



Making  
Healthcare  
Interoperable



Integrating  
the Healthcare  
Enterprise

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

*for*

***IHE Japan 2023 Connectathon***

**2023.10.18**



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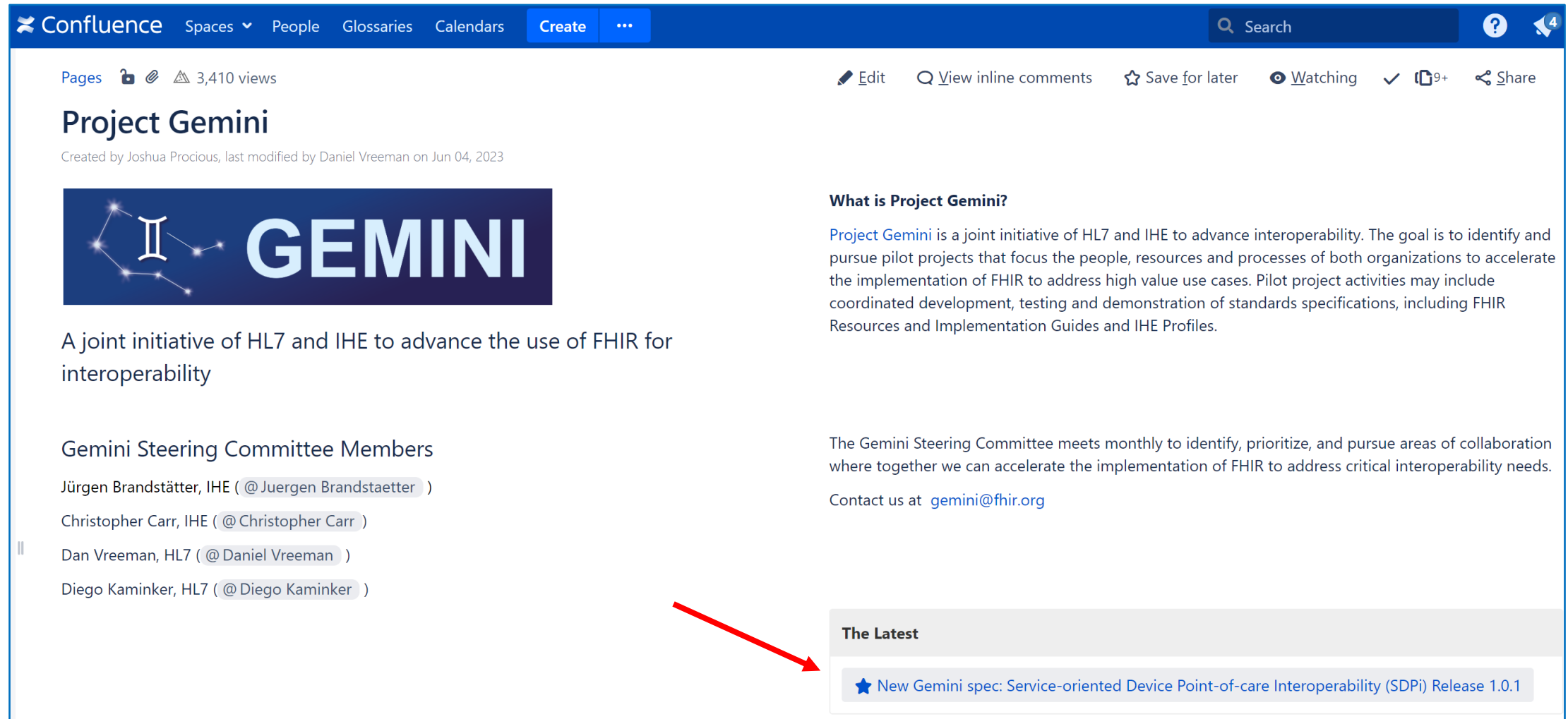
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# *Joint HL7-IHE Gemini – Device Interoperability Project*

# Gemini – Joint HL7-IHE Projects

## Gemini Device Interoperability project started early 2020




Confluence Spaces People Glossaries Calendars Create ... Search ? 4

Pages 3,410 views

## Project Gemini

Created by Joshua Procius, last modified by Daniel Vreeman on Jun 04, 2023



A joint initiative of HL7 and IHE to advance the use of FHIR for interoperability

### Gemini Steering Committee Members

Jürgen Brandstätter, IHE ( @Juergen Brandstaetter )

Christopher Carr, IHE ( @Christopher Carr )

Dan Vreeman, HL7 ( @Daniel Vreeman )

Diego Kaminker, HL7 ( @Diego Kaminker )

### What is Project Gemini?

Project Gemini is a joint initiative of HL7 and IHE to advance interoperability. The goal is to identify and pursue pilot projects that focus the people, resources and processes of both organizations to accelerate the implementation of FHIR to address high value use cases. Pilot project activities may include coordinated development, testing and demonstration of standards specifications, including FHIR Resources and Implementation Guides and IHE Profiles.

The Gemini Steering Committee meets monthly to identify, prioritize, and pursue areas of collaboration where together we can accelerate the implementation of FHIR to address critical interoperability needs.


Contact us at [gemini@fhir.org](mailto:gemini@fhir.org)

### The Latest




★ New Gemini spec: Service-oriented Device Point-of-care Interoperability (SDPi) Release 1.0.1

# Gemini – Joint HL7-IHE Projects

## Why Gemini for Device Interoperability?

 Confluence Spaces ▾ People Glossaries Calendars Create ...

Search ?

Pages / Project Gemini / Projects    5,538 views

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## Device Interoperability using SDPi+FHIR

Created by Joshua Procius, last modified by Todd Cooper on Aug 02, 2022

**Note to reader:** Mysterious words and symbols?: [Go To Abbreviations and Glossary Page](#)

### Gemini SDPi+FHIR Program Backgrounder

This joint HL7-IHE Gemini program pulls together established and emerging work in the [HL7 Devices](#) and [IHE Devices](#) working groups to achieve a greater degree of collaboration efficiency as well as coordination and cohesion between the activities and work products of the two groups. The program objectives include:

- [One simple device interoperability story](#) – from Surgery to Surfing!
- [One coordinated / cohesive set of specifications & implementation / test tools](#)
- [One centralized collaboration place & tool set](#) flying under the “[SDPi+FHIR](#)” banner

The Gemini project proposal and regular program updates provide an overview of the objectives and *initial* work program of the initiative, as well as it's current status. Here are a couple of the early presentations, but a more current and comprehensive list is in the [Library](#):

#### What Lays Below ...

- › [Gemini SDPi+FHIR Program Backgrounder](#)
- › [SDPi+FHIR Narratives](#)
- › [Standards Framework Models ... never enough!](#)
- › [SDPi+FHIR Projects](#)
- › [SDPi+FHIR Development Support](#)
- › [SDPi+FHIR Documents](#)
- › [Gemini SDPi+FHIR Program Backgrounder](#)
- › [SDPi+FHIR Narratives](#)
- › [Standards Framework Models ... never enough!](#)
- › [SDPi+FHIR Projects](#)
- › [SDPi+FHIR Development Support](#)
- › [SDPi+FHIR Documents](#)

[Everything is on the HL7 Confluence “Gemini” Space](#)

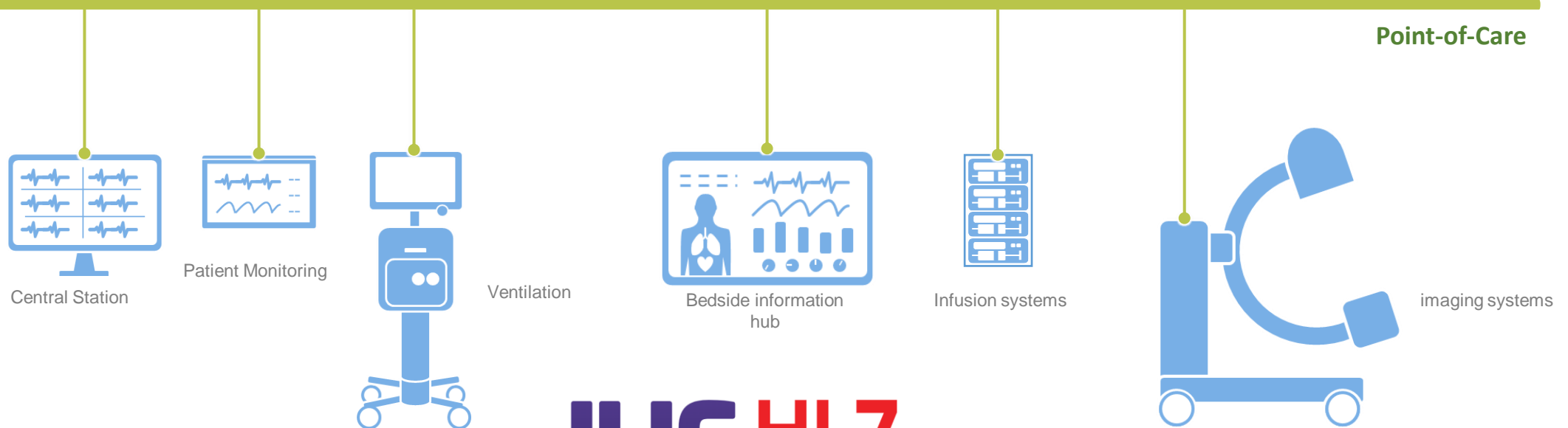
# Gemini SDC/SDPi+FHIR – *D2D Plug-and-Trust Interoperability*

# D2D Plug-and-Trust Point-of-care Ecosystem

Enterprise



Point-of-Care



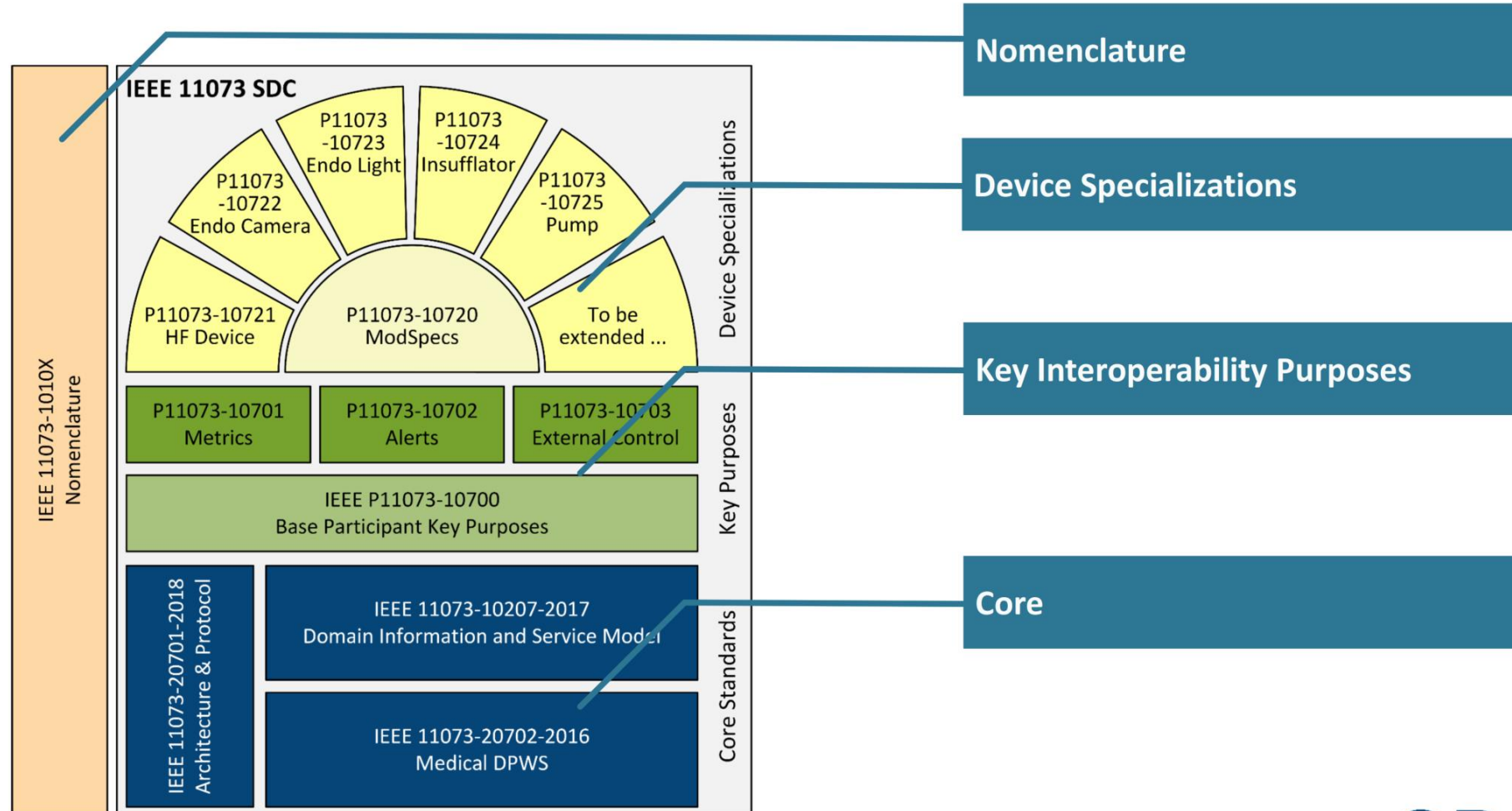
**Service-oriented Device Point-of-care  
Interoperability (SDPi) Profiles**

# ISO/IEEE 11073 Service-Oriented Device Connectivity

## The SDC Standards Family

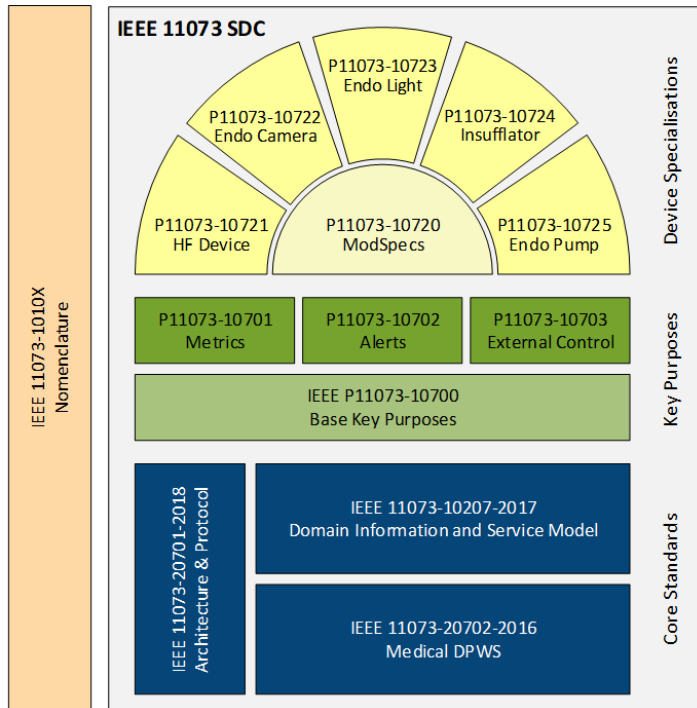


### “Cathedral” Model

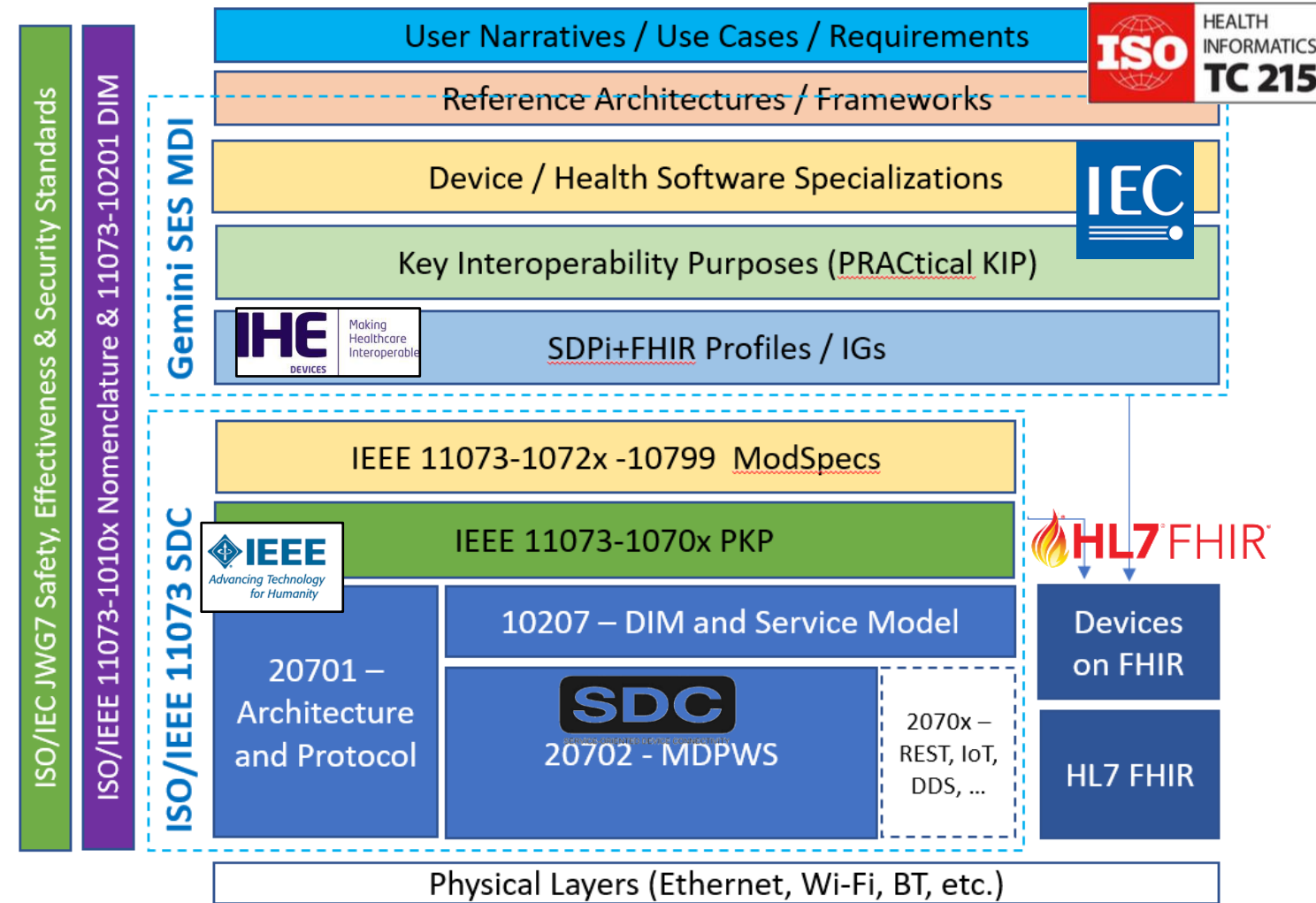


# From Cathedral to Hanging Gardens ...

## The Cathedral



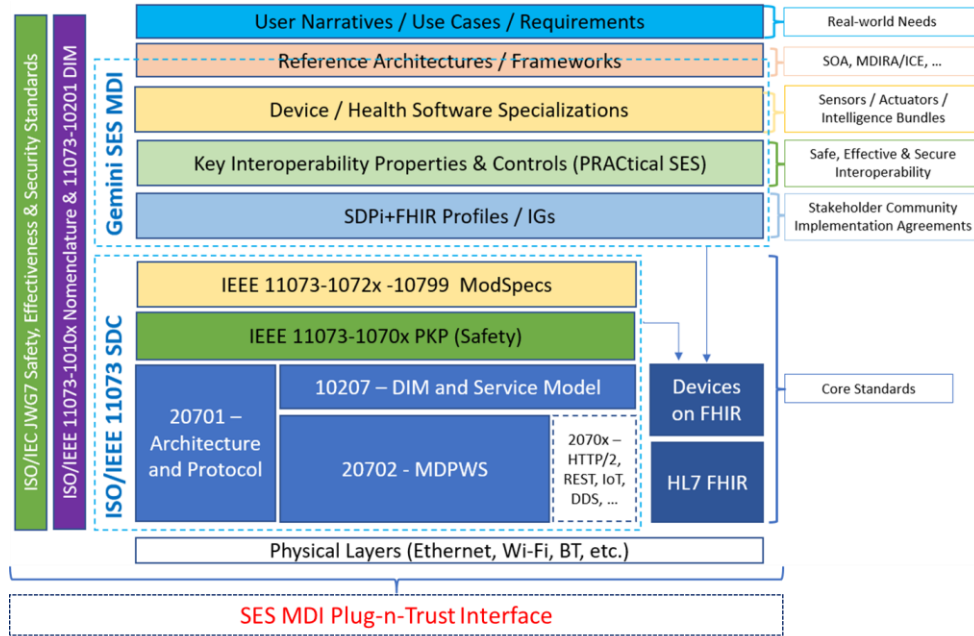
## The Hanging Gardens



SES MDI Plug-n-Trust Interface

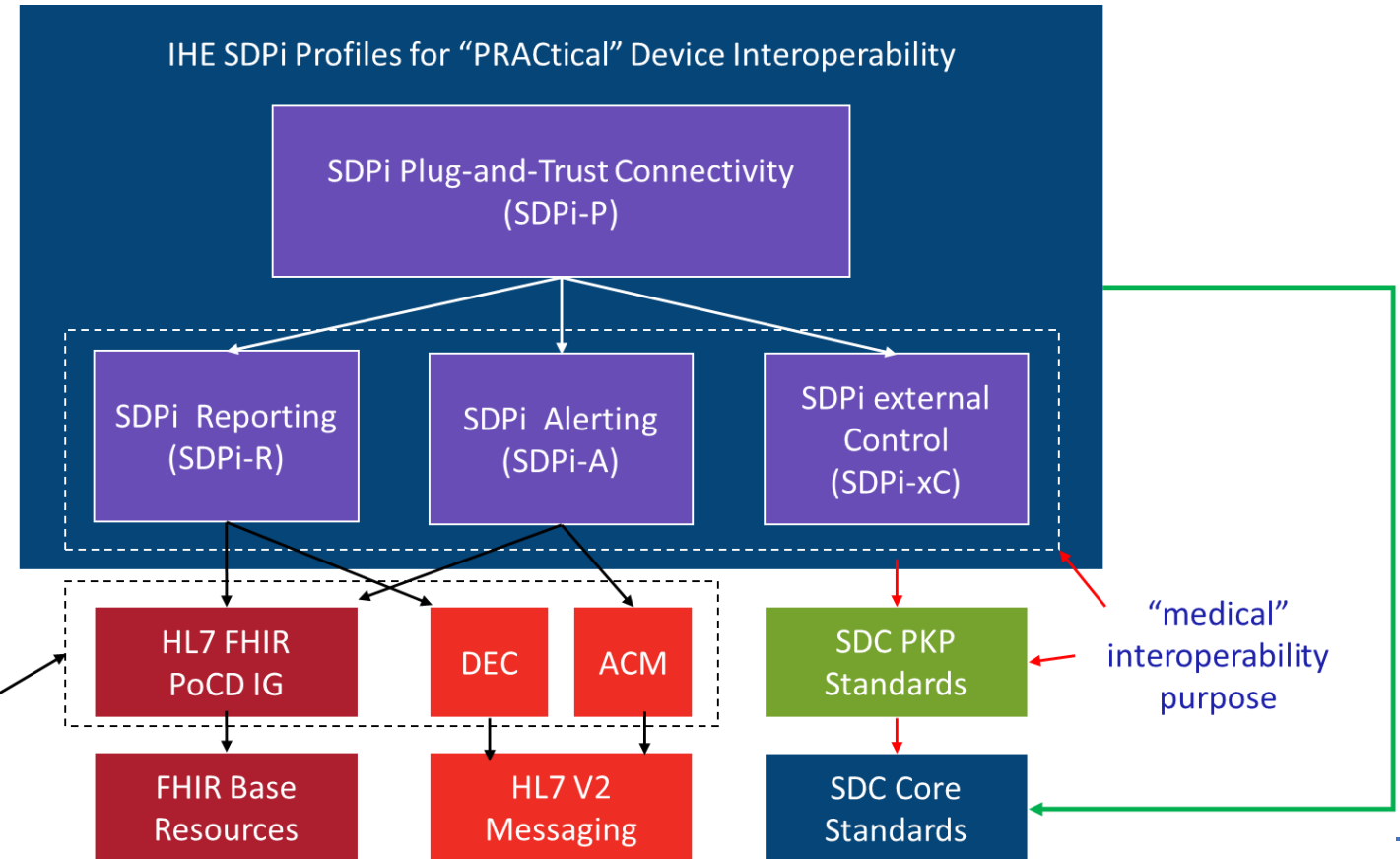


# SDPi – 4 Profiles Built on IHE/HL7 Successes



**Many Standards – One Interface!**

IHE “Gateway” Actors Defined



# Gemini SDPi Publication— *Generating HTML + JSON Requirements*

# Gemini SDPi Publication – AsciiDoc Source

DEV.SDPi > asciidoc > volume1 > tf1-ch-2-overview.adoc

Project > DEV.SDPi > C:\Docs\macStuff\Trusted Solutions\SDPi > .ci > .github > .idea > articles > sdpi-article-asciidoc-cheat-sheet.adoc > sdpi-article-ihe-tf-asciidoc-cookbook.adoc > asciidoc > css > fonts > images > js > listings > plantuml > volume0 > tf0-ch-9-copyrights.adoc > tf0-ch-a-actors.adoc > tf0-ch-b-transactions.adoc > tf0-ch-d-glossary.adoc > tf0-ch-d-glossary.html > tf0-main.adoc > volume1 > conformance-statements > use-cases > tf1-ch-2-overview.adoc > tf1-ch-10-sdpi-p.adoc > tf1-ch-11-sdpi-r.adoc > tf1-ch-12-sdpi-a.adoc > tf1-ch-13-sdpi-xc.adoc > tf1-ch-a-requirements-interoperability.adoc > tf1-ch-b-ref-standards-conformance.adoc > tf1-main.adoc > volume2 > volume3 > docinfo.html > document-declarations.adoc > sdpi-supplement.adoc > sdpi-supplement-intro.adoc > sdpi-supplement-issues.adoc > referenced-artifacts > sdpi-supplement > sources > .gitattributes > .gitignore > CHANGELOG.md > README.md > External Libraries > Scratches and Consoles

tf1-ch-2-overview.adoc

46 section assumes that it will be integrated with the technical framework section that is organized based on TF-1 section headings (e.g., chapter 10 for SDPi- would have a summary here as 2.10. No provision is made, though, for general introductory sections such as the SDPi Overview & Framework discussion below.

47

48 In this version, the content is added as 2.3.1, and then the profiles as 2.3.10 to 2.3.13. Though the content is valid, it may be repositioned in subsequent versions to better integrate with the IHE DEV TF at a future date.

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50 *\*Omitted from this version are profile-specific option summaries\* (e.g., 3.10.1?). It is unclear where to best place this content, and they are listed explicitly in each profile's detailed specification.*

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FRAMEWORK

The Service-oriented Device Point-of-care Interoperability (SDPi) Profiles are built upon a foundation of standards and profiles from [\[acronym hl7\]](#), [\[acronym ieee\]](#), IHE and other organizations. An overview of the profiles and their relationships is provided in [IHE SDPi Profiles & Foundational Standards](#).

Figure 1. IHE SDPi Profiles & Foundational Standards

There is a particular challenge with SDPi profiling of [\[acronym sdc\]](#) that resulted in the definition of (4) profiles and not one:

How to represent a [\[acronym soa\]](#)-based architecture supporting an interactive [\[term plug and trust\]](#) device-to-device (multi-way, M:N) interoperability specification using established IHE technical framework constructs?

NOTE

The arrows indicate reference relationships and not specializations. For example, The three SDPi-R, -A and -xC Profiles refer to the foundational SDPi-P profile. This is achieved by the use of IHE "grouped actors". Or IHE "gateway" actors include mappings to the foundational, non-SDC standards.

57:178 CRLF UTF-8 4 spaces master

**Device Interoperability**  
***Plug-and-Trust***  
**Specification**  
**Published for**  
**Trial Implementation**

Contents

Foreword

Introduction to this Supplement

IHE Technical Frameworks General Introduction

Volume 1 — Profiles

Volume 2 — Transactions

Volume 3 — Content Modules

[profiles.ihe.net/DEV/SDPi](https://profiles.ihe.net/DEV/SDPi)

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



**IHE Devices**  
**Technical Framework Supplement**  
**Service-oriented Device Point-of-care**  
**Interoperability (SDPi)**

Revision 1.0.1 — Trial Implementation

Date: 2023-04-14 14:47:11 UTC

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General Volume 1 Volume 2 Volume 3 Top

# Github/AsciiDoc to HTML to JSON Requirements!

## Supplements for Trial Implementation

Submit your comments [here](#). Additionally, for documents maintained in the IHE GitHub Repository, a link to submit GitHub issues is included following the document name in the list below.

The IHE Devices Technical Committee invites organizations to begin development work based on the following supplements to the Devices Technical Framework. These trial implementation profiles are eligible for testing at subsequent IHE Connectathons.

- [Medical Equipment Management Device Management Communication \(MEMDMC\)](#) - Revised 2023-04-07
- [Medical Equipment Management Location Services \(MEMLS\)](#) - Revised 2023-04-07
- [Personal Health Device Observation Upload \(POU\)](#) - Published 2020-04-13
- [Point-of-Care Identity Management \(PCIM\)](#) - Published 2018-12-07
- [Pulse Oximetry Integration \(POI\)](#) - Published 2012-08-16
- [Retrospective Data Query \(RDQ\)](#) - Published 2012-08-16
- [Service-oriented Device Point-of-care Interoperability \(SDPi\)](#) - Revised 2023-07-21 🌐 (Create a [GitHub Issue](#))
  - [SDPi Requirements Compilation](#) (for current release)
- [Subscribe to Patient Data \(SPD\)](#) - Published 2007-07-29 (Reissued for NA2012 on 2011-11-11)
- [Waveform Content Module \(WCM\)](#) - Revised 2018-01-08

**Source:** [profiles.ihe.net/DEV](https://profiles.ihe.net/DEV)



# Gemini SDPi Publication – Requirements Data

The screenshot displays the IHE SDPI Profiles website. On the left is a navigation menu with sections like Foreword, Introduction, General Introduction, Volume 1 — Profiles, and Volume 2 — Transactions. The main content area shows two profile cards: R2000 and R2001.

**R2000 Profile:**

- Title: A SOMDS Participant shall periodically send Hello messages at random intervals between 60 seconds and 120 seconds.
- Notes: There are no additional requirements for this profile.

**R2001 Profile:**

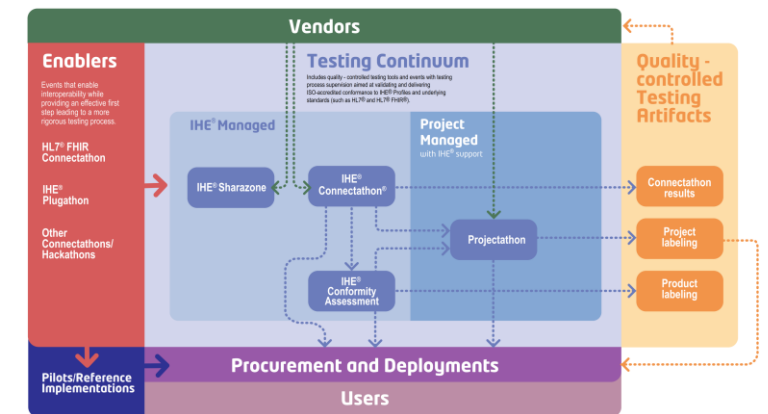
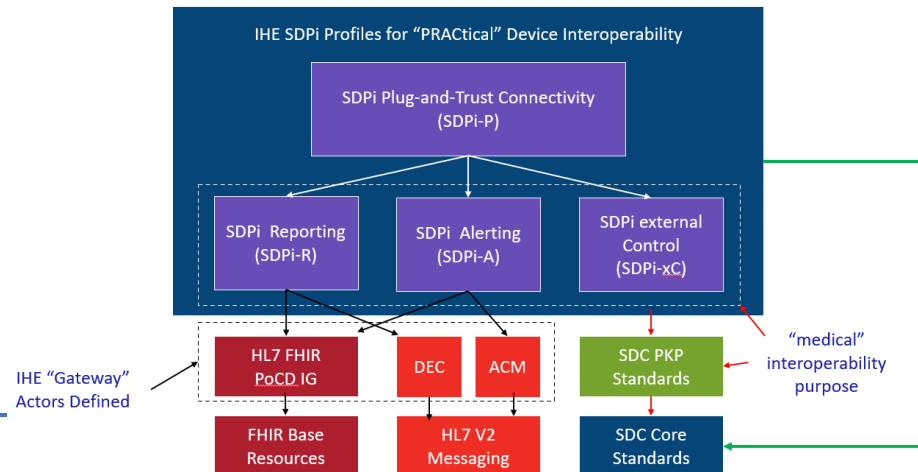
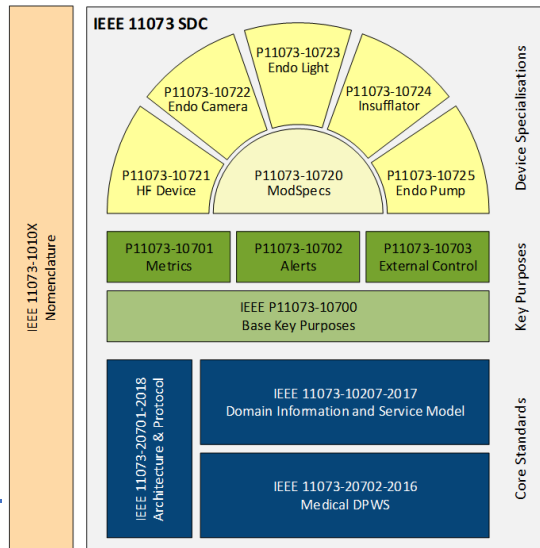
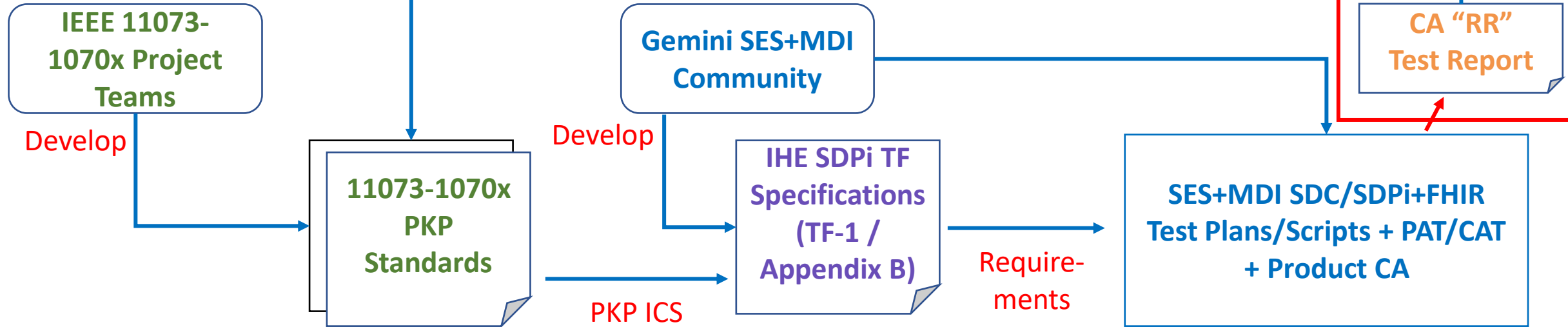
- Title: A SOMDS Provider shall periodically send Hello messages at random intervals between 60 seconds and 120 seconds.
- Notes: The random interval between 60 seconds and 120 seconds aims to prevent SOMDS Providers from congesting the network by sending recurring Hello messages at the same time.

A code editor window is overlaid on the right side of the page, displaying the JSON representation of the R2001 profile:

```
{
  "number": 2001,
  "level": "SHALL",
  "maxOccurrence": 1,
  "asciiDocAttributes": {
    "attributes": {
      "1": "sdpi_requirement",
      "cloaked-context": "sidebar",
      "sdpi_req_level": "shall",
      "id": "r2001",
      "role": "requirement",
      "title": "R2001"
    }
  },
  "asciiDocLines": [
    "A <<vol1_spec_sdpi_p_actor_somds_provider>> shall periodically send Hello messages at random intervals between 60 seconds and 120 seconds.",
    "",
    ".Notes",
    "[%collapsible]",
    "====",
    "NOTE: The random interval between 60 seconds and 120 seconds aims to prevent <<vol1_spec_sdpi_p_actor_somds_provider>>s from congesting the network by sending recurring Hello messages at the same time.",
    ""
  ]
}
```

# SDPi CA – Requirements Interoperability Testing

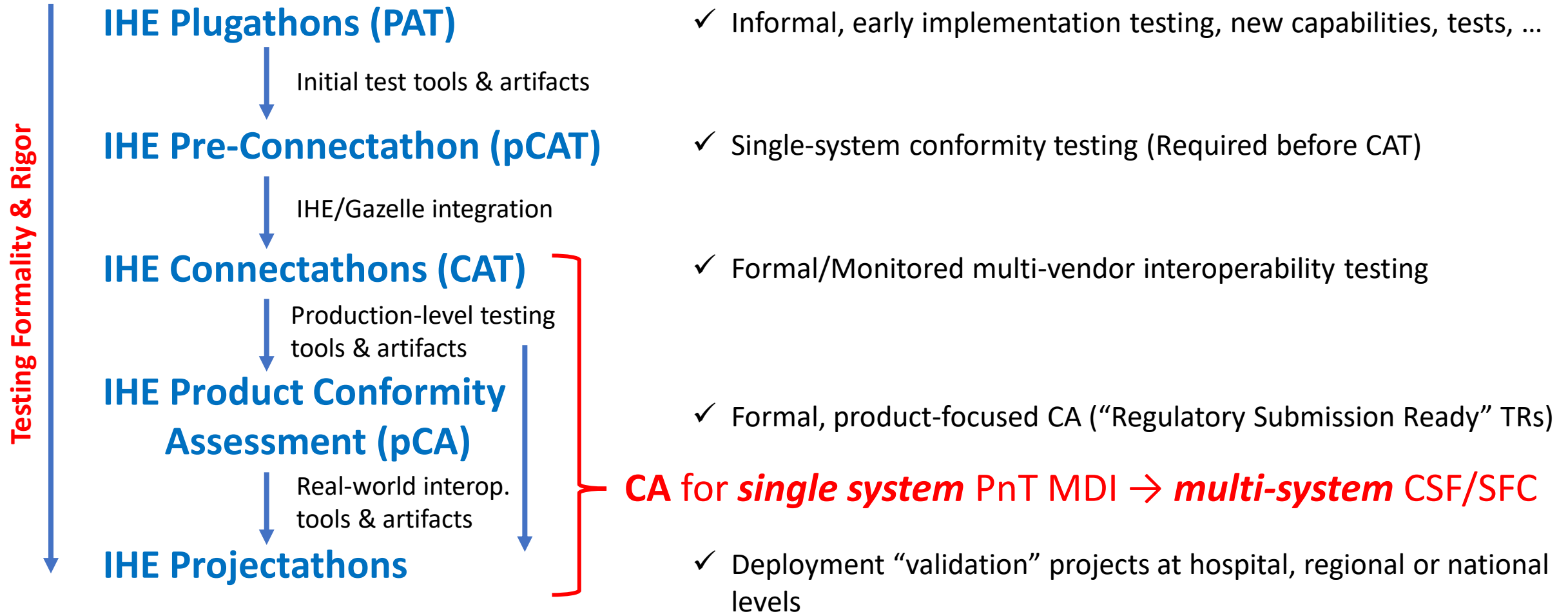
Traceability & Coverage back to 11073-1070x PKP ICS Specifications (via “RI”)



# Gemini SDPi Testing & Tooling – *Pathway to “Regulatory Ready”*



# SDPi CA – IHE Process Overview



**Goal: vCAT & hybrid-CAT for 24/7 SDPi+FHIR Testing**

## **Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices**

### **Guidance for Industry and Food and Drug Administration Staff**

Document issued on September 14, 2018.

The draft of this document was issued on May 13, 2014.

This document supersedes “Guidance for Industry and FDA Staff; Recognition and Use of Consensus Standards,” issued on September 17, 2007, “Frequently Asked Questions on Recognition of Consensus Standards,” issued on September 17, 2007, and “Guidance for Industry and for FDA Staff: Use of Standards in Substantial Equivalence Determinations,” issued on March 12, 2000.

For questions about this document regarding CDRH-regulated devices, contact the Office of the Center Director at 301-796-5900; or Scott Colburn at 301-796-6287 or by e-mail at [scott.colburn@fda.hhs.gov](mailto:scott.colburn@fda.hhs.gov).

For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Center for Biologics Evaluation and Research

## **FDA Programs Support Use of Standards –**

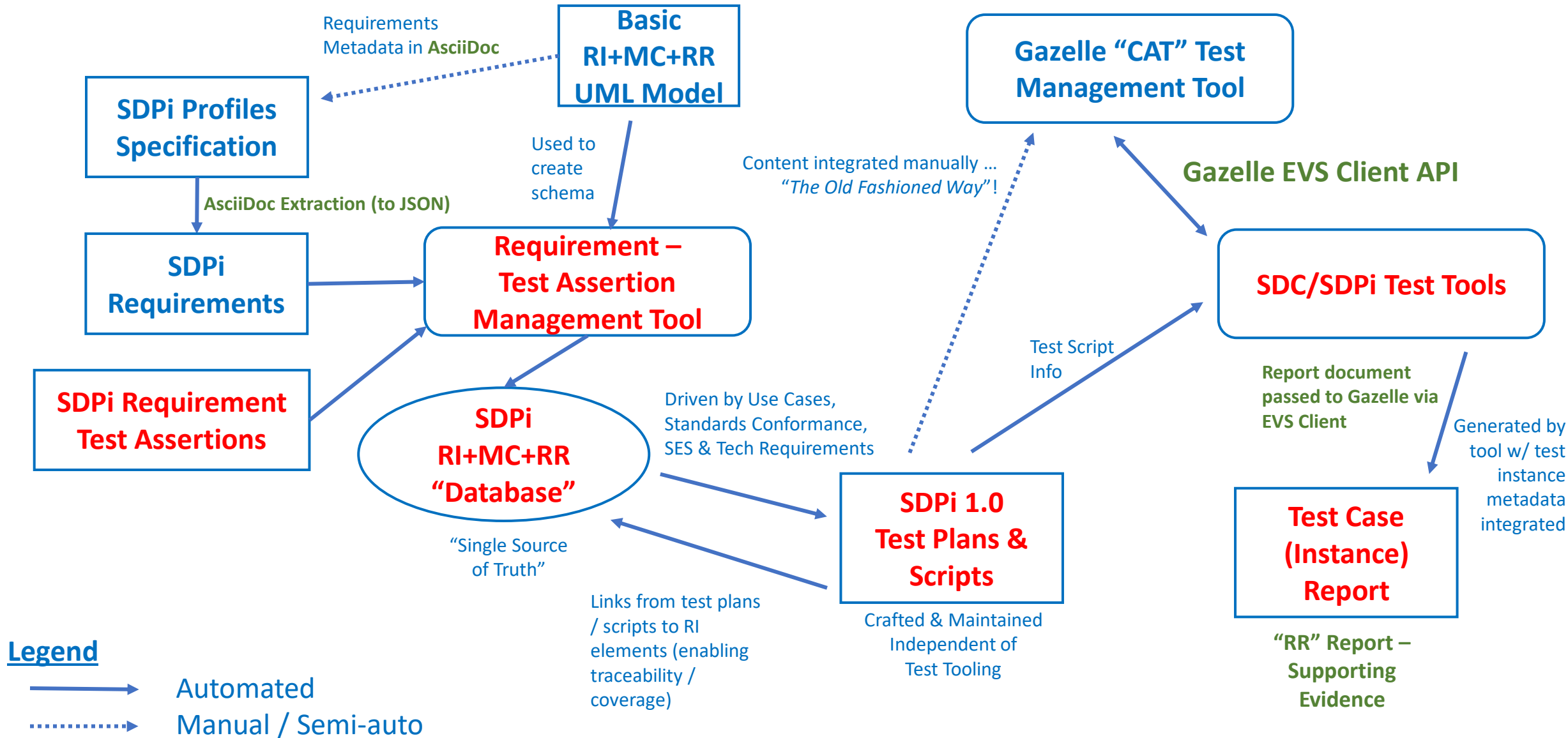
- [S-CAP Standards & Conformity Assessment Program](#)
- [ASCA Accreditation Scheme for Conformity Assessment](#)



**Goal: *Regulatory Submission Ready*  
IHE CA Test Reports & Declarations of Conformity**

Source: [FDA Guidance - Standards Pre-Market Use](#)

# SDPi CA – Gazelle Test Management Tooling



# *SDPi CA & Tooling 2024 Summit*

How to transition beyond PAT testing?

## **Gemini CA & Tooling Summit 2024!**

- ❑ Mid-January @ Vector Informatics – Stuttgart
- ❑ Participants: Product Testing & Tool Developers from Implementation Community
- ❑ Participants: Organizations & government agencies with a focus on medical device CA
- ❑ Establish a roadmap for SDC/SDPi+FHIR product CA & Tooling
- ❑ Identify test artifacts that need to be developed along with project planning / budgeting
- ❑ Define a program of virtual & hybrid testing from regular PAT events to 24/7 testing to quarterly & annual events – including National IHE Connectathons
- ❑ Identify resource & funding sources (including HL7-based Accelerator program)

# Joint ISO-HL7 Project – *Personalized Health Navigation*

# Personalized Health Navigation (PHN) –

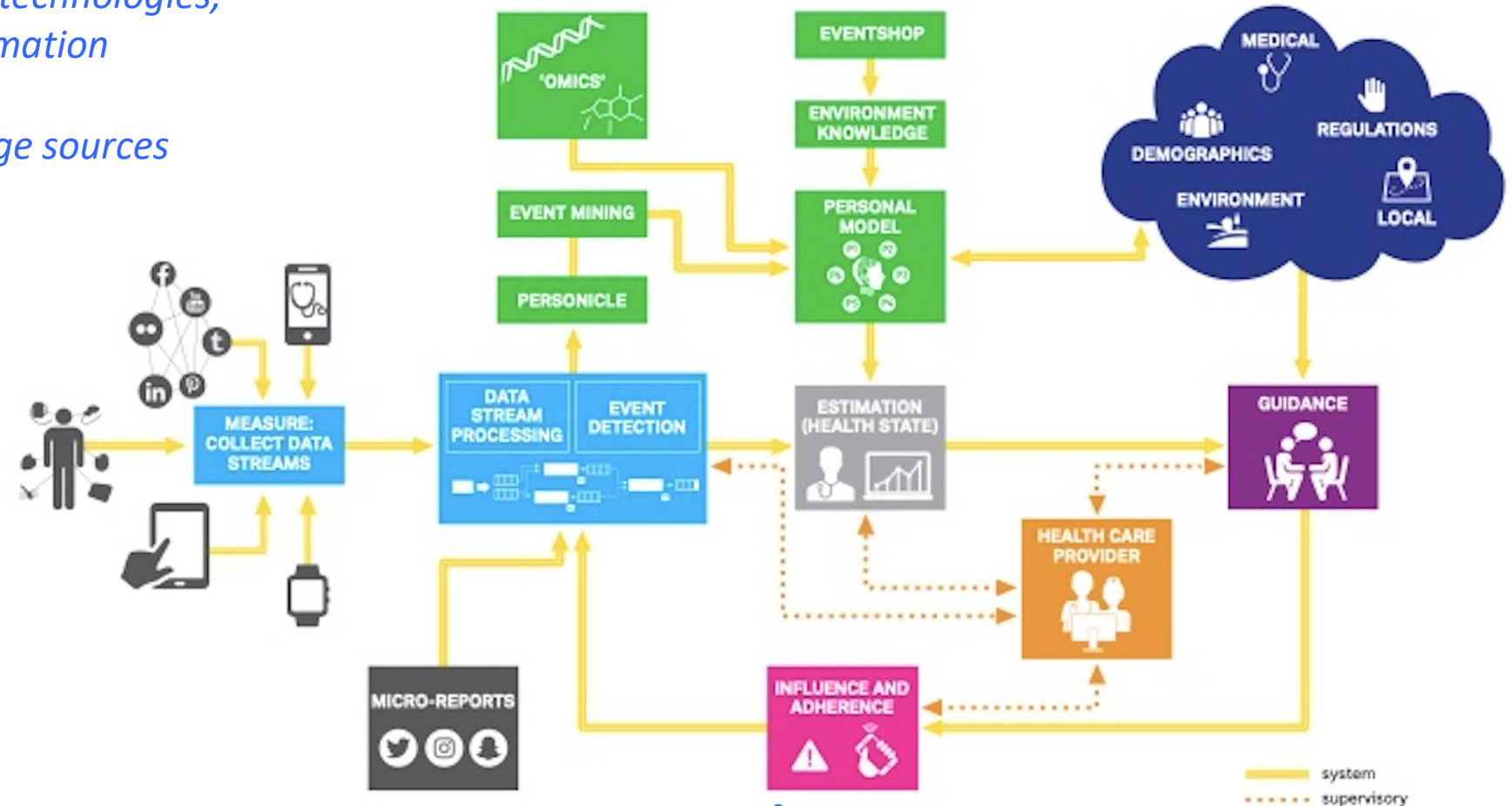
*Enables & empowers individuals  
to intentionally pursue their  
own health and wellness journey...*

*By utilizing intelligent navigational technologies,  
integrating comprehensive information  
from their daily lives &  
factoring in all relevant knowledge sources*

*To personalize, optimize and guide  
self-directed health, wellness &  
healthcare activities &*

*To facilitate coordination with  
family, community, caregivers &  
healthcare teams*

*All to attain their desired goals.*





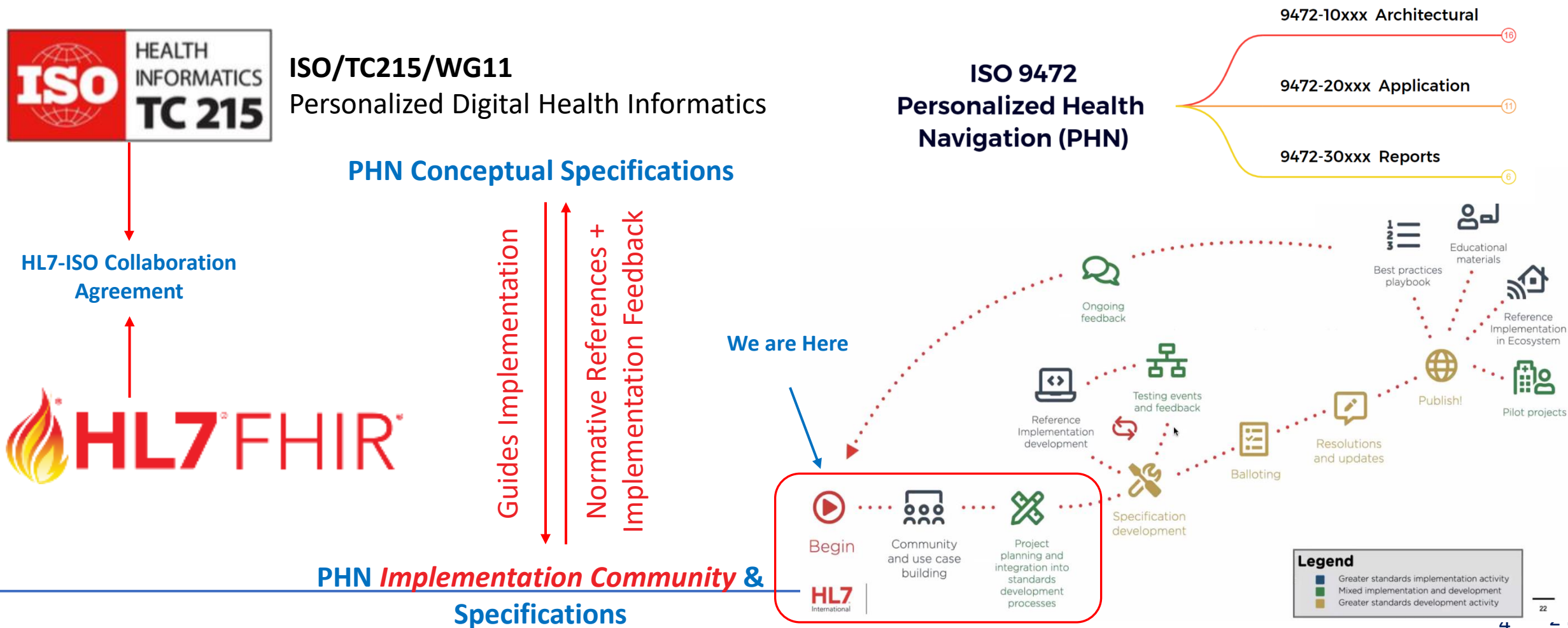
# Sharon Sorting Mom's Drugs ...



*Hmmmm ... “Betty – should I tell the doctor that mom has lost 10 pounds since that change in her water pill a few weeks ago?”*



# Integrated ISO 9472 & HL7 PHN Programs





# 1<sup>st</sup> Ever PHN Food & Nutrition Workshop – Tokyo!

Confluence

Spaces ▾

People

Glossaries

Search

?

## PHN Food & Nutrition Workshop

Created by Todd Cooper, last modified on Sep 05, 2023

Food & Nutrition (**F&N** is one – if not THE – primary factor in an individual's overall health and wellness, and is often a key element of any healthcare treatment protocol. When looking at the broad field of health informatics, though, and focusing on the crucial aspect of F&N, it is one of the least understood and under standardized aspects of health information technology systems. A good example is looking at the nutrition labeling on packaged foods. Though there is an entire industry dedicated to the analysis of food products and accurate creation of these labels, and though many government regulatory agencies have guidance and code to which industry must comply, and even though the increasingly health-conscious public has demanded many restaurants publish (somewhere) the nutritional content of their menu items – when reviewing the specification maturity, state of interoperability and even intelligence of the implementation technologies, it is clear that **F&N is not only far behind other health informatics disciplines**, but there are **significant gaps in understanding** how best to address this important area of health.

**Personalized Health Navigation (PHN)** enables individuals to pursue their own health, wellness and healthcare goals using well established navigational technologies. (Note: Consult the [HL7 PHN Bibliography & Resources](#) confluence section for a broad range of background materials.)

To address this understanding "gap" and establish a strategy for how to advance health informatics standardization and implementation technologies ...

**Personalized Health Navigation – International Food & Nutrition Workshop**

**October 13-14, 2023**

**Tokyo, Japan**

This workshop will be conducted in coordination with standards development projects in the Japanese *Institute of Health Data Infrastructure for All (IDIAL)*, and *ISO/TC 215/WG11 Health Informatics - Personalized Digital Health* and *Health Level Seven International*, and the *University of California, Irvine – Institute for Future Health*, where PHN originated! For more information, the IDIAL office can be contacted directly at: [health-std.office@idial.267pxor.jp](mailto:health-std.office@idial.267pxor.jp)



Workshop presentation & notes @ <https://confluence.hl7.org/x/rA2LCw>

# Questions?



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

*for*

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**2023.10.18**



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