

Safe Effective & Secure Medical Device Interoperability – *Can we make sense of all these standards?!*

Todd Cooper, AFC! “Standards Guy” ~ March 2020



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First: Some Definitions *(standards guys love acronyms!)*

SDO: Standards Development Organization ... ISO / IEC / IEEE / IHE / HL7 / ...

SES: Safe, Effective & Secure ... simple reference to “JWG7” standards
*Community focus: **quality, regulatory & legal concerns*** [think “process guys”]

MDI: Medical Device Interoperability ... “from the device interface” / MD2MD @ bedside
*Community focus: **research & engineering*** [think “tech guys”]

SDC: Service-oriented Device Connectivity ... SOA for MD2MD interoperability @ bedside

SDPi: Service-oriented Device Point-of-care Interoperability ... IHE “Profile” of SDC

FHIR: Fast Healthcare Interoperability Resources ... HL7 standard taking world by storm!

Does it have to be this hard?



The Problem of *SDO & Standards Multiplicity*

Problem #1: *All these SDOs ... all these standards = Confusing Complexity*

Impact: Need a “Standards PhD” to sort out what is relevant from what is noise

Problem #2: *SES & MDI Communities ... don't work well together!*

Impact: Their standards are also developed in *decoupled parallel universes*

Problem #3: *Requirements inconsistently specified, not “CA Ready”, not integratable*

Impact: Companies have to spend huge ~~W W W~~ ... inefficiency & status quo rut

Problem #4: *Real-world products have to achieve this integration in an ad hoc manner*

Impact: Companies have to form “requirements management” teams and tools ...

Ultimate Problem ...

Companies have finite time and resources for product development!

Ultimate Impact ...

Use standards? Forget it!

After 40 years of effort, SES MDI doesn't exist!

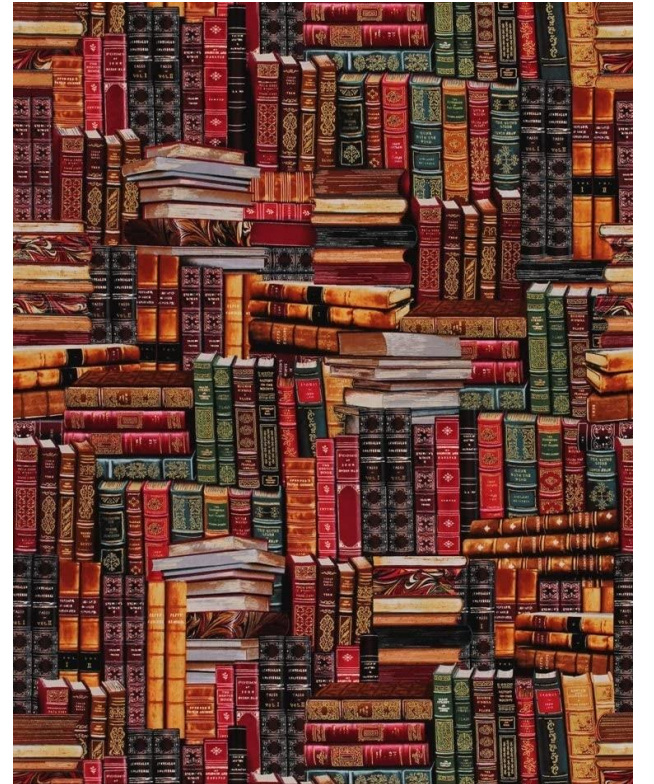
Is there hope?!

As we ponder the NEXT 40 ...



What do standards guys do to “make sense of it all”?

Write more standards ... of course!
+ Build frameworks ...



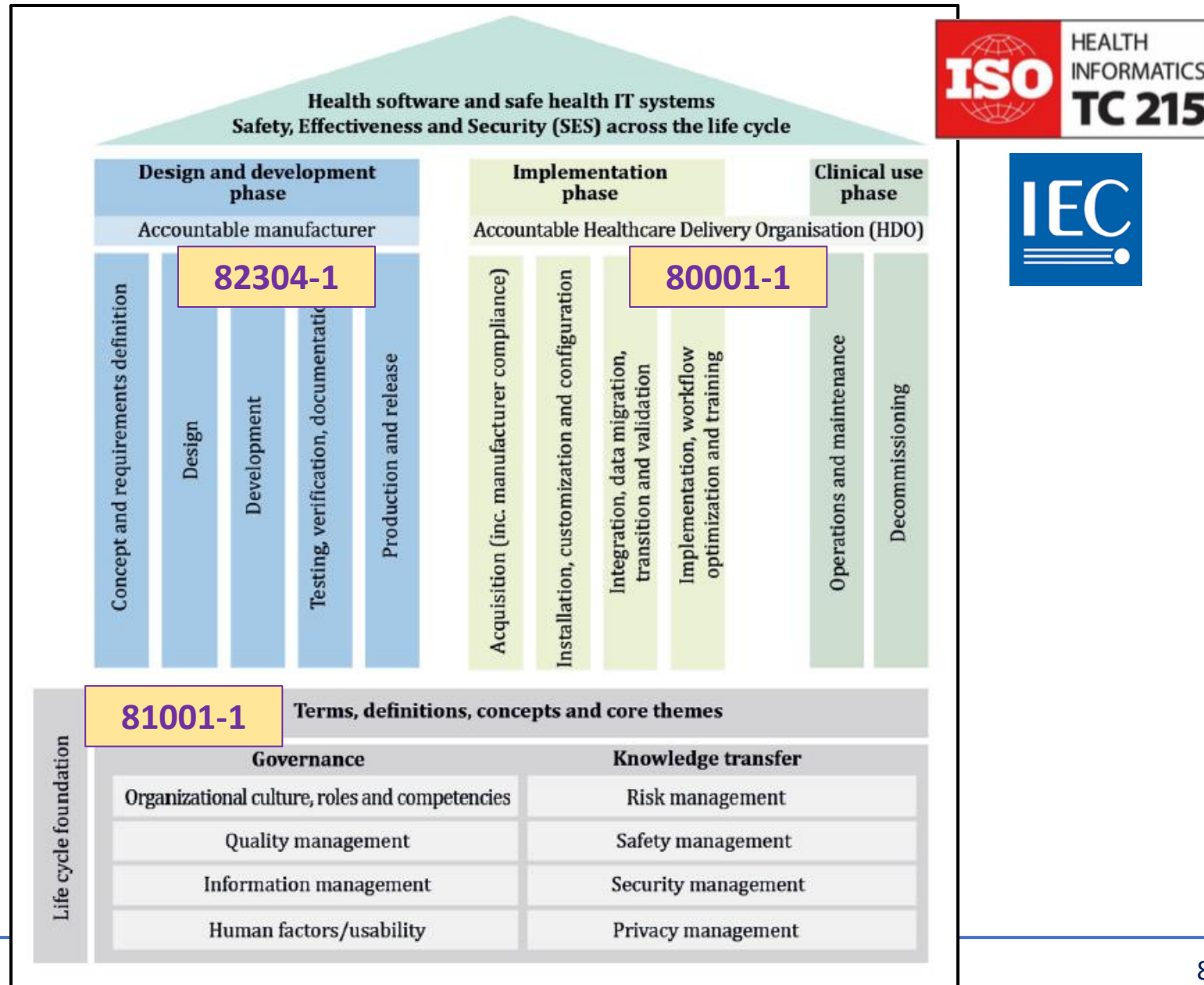
JWG7 “SES Guys” standardized their own framework

The JWG7 SES “*Temple Diagram*” identifies core topic / subject areas ...

... standardized in *81001-1* ...

... over which you can “make sense of” *specific standards* ...

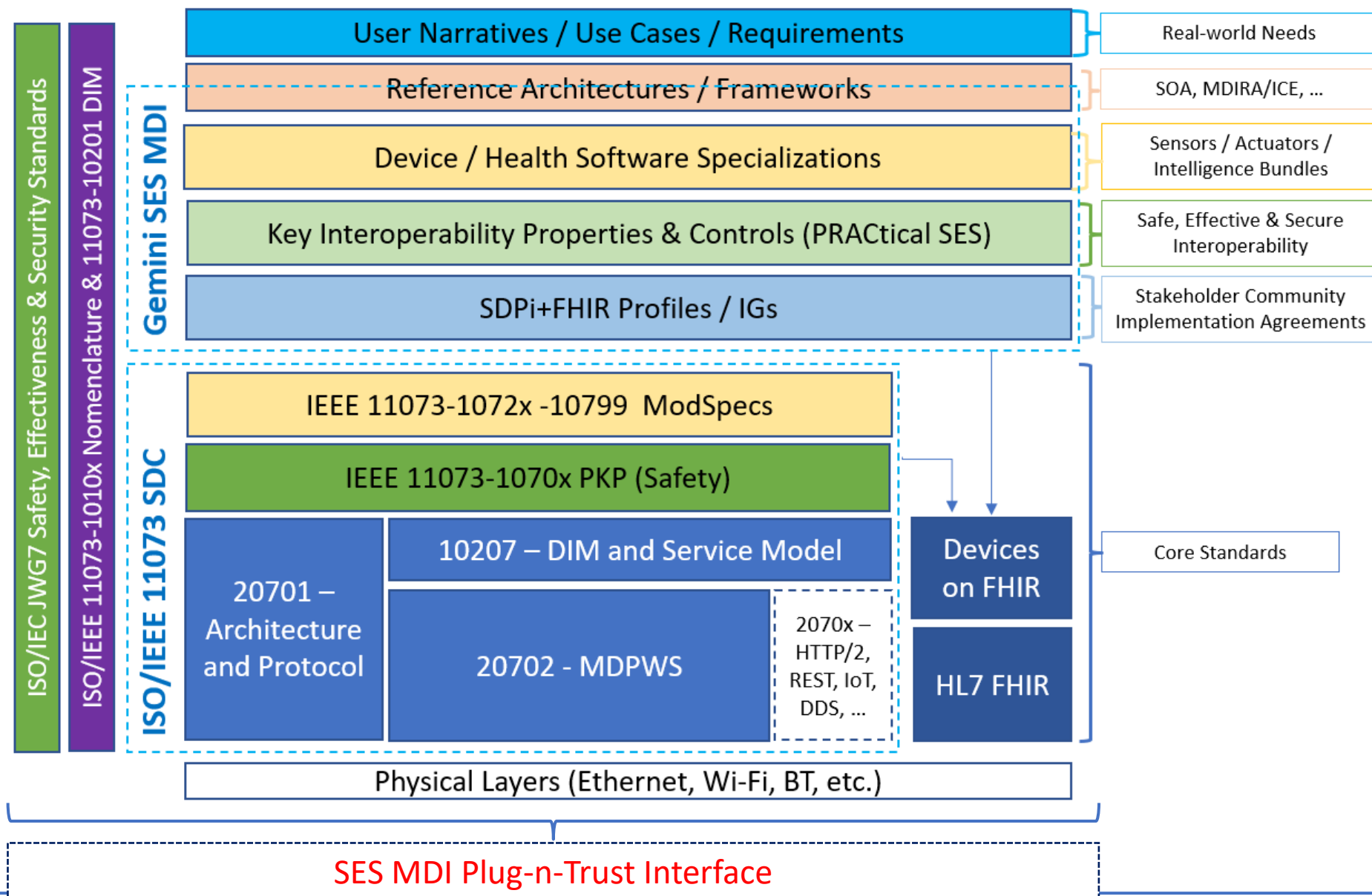
... all with a process / quality / regulatory / legal “*SES*” *community* subject focus



What about the “MDI Guys”?



Consider the
SES MDI
“Hanging
Gardens”
Framework ...

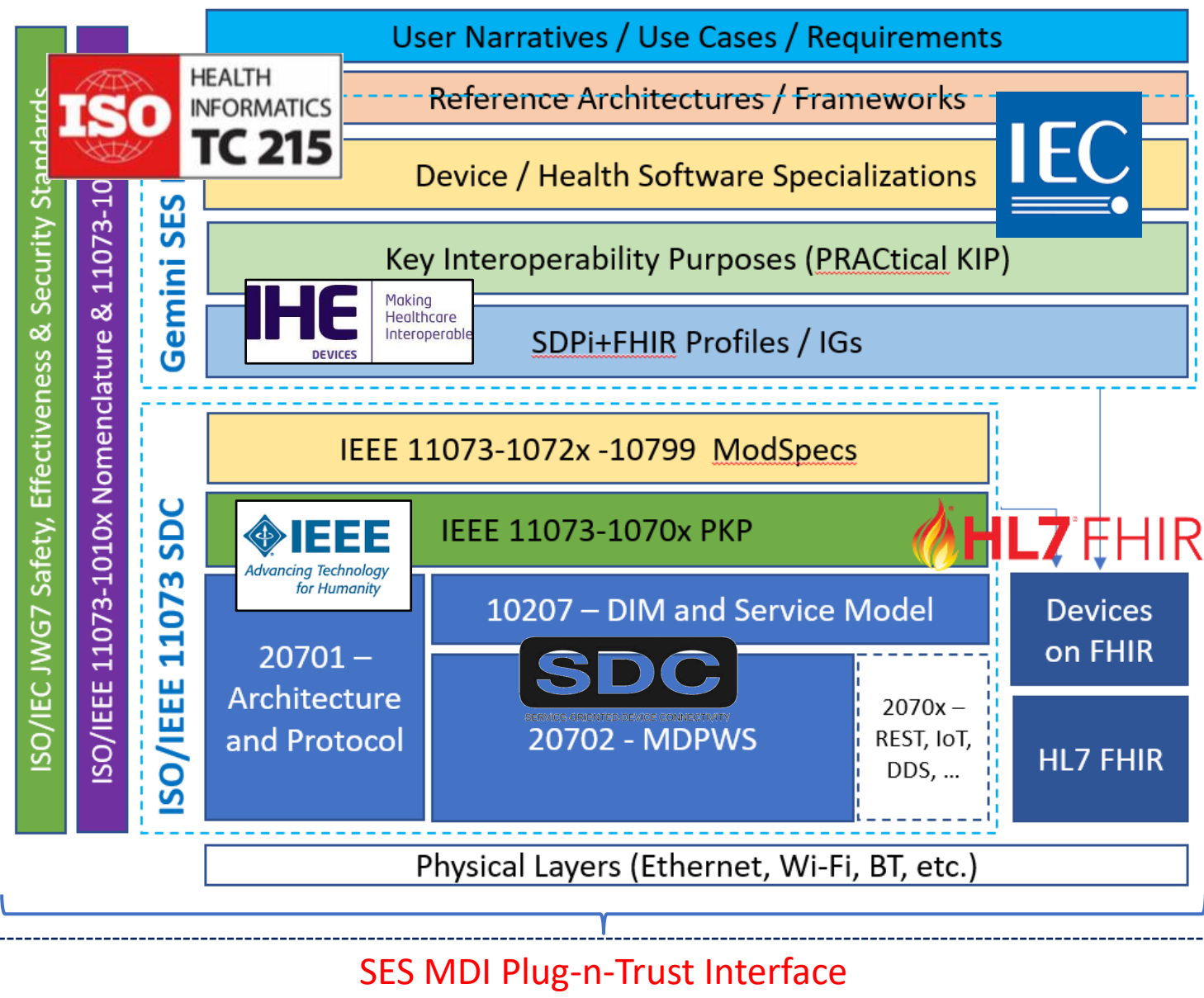


But does this truly help or just add to the confusion?!

“Beauty is in the eyes of the beholder” ... in this case, Standards guys!

... the Gardens help “make sense” of *specific standards* from *different SDOs* ... in a pragmatic real-world product context ...

... all with a combined technical & process *“SES MDI” community* subject focus



Yes! There is hope ... the *Gemini SES MDI Project*!



Making
Healthcare
Interoperable



IHE-HL7 Gemini MDI SDPi+FHIR – *Project Update*

for

Joint IEEE / HL7 / IHE Working Group Meetings
2021.01.27 (Finalized 2021.02.19)



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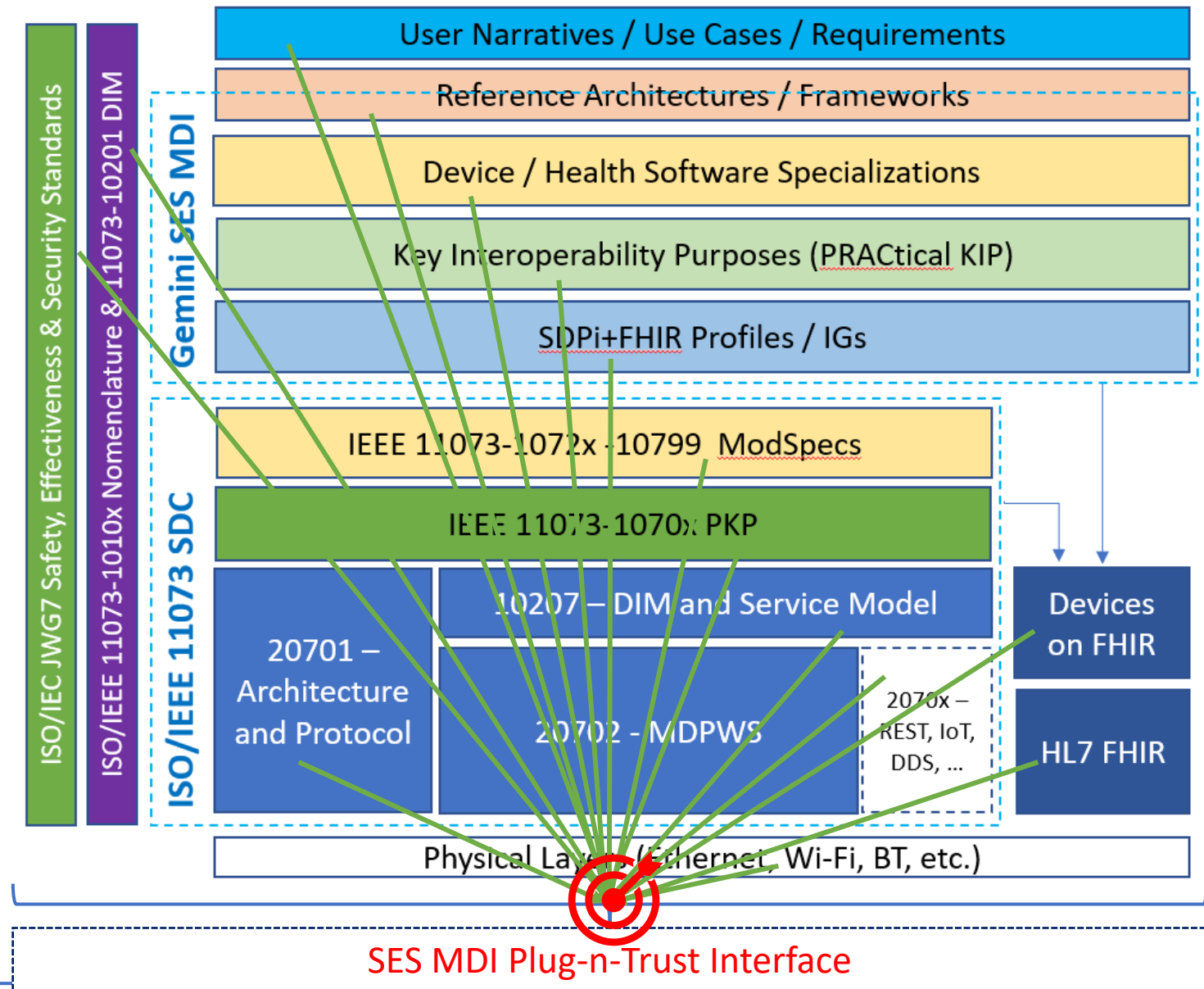
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Gemini SES MDI SDPi+FHIR Project

Innovators Challenge: *One Interface / <X> Standards*

The Hanging Gardens framework provide a perspective on the various standards and specifications that are *integrated into each individual product's interface ...*

**One Layer &
One Standard
at a Time!**

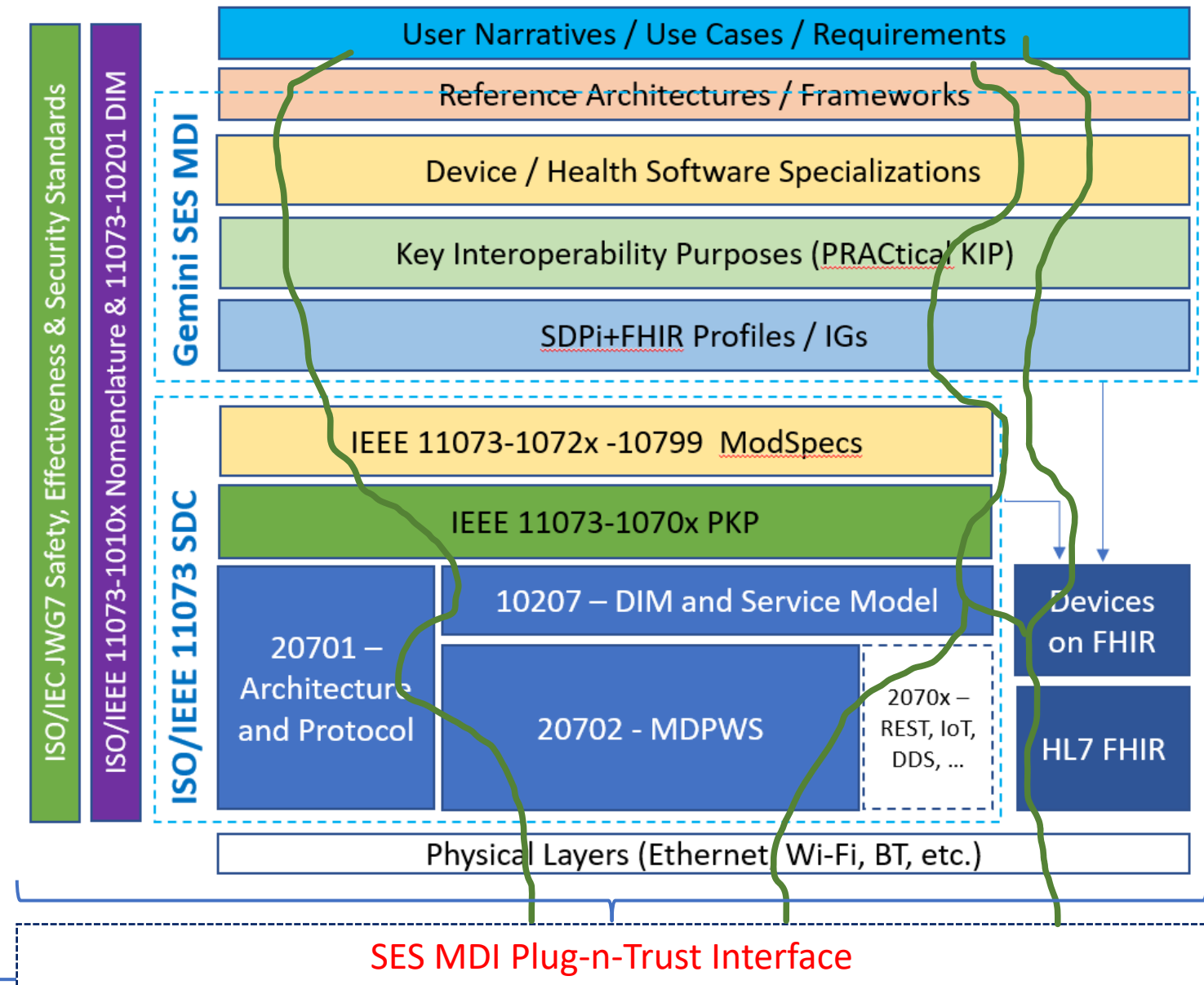


Innovators Hope: *Requirements Integration*

The Hanging Gardens framework can also enable a much simpler, streamlined requirements pathway through *through each standard's needs & capabilities* ...

... the *Happy Path* charts *traceability* from the interface back to each standard specification and their *requirements*

How hard can it be?!



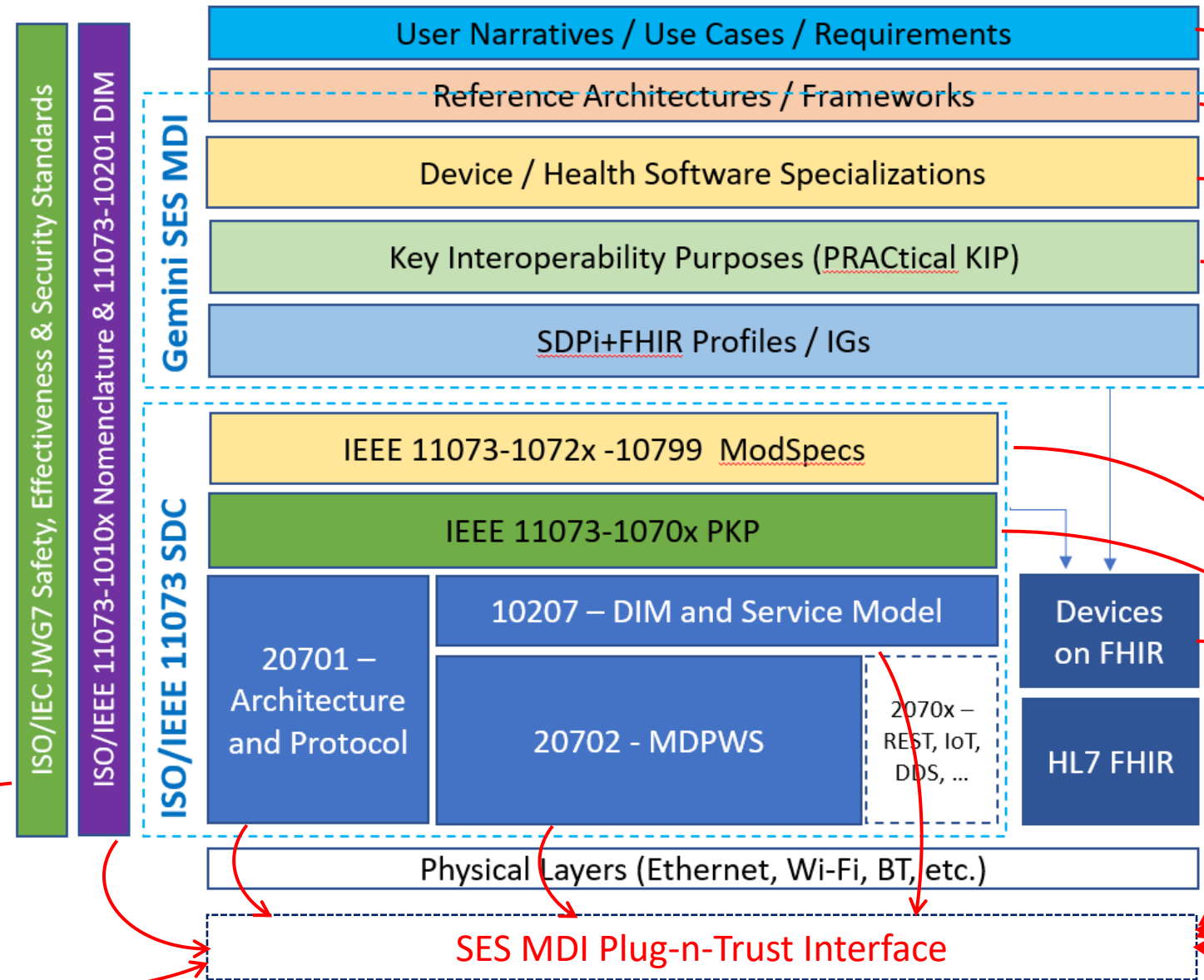
Life Without RI – *In a Hanging Gardens World*

In the absence of a clearly defined **Requirements Interoperability model** to enable connection between standards ...

How hard can it be?

PRETTY HARD!!!

(via Ad Hoc Requirements Integration)



Standards Guys' Challenge @ *SES MDI RI*

Gemini SES MDI Project Focus (2021/Year 3):

Challenge #1: *Standards are inconsistent in how they specify requirements*

Focus Area: Establish a *Requirements Interoperability Model* & Inter-Standard Mappings (Capabilities “API” + Needs / Dependencies)

Challenge #2: *Crafting standards specifications that support RI & “Happy Path” Tracing*

Focus Area: Create authoring tools that transparently capture the computable artifacts necessary for standards integration automation

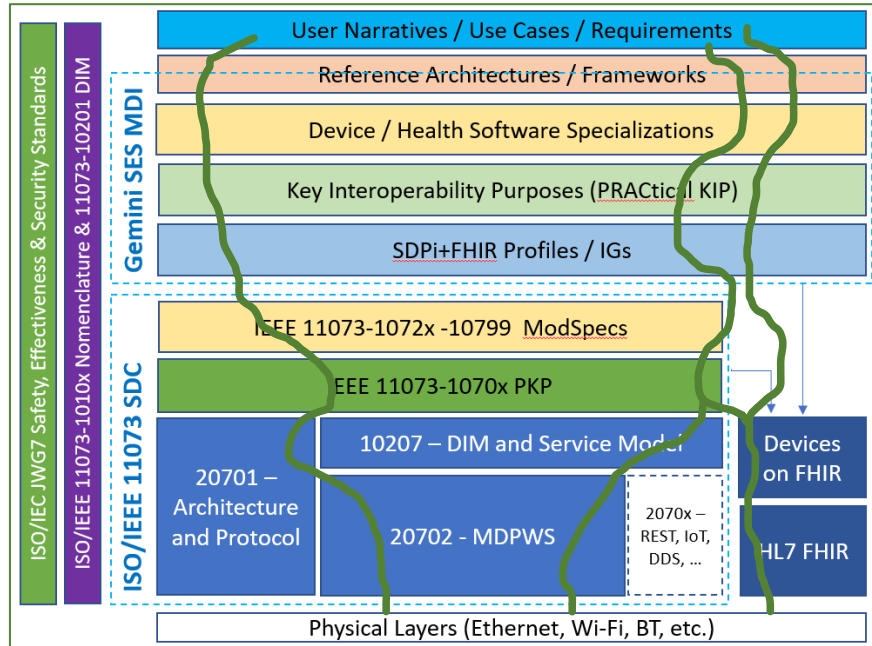
Challenge #3: *Conformity Assessment reports that are “Regulatory Submission Ready”!*

Focus Area: Generate test plans & test scripts that ensure verification of requirements + traceability & CA to <X> standards & specifications

Challenge #4: HTML-based “*continuous build*” *publication* supporting implementation

Focus Area: Develop publication tooling that enables frequent (daily) updates & inter-standard integration / navigation

Next Step: *Requirements Interoperability Pilot*



Gemini SES MDI RI Pilot Standards could include:

- ✓ Use Cases: Silent Bed & Isolation Point-of-Care
- ✓ “MD-SOA” & MDIRA/ICE Architectures
- ✓ ISO/IEC 60601-1-8 & -2-x Safety & Essential Performance stds.
- ✓ IEC 80001-1 2nd Edition
- ✓ IHE SDPi+FHIR Profile & MDIRA Profiles
- ✓ IEEE 11073-10700 Participant Key Purposes standard
- ✓ IEEE 11073 SDC Core Standards



RI Pilot tasks include:

- ✓ *Crafting an interoperability semantics UML Metamodel (including OMG ReqIF)*
- ✓ *For each standard, drafting representative set of requirements using metamodel*
- ✓ *Creating inter-standard requirements mapping “links”*
- ✓ *Validate ability to trace “Happy Path” from interface to implemented standards*

Next Step ... for YOU!

Many opportunities to participate & learn & shape the future of SES MDI:

- ✓ *Medical Device Industry Promotion Foundation @ www.medif.or.kr*
- ✓ *Smart Medical Device Standard Expert Forum @
project.medif.or.kr/subList/10000003198*
- ✓ *Gemini SES MDI Project @ confluence.hl7.org/display/GP/Community+Engagement*