IHE-HL7 Gemini SES+MDI – Program Update

for

Joint IEEE – HL7 Devices Working Group Meetings

2022.05.13

FHIR is a trademark of Health Level 7, International.

SDC is a registered trademark of OR.NET
Gemini SES+MDI using SDPi+FHIR

General Project Update – January to May 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
What have been the primary activity threads since the January 2022 working group meetings?
Gemini SES+MDI Updates ...

Building on two years of updates ...

IHE-HL7 Gemini SES MDI SDPi+FHIR – Program Update
for Joint IEEE – HL7 Devices Working Group Meetings
2022.01.21

IHE-HL7 Gemini SES MDI SDPi+FHIR – Project Update
for Joint IEEE / HL7 / IHE Working Group Meetings
2021.05.26

See recordings posted at ... https://confluence.hl7.org/pages/viewpage.action?pageId=113674346#LibrarywithEVERYTHINGyoueverwantedtoknow...-GeneralUpdate&BriefingPresentations
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) #8 successfully completed**, #9 planned for July 2022 (to be confirmed) *(Example PAT messages have been posted HERE)*

✓ **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”

Interplay of standards development and implementation

Gemini SES+MDI Accelerator?

Joint IHE-HL7 Gemini projects?

Legend
- Greater standards implementation activity
- Mixed implementation and development
- Greater standards development activity
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 ... )
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 ...

Pathway to an Ecosystem of Plug-and-Trust Products

The 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 (SDP) profile specifications, and HL7 Devices on FHIR (DoF) implementation guides. Thus "SDC/SDP==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 B1001-1, and determines how to apply them to the technical implementations envisioned by the MDI SDC/SDP=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

Visit EP confluence home page ...
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) ToI tables ...
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

Meeting Discussion Notes → Topics of Interest Table → Topic Discussion Pages → Topic Resolution → Formalized in SES+MDI Artifacts

All content is captured & publicly available at ...

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

Consensus statement with specific requirements + guidelines, and where they will be implemented

Gemini “sdpi-fhir” Github repository folders provided @
github.com/IHE/sdpi-fhir/tree/master/Ecosystem Pathway
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

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**Gemini EP “Topics of Interest” Table**

<table>
<thead>
<tr>
<th>Priority</th>
<th>Topic</th>
<th>Date</th>
<th>Proposer(s)</th>
<th>Lead(s)</th>
<th>Synopsis</th>
<th>Status</th>
<th>SES-NDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-High</td>
<td>Topic: SDR+tc with Mixed Device Safety Classes</td>
<td>2023-09-23</td>
<td>David Gregory, Peter Krasich</td>
<td></td>
<td>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 Section 7 &amp; 8 Notes)</td>
<td>initiating</td>
<td></td>
</tr>
<tr>
<td>2-High</td>
<td>Topic: SES Standards Landscape</td>
<td>2023-02-01</td>
<td>Matthias Marksteiner</td>
<td></td>
<td>An important scoping exercise for the Ecosystem Pathways group is identification of those SES standards and guidelines that need to be considered. Beyond the initial interoperability specifications as part of the MD effort.</td>
<td>initiating</td>
<td></td>
</tr>
<tr>
<td>3-High</td>
<td>Topic: SES-MD / CA Process</td>
<td>2023-02-01</td>
<td>Matthias Marksteiner</td>
<td></td>
<td>Where on the 510k_tc the design documentation for interoperable products refer. Which content can be segregated to review the submission in regard of clinical functionality, supported by the BDCA interface.</td>
<td>initiating</td>
<td></td>
</tr>
</tbody>
</table>

(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 ...

See also the parent: IHE OID Registration
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 (version 1)
      iv. 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

Source: Gemini 2022-04-08 SDPi Friday (Discussion Notes 3.a.v.i)
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 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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2022.05.13
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)

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](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 ....

- 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
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 ...

Michael “RTMMS Tool Smith” Faughn’s Mind!

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

Gemini SES MDI – Contemplating “MDC” 2.0

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
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 protoSDC.org
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

**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

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