JOHNS HOPKINS
APPLIED PHYSICS LABORATORY

Medical Device Interoperability Reference Architecture (MDIRA) Project

Update & Standards Gap Mitigation Proposals

for

Joint HL7 / IEEE / IHE Devices Virtual WGM 2020.09.23

Prepared by
The Johns Hopkins University
Applied Physics Laboratory

23 Sept 2020

JHU/APL MDIRA Project Update

- MDIRA Project Update –
  - 3rd update to IEEE / IHE / HL7 Devices Joint Working Group Meetings
- MDIRA Standards Engagement Overview
- Summary of identified MDI Standards “Gaps”
- Addressing the Gaps:
  - IEEE PAR Proposals – new & published standards
  - IHE DEV “MDIRA Profile” Proposal
- Q & A

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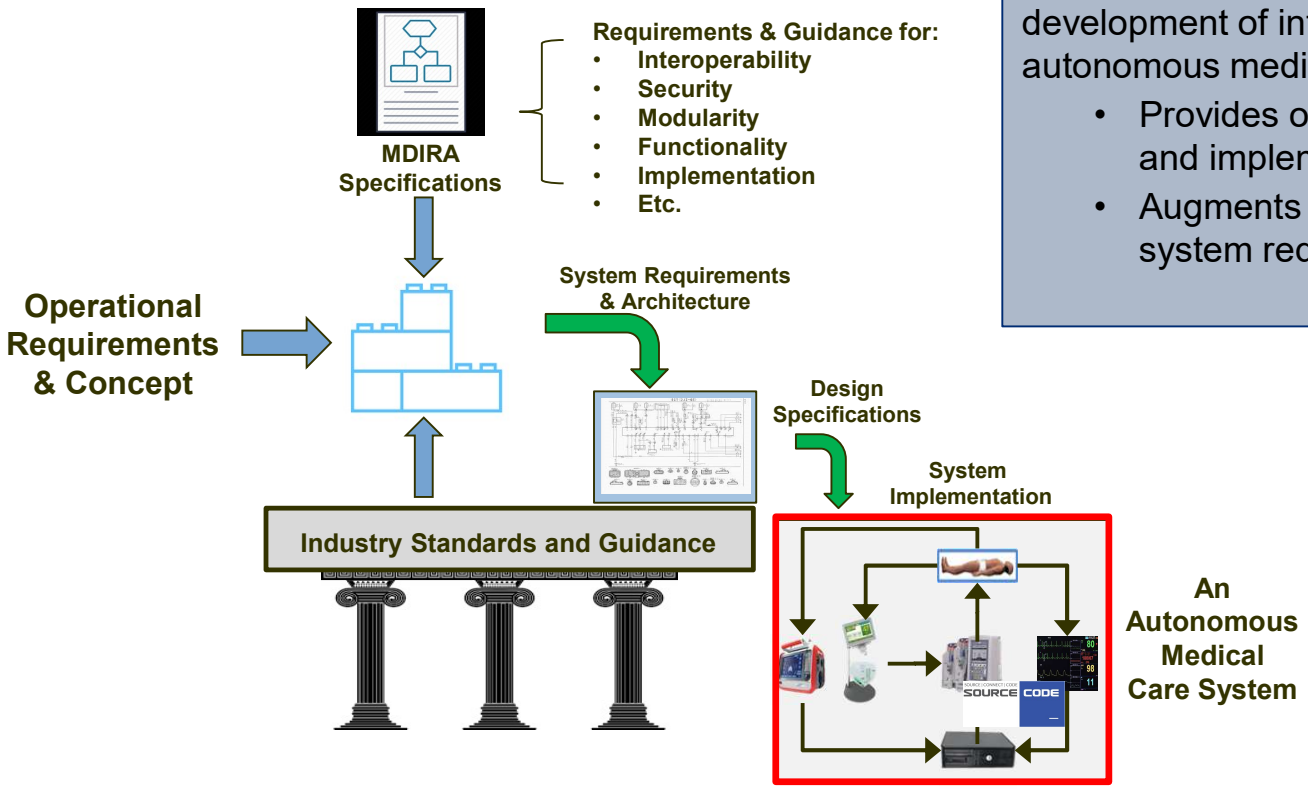
MDIRA - Medical Device Interoperability Reference Architecture



MDIRA is a technical framework that guides development of interoperable and autonomous medical device systems

- Provides overarching requirements and implementation guidance
- Augments the customer-driven system requirement

Project Objectives

- Advance medical device interoperability, openness and security
- Cultivate multi-partner federal/industry collaborations
- Develop specifications and prototypes that can enable development of autonomous medical care systems

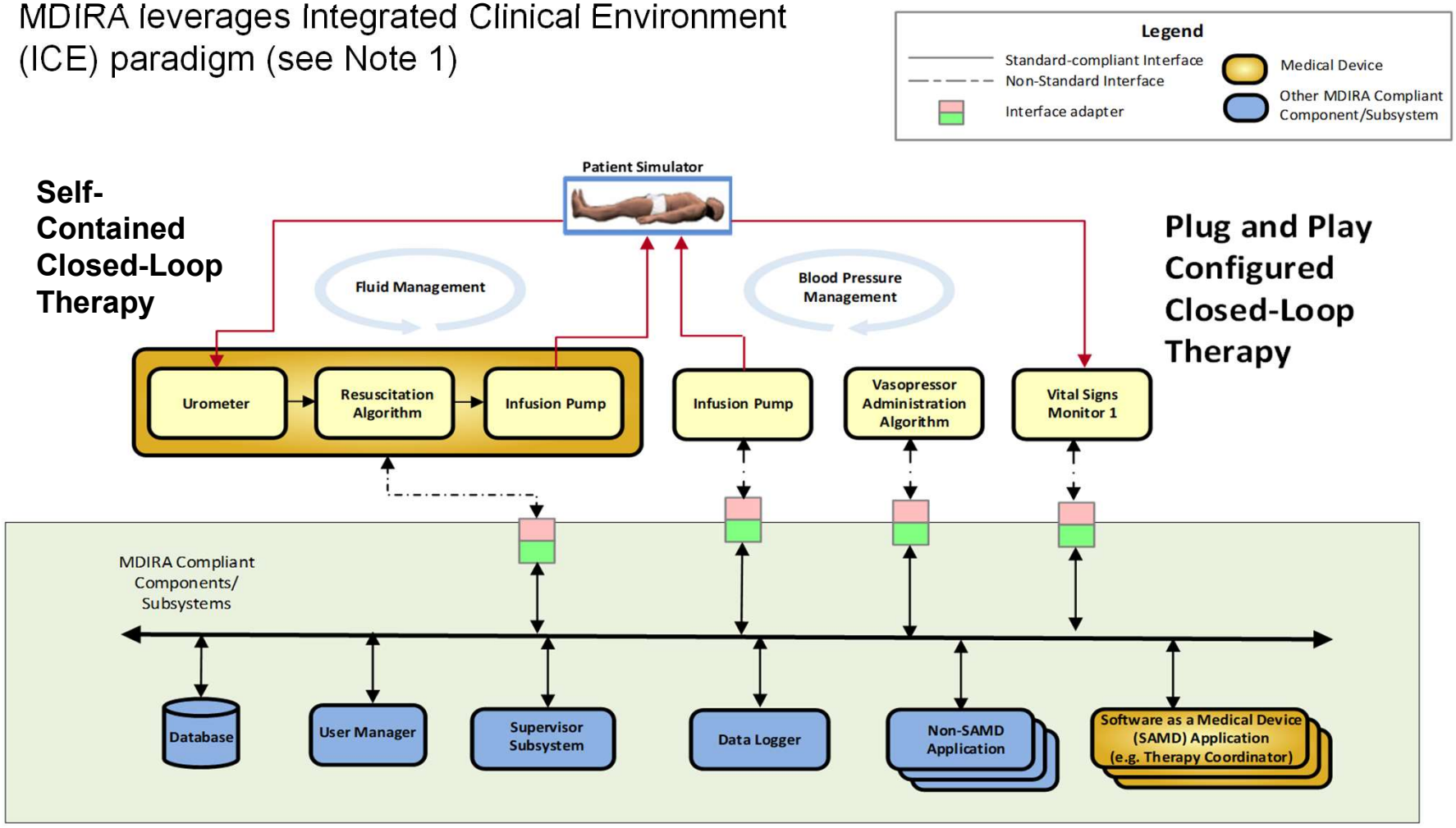
MDIRA Project on the Web …

Current Status

- Draft MDIRA Specification released
  - Video and specification are at the following link: https://secwww.jhuapl.edu/mdira/
- Developing MDIRA Reference implementations (RIs) to:
  - Demonstrate key concepts and mature the reference architecture
  - Stimulate industry interest and collaboration
  - Identify gaps in standards

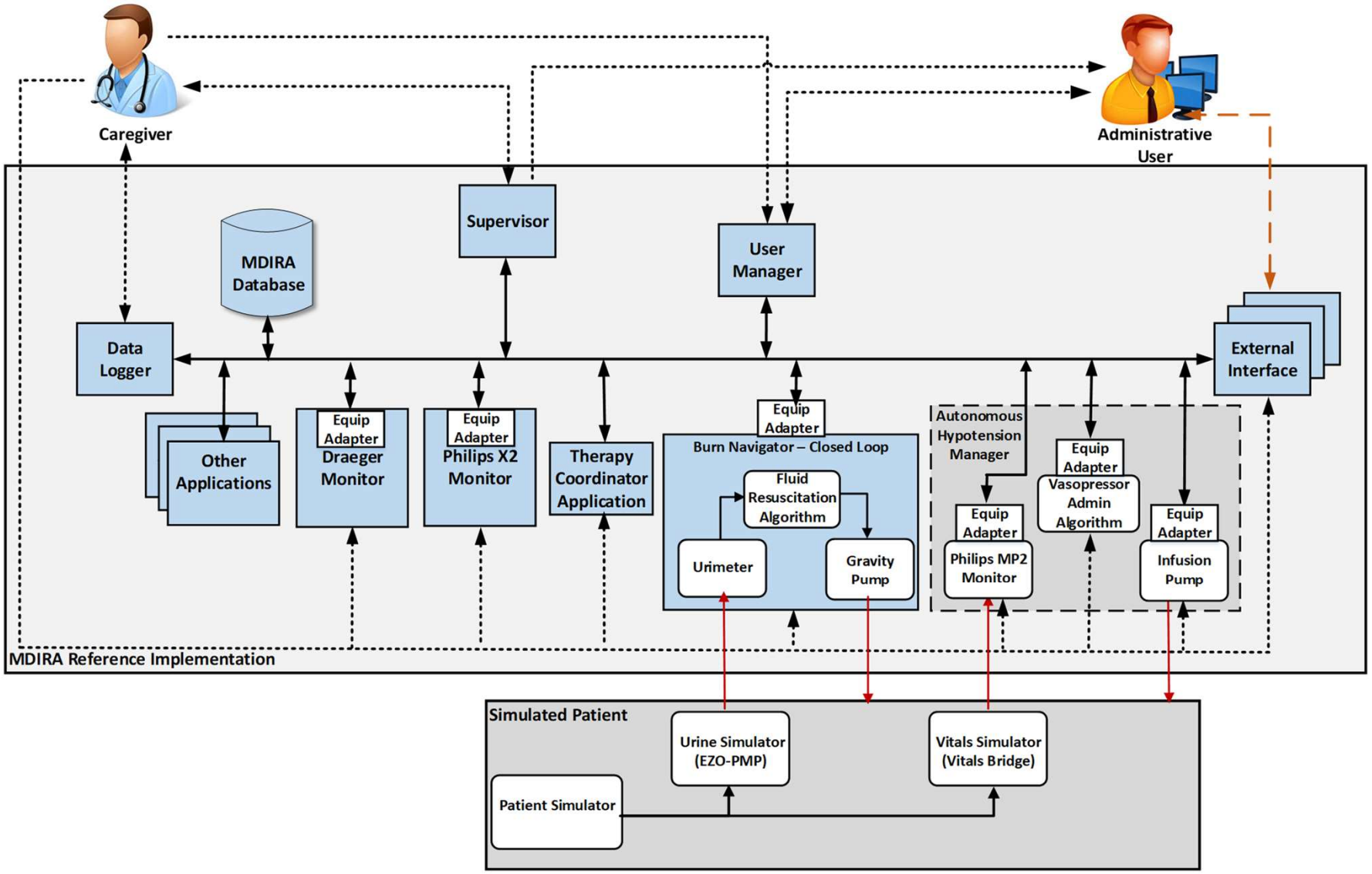
MDIRA Reference Implementation Concept

MDIRA leverages Integrated Clinical Environment (ICE) paradigm (see Note 1)



Note 1. ANSI/AAMI 2700-1, Medical Devices and Medical Systems – Essential safety and performance requirements for equipment comprising the patient-centric integrated clinical environment (ICE), Part 1: General requirements and conceptual model

First MDIRA RI Demonstration System Layout



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MDIRA Team Standards Focus To Date

- **IEEE* 11073-10101 Nomenclature** (2019 update)
  - Related resource: the National Institute of Health (NIST) Rosetta Terminology Mapping Management System (RTMMS)
- **IEEE* 11073 Service-orient Device Connectivity (SDC)**
  - Focus here is the medical device Participant Model of Part 10207 (An MDIB information model) circa 2017
  - Unless otherwise stated, Participant Model gaps would also apply to the legacy IEEE 11073-10201 Domain Information Model (DIM) circa 2004
- **IHE* Devices (DEV) Technical Framework**
- **AAMI* 2700 Part 2-1 (draft) Requirements for Forensic Data Logging**
- **HL7* Fast Healthcare Interoperability Resources (FHIR)** with underlying terminology standards (e.g. Logical Observation Identifiers Names and Codes (LOINC))

There are other relevant standards. These listed are most relevant to the first MDIRA Reference Implementation under development

* A Standard Development Organization (SDO)

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Summary of Gap Topics (1 of 2)

A. Discovering the capability of an *autonomous medical system* in the ICE
   - BICEPS "containment tree" for these types of systems

B. Standard terms/codes for the key characteristics of autonomous medical systems
   - There is no *classification* (*typology*) *framework* for *autonomous medical systems*

C. Standard terms/codes for the key characteristics of controllers
   - There is no classification (typology) framework for *controllers in autonomous medical systems*

D. More *examples* in IEEE 11073-10207
   - Examples needed for representing medical device capabilities, services and states using of the MDIB structure

Detailed charts available

Summary of Gap Topics (2 of 2)

E. Should a medical device be required to *communicate* its *data needs* to an *ICE Supervisor*?
   - How much information does the ICE Supervisor need to manage ICE resources and ensure patient safety?

F. Standards do not adequately constrain alternative design options
   - Leads to systems that do not interoperate.

G. Representing *video data capabilities* a medical device can produce
   - No explicit means to represent this capability in the MDIB structure

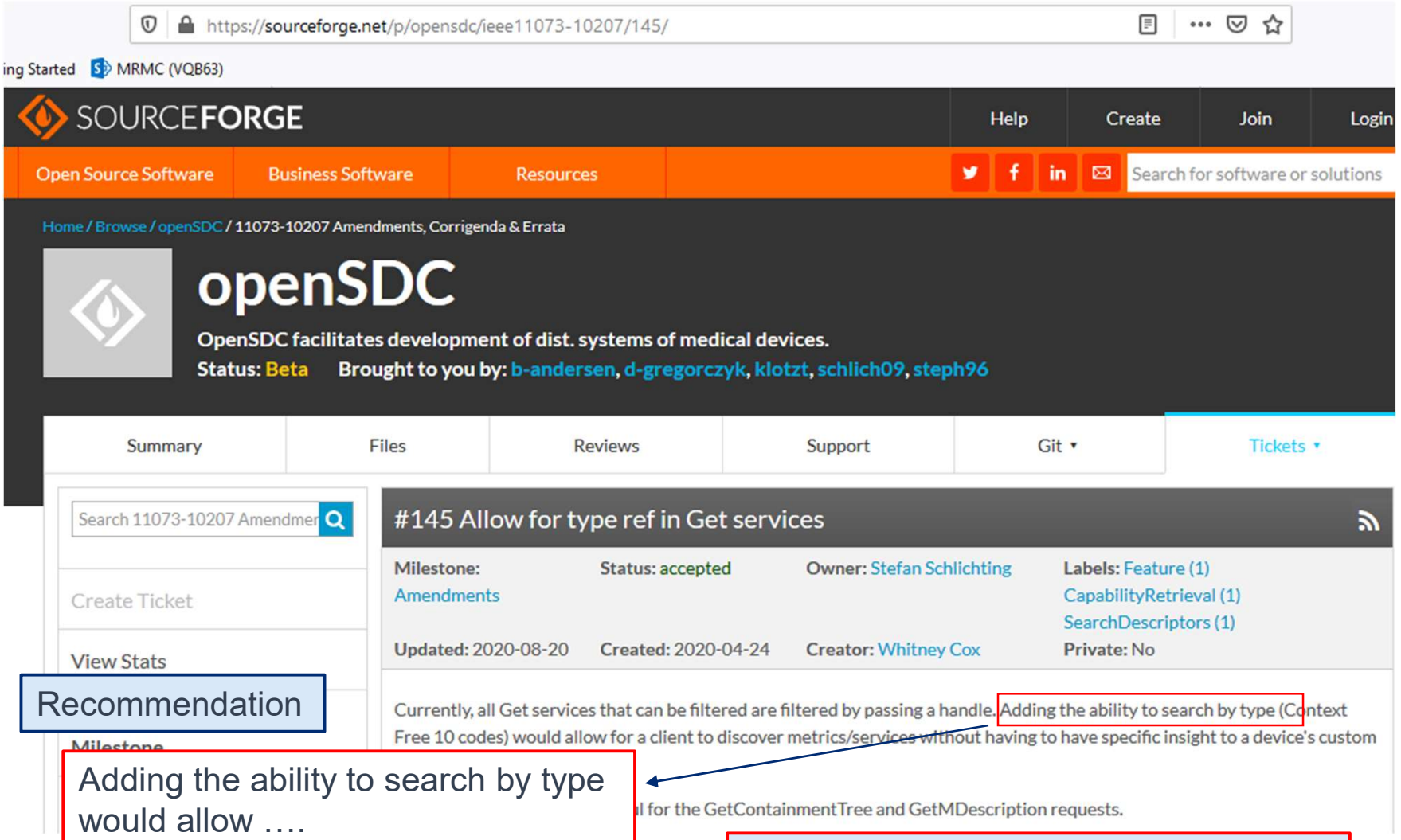
H. Software as a Medical Device (*SaMD*)
   - There is no classification (typology) framework at the functional level for SaMDs

I. Challenge of *searching MDIBs*
   - Key practical consideration of applying the MDIB paradigm

J. Support for *MDIRA* telemedicine / *remote care using SDC/BICEPS*
   - Consider HTTP/2 & gRPC as MDPWS alternative SOMDA transport

Detailed charts available

SourceForge: Official Portal for IEEE 11073 SDC Change Recommendations That Might Result in a PAR



SourceForge Process Example (1 of 2)

Preceding Correspondence Not Shown

Whitney Cox - *2020-05-22*

Hi Stefan,

Sorry for the delay. I have attached a quick draft for a more advanced searching service. The service addresses some of the inefficiencies that occur when using the GetContainmentTree service and allows a service consumer to resolve handles offered by a provider using a type code.

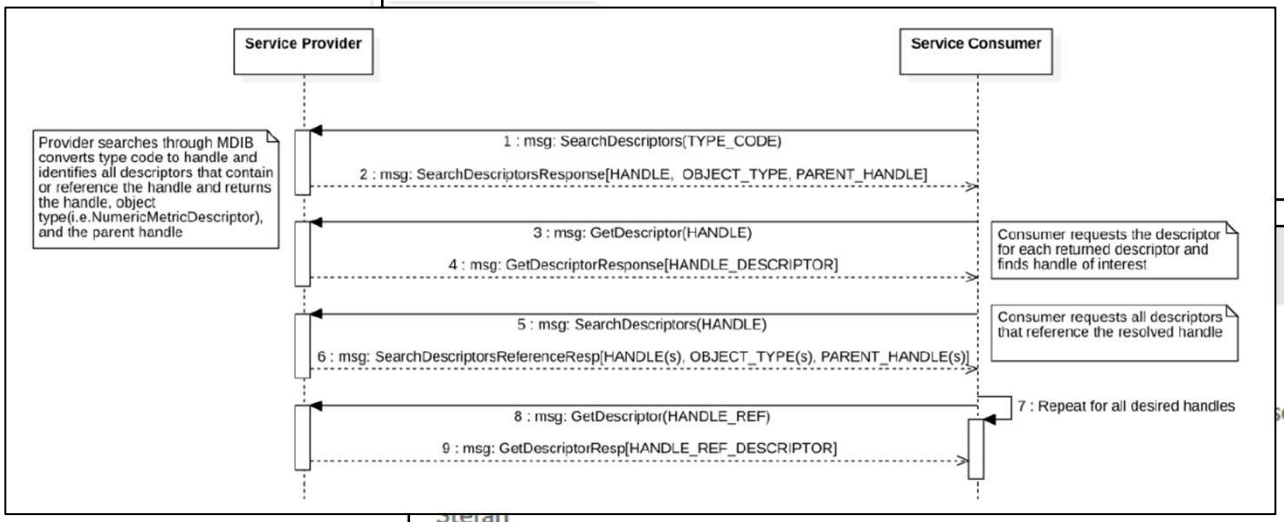
This proposed service can also be used by a consumer to quickly discover types offered by a provider without passing over the entire MDIB.

Let me know if you have any questions.

Thanks,
Whitney

The proposed service can be used by a consumer ….

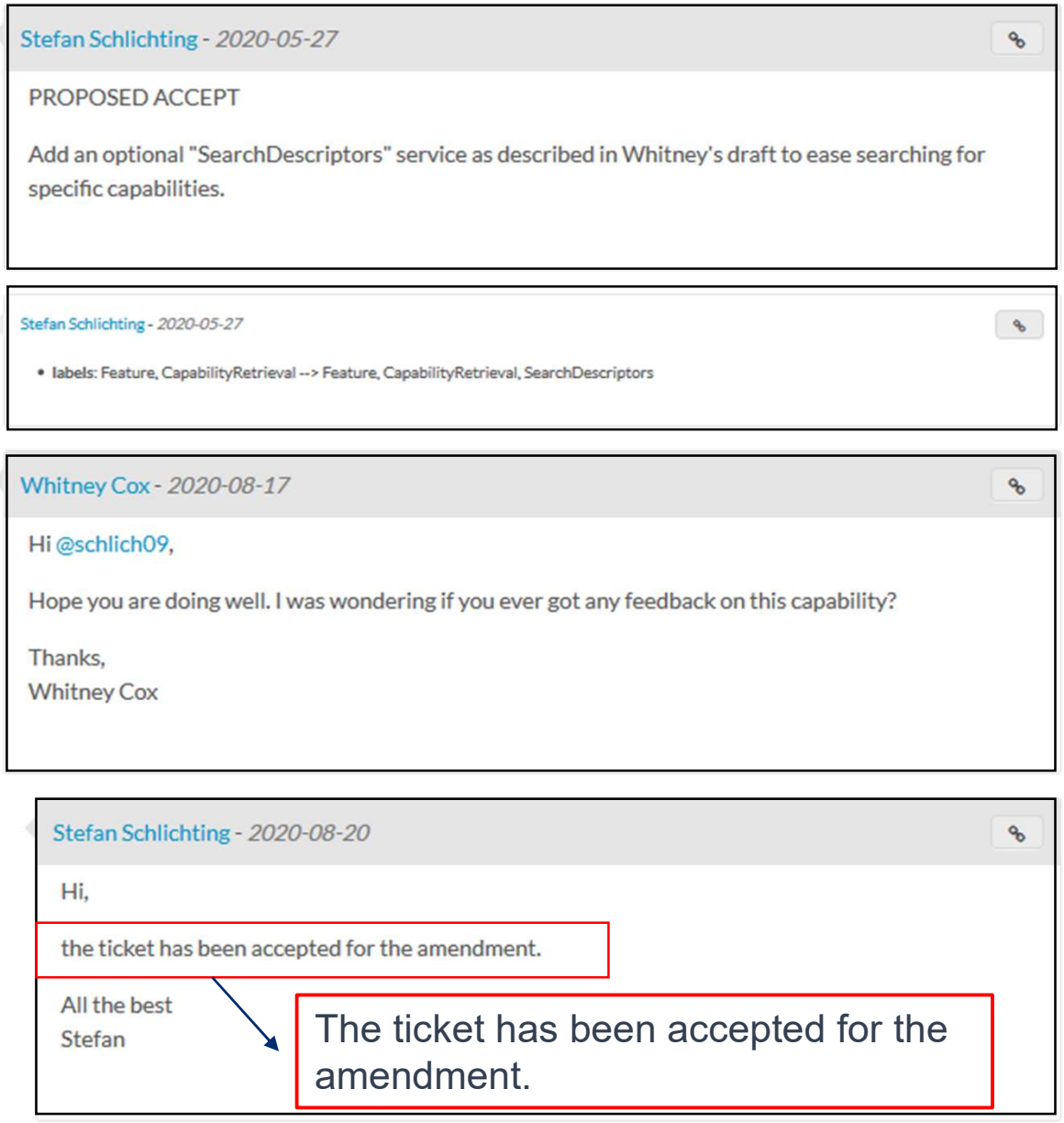
Proposed Approach



se to accept it.

Stefan

SourceForge Process Example (2 of 2)



Stefan Schlichting - *2020-05-27*

PROPOSED ACCEPT

Add an optional "SearchDescriptors" service as described in Whitney's draft to ease searching for specific capabilities.

Stefan Schlichting - *2020-05-27*

- **labels:** Feature, CapabilityRetrieval --> Feature, CapabilityRetrieval, SearchDescriptors

Whitney Cox - *2020-08-17*

Hi @schlich09,

Hope you are doing well. I was wondering if you ever got any feedback on this capability?

Thanks,
Whitney Cox

Stefan Schlichting - *2020-08-20*

Hi,

the ticket has been accepted for the amendment.

All the best
Stefan

The ticket has been accepted for the amendment.

Amendment Accepted as Part of Future PAR Submittal

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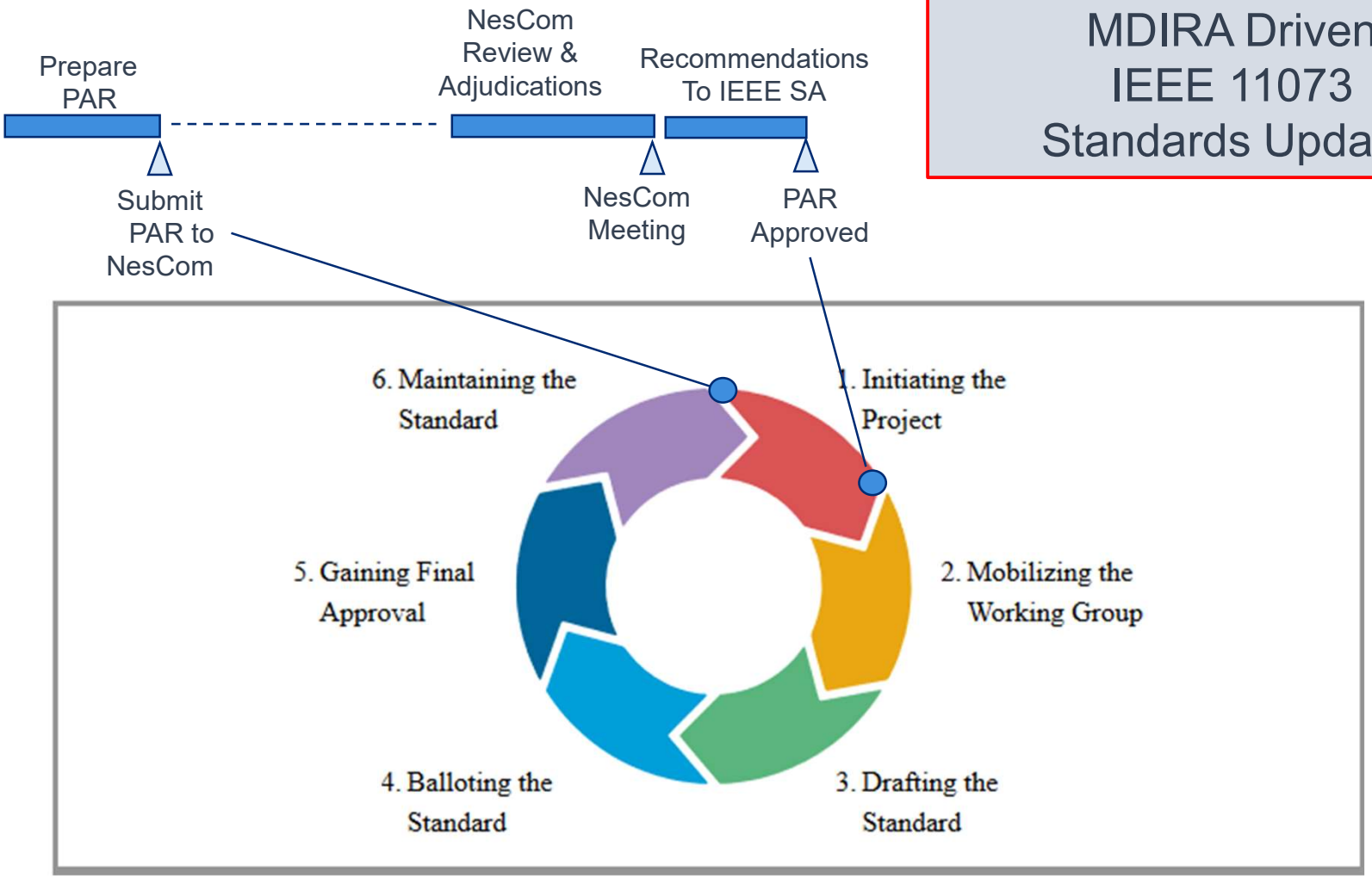
Updates to IEEE Standards: Project Authorization Request (PAR) First Step

Formal Route for addressing MDIRA Driven IEEE 11073 Standards Updates



NesCom: IEEE New Standards Committee

IEEE SA: IEEE Standards Association

NOTE: Next IEEE NesCom Meeting 2021 January

IEEE PAR Considerations

PAR Options to be considered:

1. ***Revision / Corrigenda / Amendment of published standard***
   - ✓ 11073-1010x Nomenclature / Terminology
   - ✓ 11073-10207 SDC/BICEPS
   - ✓ 11073-20701 SDC/SOMDA "Glue"
   - ✓ 11073-20701 SDC/MDPWS
2. ***Existing PAR / Project "Expanded"***
   - ✓ 11073-10107 Control Terminology
   - ✓ 11073-107xx Device Specializations
3. ***New Project (Guidance, Recommended Practice or Standard)***
   - ✓ 11073-xyz Autonomous Medical Systems (incl. SAMD)

Additional Options:

- ✓ ***WG position papers*** to quickly assess topics & expert consensus
- ✓ ***Joint work*** between IEEE 11073 and other interested SDOs
- ✓ IHE / HL7 DEV ***profiles*** vs. IEEE 11073 ***standards***

ASK: *Establish a regular IEEE 11073 WG discussion on these topics to establish and begin execution of a strategy to address the identified gaps, including any PARs for submission at the next IEEE NesCom meeting.*

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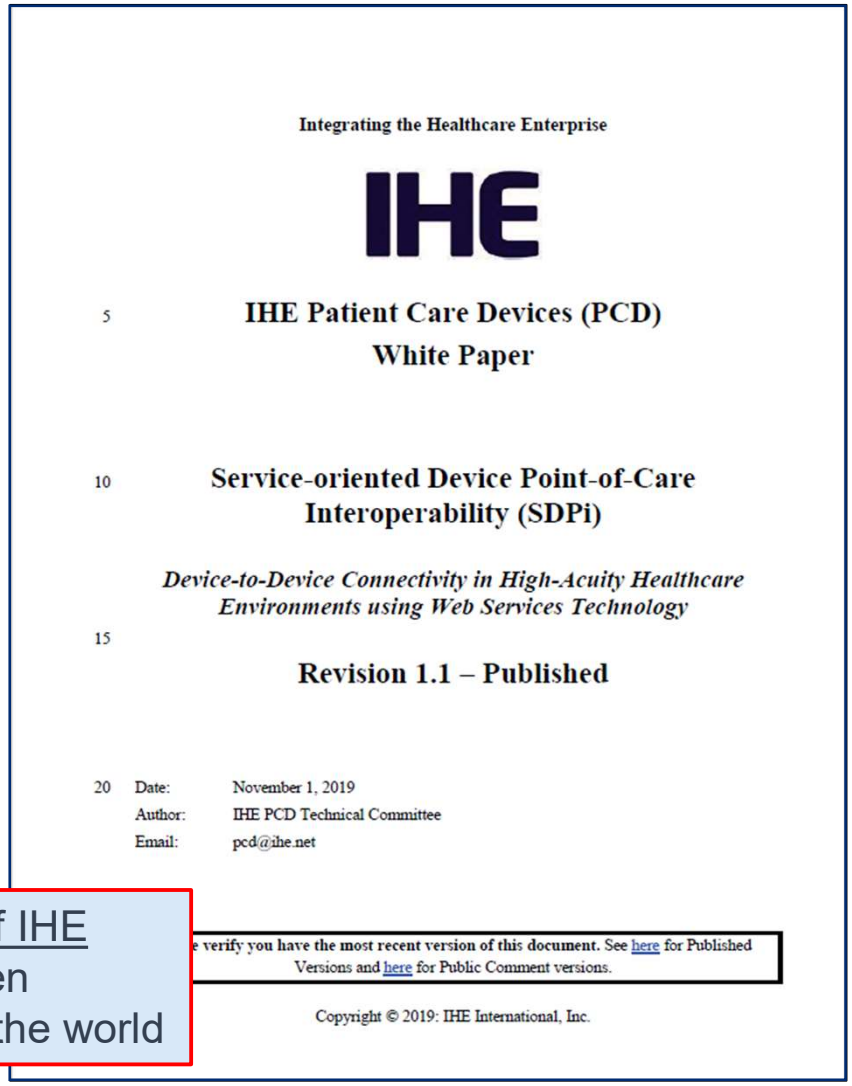
MDIRA Use Case Formally Recognized by IHE !

Use Cases in Section 10.1:

- Functional Endoscopic Sinus Surgery OR Integration
- MDIRA & Autonomous Medical Systems
- IHE PCD “Quiet Hospital”
- Preeclampsia During Pregnancy Across the Continuum of Care



Integrating the Healthcare Enterprise

IHE

IHE Patient Care Devices (PCD)
White Paper

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

Device-to-Device Connectivity in High-Acuity Healthcare Environments using Web Services Technology

Revision 1.1 – Published

Date: November 1, 2019
Author: IHE PCD Technical Committee
Email: pcd@ihe.net

e verify you have the most recent version of this document. See here for Published Versions and here for Public Comment versions.

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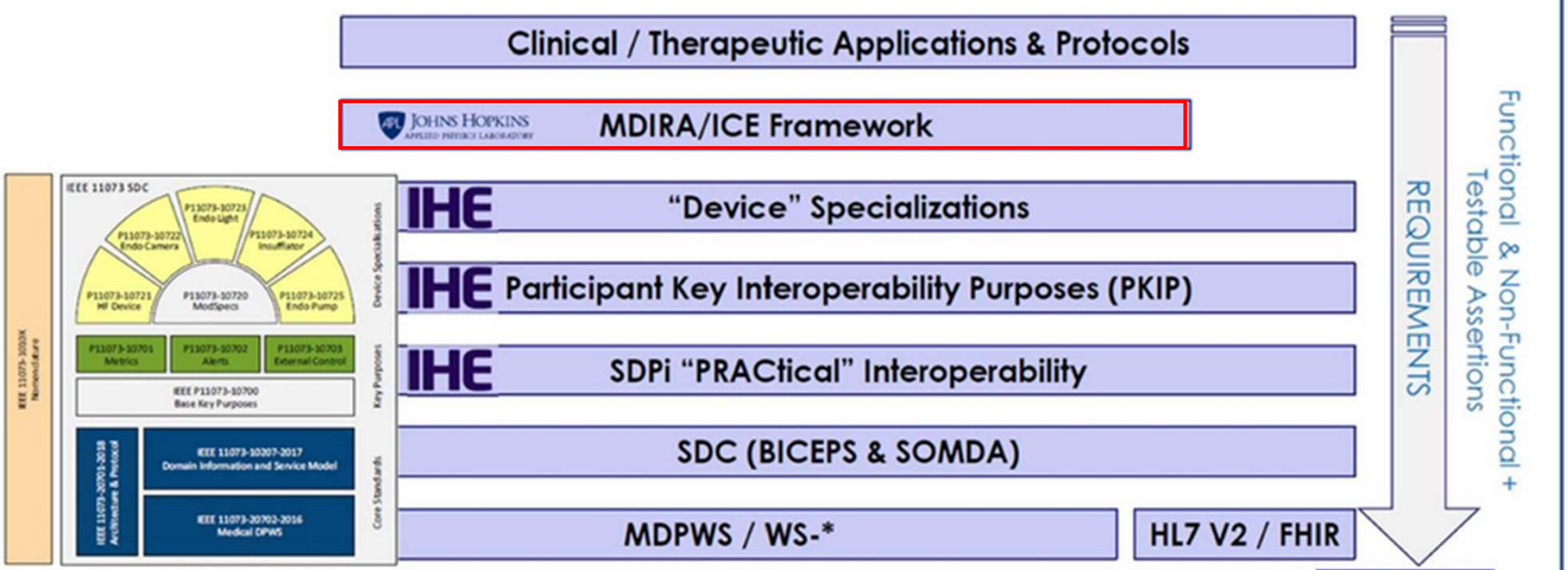
Publication required layers of IHE and public review. It has been presented to groups around the world

MDIRA Depicted as an Overarching Framework Specification – Affirms Concept of Previous Slide

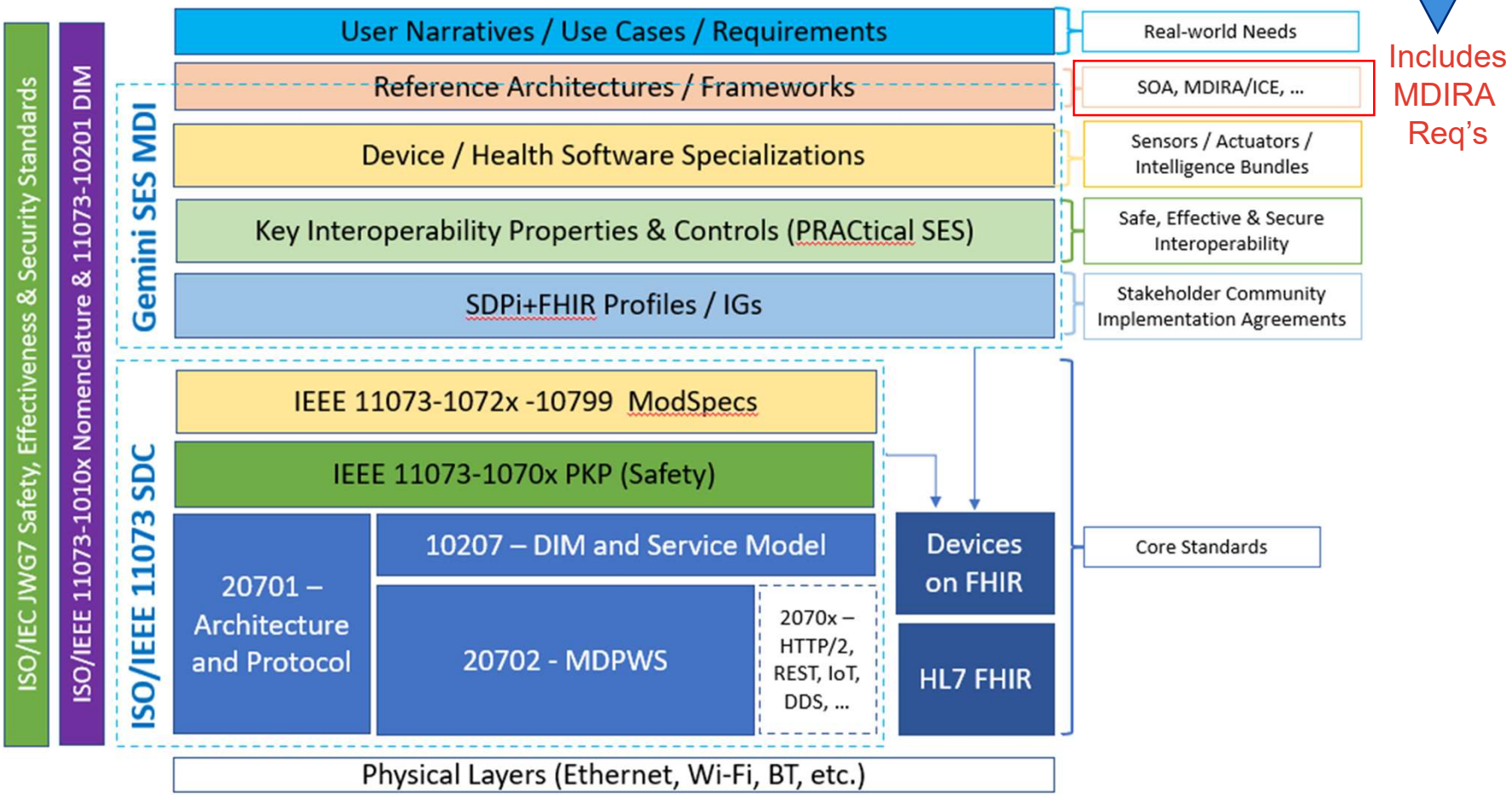
HIMMS 2020 Briefing



Authors: Tobias Klotz (Draeger) and Todd Cooper (Trusted Solutions Foundry)

Possible "Landing Pad" for the MDIRA Specification: An IHE-Recognized Reference Architecture

IHE-HL7 Gemini Medical Device Interoperability (MDI) Project Framework Model



Graphic developed by the Gemini MDI Team

IHE DEV “MDIRA Profile” Proposal

Proposal Summary

Building on the foundation established in the SDPi white paper and draft supplement, as well as the SDC-based MDIRA RI, create an IHE DEV “MDIRA Profile” that enables IHE conformant implementations adding actor, transaction and content module specifications, including ICE Supervisor and Data Logger components, as well as “apps” such as a Therapy Coordinator. The profile project would be established under the IHE DEV DPI Program.

NOTE: See *MDIRA IHE Brief Profile Proposal draft document*.

Profile Proposal Timeline

2020.09.23	Review Draft Brief Profile Proposal (BPP) draft @ joint WGM
2020.09.25	IHE DEV DPI Program – Review & Recommendation to DEV
2020.09.25	Circulate MDIRA BPP to IHE DEV for domain-wide review
2020.10.05	IHE DEV MDIRA BPP Approval Vote during Plenary Meeting
2020 - 2021	Begin project team formation with public call for participation
	Begin development of the profile early 2021
	Target Draft 1.0 Completion by end 2021

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