Gemini SES+MDI
From Use Cases to Test Reports
2022 RI+MC+RR Strategy

Landscape Outlook for SDPi Specification & Testing in 2022

SDPi 1.0 – RI+MC – Basic Support
SDPi 1.0 – Testing & CA & Tooling – Basic Support
Possibilities but not Probabilities but .. *Opportunities*?!
Gemini SES+MDI – 2022 RI+MC+RR Strategy –

*Landscape Outlook for SDPi Specification & Testing in 2022*

With a goal of publishing the SDPi 1.0 in 2022-Q2 and achieving first IHE CAT testing before the end of 2022 ... and given the *realities of what we have NOW* vs. our long-term vision for RI+MC+RR ... *what’s the near-term strategy?*
SDPi 1.0 Spec-to-Test – ‘22 Landscape Realities

2022 Landscape realities ...

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

Working within these landscape realities...

‘22 Gemini SES+MDI Roadmap
“Basic” SDPi 1.0 can be successfully achieved
Gemini SES+MDI – 2022 RI+MC+RR Strategy – SDPi 1.0 – RI+MC – Basic Support

Given the landscape before us at the start of 2022, what can we *realistically* achieve for advancing the requirements interoperability and model centric initiatives? *What does “basic support” look like?*
SDPi 1.0 & RI+MC – “Basic” Support

What does SDPi 1.0 “Basic” Support look like?

✓ SDPi 1.0 Specification –
  ❖ Word-based – > 200 page supplement “skeleton” already crafted
  ❖ Publish as PDF (traditional) – optionally HTML via NIST V2plus Tooling (adapted)
  ❖ 2022 Capabilities identified in the roadmap are detailed in the TF supplement

✓ Requirements Interoperability –
  ❖ RI UML Model linked to Word constructs (Styles / Bookmarks / Links)
  ❖ Requirements sources modeled: Use Cases + Ref’d Standards + SES/RM + Tech Specific
  ❖ Requirements flow established: TF-1 Appendix B & C to TF-1, TF-2 & TF-3 elements

✓ Model Centric –
  ❖ Basic UML Model for RI + Testing Elements ... perhaps incl. modeled IHE TF elements
  ❖ NIST tooling (for V2plus) leveraged to create initial “single source of truth” database
SDPi 1.0 & RI+MC – “Basic” Support

What does SDPi 1.0 “Basic” Support look like?

✓ Regulatory Ready / CA & Tooling –
  ❖ Test plans / cases incl. content as for previous profiles ... *but maintained external to test tooling*
  ❖ IHE PAT events leveraged to continue test tooling & test cases / scripts development
  ❖ Manually integrate into Gazelle ... *as for previous profiles*
  ❖ Test plan / case information and linkages integrated into SST Database for basic RI –
    traceability & coverage from test cases to requirement sources
With basic support for RI+MC in hand, how might we *advance “RR”* – regulatory submission ready – test reports? Given the early 2022 testing and tooling landscape, how can *test plans, scripts, Gazelle test management, SDC/SDPi tooling* be leveraged to provide basic support for IHE Connectathon events ... in 2022?
From Specs to Test Reports – “Basic” Strategy

- SDPi 1.0 Specification
  - SDPi RI+MC+RR Database
    - “Single Source of Truth”
    - “Simple” Word Docx
    - Driven by Use Cases, Standards Conformance, SES & Tech Requirements
  - Michael’s Amazing Word-to-Database Transformation Tool
    - Used to create DB schema
    - “Simple” Word Docx
    - Content integrated manually… “The Old Fashioned Way”!
- SDPi 1.0 Test Plans & Scripts
  - Links from test plans / scripts to RI elements (enabling traceability / coverage)
  - “Single Source of Truth”
- SDPi 1.0 Test Plan & Scripts
  - Crafted & Maintained Independent of Test Tooling
- Gazelle Test Management Tool
  - Basic test instance metadata provided to Test Tool… somehow
  - Test Script Info
  - Report document “attached” to test instance and reviewed by Monitor
- SDC/SDPi Test Tool
  - Generated by tool w/ test instance metadata integrated
- Test Case (Instance) Report
  - “RR” Report – Supporting Evidence

Legend
- Automated
- Manual / Semi-auto

Gemini SES+MDI SDPi+FHIR Project
Spec-to-Test Strategy – *RI+MC+RR Model*

"Basic" Requirements Interoperability Model for SDPi 1.0 Document:

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

**ReqIF Example:** Requirement related to System Function Contribution

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

19. **R0062:** If an SDC PARTICIPANT produces EXCESSIVE LOAD CONDITIONs, each SDC PARTICIPANT that is affected by these conditions SHALL maintain its SYSTEM FUNCTION CONTRIBUTIONs for other SDC PARTICIPANTS.

**Observation:** ReqIF Used for Document Creation – *Not requirements formalization!*
“Basic” Requirements Interoperability Model for Test Plans/Cases:

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

Note: Model for early discussion purposes only (not formal UML!)
Spec-to-Test Strategy – To a SST Database

Road to an SDPi 1.0
Single Source of Truth Database:

❖ Build SDPi 1.0 Word document w/ content aligned to basic RI+MC(+RR) UML model

❖ Utilize “Extensive Scripts” to extract content from Word documents to Database

❖ Utilize UML Model to create database schema

Extract from MS Word

Source: Michael Faughn 2022 January WGM Update / V2plus Project
Spec-to-Test Strategy – To Gazelle Integration

Gazelle Master Model (GMM) –
❖ GMM content leveraged by all instances of the test management tool
❖ All profile & test information entered manually via GMM UX

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

Source: GMM User’s Guide
Spec-to-Test Strategy – Gazelle Assertion Manager Tool –

**Gazelle Assertion Manager Tool**

- **IdScheme**
  - {one source document}
  - 1..*

- **Scope**
  - 1..*

- **Assertion**
  - 1..*
  - applies to 1..*

- **Actor**
- **AIPO**
- **Integration Profile**
- **Standard**
- **Transaction**
- **Audit Message**

**Security?**

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

- **Assertion Coverage**
  - achieved by ???

- **Validator**
  - 1..*

- **TF Rule** (constraint)

- **Test**

- **Test Step**

- **Model-Based Validation Service**

**Source:** [Gazelle Assertion Manager Guide](#)

**Gemini SES+MDI SDPi+FHIR Project**

**Note:** See previous slides for GMM TF / Tests elements + “Assertions in Test Steps?”
Spec-to-Test Strategy – Closing the Loop / EP Style

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

IEEE 11073-1070x Project Teams

Develop

11073-1070x PKP Standards

Gemini SES+MDI Community

Develop

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

PKP ICS Tables

Require-ments

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

CA “RR” Test Report

IHE SDPI Profiles for “PRACTical” Device Interoperability

SDPi Plug-and-Trust Connectivity (SDPi-P)

SDPi Reporting (SDPi-R)

SDPi Alering (SDPi-A)

SDPi External Control (SDPi-xE)

“medical” interoperability purpose
Spec-to-Test Strategy – *Closing the Loop?*

*Pathway with RI+MC+RR Support …*

**Gemini SES+MDI “RI” Test Report**

**SDPi 1.0 Specification**
- Word Styles / Bookmarks / Links
- “Simple” Word Docx

**SDPi RI+MC+RR Database**
- “Single Source of Truth”
- Links from test plans/scripts to RI elements (enabling traceability/coverage)

**SDPi 1.0 Test Plans & Scripts**
- Crafted & Maintained independent of Test Tooling
- Links to Script Info

**SDCi/SDPi Test Tool**
- Report document “attached” to test instance and reviewed by Monitor
- Generated by tool w/test instance metadata integrated

**Gazelle Test Management Tool**
- Basic test instance metadata provided to Test Tool … somehow
- “The Old Fashioned Way”!

**Gemini SES+MDI SDPi+FHIR Project**

**IHE CAT System Test Report**
Spec-to-Test Strategy – “RR” Test Reports?

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

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

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

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

How are CA test reports created today? Historically? Separate tool from Gazelle? Extended Gazelle instance?
Spec-to-Test Strategy – FHIR TestScript “Friendly”

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

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

MHD Test Plan

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

Source: **IHE MHD Test Plan**

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

Landscape Realities

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

Asbestos Value Proposition

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

Interoperability Test:
FHIRE ToolKit acts as a proxy between Systems Under Test.

Logs are analyzed for results.
Test Tool Strategy – NIST Asbestos for SDC/SDPi

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

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

Source: [https://profiles.ihe.net/ITI/PDQm/index.html](https://profiles.ihe.net/ITI/PDQm/index.html)
Gemini SES+MDI — 2022 RI+MC+RR Strategy — IHE DE PAT Testing — May 2022

Starting point for the 2022 testing strategy includes what has been progressed as part of the IHE Germany Plugathon (PAT) testing events, and ... how much of this approach and tooling can be leveraged going forward?
Test Tool Strategy – IHE DE PAT ‘22 Testing

Comparing actual exchanges (from PROVIDER SUT) with Reference MDIB

Test app (consumer)

Device under test (provider)

App at https://github.com/IHE/sdipi-fhir/tree/master/Tooling/sdc11073

MDIB & Certificates @ https://confluence.hl7.org/x/LZLGBg
Test Tool Strategy – *IHE DE PAT #7 ‘22 Testing*

**See PAT #7 Test Matrix for Example Results**

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

**What current PAT testing does *not* include:**
1. Unit Testing (automation)
2. Consumer SUT Testing (unit)
3. Proxy (with security)
4. Test “Engine” w/ scripts & reports & configuration ... (see sdcTest in github sdpi-fhir github repo)

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

Source: [https://confluence.hl7.org/x/LZLGBg](https://confluence.hl7.org/x/LZLGBg)
Test Tool Strategy – Testing for HIMSS’23 & Beyond

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

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

SAS = Smart Alert System
DAS AI = Distributed Alarm System / Alarm Integrator

See detailed scenarios posted at Gemini Topic of Interest DAS + Smart Alerting Challenges

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!
Additional Materials
Orientation Tour: IHE TF & SDPi Profiles

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

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

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

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)
Orientation Tour: From Volume 1 to 2 to 3

SDPi TF Supplement Vol.1 Integration Profiles

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

SDPi-Reporting Profile ...

SDPi-Alerting Profile ...

SDPi-xControl Profile ...

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

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.
Orientation Tour: From Volume 1 to 2 to 3

SDPi TF Supplement Vol.1 Integration Profiles

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

SDPi-Reporting Profile ...

SDPi TF Supplement Vol.2 Transactions

DEV-23 Announce Network Presence
- Scope
- Actor Roles & Referenced Standards
- Messages (at BICEPS level w/ links to Appendix A)
- Protocol Requirements
- SES Considerations

DEV-24 Discover Network Participants
...

SDPi TF Supplement Vol.3 Content Modules

DEV Semantic Content Modules
- General Device Content Considerations
- SDC / BICEPS Semantic Content

DEV Specialization Content Modules
- Device: Infusion Pump
- SDC / BICEPS Content Module
- Device: Ventilator ...
- Device: Physiologic Monitor ...
- Devices: Surgery ... (new)
- Devices: Anesthesia ... (new)
- Devices: Dialysis ... (new)

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

IHE DEV SDPi TF – Intro & Overview
IHE Catalyst (formerly IHE EU/IHE Services)

Factoring in the IHE Testing Continuum & Ecosystem ....

✓ IHE Catalyst is central to all IHE based CA & Testing
✓ Gemini program “home” considered for Catalyst or HL7
✓ Study project (funded) being advanced with IHE Catalyst

2021.09 Gemini Update to IEEE-HL7 WGM
SDC Conformance Principles

OR.NET 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/
IHE & IHE Catalyst: Advancing Interoperable MedTec Solutions with "Regulatory Submission Ready" Conformity Assessment

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

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

16/06/2021
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
- System-of-Products Functions
- Key Interoperability Purpose Requirements
- System Element / Product Requirements

**Product**
- Putting in service / Clinical Operations
- Reference System V&V (Testing for suitability to context of use)
- Communication Interface Verification
- System Element / Product V&V

**Hospital System Validation**

**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

MedTech Regulatory Pathway – Core to SDC/SDPi Specifications

FDA Guideline also applicable for CE market?

IHE/IHE Catalyst for «Regulatory Submission Ready» CA
MF’s musings ... toward a layer model

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

Future – Support RI Component “assembly” automation