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

Updated: 2022.02.17
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?
Section contains:

1. Objectives
   ✓ Givens / realities
   ✓ SDPi Tech, EP and CA group coordination
   ✓ RI+MC+RR achievable “basic support”

2. List “realities” per objectives
   ✓ Time & Resources
   ✓ Gazelle is what Gazelle is ... today
   ✓ Tooling automation is what it is ... today
   ✓ Word-based spec is simplest path forward ... today
   ✓ Leverageable test planning / scripting is what it is (presently? nada) ... today
   ✓ Med Tech Industry realities – esp. SES ... just starting to get momentum ... today
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?
Section contains:

1. Basic Support Objectives
2. RI in Specification Document
   ✓ Model: Requirement -> Capability … Word Style / Link / Bookmark – Unidirectional
   ✓ Types: Use Cases / ICS / Tech Specs
   ✓ Primary flow: App B & C to TF-1 TF-2 (maybe TF-3)
3. MC for Single Source of Truth DB
   ✓ Create simple UML model for DB schema
   ✓ Extract basic (RI) Word content into database
   ✓ Integrate “model” for testing constructs as well
4. …
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?
Section contains:

1. **Basic Support Objectives:**
   1. Test Plan: All capabilities for SDPi 1.0 ... per roadmap
   2. Test Cases: Use Case Driven (SORD, Silent ICU, IPoC), Standards Driven, Technology Driven
   3. Leverage basic RI+MC => Database of requirements / test assertions

2. **CREATE GRAPHIC showing flow (see sketch on subsequent slide)**

3. **FHIR IPS test approach examples**

4. **Graphic showing flow ... with Today's**

5. **Questions:**
   - Test Plan Formalization?
   - Test Case Formalization?
   - Language for Gazelle API 1.0? (Catalyst Study Provided?)
   - Use of FHIR TestScript?
   - TESTABLE ASSERTIONS: Format, Content, Where specified? (Gazelle tool?)
From Specs to Test Reports - Strategy

SDPi 1.0 Specification

- Word Styles / Bookmarks / Links
- “Simple” Word Docx

Basic RI+MC+RR UML Model

- Used to create schema

Michael’s Amazing Word-to-Database Transformation Tool

- Driven by Use Cases / Standards CA & Tech Requirements
- Links from test plans / scripts to RI elements (enabling traceability / coverage)

SDPi RI+MC+RR Database

- Basic test instance metadata provided to Test Tool ... somehow
- Basic test instance metadata provided to Test Tool ... somehow

Gazelle Test Management Tool

- Content integrated somehow!
- Report document “attached” to test instance and reviewed by Monitor
- Format?
- Content organization?
- Access?

SDPi 1.0 Test Plans & Scripts

- Format?
- Content organization?
- Access?

SDC/SDPi Test Tool

- SDC/SDPi Test Tool
- Generated by tool w/ test instance metadata integrated

Test (Instance) Report

- Format?
- Content organization?
- Access?

Where do Testable Assertions live?!

Add legend

Add 1/21 MF presentation link

See notes from 2/17 CA meeting re. open questions to be asked

Gemini SES+MDI SDPi+FHIR Project
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!*
Section contains:

1. Gazelle Roadmap 2022 & EVS Client API V1’ w/ new UI Gazelle TM support
2. SysML 2.0 may show up with tooling vendors!
3. Funded program may bring in HL7 FHIR DoF $ and org’s to advance that part of the development
4. Editor that we can use or migrate toward besides Word …
5. … Other opportunities … ???
IHE-HL7 Gemini SES+MDI – From Use Cases to Test Reports – 2022 RI+MC+RR Strategy
Additional Materials
Gemini EP Work Group Operating Principles

Core principles for how the group will achieve its objective:

**Open**
Operates under IHE-HL7 Governance but no firewalls, up-front membership requirements, publicly viewable / transparent, etc.

**Consensus**
Agreement of those who care, silence of those who don’t
(Requires participation of the appropriate stakeholder experts!)

**SES Standards**
Application of existing “foundational” standards (e.g., 80001-1)

**MDI Standards**
Application focus is on the SDC/SDPi+FHIR standards framework

**SES Requirements**
Guidance will focus on specific, testable requirements

**Total Product Life Cycle**
Pathway will include the entire lifecycle from concept to market to implementation to use to decommissioning

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

(See subsequent section for details on “artifacts”)

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 Tol Table

7. **Resolutions** include which EP “artifacts” are to be created and updated as a result of the discussion
Ecosystem Pathway Roadmap to be developed ...

1. 3+ Year Window
2. Major product pathway milestones including 1st product Conformity Assessment “RR” test report capability
3. Factor in “priorities” / resolutions / artifacts from “Topics of Interest” discussions
4. Coordinate with other roadmap workstreams, including MDI Technical (SDC/SDPi+FHIR and MDIRA profile specifications), CA & Tooling, Testing (CAT & PAT) & Demo & Educational/Workshop events, etc.
5. See also “Requirements & Guidance” section below
The EP effort does not start from scratch with a blank slate – there are a core set of foundational standards and specifications – both MDI and SES – that are to be evaluated and appropriately applied. Understanding this standards landscape context significantly focuses the work of the group!
Gemini EP SES Standards Objective

Objective: Identify and apply existing quality, safety, security – SES – standards to SDC/SDPi+FHIR – MDI – ecosystem product implementations, specifying the relevant principles, requirements and guidance, along with the V&V that will ensure their proper use across all components. Gaps and revisions may be proposed back to the responsible authors.

Note: We know these standards!

Consistent linkages to SDC/SDPi+FHIR standards +
Consistent implementation & Conformity Assessment of products

is another problem altogether!
Model developed over last 10 years in response to better manage the interrelations ...

✓ Across Stakeholders ...
✓ Across Product Lifecycles ...
✓ Across Subject Areas
✓ Across Multiple Standards

**Problem:** SES+MDI “Trust Gap” recognized but no practical real-world solutions – too resource & labor intensive

Source: ISO/IEC 81001-1:2021
ISO/IEEE 11073 SDC MDI “Cathedral” Model
Gemini SES+MDI “Hanging Gardens” Framework

User Narratives / Use Cases / Requirements
Reference Architectures / Frameworks
Device / Health Software Specializations
Key Interoperability Properties & Controls (PRActical SES)
SDPi+FHIR Profiles / IGs
IEEE 11073-1072x -10799 ModSpecs
IEEE 11073-1070x PKP (Safety)

20701 – Architecture and Protocol
10207 – DIM and Service Model
20702 - MDPWS

2070x – HTTP/2, REST, IoT, DDS, ... 

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

SES+MDI Plug-n-Trust Interface

More @ https://confluence.hl7.org/x/4ijxB
Problem? Ecosystem Pathway group will leverage the SES+MDI “Hanging Gardens” Framework ... to address the pesky “Trust Gap” product ecosystem challenges!
Gemini EP SES Standards Landscape

Ecosystem Pathway will ...

1. **Identify** existing SES standards relevant to establishing Plug-n-Trust product ecosystem (along with the scope and rationale for their use)

2. Determine **how** the requirements from each standard should be applied (both in principle and specifically / concretely)

3. Integrate **SES requirements / principles / guidelines with MDI SDC/SDPi+FHIR technology** (SES requirement <X> is addressed by MDI <xyz> requirements / capabilities)

4. Specify **how** standards-specific **conformity** will be **determined** and by whom (IHE CAT/CA vs. company-product-specific V&V)

5. Provide **feedback** as appropriate to standards developers regarding **gaps & issues** (recognizing that SES+MDI may include near term “workarounds”)

**Note:** Not detailed here, but wholly applicable, is the EP role in advancing “requirements interoperability” (e.g., 80001-1 with PKPs) and “regulatory submission ready” test reports with traceability and coverage.
Gemini SES+MDI / Ecosystem Pathway – Formalizing Requirements & Guidance

As the EP group works through its issues and tasks, **WHAT** will they do with the requirements & guidance that is developed? What documents will be created or updated? What artifacts for conformity assessment and testing are created to ensure that at the end of the day, *implementers* following the *product ecosystem pathway*, can *trust* that *everyone* got to the same place without leaving out any steps?
Gemini EP Formalizing Requirements & Guidance

Ecosystem Pathway Guidance document
- “Start here...” source for all EP community discussions & deliverables
- EP “Cookbook” approach
- PnT Ecosystem IFU Template
- See EP confluence page home

IHE SDPi Supplement document
- “SES” section content
- SES standard conformity sections + principles & guidelines
- Use Case SES requirements

Testing & Conformity Assessment artifacts
- V&V Process for PnT Ecosystem
- Test plans & protocols
- Test Report Template (for “RR”)

Educational Materials
Service-oriented Device Point-of-care Interoperability (SDPi)

✓ Four profile specifications:
  • SDPi-P for Plug-and-Trust Interoperability
  • SDPi-R for Reporting Medical Information
  • SDPi-A for Alerting
  • SDPi-xC for External Controlling

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

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

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

**Appendix B: Referenced Standards Requirements Coverage**
- <including ISO/IEEE 11073 SDC PKP tables>

**Appendix C: Device Point-of-care Interoperability Use Cases**
- <including Gherkin detail & SES Considerations 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

**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](https://github.com/IHE/sdpi-fhir) for full details.
SDPi “RI” – Starter Model @ SES

NOTE: 11073-1070x PKPs linked here from TF-1 Appendix B ICS Tables will be a primary source of these requirements
## Next Step: Requirements Interoperability Pilot

### Hanging Gardens Layer

<table>
<thead>
<tr>
<th>User Narratives / Use Cases / Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference Architectures / Frameworks</td>
</tr>
<tr>
<td>Device / Health Software Specializations</td>
</tr>
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<td>Key Interoperability Properties &amp; Controls (PRACtical SES)</td>
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<td>ISO/IEC JWG7 Safety, Effectiveness &amp; Security Standards</td>
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<td>IEEE 11073-1072x-10799 ModSpecs</td>
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</tr>
<tr>
<td>ISO/IEEE 11073-1010x Nomenclature &amp; 11073-10201 DIM</td>
</tr>
<tr>
<td>10207 – DIM and Service Model</td>
</tr>
<tr>
<td>20701 – Architecture and Protocol</td>
</tr>
<tr>
<td>20702 - MDPWS</td>
</tr>
</tbody>
</table>

### SDPi 1.0 – Basic RI

<table>
<thead>
<tr>
<th>STANDARDS</th>
<th>SDPi TF Sections</th>
</tr>
</thead>
<tbody>
<tr>
<td>SORD &amp; SPoC &amp; SICU</td>
<td>TF-1 Apdx. C + Profile Specific Map.</td>
</tr>
<tr>
<td>MD-SOA (SDC Core)</td>
<td>TF-1 SDPi Profiles Overview</td>
</tr>
<tr>
<td>IHE TF-3 &amp; X73 Stds.</td>
<td>TF-3 BICEPS sections</td>
</tr>
<tr>
<td>(Null layer)</td>
<td>TF-1 Apdx. A “SES MDI” Section</td>
</tr>
<tr>
<td>80001-1 (2nd Ed.), Annex A</td>
<td>TF-1 Apdx. B + TF SES Sections</td>
</tr>
<tr>
<td>(opt) PIXm / PDQm</td>
<td>TF-1 SDPi-P FHIR (in) Gateway</td>
</tr>
<tr>
<td>11073-1070x ICS + R’s?</td>
<td>TF-1/-2/-3 SDPi SES Sections</td>
</tr>
<tr>
<td>RTMMS + DIM ICS Tables?</td>
<td>TF-3 + TF-1 “Content Profiles” Sections</td>
</tr>
<tr>
<td>ICS Tables + Rxxxx’s?</td>
<td>TF-1 Apdx. B + Profile Mappings</td>
</tr>
</tbody>
</table>

( **BLUE** = Priority Roadmap & RI items + **RED** indicate normative RI Items)
### B.5.2 General ICSs applicable to SDC PARTICIPANTSs

General Base PKP requirements for all SDC PARTICIPANT systems. For the SDPi profiles, this is represented as the SDPi-P “SOMDS Participant” actor.

<table>
<thead>
<tr>
<th>Index</th>
<th>Reference</th>
<th>Status</th>
<th>Requirement Text</th>
<th>SDPi Support</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICS-1285</td>
<td>RR1285</td>
<td>m</td>
<td>Where there is potential of injury or death resulting from the use of an SDC PARTICIPANT, the MANUFACTURER SHALL use a risk management process and a usability engineering process conforming to recognized standards.</td>
<td>&lt;link to the SES section for SDC Participant&gt;</td>
</tr>
<tr>
<td>ICS-1005</td>
<td>RR1005</td>
<td>m</td>
<td>When the MANUFACTURER of an SDC PARTICIPANT reveals deficiencies of another SDC PARTICIPANT, the MANUFACTURER SHALL provide information about the deficiency to the MANUFACTURER of the other SDC PARTICIPANT, unless the deficiency is already disclosed in the MEDICAL DEVICE’s list of non-conformities.</td>
<td>&lt;out-of-scope for SDPi&gt;</td>
</tr>
<tr>
<td>ICS-1241</td>
<td>RR1241</td>
<td>m</td>
<td>The MANUFACTURER of an SDC PARTICIPANT SHALL provide a list of OIDs in the accompanying documentation to express which sets of requirements the SDC PARTICIPANT satisfies.</td>
<td>&lt;is this “CA by inspection” + linkage to OIDs list in this document &amp; how discovered dynamically; see Note under requirement that this is to help RO’s identify potential incompatibilities&gt;</td>
</tr>
</tbody>
</table>
## B.6.2 Support for specific requirements

The following requirements from the 80001-1:2021 standard are from the informative Annex A, Table A.1 that identifies requirements based on the sections of the standard in which they appear. Note that many requirements of this standard are completely out-of-scope for this specification, such as those that pertain to organizational management. When that is the case, the requirement scope is appropriately indicated. In other cases, the risk mitigation requirement may be reflected in a specific SDPI specification element, or may be verified based on capabilities contained in the specification.

<table>
<thead>
<tr>
<th>Section</th>
<th>Requirement</th>
</tr>
</thead>
</table>
| 6.1.2.3 HAZARD identification | The ORGANIZATION shall:  
   a) identify and document known, and foreseeable HAZARDS associated with deployment of the HEALTH IT SYSTEM and its use under both normal and foreseeable operating conditions.  
   b) review HAZARDS identified in any ACCOMPANYING DOCUMENTS supplied by the HEALTH SOFTWARE or MEDICAL DEVICE MANUFACTURER for applicability in the context of deployment, use or decommissioning of the HEALTH IT SYSTEM; and  
   c) where no HAZARDS are identified, record the justification for this conclusion within the RISK MANAGEMENT FILE. |
| 6.1.4.3 VERIFICATION of RISK CONTROL measures | The ORGANIZATION shall:  
   a) implement the RISK CONTROL measures, identified in accordance with 6.1.4.1;  
   b) verify the EFFECTIVENESS of each RISK CONTROL measure; and  
   c) incorporate the results of the RISK MANAGEMENT activities undertaken through the requirements in this subclause in the ASSURANCE CASE and record them in the RISK MANAGEMENT FILE. |

**SDPI Support**

- Support in SDPI for identifying HAZARDS and their mitigations?
- Support for ACCOMPANYING DOCUMENTS ... info that RO needs for RM?
- Links from 80001-1 requirements to PKP ICS table entries to SDPI risk management SES constructs?

**Note:** 80001-1 referenced informatively from 11073-10700
Gemini EP Deliverables & Artifacts

Ecosystem Pathway will create ...

1. **Multi-year (3+) EP Roadmap** leading to a point where an ecosystem PnT products can be assessed for conformity, placed into use, and monitored for SES+MDI

2. **Guidance document** that will serve as the primary resource for the principles, requirements and guidelines for achieving SES+MDI across the product ecosystem

3. **SES content** in the SDC/SDPi+FHIR specification documents (w/ requirements interoperability)

4. **Test** and **Conformity Acceptance** requirements, principles, guidelines (incl. test cases, scripts, etc.)

5. **Test Report template** (in support of “regulatory submission ready”)

6. **Educational materials** + workshops, roundtables, etc.

**Note:** Formal “deliverables” governance (approval / balloting) and publication will be under the auspices of IHE and HL7; however, the specific details have yet to be finalized.
One key focus of the EP discussions will be to effectively integrate the requirements of the IEEE 11073-1070x Participant Key Purposes (PKP) standards, which will provide a core consensus set of risk mitigations within the ISO/IEEE 11073 Service-oriented Device Connectivity (SDC) family of interoperability standards.
Gemini EP Role of 11073 PKP Standards

Challenge: Achieving an SES+MDI ecosystem of Plug-and-Trust component products includes multi-vendor shared risk and requires ...

- All stakeholders contribute to and have confidence in the pathway elements that lay the basis for SES+MDI trustworthiness
- Each product (manufacturer) fully adheres to SES pathway requirements & guidelines – verified by product CA & discoverable at run-time
- Each product (manufacturer) can “trust but verify” in real-time that the other products are operating in a trustworthy way
- Systems of products can be monitored and managed in real-time to ensure SES+MDI is achieved and maintained

Objective: Ecosystem Product Pathway must integrate an open consensus risk management process, including implementation of the IEEE 11073-1070x Participant Key Purposes (draft) standards
Gemini EP Role of 11073 PKP Standards

Fully integrated into the Gemini SES+MDI standards landscape!
IEEE 11073-1070x Participant Key Purposes standards provide ...

- **Shared / consensus risk management**
- **Safety, Security & Interoperability focused**
- **Scoped to 11073 SDC Plug-and-Trust MDI**
- **Risks, Controls, IFU, etc.**

For an Ecosystem of SDC/SDPi+FHIR Plug-and-Trust Component Products!

Note: See overview and status update presentations in Ecosystem Pathway / Reference Materials confluence page
Gemini EP From PKPs to Product CA

Traceability & Coverage back to 11073-1070x PKP ICS Specifications (via “RI”)

IEEE 11073-1070x Project Teams

Develop

11073-1070x PKP Standards

Develop

Gemini SES+MDI Community

PKP ICS Tables

IHE SDPi TF Specifications (TF-1 / Appendix B)

SES+MDI SDC/SDPi+FHIR Test Plans/Scripts + PAT/CAT + Product CA

CA “RR” Test Report

EP Managed
Gemini EP Role of 11073 PKP Standards

And there’s more …

✓ SES of “gateway” actors (FHIR & V2)?
✓ MDIRA profile role in SDPi SES+MDI?
✓ Runtime computable “IFU” for SoP operational health?
✓ CA programs like FDA ASCA Pilot?
✓ Composable / computable SES+MDI Assurance Cases?
✓ Simulation enabled by “model centric” use of MBSE / SysML2.0?

Note: See PKP overview and status update presentations in Ecosystem Pathway / Reference Materials confluence page
Risk Management in a multi-vendor “decoupled” plug-and-trust product ecosystem?
Updated Value of MDI Study

### USE CASES

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Overall Rank</th>
<th>RANK</th>
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<tbody>
<tr>
<td>Isolation Room</td>
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<td>1</td>
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<tr>
<td>Digital Charting</td>
<td>47%</td>
<td>2</td>
</tr>
<tr>
<td>Ward Round Pol</td>
<td>44%</td>
<td>3</td>
</tr>
<tr>
<td>Quiet ICU Ward</td>
<td>41%</td>
<td>4</td>
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<tr>
<td>Integrated UI</td>
<td>41%</td>
<td>5</td>
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<tr>
<td>Surgical Display</td>
<td>31%</td>
<td>6</td>
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<tr>
<td>Spotcheck Monitoring</td>
<td>27%</td>
<td>7</td>
</tr>
<tr>
<td>Automated OR Setup</td>
<td>22%</td>
<td>8</td>
</tr>
<tr>
<td>Service – Predictive Maintenance</td>
<td>18%</td>
<td>9</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use Case</th>
<th>HDO Rank</th>
<th>MDM Rank</th>
<th>ICU Rank</th>
<th>OR Rank</th>
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<tbody>
<tr>
<td>Isolation Room</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>-</td>
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<td>2</td>
<td>1</td>
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<td>Ward Round Pol</td>
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<td>3</td>
<td>5</td>
<td>-</td>
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<tr>
<td>Quiet ICU Ward</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Integrated UI</td>
<td>8</td>
<td>2</td>
<td>4</td>
<td>3</td>
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<td>Surgical Display</td>
<td>6</td>
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<tr>
<td>Spotcheck Monitoring</td>
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<tr>
<td>Service – Predictive Maintenance</td>
<td>17</td>
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<td>5</td>
</tr>
</tbody>
</table>

**Physiological Closed Loop Control** 17%
**Central Patient Watch** 15%
**Intra-Hospital Transport Monitor** 12%
**Service – Biomed Notification** 9%
**Treatment Recommendation** 6%
**Augmented Surgical Display** 3%
**Personal Health Integration** 0%
**Safety Interlock** 4%
**Dual Bedside Display & Control** -11%
**Benchmark Therapy** -18%

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**THE REAL VALUE OF MEDICAL DEVICE INTEROPERABILITY IN HOSPITALS**

Medical Device Interoperability (MDI) is one of the most relevant technology trends in the development of medical devices. As the result of a study conducted with more than 230 participants from the main areas of patient care in hospitals, we summarize which MDI use cases are valued most by both medical technology manufacturers and especially the previously neglected perspective of healthcare professionals. We also provide valuable recommendations for the future direction of MDI development.

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Gemini SES MDI – SES Ecosystem Pathway Launch

Proposed September 2021, this new group will focus on the “SES” challenges for developing products along a pathway that includes ensuring system quality and risk management, along with regulatory affairs.
Recognizing the need to advance the non-MDI tech ... SES issues discussion, a new initiative was proposed during the 2021-09 WGM ...

**BUT**
- ✓ The “R” word was challenging!
- ✓ The need was clear but the formal scope and ToR were challenging

**SO**
- ✓ A group of key leaders met in October - December
- ✓ Issues were discussed ... at length! ... and progress made!

Gemini SES MDI – SES Ecosystem Pathway

**Gemini SES MDI – Regulatory Initiative**

“Regulatory Submission Ready” CA test reports is easy to say ...

**Challenges on the road to RR and an ecosystem of PnT products:**
- ✓ Engaging those whose “day job” is quality & regulatory affairs (IOW ... SES)
- ✓ Plug-and-Trust component products that are developed “regulatory decoupled” ... is new!
- ✓ How to build understanding and confidence that a “shared risk” product ecosystem is ... trustworthy?
- ✓ In an increasingly virtualized world – how much virtual testing (vCAT’s) can be used vs. in-person device-connected-directly-to-device testing to build confidence in the SES community?
- ✓ How will post market surveillance be achieved & what role might MDIRA profile actors play?
- ✓ What about the addition of clinical / therapeutic / Dx & DTx “apps” (SaMD) to the ecosystem?
- ✓ How can the regulatory “burden” be reduced for all stakeholders, balancing between safety & innovation for these new technologies?

**Proposal: Create a Gemini SES/Regulatory Initiative**

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

**2022 January Update to IEEE/HL7 Working Group Meetings**
Announcing a new Gemini SES MDI Group: Ecosystem Pathway

(Pathway to an Ecosystem of Plug-and-Trust Products)

**Participants:** SES Product Quality / Risk Management / Regulatory Affairs Stakeholders

**Work focus:** Issues related to decoupled product development & use ... see EP Tol Table

**Launch:**
- Google Group Formed
- Bi-weekly Zoom meetings (starting Feb 1st)
- EP confluence home page (in development)

**CALLING ALL SES EXPERTS!!!**

Source: 2021-09 Gemini SES MDI Update to HL7 WGM
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
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/
More detail is provided in ...

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
Example: External Control of Ventilator using Device A

- **Ventilator**
  - Provides function to change ventilation settings
  - Adjust ventilation based on request

- **Device A**
  - SaMD
  - Provides UI for user to change ventilation setting

- **SDC Service Provider**
  - External Control Provider
  - ...

- **SDC Service Consumer**
  - External Control Consumer
  - ...

**Decoupled Plug’n’Trust**
V-Model for Systems of MedTech Products

V&V Levels for Interoperable Medical Devices

- Customer Needs
- Clinical Scenarios
- Requirements
- System-of-Products Functions
- Key Interoperability Purpose Requirements
- System Element / Product Requirements
- Device N
- Device A
- Communication Interface Verification
- Reference System V&V
- (Testing for suitability to context of use)
- Hospital System Validation
- Putting in service / Clinical Operations

Product V&V + Interface Verification + Reference System V&V + Hospital System Validation = Objective Evidence

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

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

A lack of end-to-end testing responsibility is observed in traditional SE
Verification and validation responsibilities
Example Medical Device

Putting in service / Clinical Operations

Hospital System Validation

SoP V&V
(Testing for suitability to context of use)

System Element / system validation

System element / system Verification

Reference System V&V
(Testing for suitability to context of use)

Communication Interface Verification

FDA Guideline

FDA Guideline also applicable for CE market?

16/06/2021
IHE/IHE Catalyst for «Regulatory Submission Ready» CA
The next step ahead
From standards to market

Safety and performance requirements for the medical device

+ System Functionality

+ Interoperability contributions

Vision: Regulatory review convergence throughout different device sectors and globally harmonized
# Poster: Pathway to FDA pre-submission

## Integration

- Roles, Responsibilities and Activities for Health Care Facilities

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<thead>
<tr>
<th>Integration:</th>
<th>• Typical functionality in reference System</th>
<th>• Clinical evaluation</th>
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## Validation

- Domain Specific standardized Information models (PKP)

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<th>• PKB</th>
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<td></td>
<td>• RM</td>
<td>ISO 14971</td>
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<td>• HF</td>
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<td>• TDoc</td>
<td>ISO 20417</td>
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<tr>
<td>A Purpose</td>
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<tr>
<td>C Risk Management</td>
</tr>
<tr>
<td>B Anticipated Users</td>
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<tr>
<td>D Validation</td>
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<td>E Labeling</td>
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<td>F Consensus standards</td>
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## Verification

- Standardized Safe and Secure meshed network

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<thead>
<tr>
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<th>• Interfacetest</th>
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## Device submission

- Core documentation

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