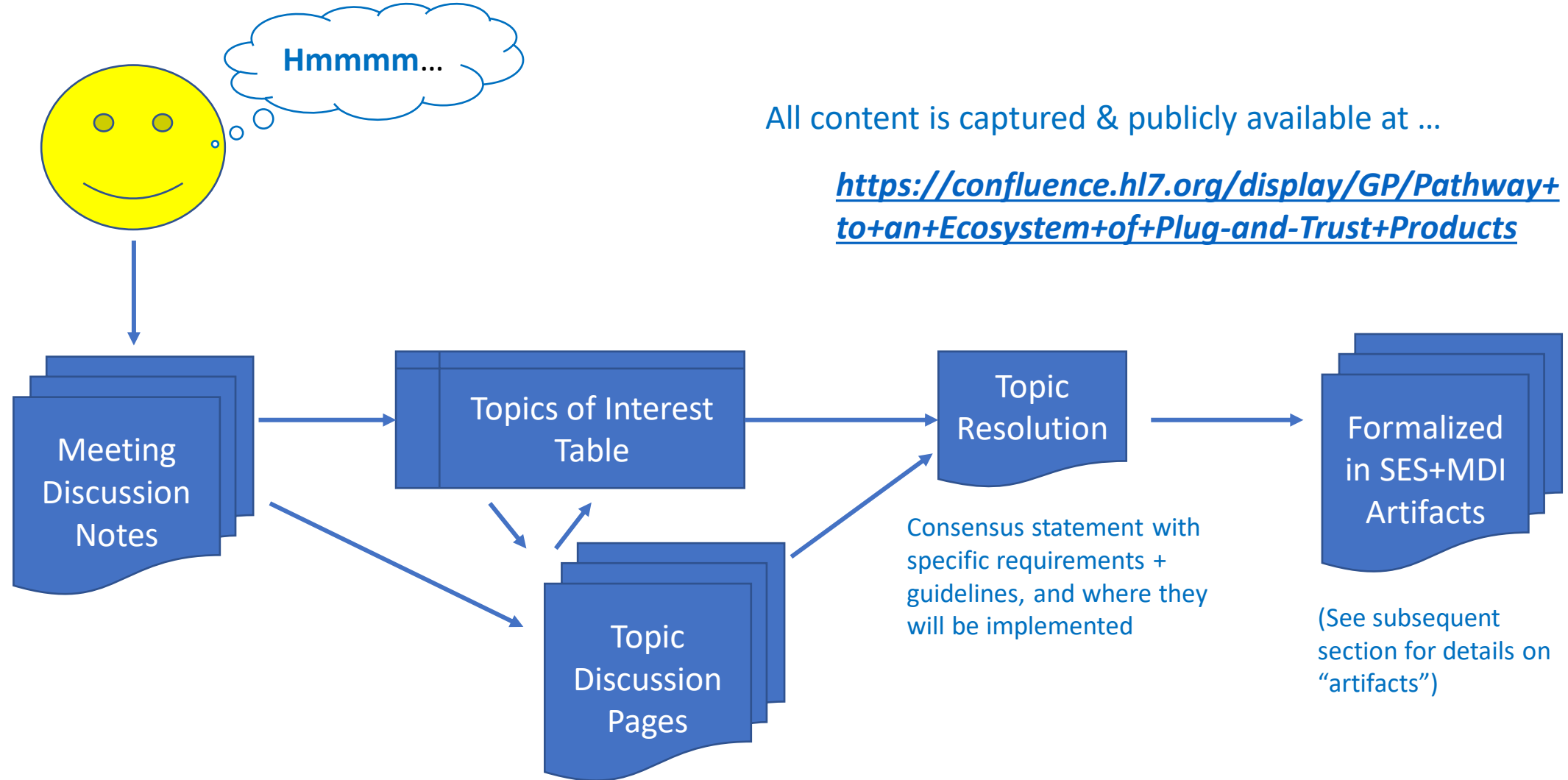
What about the 3rd EP ToI Table?

1. Supports issue identification & resolution
2. When appropriate, can link to other 2 ToI tables
3. Where else do the resolutions get formalized? (a question in the EP ToI!)

Source: <https://confluence.hl7.org/x/0yPxB>

Topics on the Table						
Priority	Topic	Date	Lead(s)	Synopsis	Status	SDPi+FHIR
high	Topic: Connect Time Delay Algorithm	2020.06.23	@ Peter Kranich	Random time delay algorithm needed to ensure that all CONSUMER systems do not try to connect with new PROVIDER at instant of "Hello" announcement; for example, connecting an infusion pump to an SDC network with 1,000 other systems connected (see Meeting Logs & Notes - 2020.06.23) (SDPi 1.0) 8/20 Confirmed	resolved	TF-2
high	Topic: Handling missed discovery messages	2020.06.23	@ David Gregorczyk	An agreed approach is needed to handle the potential cases where discovery messages (e.g., "Hello" or probe / implicit & explicit) are missed due to network conditions or PARTICIPANT system status. For example, a simple periodic "retry" algorithm. (see Meeting Logs & Notes - 2020.06.23) (SDPi 1.0) 8/20 Confirmed	discussing	
high	Topic: Info exchanged during unsecured discovery	2020.06.23	@ Peter Kranich + @ David Gregorczyk	During initial Network Topology Discovery, which is unsecured, what information can be exchanged (what must NOT be exchanged) to enable the appropriate system-to-system connections? (see Meeting Logs & Notes - 2020.06.23) (SDPi 1.0) 8/20 Confirmed	discussing	
high	Topic: SystemContext Profiling & Use	2020.06.23	@ David Gregorczyk	How should SDPi profile use of the SDC SystemContext (Location, Patient, Ensemble, Workflow) capabilities? Including device pairing / coupling using which SystemContext component? Profile vs. PKP standards? (see Meeting Logs & Notes - 2020.06.23) (SDPi 1.0) 8/20 Confirmed	discussing	
high	Topic: SDPi-xC with Mixed Device Safety Classes	2020.06.23	@ David Gregorczyk @ Peter Kranich	What are the rules and guidelines for a SERVICE PROVIDER that supports external control services, and when a SERVICE CONSUMER of a different safety class wants to invoke the control? (see Meeting Logs & Notes - 2020.06.23) (SDPi 1.0) 8/20 Confirmed (need plan for resolution and what / if that is possible)	discussing	
high	Topic: Alert Delegation Chains	2020.06.23	@ Peter Kranich @ David Gregorczyk	Alert delegation from a source PARTICIPANT to a delegated-to PARTICIPANT is simple enough (e.g., for cockpit scenarios); but what happens when the delegated-to PARTICIPANT adds its own "smart" alarm conditions and then either delegates to a 3rd PARTICIPANT or needs to transition delegation to another system (e.g., from bedside to central)? (see Meeting Logs & Notes - 2020.06.23) (SDPi 2.0) - Waiting for 11073-10702 Alert PKP development to progress	waiting	
high	Topic: Security Certificate Provisioning	2020.10.02	@ Peter Kranich @ David Gregorczyk	ISO/IEEE 11073-20702 MDPWS defines how WS-Security w/ X.509 certificates and Extended Key Use (EKU) provisions should be adapted for SDC; however, SDPi profiles will add specificity + address	discussing	

Gemini EP Process & Deliverable “Artifacts”

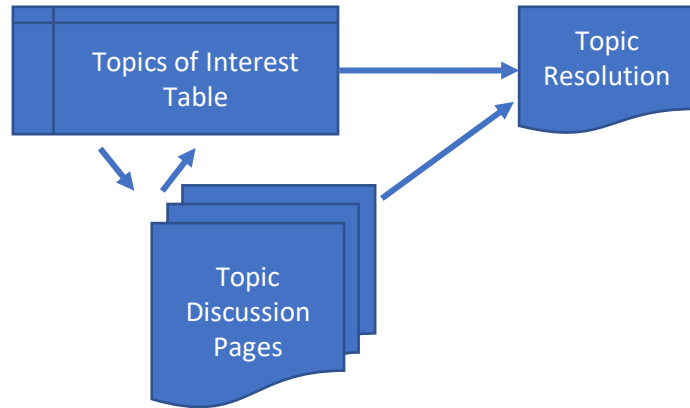


All content is captured & publicly available at ...

<https://confluence.hl7.org/display/GP/Pathway+to+an+Ecosystem+of+Plug-and-Trust+Products>

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

Gemini EP “Topics of Interest” Table



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

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

(See EP “Topics of Interest” Table)

Gemini SES+MDI – Focus: Updating IHE DEV OIDs & Supporting SDPi Extensions

Working through one of the SDPi technical challenges – a required extension to the base 11073 SDC standards – the need to define new OIDs in the IHE DEV space, but as is often the case, that is easier said than done ...

Gemini SES+MDI Updates ... *OIDs, OIDs, OIDs!*

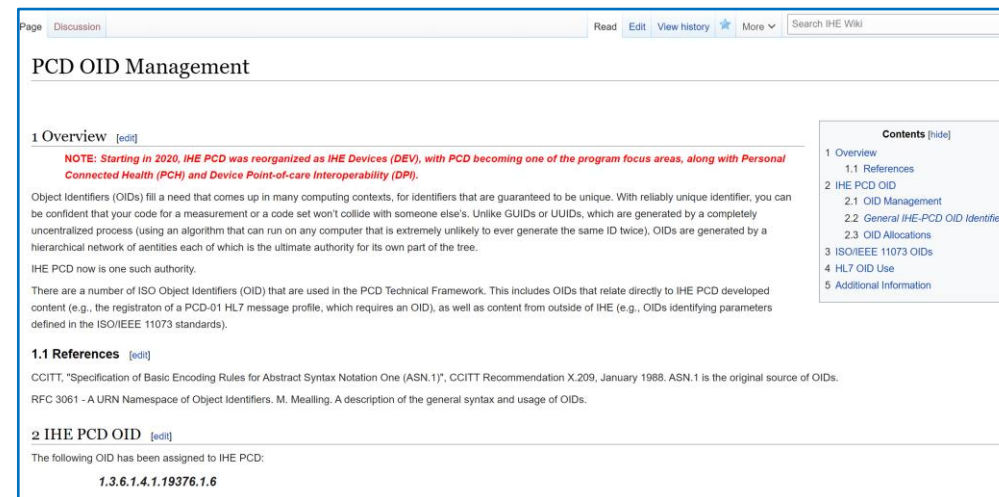
Working through an SDPi Topic:

“Topic: SDPi BICEPS Extension Namespace”

Team worked through options: URL, URN / OID, URN / IHE Namespace

URN with IHE DEV OID space selected ... [See 2022.04.08 SDPi Friday Notes](#)

Then the fun *REALLY* began ...



The screenshot shows a web browser window displaying the IHE Wiki page for "PCD OID Management". The page has a navigation bar at the top with options like "Page", "Discussion", "Read", "Edit", "View history", and "More". Below the title, there is a section for "1 Overview" with a "NOTE" in red text stating: "NOTE: Starting in 2020, IHE PCD was reorganized as IHE Devices (DEV), with PCD becoming one of the program focus areas, along with Personal Connected Health (PCH) and Device Point-of-care Interoperability (DPI)." The main text explains that Object Identifiers (OIDs) are used to uniquely identify objects in computing contexts. A "Contents" sidebar on the right lists sections: 1 Overview, 1.1 References, 2 IHE PCD OID, 2.1 OID Management, 2.2 General IHE-PCD OID Identifiers, 2.3 OID Allocations, 3 ISO/IEEE 11073 OIDs, 4 HL7 OID Use, and 5 Additional Information. Below the main text, there is a section for "1.1 References" and another for "2 IHE PCD OID" which lists the assigned OID: "1.3.6.1.4.1.19376.1.6".

See also the parent: [IHE OID Registration](#)

Gemini SES+MDI Updates ... *Updating DEV OIDs*

IHE DEV OID Definitions Update Proposal:

1. **PROPOSAL:**

- a. Update the PCD OID Management page (and the parent IHE OID Registration reference) ...
- b. Change "PCD" to "DEV" ...
- c. Analyze and update to reflect current profiles, actors and transactions ...
- d. Add support for the DEV SDPi profile as follows:
 - i. 1.3.6.1.4.1.19376.1.6.**2.10** SDPi (*abstract*)
 - ii. 1.3.6.1.4.1.19376.1.6.**2.10.1** **Extensions ...**
 - iii. 1.3.6.1.4.1.19376.1.6.**2.10.1.1** **SDC BICEPS Extensions**
 - iv. 1.3.6.1.4.1.19376.1.6.**2.10.1.1.1** (**version 1**)
 - v. 1.3.6.1.4.1.19376.1.6.**2.10.1.2** **<other general extensions, such as value sets/codes>**
 - vi. 1.3.6.1.4.1.19376.1.6.**2.11** SDPi-P (*concrete*)
 - vii. 1.3.6.1.4.1.19376.1.6.**2.11.1** (version)
 - viii. 1.3.6.1.4.1.19376.1.6.**2.12** SDPi-R
 - ix. 1.3.6.1.4.1.19376.1.6.**2.13** SDPi-A
 - x. 1.3.6.1.4.1.19376.1.6.**2.14** SDPi-xC
 - xi. 1.3.6.1.4.1.19376.1.6.**3.22** SDPi - SOMDS Participant
 - xii. 1.3.6.1.4.1.19376.1.6.**3.23** SDPi - SOMDS Provider
 - xiii. 1.3.6.1.4.1.19376.1.6.**3.24** SDPi - SOMDS Consumer
 - xiv. 1.3.6.1.4.1.19376.1.6.**3.25** SDPi - FHIR Gateway
 - xv. 1.3.6.1.4.1.19376.1.6.**3.xx** SDPi - additional actors
 - xvi. 1.3.6.1.4.1.19376.1.6.**4.23** SDPi - Transaction - SDPi-23 Announce Network Presence
 - xvii. 1.3.6.1.4.1.19376.1.6.**4.xx** SDPi - Transaction - SDPi-xyz
- e. NOTE: For more detailed background discussion, see notes at [Topic: SDPi BICEPS Extension Namespace & Gemini 2022-04-08 SDPi Friday](#)

Gemini SES+MDI – Focus: From github repo's to profiles.ihe.net/dev

In recent months, github repositories (“repos”) are taking more of a center stage across the IHE, HL7 and IEEE communities, including increased publication of artifacts to the [profile.ihe.net](https://profiles.ihe.net) space.

Gemini SES+MDI Updates ... *Github to profiles.ihe*

In recent weeks / months, use of github & publication of artifacts to profiles.ihe.net has become even more integrated:

- ✓ [IHE Devices Technical Framework repo](#)
- ✓ [Gemini sdpi-fhir repo](#)
- ✓ [HL7 Device Alerting \(DEVAL\) repo](#)
- ✓ [NIST XDS Toolkit & Asbestos FHIR Toolkit repo](#)
- ✓ [IHE Publications repo](#)

... leading to: profiles.ihe.net/dev



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Additional Information

Gemini SES MDI – RI+MC+RR Update

As reported in the 2021-09 WGM the RI+MC+RR vision was tuned to a sharper focus on key values ... ➡

Refined vision – RI+TF+CA to RI+MC+RR:

- **RI – Requirements Interoperability** – Ability to integrate & automate formal requirements and capabilities specifications defined in component specifications & standards to enable traceability & coverage at CA of the component product interface
- **MC – Model Centric** – Transition from a document-centric to a *computable model-based "single source of truth" specification* from which the Technical Framework becomes a view of the model
- **RR– Regulatory Ready** – Enable CA test reports that are genuinely "regulatory submission ready" (e.g., inclusion in a U.S. FDA 510(k) submission package)

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

That “refinement” process has continued ...

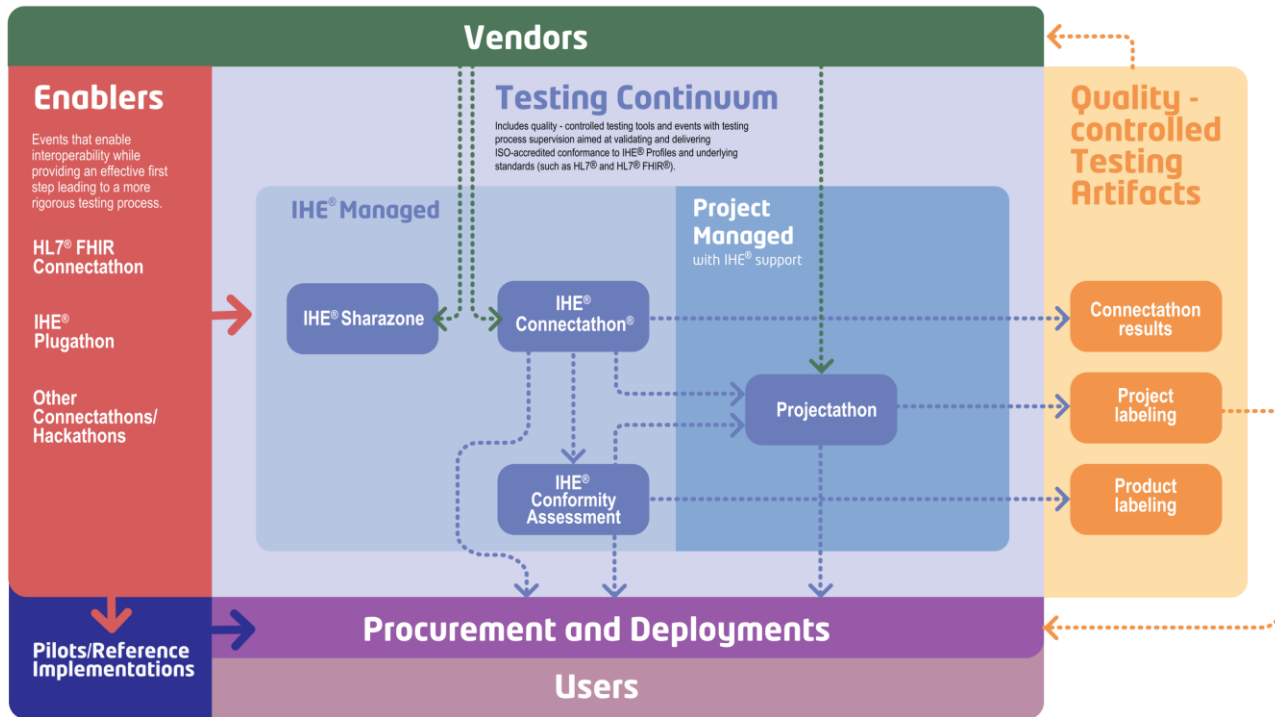
RI – Near term approach will continue to be Word styles/bookmarks/links BUT
Center of RI will be in SDPi TF-1 Appendix B & C

MC – Use of Gherkin & ReqIF will be quickly deprecated in favor of SysML 2.0 (see materials @ <https://github.com/Systems-Modeling/SysML-v2-Release/tree/master/doc>)

RR – Formation of the Ecosystem Pathway group + the IHE Catalyst Study and related investigations will provide a clear roadmap for how to achieve products that are “RR”

IHE Catalyst (formerly IHE EU/IHE Services)

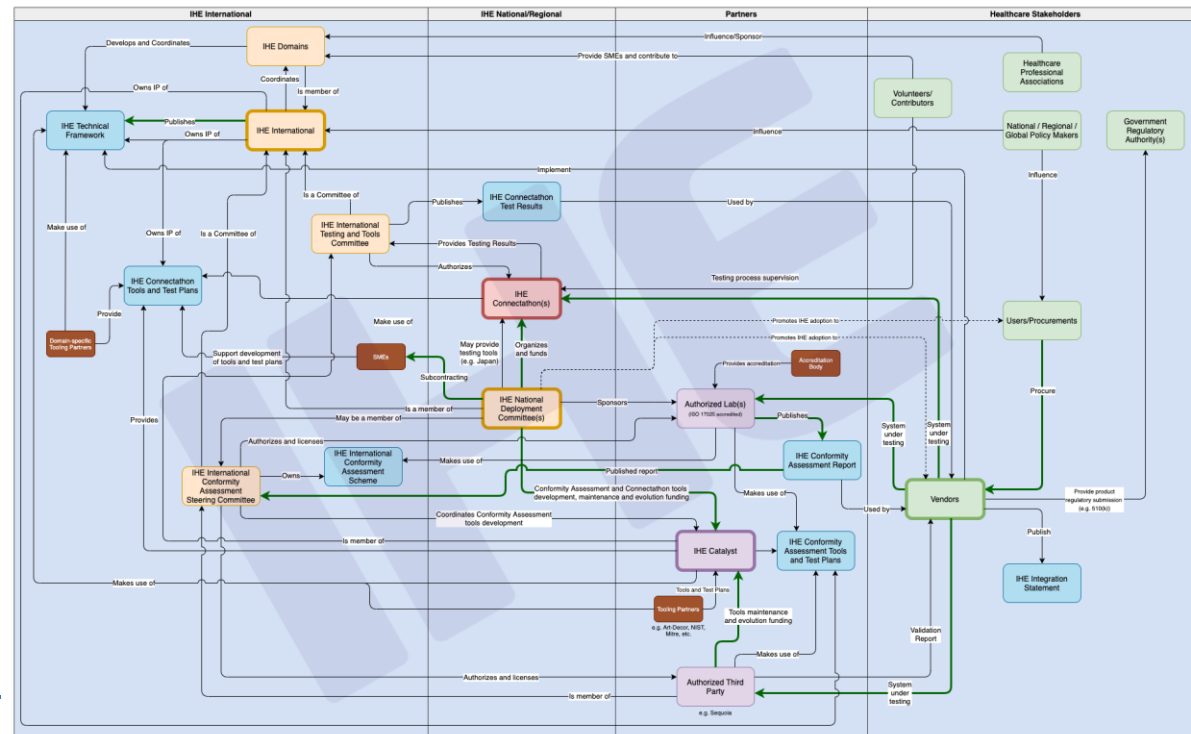
Factoring in the IHE Testing Continuum & Ecosystem ...




2021.09 Gemini Update to IEEE-HL7 WGM

- ✓ 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**

IHE IHE Ecosystem Metro Map



Gemini SES MDI – Contemplating “MDC” 2.0

In the 2021-09 WGM a conversation was initiated around what a *next generation* version of the ISO/IEEE 11073 MDC nomenclature might look like ... 

Though the Devices co-chairs have not focused on launching the proposed “Study” project ... yet ... the topic has been on mind ...

Especially ...

Gemini SES MDI – Toward “MDC” 2.0

Question: *What should a MDC 2.0 nomenclature for the 21st Century look like?*

Discussion topics would include:

- ✓ *Lessons Learned* (aka *The Michael Faughn Story*)
- ✓ *Users / Implementers Survey*
- ✓ Engage the *broader terminology community* (e.g., via the new HL7 TSMG? HL7 HTA? HL7 CIMI? ONC ISA?)
- ✓ Consider possible *areas of improvement*, including
 - *Usability* (by all stakeholders)
 - *Computability* (esp. given today’s terminology tooling)
 - *Maintainable* (incl. authoring)
 - *Integratability* (incl. mapping to other systems)
 - *Quality Improvements*, such as
 - Explicit references to scientific & medical research literature per term / group
 - Crafting of a true computable ontology to replace the current Systematic Name
 - Single “simple” key for each term (vs. 2+ with structured term code format)

Proposal: IEEE/HL7/IHE Co-chairs initiate an MDC 2.0 Study project & report back in January ’22 WGM

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

Michael “RTMMS Tool Smith” Faughn’s Mind!

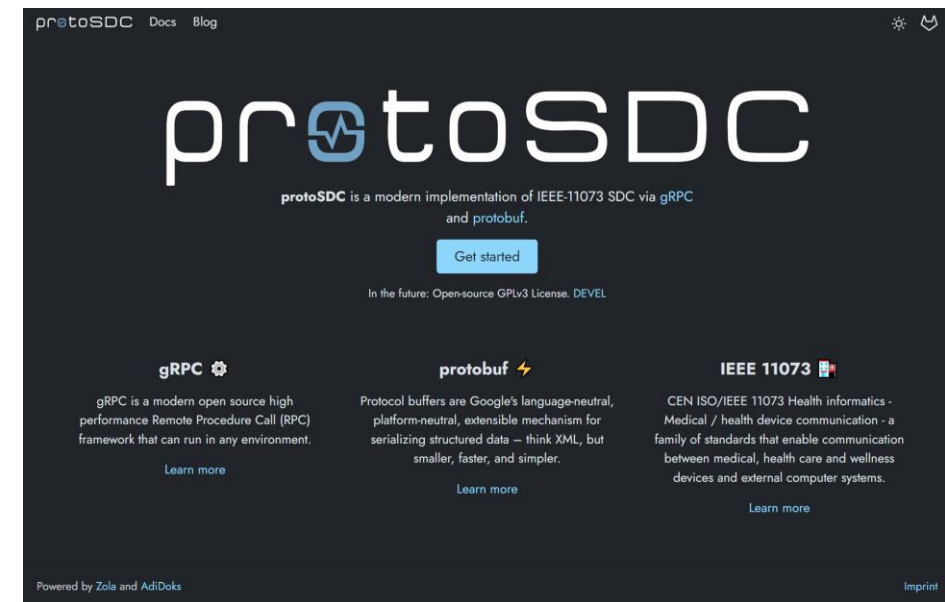
(See slides with Michael’s musings ...)

Gemini SES MDI – gRPC / Protobufs

There has been “hallway” discussion about considering an additional messaging protocol / transport as an option to MDPWS ...


1. Use of gRPC with protobufs is now being seriously considered!
2. Informal prototyping in 2020 & 2021 was very encouraging
3. PAT #5 2021-12 included a gRPC/protobuf test track ...
 - ✓ Complete success within a few hours
 - ✓ “Blazingly fast” results!!!
4. gRPC/protobuf option being added to the SDPi-P profile + added to the 3-Year Roadmap

But even more seriously ... check out



Check out ... protoSDC.org

Gemini SES MDI – 3-Year Roadmap / Workstreams

As reported in the 2021-09 WGM, development of a 3-Year Gemini roadmap was advanced ... 

The roadmap continues to evolve, with a major revision that added detailed capability targets for each major SDPi release per the following:

1. **Use Case Capabilities**
2. **SDPi Profile-Specific Capabilities**
3. **Profiled Standards / Capabilities**
4. **Gateway Interfaces**
5. **RI+MC+RR Support**

Gemini SES MDI – 3-Year Roadmap

Objective: *Establish clear **milestones** and **detailed plan** for achieving an ecosystem of interoperable plug-and-trust “regulatorily” decoupled products that are ready for providing patient care*

Roadmap “streams” include ...

- ✓ Functionality targets ... defined in detailed use cases / scenarios
- ✓ Specification Development & Publication
- ✓ Conformity Assessment (CA) & Tooling
- ✓ Computability / Implementation Support (RI+MC+RR & open source)
- ✓ Prototyping / Pilots / Demonstrations
- ✓ Education & Workshops
- ✓ Foundational Standards Support (PKP’s & DoF PoCD IGs)

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

Job #1 Remains: *Publish SDPi 1.0 ... ASAP!*

Gemini SES MDI – 3-Year Roadmap / Workstreams

Conformity Assessment (CA) & Tooling:

1. **PAT events continue to build the implementation community, test tooling, open source implementations, and test scripts -> all leading to IHE CAT events**
2. **IHE Catalyst Study will provide a clear roadmap for adding SDPi support to IHE CAT events & product CA**
3. **Virtual Profile-specific CAT's remain a priority + 24/7 testing support**
4. **Targeting IHE EU CAT 2022-09 + one vCAT**

Prototyping / Pilots / Demonstrations:

1. **Roadmap focused on supporting a HIMSS '23 Silent ICU use case demonstration**
2. **Other demonstration & education venues – especially in Europe – under consideration**

Gemini SES MDI – 3-Year Roadmap

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