Medical Device Interoperability – A Brief History & Current Initiatives

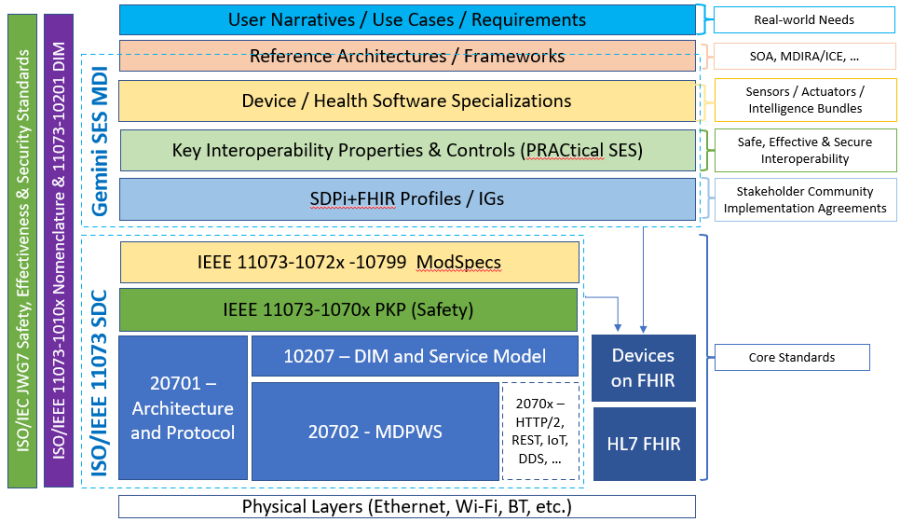
for

IEEE Tech Talk: Health Electronics ~ Seattle

2022.02.22

Todd Cooper
Trusted Solutions Foundry
San Diego – *AFC!*

Medical Device Interoperability –
A Brief History + Current Initiatives



MDI – Why is it so hard?

Current Standards-based Programs

SES+MDI – *Plug-and-Trust for Acute Care*

Personalized Health Navigation – The future?

Q & A

Medical Device Interoperability – *A Brief History*

Medical Device Interoperability Journey

40+ Year *Promise* of Medical Device Interoperability:

As we ponder the NEXT 40 …

Why do we think it will be any different?!

Medical Device Interoperability Journey

Does it have to be this hard?

Life-critical MedTech is HARD!

Is it a technology problem?

Not in the last 40 years!

Why such a challege?

#1 Misaligned Business Drivers

#2 Incomplete Standards Solutions

Acute Care MDI – *A Brief History*

MDI: *A 40 Year Wander!*

IEEE "1073" started early 1980's …

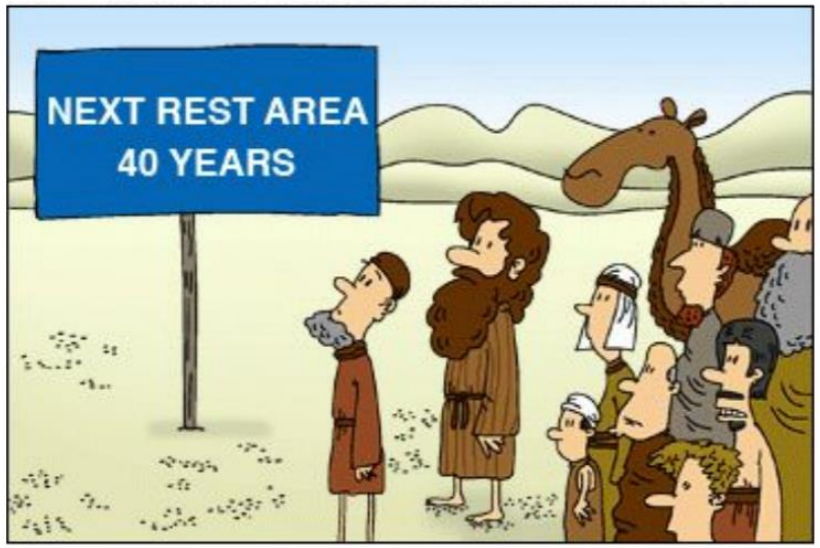
1980's *Technical solution* … Vendors choked life out of it

1990's *Technical & Business solution* … $$$$ & no user demand

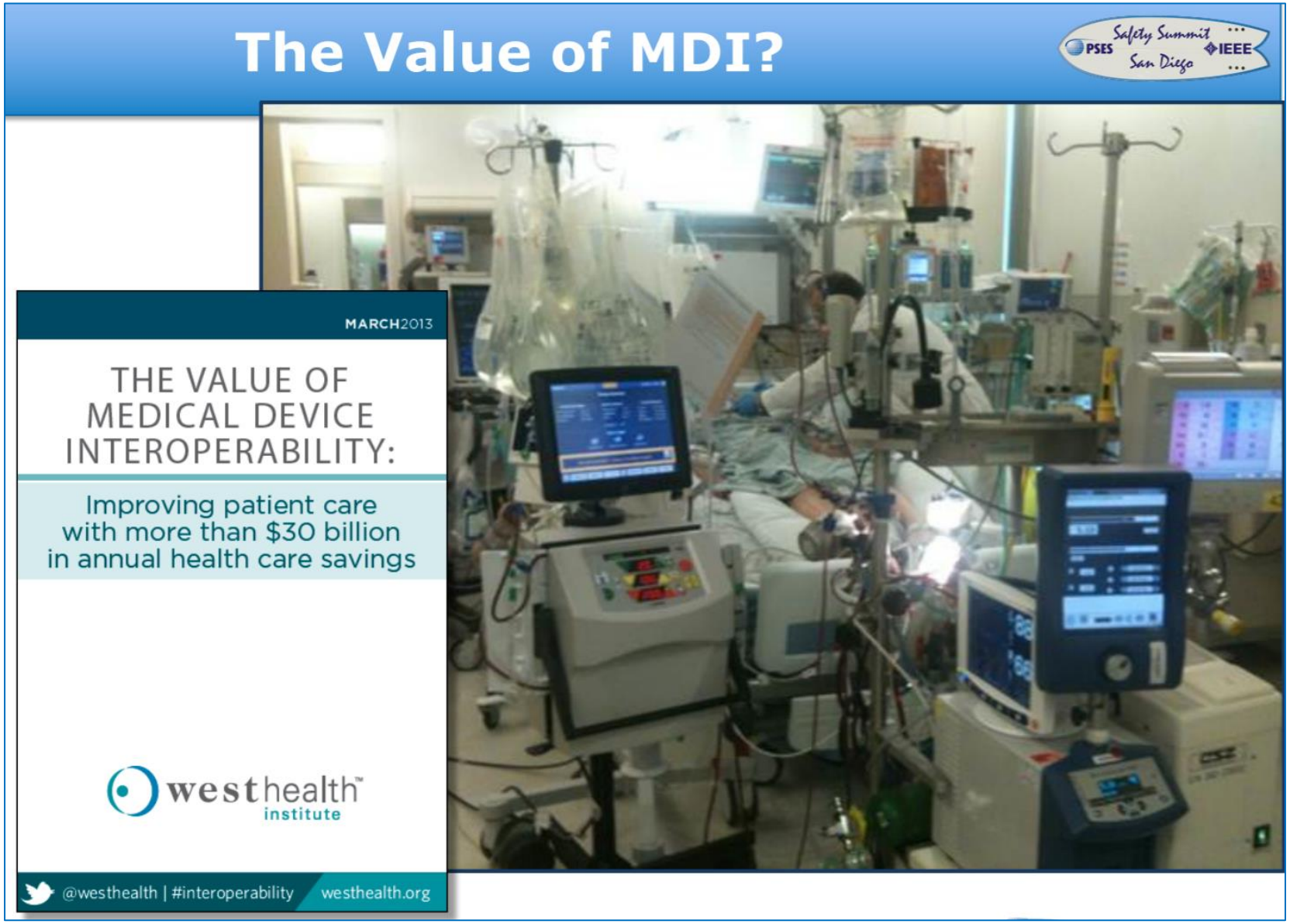
2000's *Global Standards & IHE Collaboration* … no user demand

2010's *U.S. "C4MI" Created to Focus user demand* … remains TBD

2020's *Is there hope? Yes!!!* … maybe …



Acute Care MDI – *Today's Reality!*

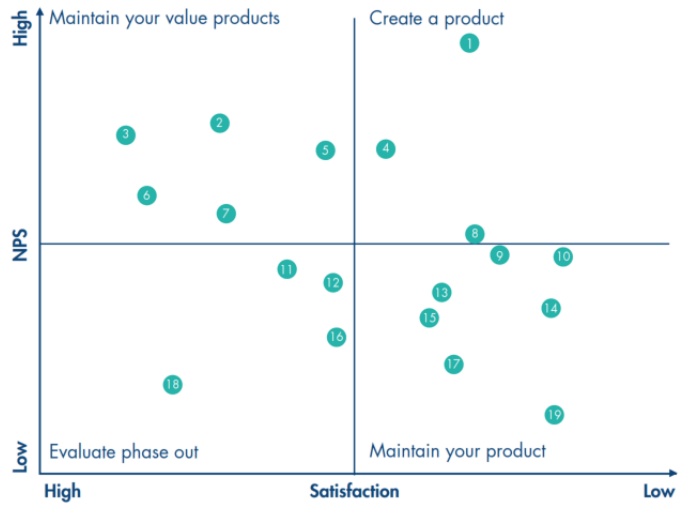


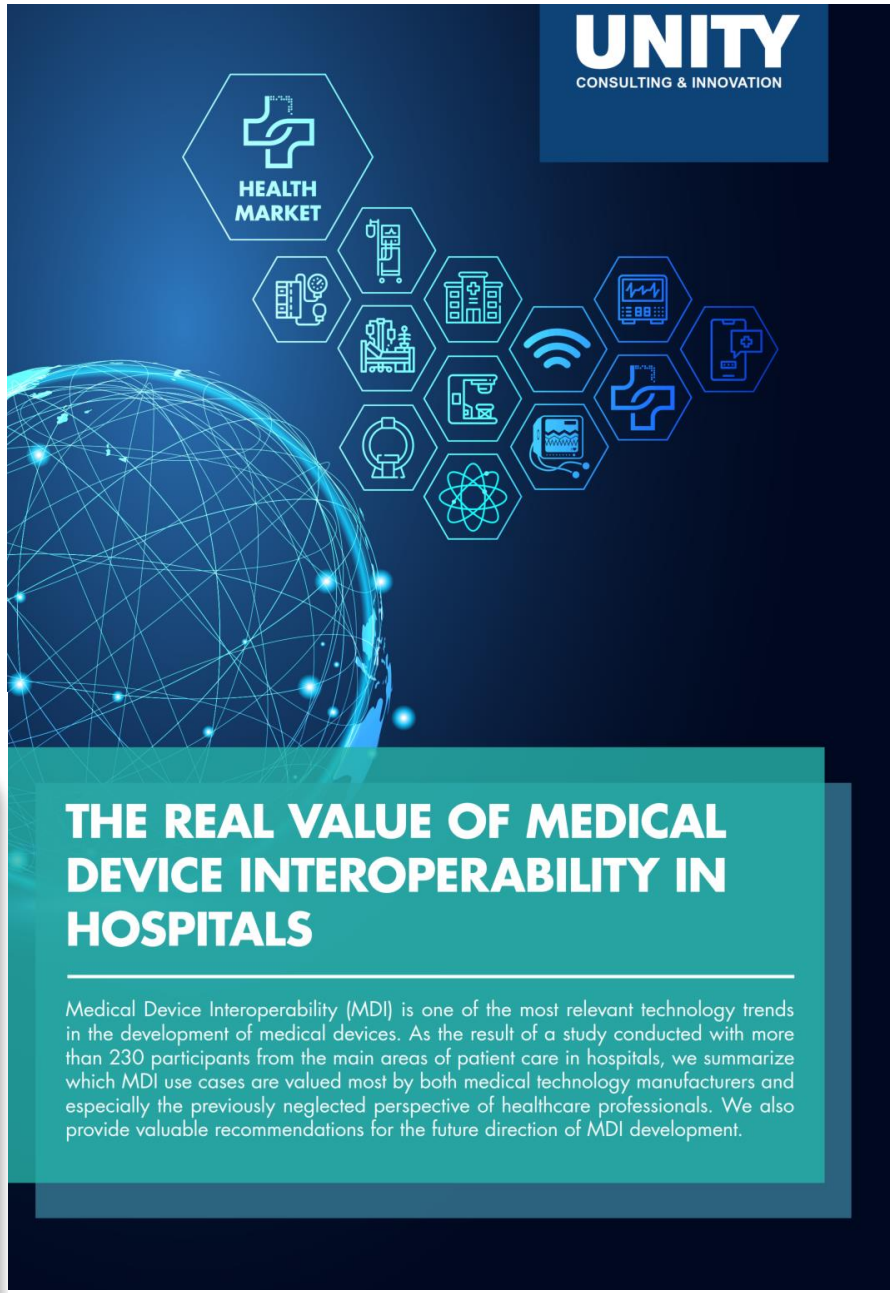
Updated Value of MDI Study

USE CASES	Overall NPS	RANK	HDO RANK	MDM RANK	ICU RANK	OR RANK
Isolation Room	65 %	1	2	1	1	-
Digital Charting	47 %	2	1	4	2	1
Ward Round Pol	44 %	3	5	3	5	-
Quiet ICU-Ward	41%	4	3	5	3	-
Integrated UI	41%	5	8	2	4	3
Surgical Display	31%	6	6	7	-	2
Spot-check Monitoring	27%	7	4	10	-	-
Automated OR Setup	22%	8	10	8	-	4
Service – Predictive Maintenance	18%	9	17	6	6	5
Physiological Closed Loop Control	17%	10				
Central Patient Watch	15%	11				
Intra-Hospital Transport Monitor	12%	12				
Service – Biomed Notification	9%	13				
Treatment Recommendation	6%	14				
Augmented Surgical Display	3%	15				
Personal Health Integration	0%	16				
Safety Interlock	-6%	17				
Dual Bedside Display & Control	-11%	18				
Benchmark Therapy	-18%	19				

USE CASES

1. Isolation Room
2. Digital Charting
3. Ward Round Pol
4. Quiet ICU-Ward
5. Integrated UI
6. Surgical Display
7. Spot-check Monitoring
8. Automated OR Setup
9. Service – Predictive Maintenance
10. Physiological Closed Loop Control
11. Central Patient Watch
12. Intra-Hospital Transport Monitor
13. Service – Biomed Notification
14. Treatment Recommendation
15. Augmented Surgical Display
16. Personal Health Integration
17. Safety Interlock
18. Dual Bedside Display & Control
19. Benchmark Therapy





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Medical Device Interoperability – *Current Standards-based Programs*

Device Interoperability Standards Landscape

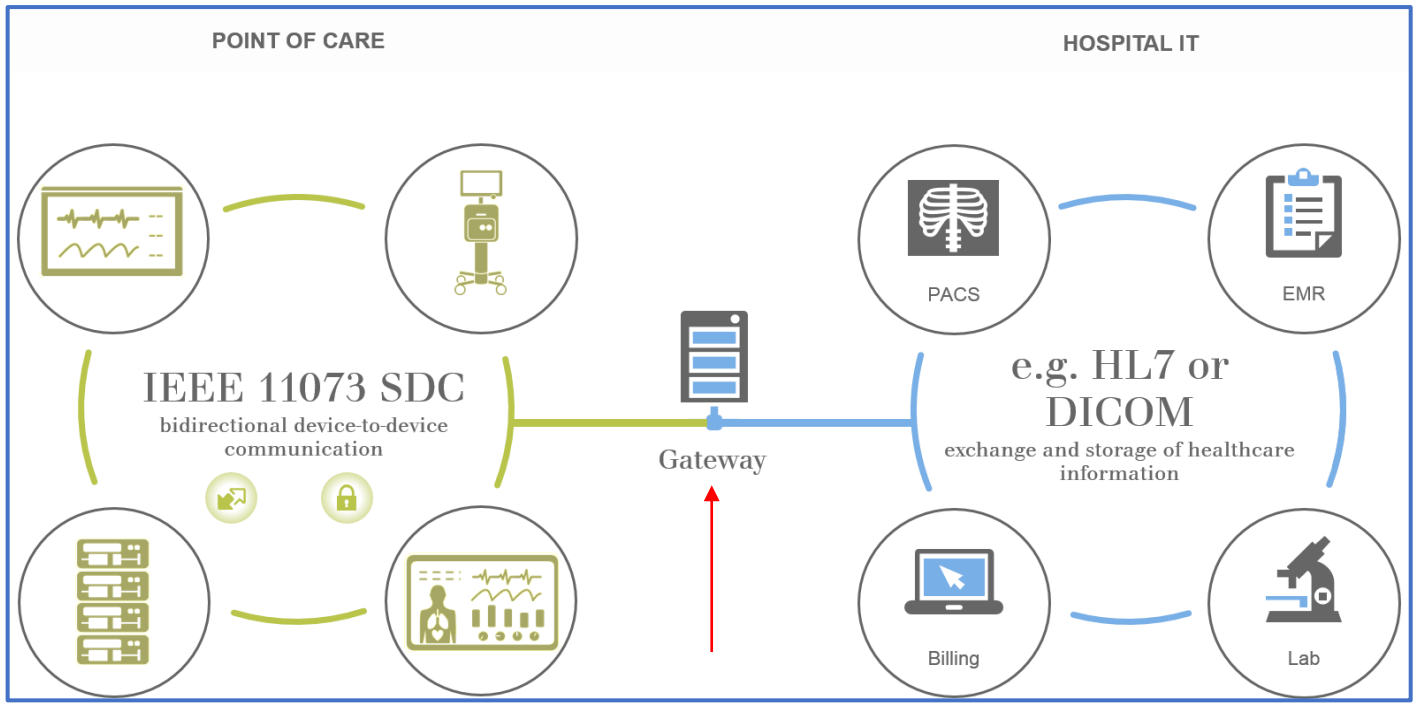
DevDays HL7® FHIR®

Program	IHE PCD	IEEE PHD / Continua	IEEE SDC / IHE SDPi	HL7 Devices on FHIR	IEEE / EMBS Mobile Health Data (P1752)
Primary Use Context	Healthcare Enterprise	Home / Mobile	High Acuity (OR/ICU/ED)	Enterprise / Mobile / Home	Mobile (wearables)
Technical Base	HL7 V2.6 [1]	IEEE 11073	WS*	REST / HTTP	Open mHealth / JSON
Maturity / Production Systems	Dozens of commer- cially available products	100's of Certified PnP Products	Prototyped; First devices placed into patient use; tools & open source	PoCD & PHD IGs; FHIR Connectathons; Continua FHIR Guidelines & Source	Early stages of development – TBD sync w/ FHIR
Semantics	IEEE 11073 Terminology & Model [2]				

FHIR Now Integrated Horizontally

[1] + 2.7, 2.8.x [2] Core 11073 terms mapped to LOINC

2019 IHE PCD Domain => DEV Domain

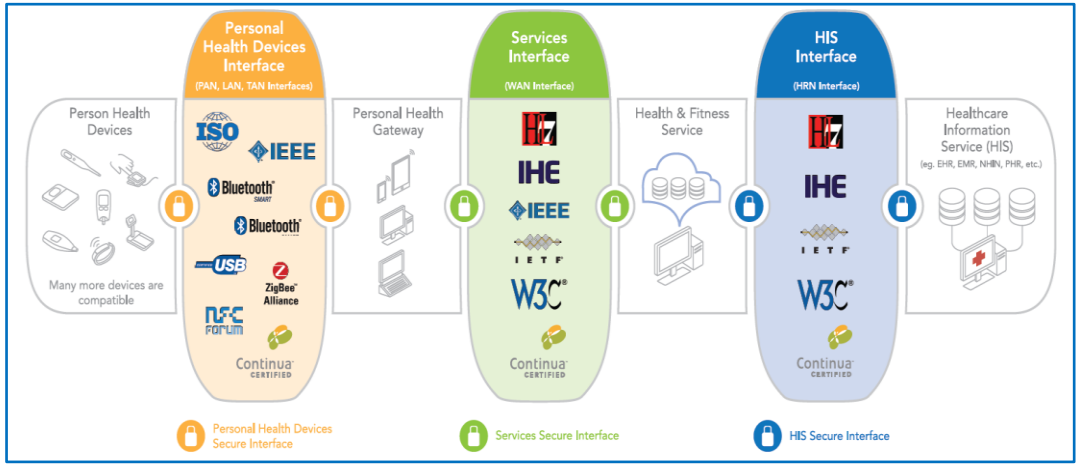


SDC Point-of-Care Context

IHE "Enterprise" Context

IHE DEVICES | Making Healthcare Interoperable

3 Device Use Contexts …
One consolidated IHE Technical Framework



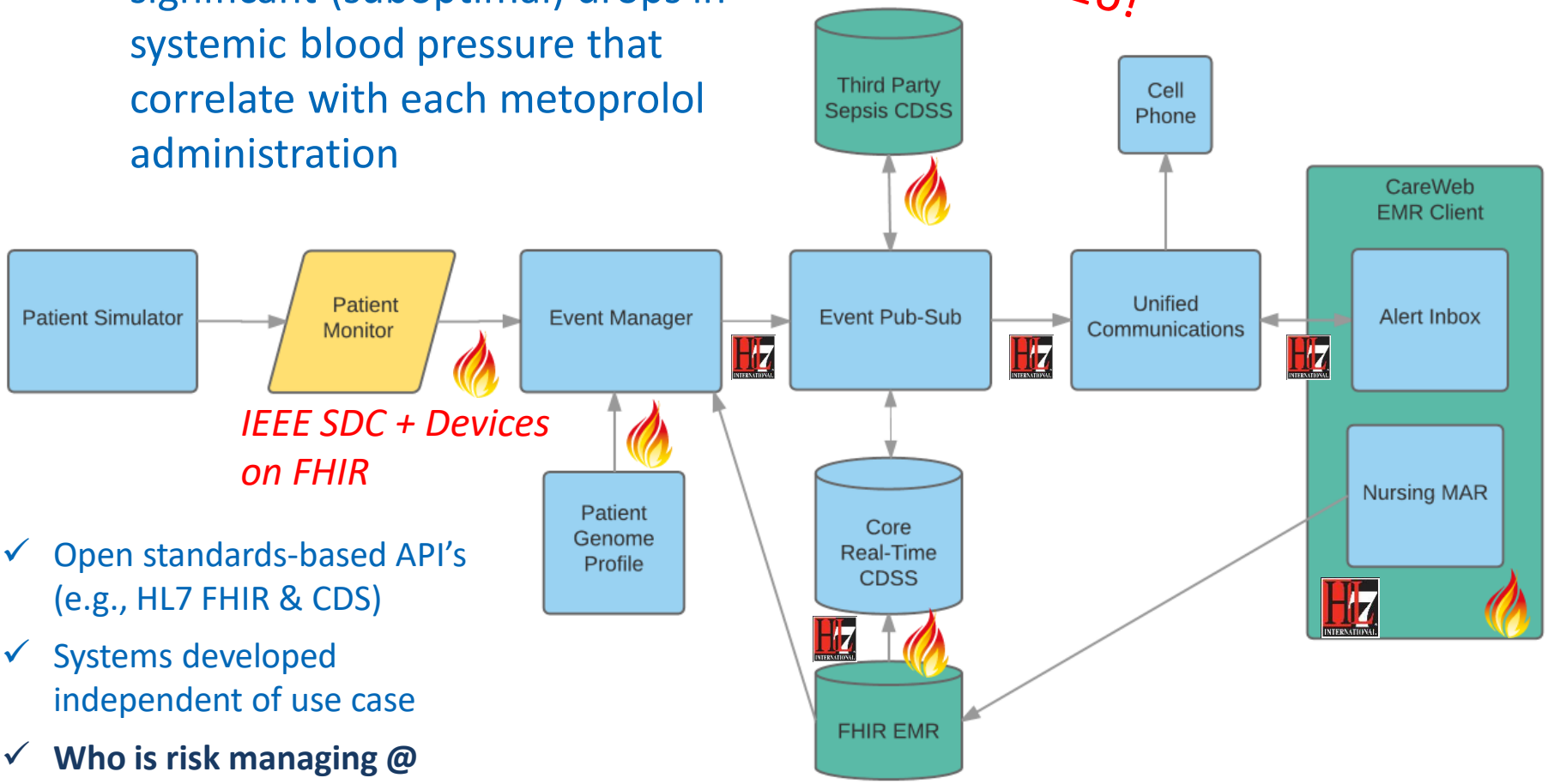
Download @ www.pchalliance.org/continua-design-guidelines

HSPC/Cognitive Medical HIMSS'16 Demo …

- ✓ Use Case: Transient, but clinically significant (suboptimal) drops in systemic blood pressure that correlate with each metoprolol administration

From 2016!

Cognitive Medical Systems



IEEE SDC + Devices on FHIR

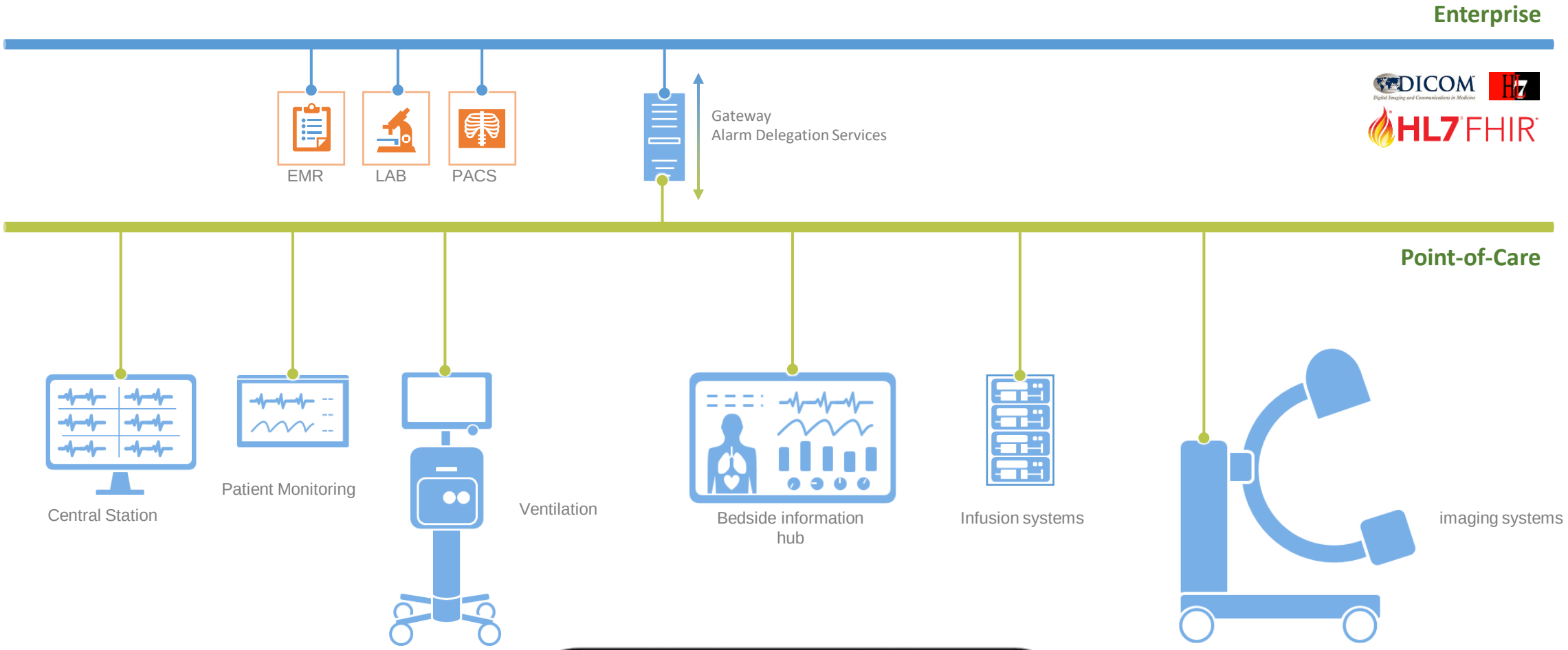
- ✓ Open standards-based API's (e.g., HL7 FHIR & CDS)
- ✓ Systems developed independent of use case
- ✓ **Who is risk managing @ implementation & use?!** (note 80001-1 revision)

See cognitivemedicalsystems.com/

What devices are we talking about?

- Wearables + IoT + Cloud + …
- Spans home to hospital contexts
- Mostly simple … but Billions of them!
- Physio parameters + environmental + patient generated + …
- Personal & Professional Users

Medical Device Interoperability – *SES+MDI – Plug-and-Trust for Acute Care*



Standards for device-to-device interoperability at Point-of-Care ?

SDC

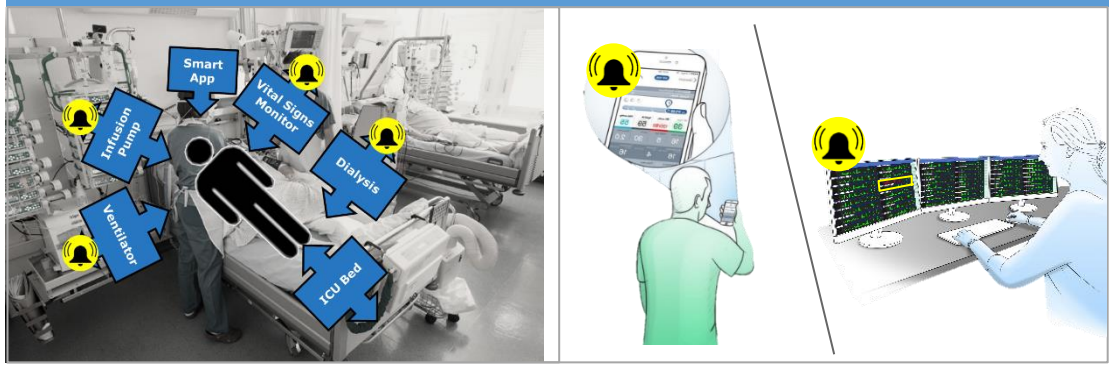
SERVICE-ORIENTED DEVICE CONNECTIVITY

SDC & Silent ICU Use Case Narrative …

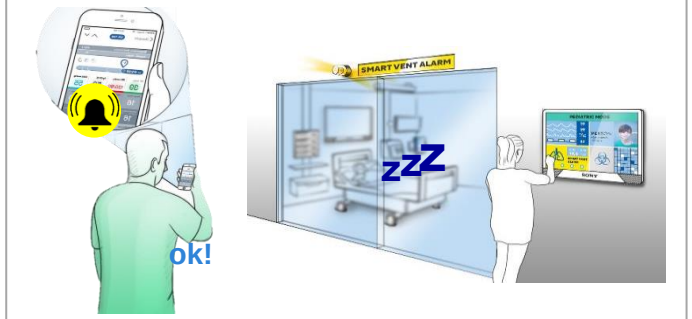
HIMSS '20

SILENT ICU BY ALARM SIGNAL DELEGATION

Today



Tomorrow



~ 80 - 95 % clinically irrelevant

up to 40 min. to alarm confirmation

50 % are not noticed

~ 40 different sounds in one ICU

Reduction of alarms

Alarm Distribution

road to **1** alarming device per patient

SDC & Silent ICU Use Case Narrative …

HIMSS '20

SILENT ICU BY ALARM SIGNAL DELEGATION

- REQUIREMENTS

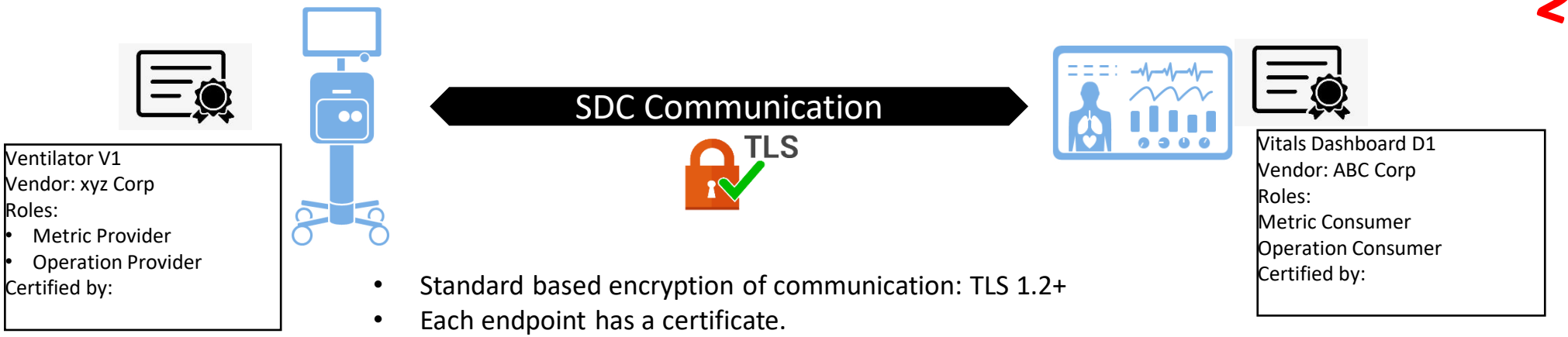
"**Delegation**" – *Safely enabling one system to annunciate alerts on the behalf of another system*

1. The alarm producer has to make **all information available** that are necessary for the remote alarm notifiers, like alert condition presence, alert manifestation, etc. **Interoperability** and semantical interpretability have to be ensured.
2. The system has to be suitable for **multiple alarm producers** and **several remote alarm notifying devices**.
3. The alarm producer has to be able to determine whether other devices are **ready to generate the alarm notification**.
4. The alarm producer has to be able to observe that the **alert is generated correctly**.

Some more information: „A Safe and Interoperable Distributed Alarm Notification System for PoC Medical Devices using IEEE 11073 SDC", Kasparick et al.

SDC – Security is a Core Capability

HIMSS '20



- Standard based encryption of communication: TLS 1.2+
- Each endpoint has a certificate.
- Authentication at both endpoints
- No communication if no trust chain can be established

- Certificates are used to secure communication
- Authorization and Authentication
- *Certificates carry roles of participants*
- Each device can decide if remote control is OK based on certificate roles and certifying organization

SDC = Enables *Trusted Interoperable Product Decoupling*

SDC Basics …

The concept of a

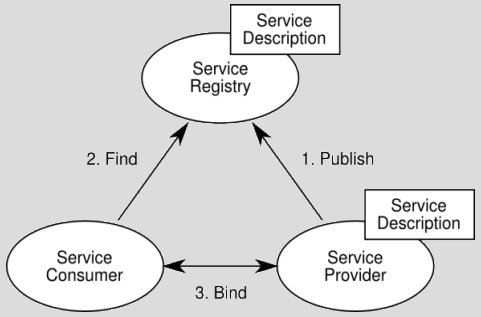
clinical workplace service-oriented medical device architecture

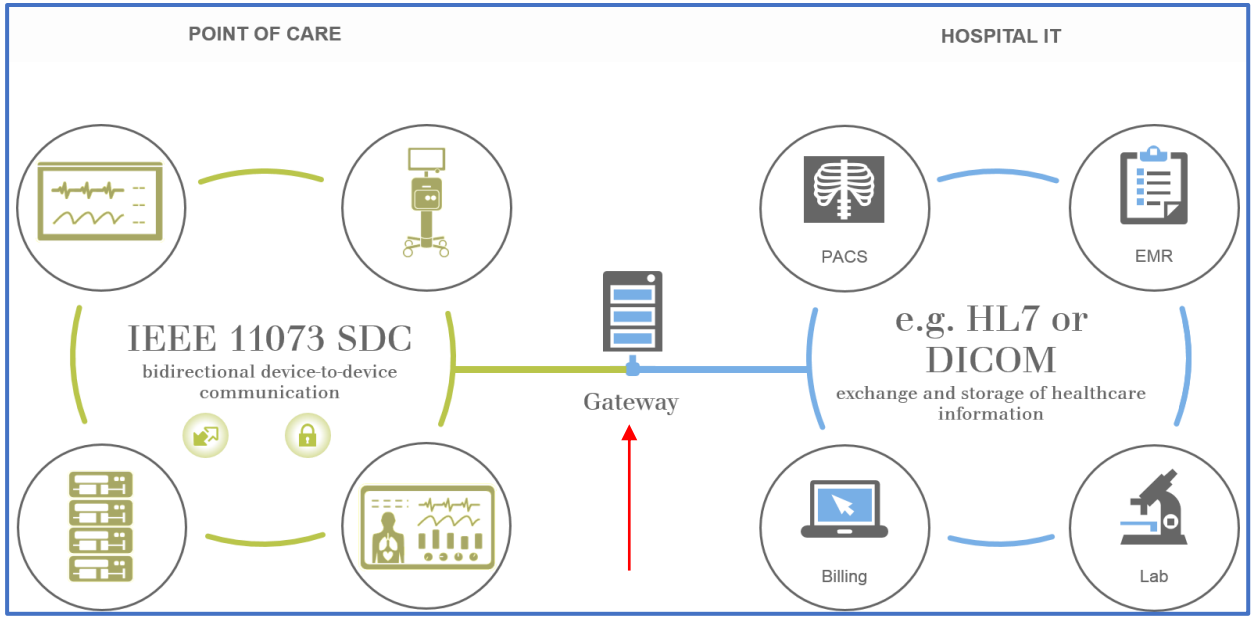
transfers the concept of a

service-oriented architecture

to the domain of

distributed system of medical devices for one clinical workplace.



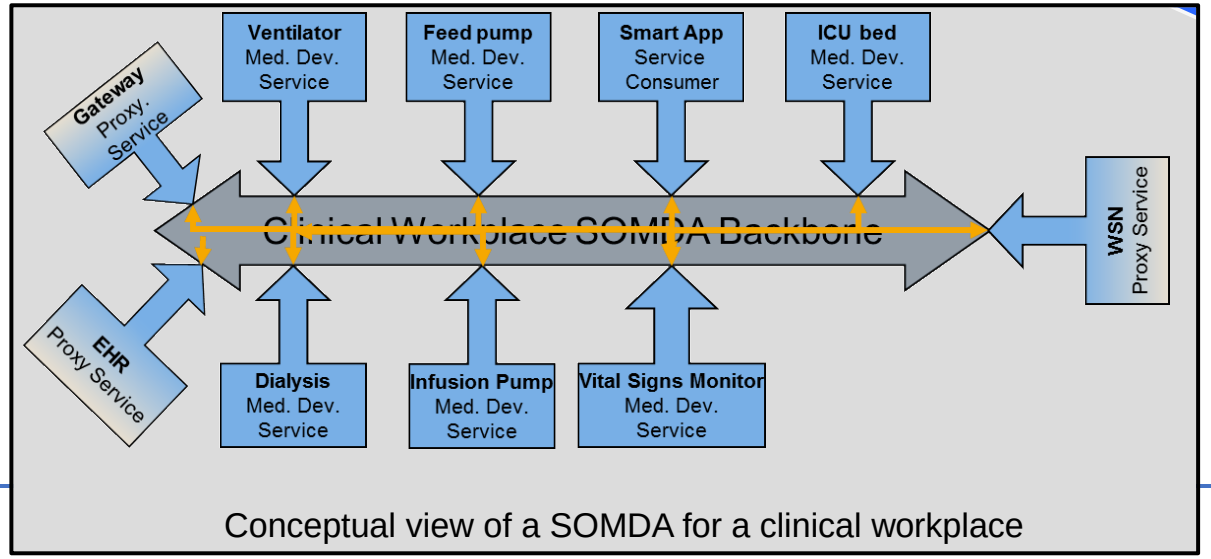


SDC Point-of-Care Context

HIT "Enterprise" Context

Device-to-Device Plug-and-Play for Reporting, Alerting & Controlling

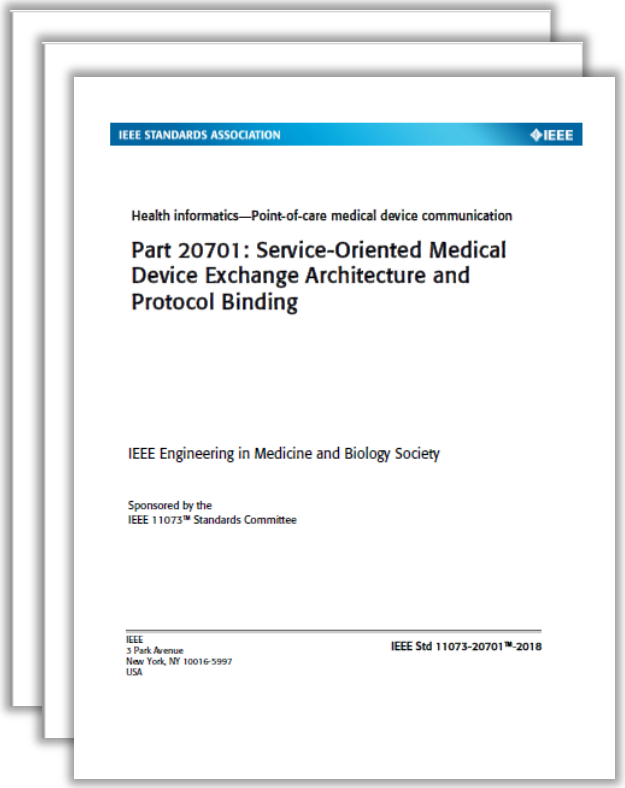
(**PRAC***tical Interoperability*)

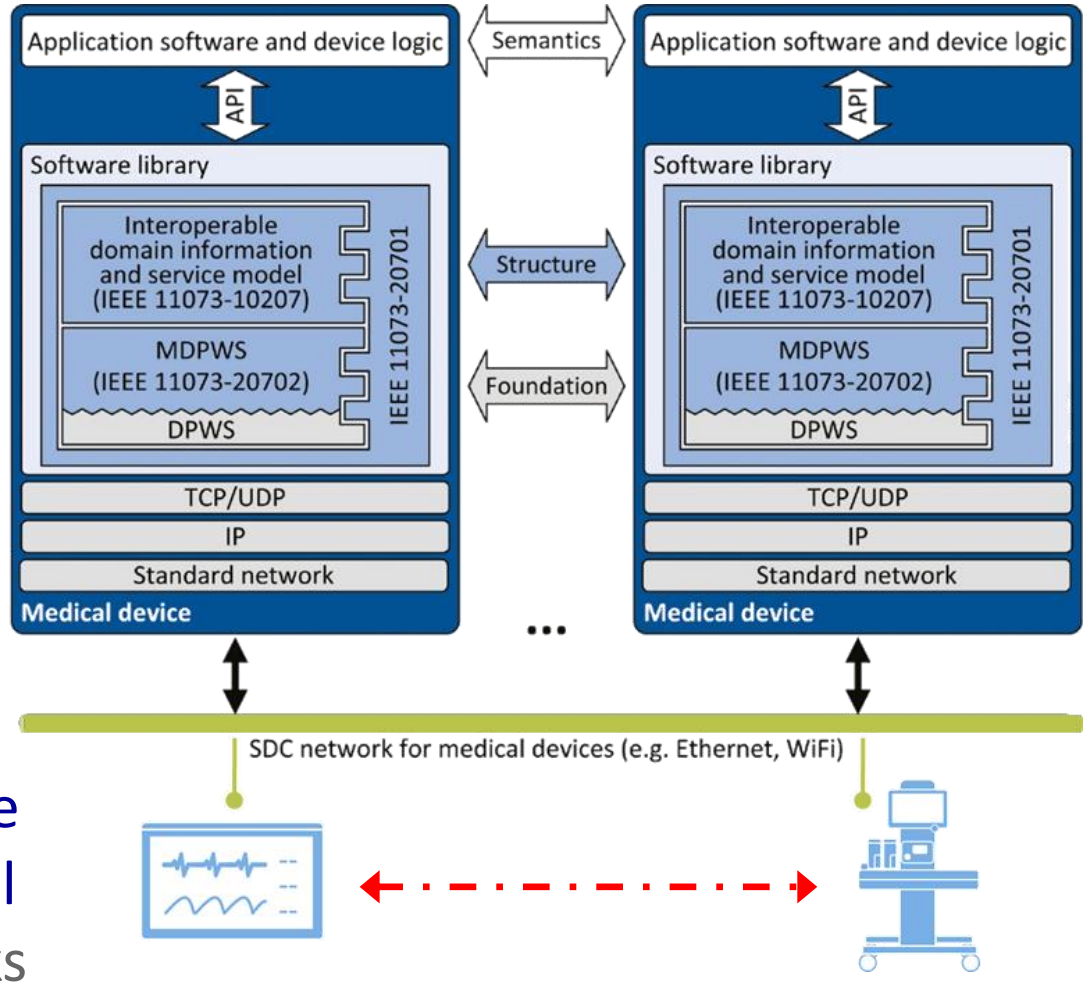


Conceptual view of a SOMDA for a clinical workplace

What is SDC?

Service-oriented Device Connectivity





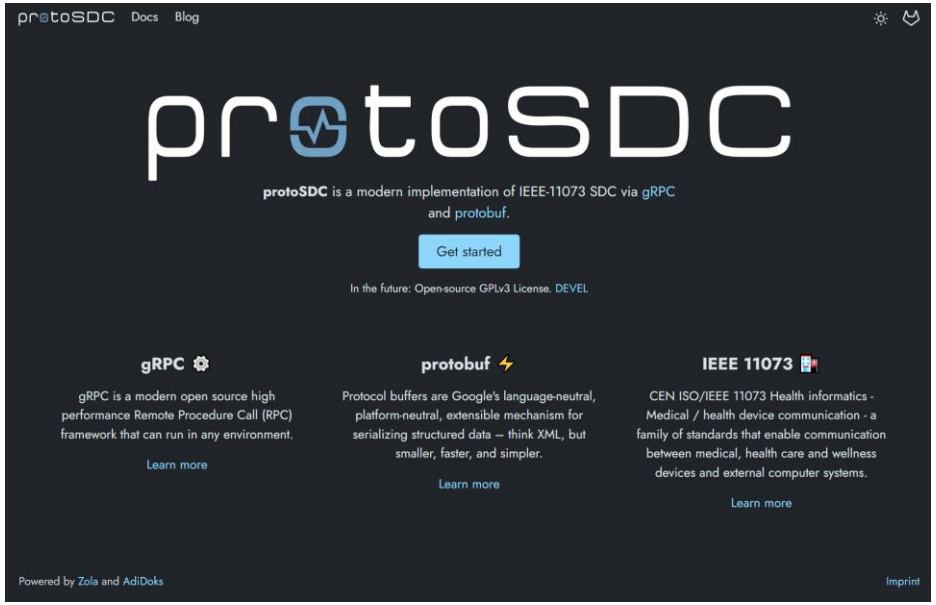
A family of international standards for interoperable exchange of real-time information between medical devices and external systems in dynamic IP networks

Gemini SES MDI – gRPC / Protobufs

There has been “hallway” discussion about considering an additional messaging protocol / transport as an option to MDPWS …

1. Use of gRPC with protobufs is now being seriously considered!
2. Informal prototyping in 2020 & 2021 was very encouraging
3. PAT #5 2021-12 included a gRPC/protobuf test track …
   - ✓ Complete success within a few hours
   - ✓ “Blazingly fast” results!!!
4. gRPC/protobuf option being added to the SDPi-P profile + added to the 3-Year Roadmap

But even more seriously … check out



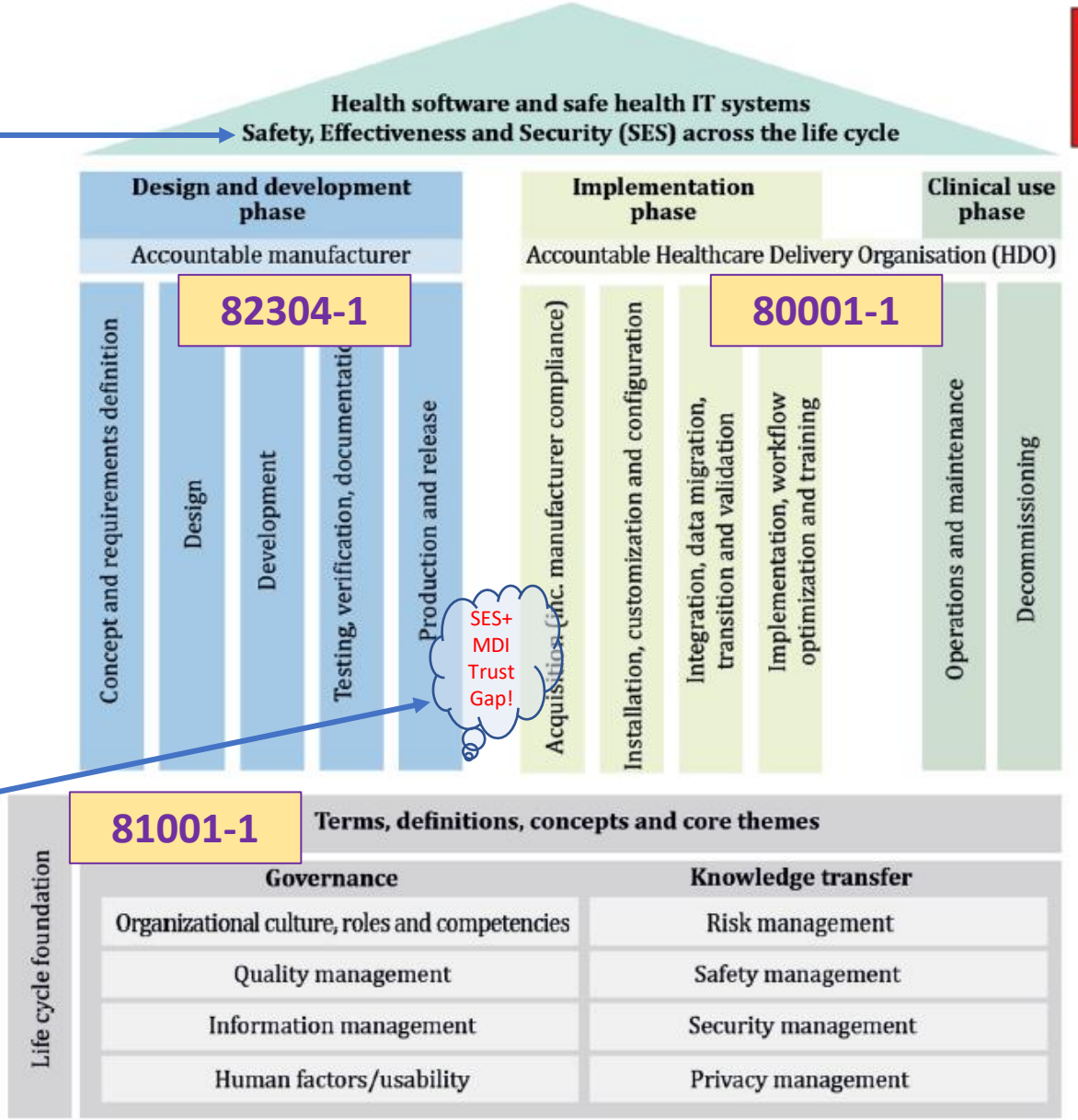
Check out … **protoSDC.org**

JWG7 SES "*Temple*" Diagram

Model developed over last 10 years in response to better manage the interrelations …

- ✓ Across Stakeholders …
- ✓ Across Product Lifecycles …
- ✓ Across Subject Areas
- ✓ Across Multiple Standards

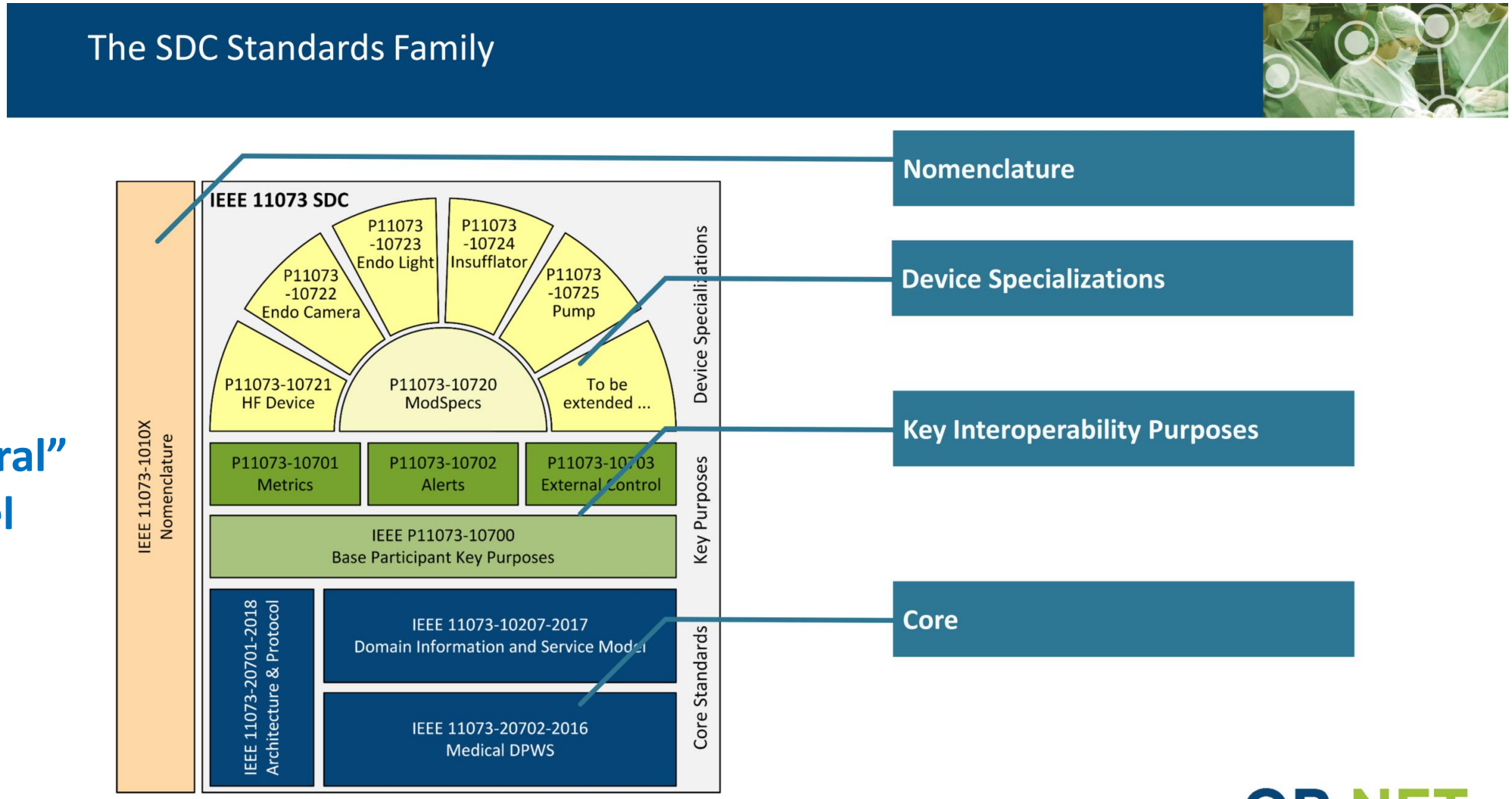
Problem: *SES+MDI "Trust Gap" recognized but no practical real-world solutions – too resource & labor intensive*



Source: ISO/IEC 81001-1:2021

ISO/IEEE 11073 SDC MDI "*Cathedral*" Model

"Cathedral" Model



Gemini SES+MDI "*Hanging Gardens*" Framework

ISO/IEC JWG7 Safety, Effectiveness & Security Standards

ISO/IEEE 11073-1010x Nomenclature & 11073-10201 DIM

ISO HEALTH INFORMATICS TC 215

Gemini SES MDI

User Narratives / Use Cases / Requirements — Real-world Needs

Reference Architectures / Frameworks — SOA, MDIRA/ICE, …

Device / Health Software Specializations — IEC — Sensors / Actuators / Intelligence Bundles

Key Interoperability Properties & Controls (PRACtical SES) — Safe, Effective & Secure Interoperability

SDPi+FHIR Profiles / IGs — IHE DEVICES Making Healthcare Interoperable — Stakeholder Community Implementation Agreements

ISO/IEEE 11073 SDC

IEEE 11073-1072x -10799 ModSpecs

IEEE Advancing Technology for Humanity

IEEE 11073-1070x PKP (Safety)

HL7 FHIR

20701 – Architecture and Protocol

10207 – DIM and Service Model

SDC SERVICE-ORIENTED DEVICE CONNECTIVITY

20702 - MDPWS

2070x – HTTP/2, REST, IoT, DDS, …

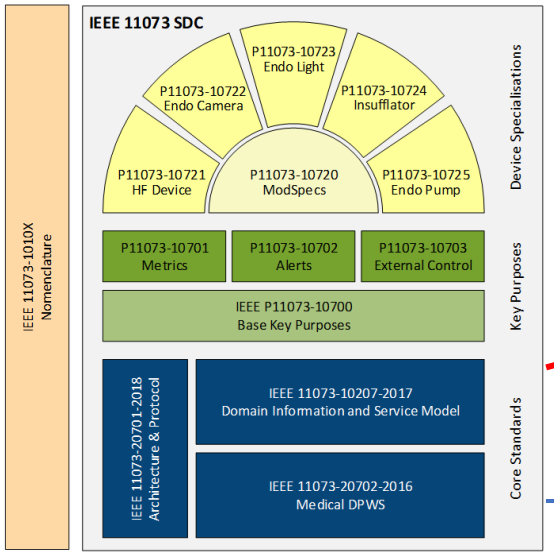
Devices on FHIR

HL7 FHIR

Core Standards

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

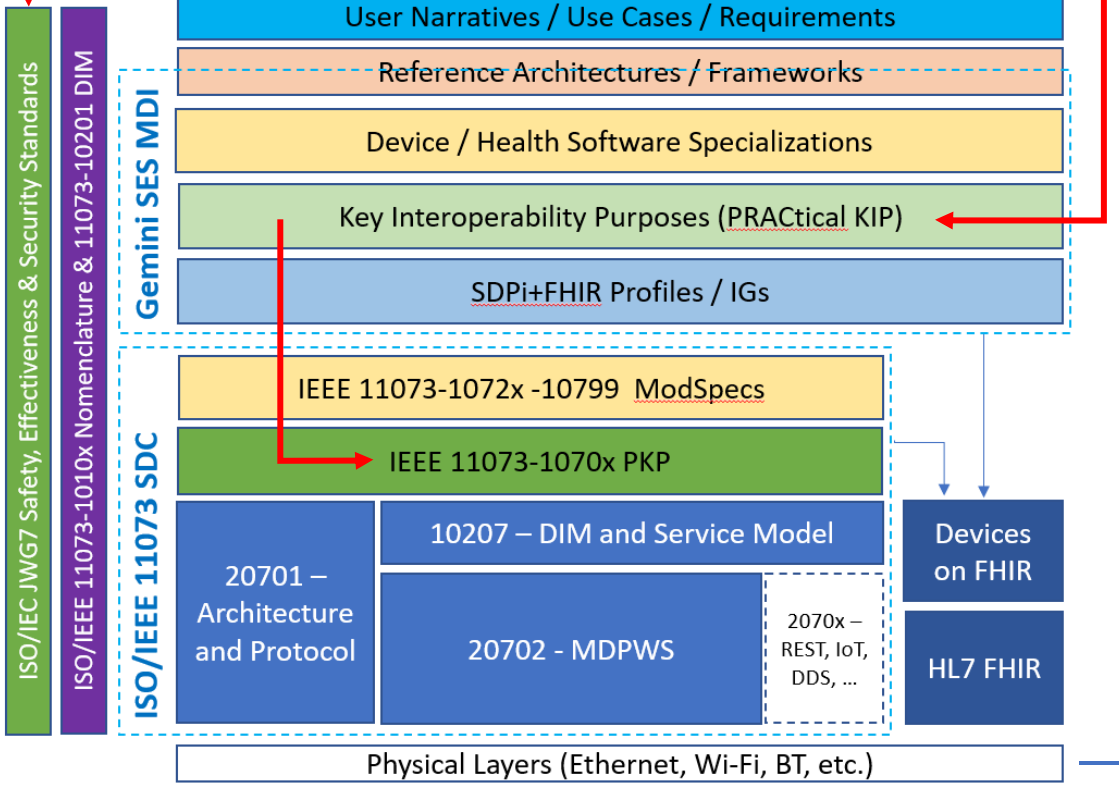
SES+MDI Plug-n-Trust Interface

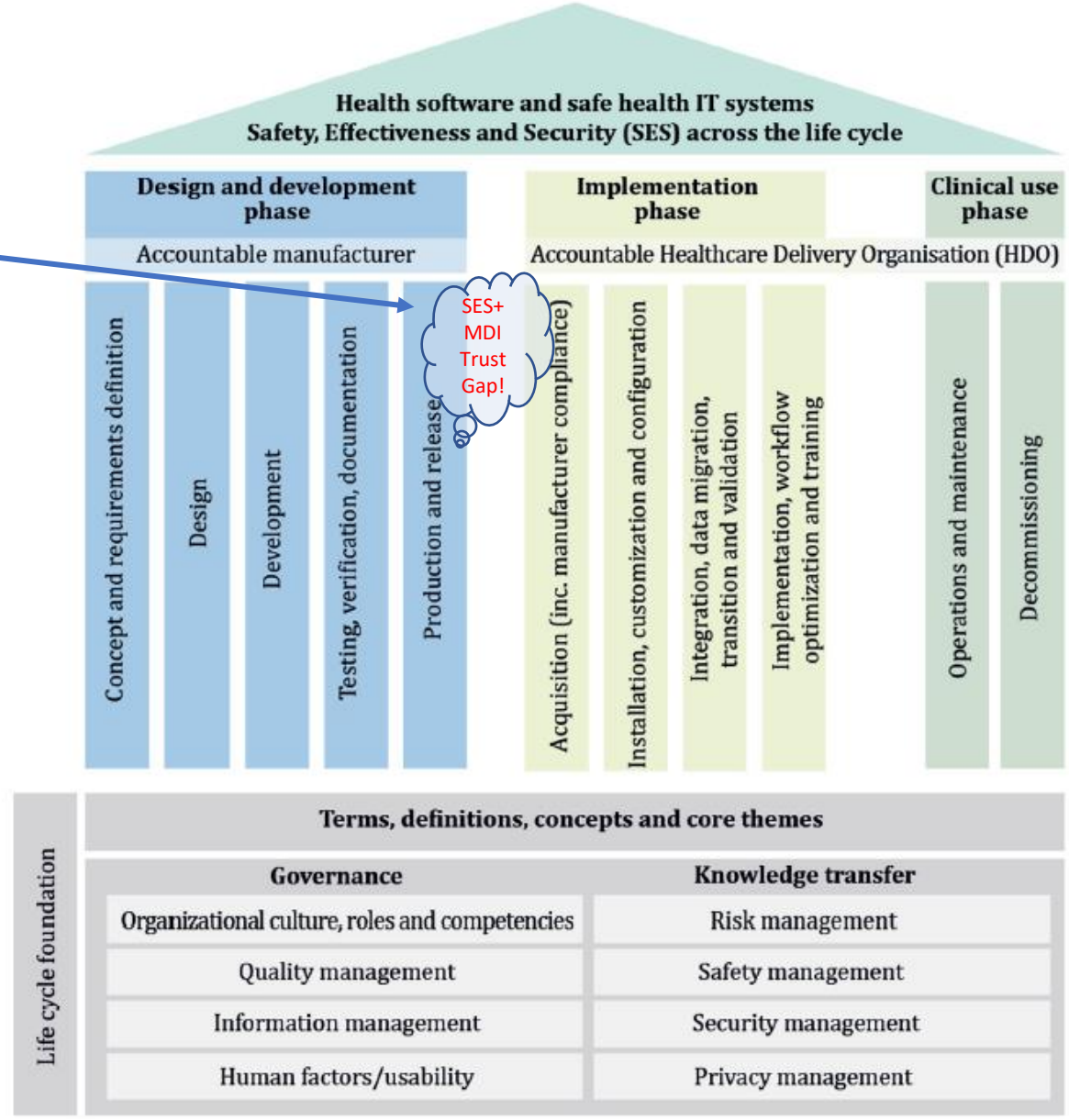


(More @ https://confluence.hl7.org/x/4ijxB)

Gemini SES+MDI & *Ecosystem Pathway …*

Problem? Ecosystem Pathway group will leverage the *SES+MDI "Hanging Gardens" Framework … to address the pesky "Trust Gap" product ecosystem challenges!*





Medical Device Interoperability – *Personalized Health Navigation … The future?*

What should healthcare look like in 10 years?

THT: What do people want ... In 10 years!

To create a digital health legacy for Southern California, we asked people for their opinions:

- #1: ***Access*** & ***Affordability***
- It is about ***ME*** … I am in control of all info & care
- Focus: ***Health & Wellness***
- ***Healthcare*** when & where I need it to return to health & wellness … optimally (time & therapy)
- Available to everyone … ***EVERYONE***
- Use latest ***best technology*** & ***knowledge***

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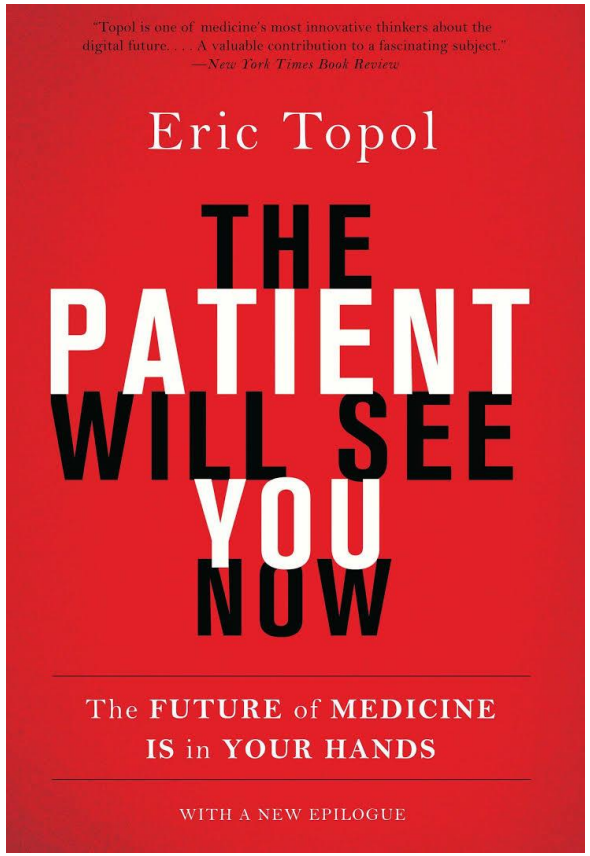
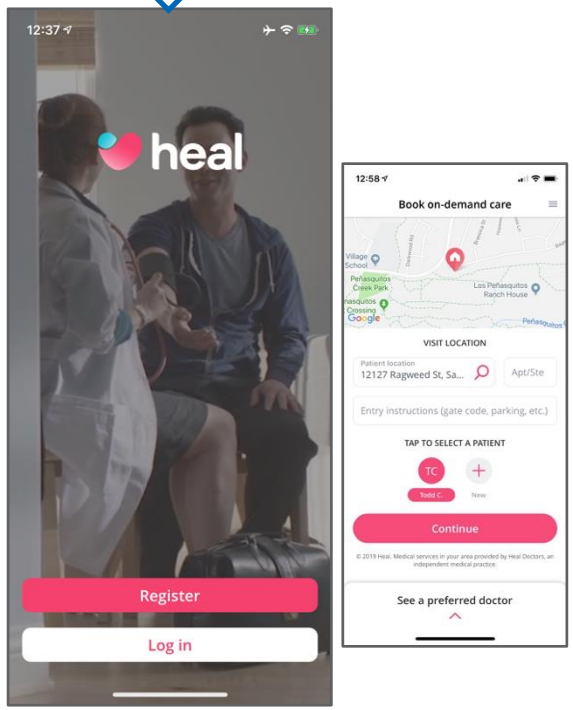


One September in San Diego …

- ✓ Hives? Maybe
- ✓ Go to Ready Care? No!
- ✓ Call "ÜberDoc"!
- ✓ MD + Assistant …
- ✓ in my home …
- ✓ < 90 minutes …
- ✓ $99 flat fee

They spent 45 minutes with me!

(in the U.S., that's unheard of …)



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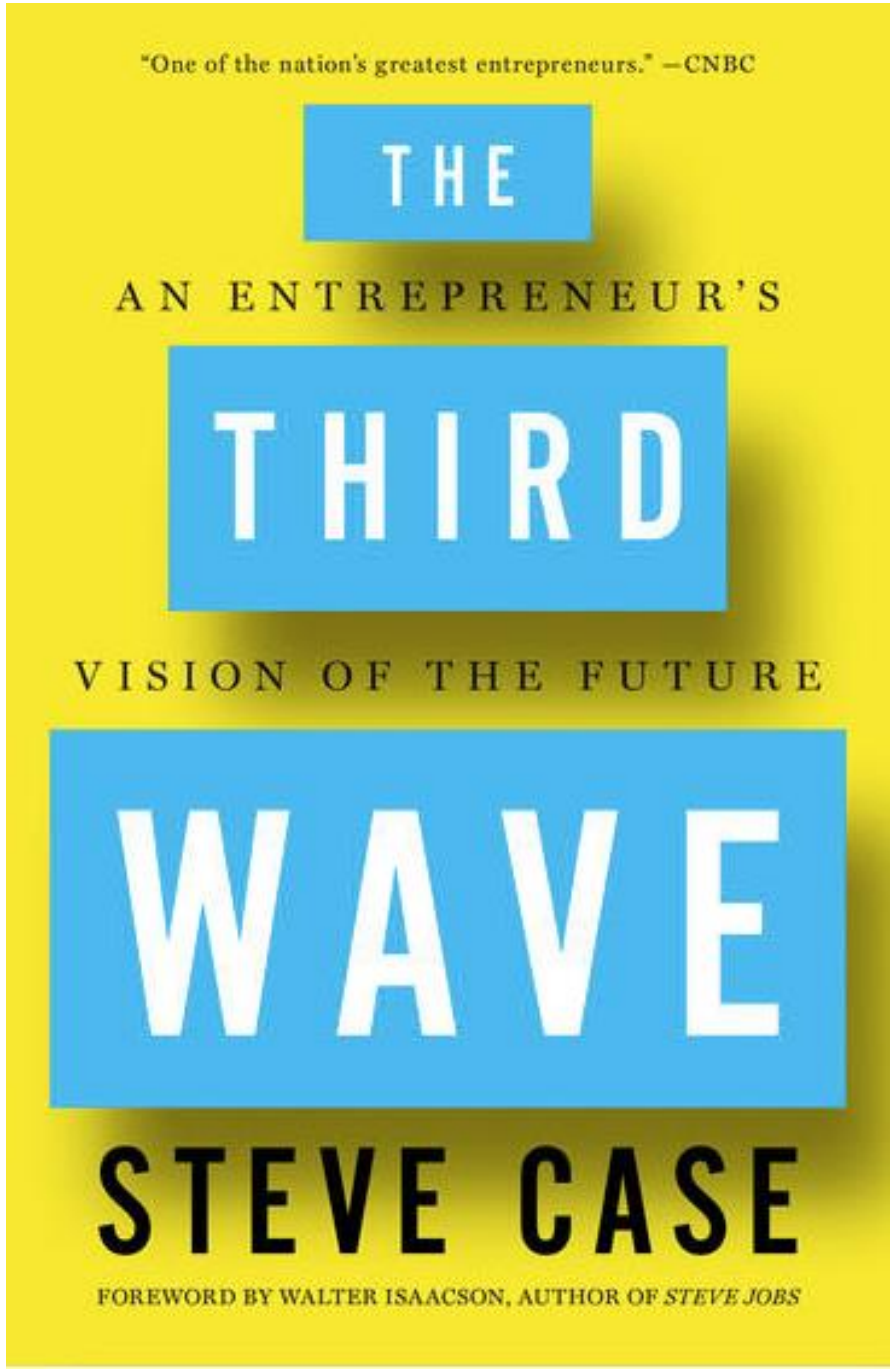

The First Wave of the Internet was all about building the infrastructure and foundation for an online world.

The Second Wave was about building on top of the Internet. ***Search engines*** like Google made it easier to explore the sheer volume of information available on the web. ***Amazon*** and ***eBay*** turned their corner of the Internet into a one-stop shop. It was during the Second Wave that ***social networking*** came of age…

The Third Wave is characterized by:

- ✓ Ubiquitous communication (IoT)
- ✓ Unlimited computing power (cloud)
- ✓ Data-/Knowledge-Driven (Big Data)
- ✓ AI & ML + VR & MR
- ✓ Personalized

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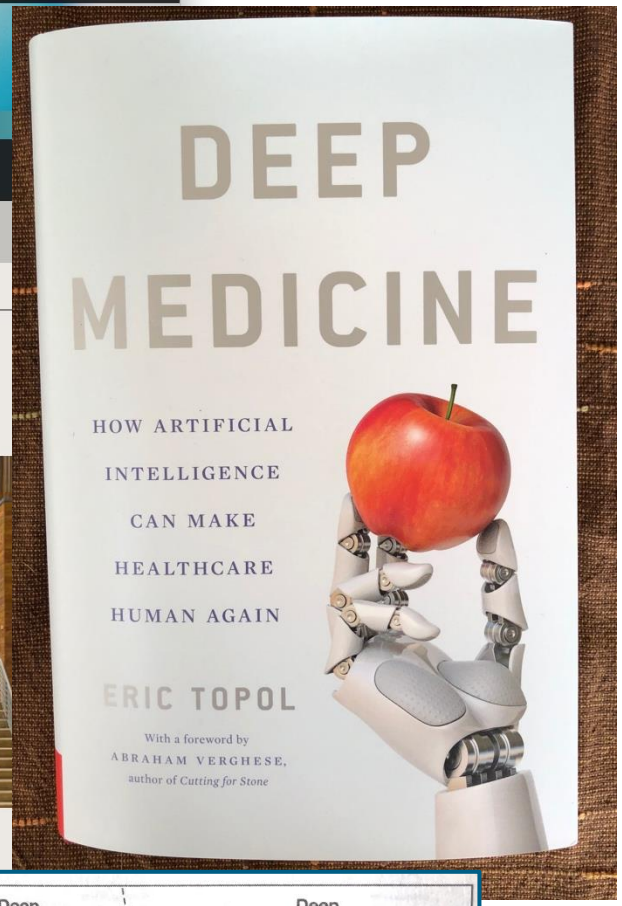
Future of Individualized Medicine

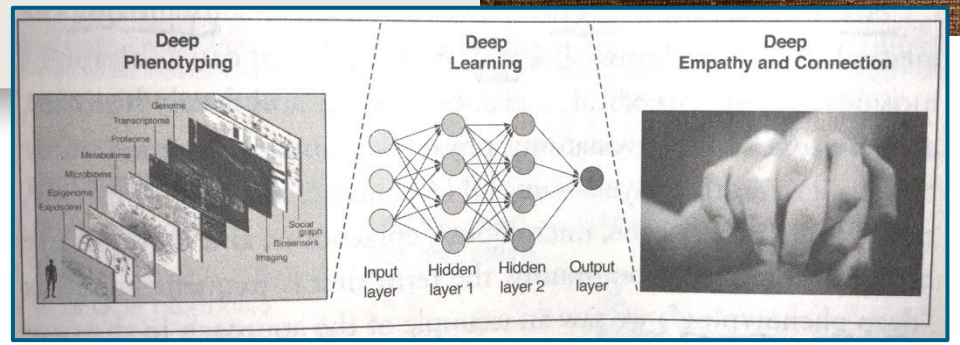
March 14-15, 2019 | La Jolla, California

* Online registration has closed. Walk-in registration will be available onsite. *

After 11 annual conferences exploring genomic medicine, we're broadening our scope.

In 2019, the newly renamed *Future of Individualized Medicine* (formerly *Future of Genomic Medicine*) conference will expand to include additional perspectives on how to tailor medicine to the individual. Individualized medicine takes into account a person's genes—and genomics will remain a core topic for exploration and discussion—but it also considers the full spectrum of a person's uniqueness from their biologic, physiologic, anatomic, lifestyle and environmental information. The *Future of Individualized Medicine* conference will thus incorporate perspectives from the emerging fields of digital medicine, artificial intelligence and machine learning, behavioral science and others. This is truly a multidisciplinary forum





https://www.scripps.edu/science-and-medicine/translational-institute/about/events/foim/

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The New York Times

Opinion

The A.I. Diet

Forget government-issued food pyramids. Let an algorithm tell you how to eat.

By Eric Topol
Dr. Topol is a cardiologist.

March 2, 2019

Some months ago, I participated in a two-week experiment that involved using a smartphone app to track every morsel of food I ate, every beverage I drank and every medication I took, as well as how much I slept and exercised. I wore a sensor that monitored my blood-

For now, it's striking that it took big data and A.I. to reboot our perceptions about something as fundamental as what we eat. We're still a ways away from "You Paleo, me Keto," but at least we're finally making progress, learning that there is no such thing as a universal diet.

https://www.nytimes.com/2019/03/02/opinion/sunday/diet-artificial-intelligence-diabetes.html

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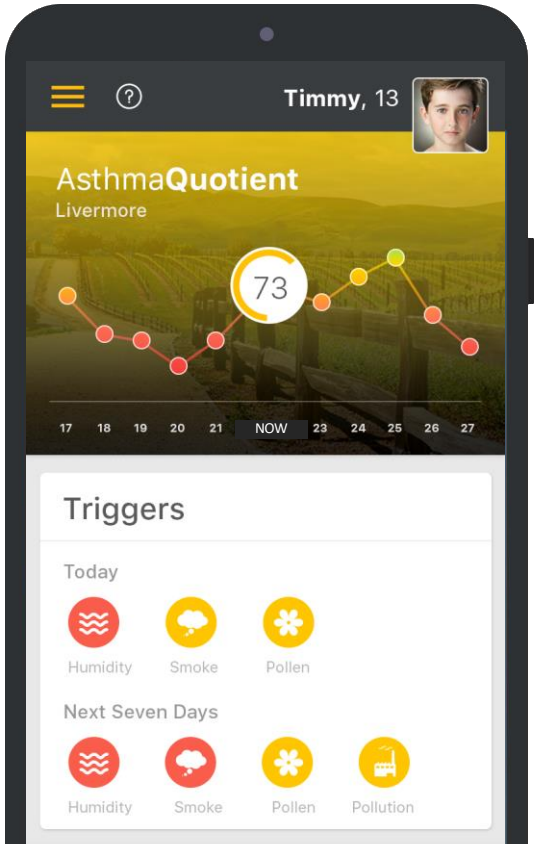
AsthmaBrain

NEURAL INTELLIGENCE SOLUTION for PRECISION HEALTHCARE

Preventing ED & Hospital Visits Due to Asthma and COPD,
Using Deep Learning Technology and Real-Time Data



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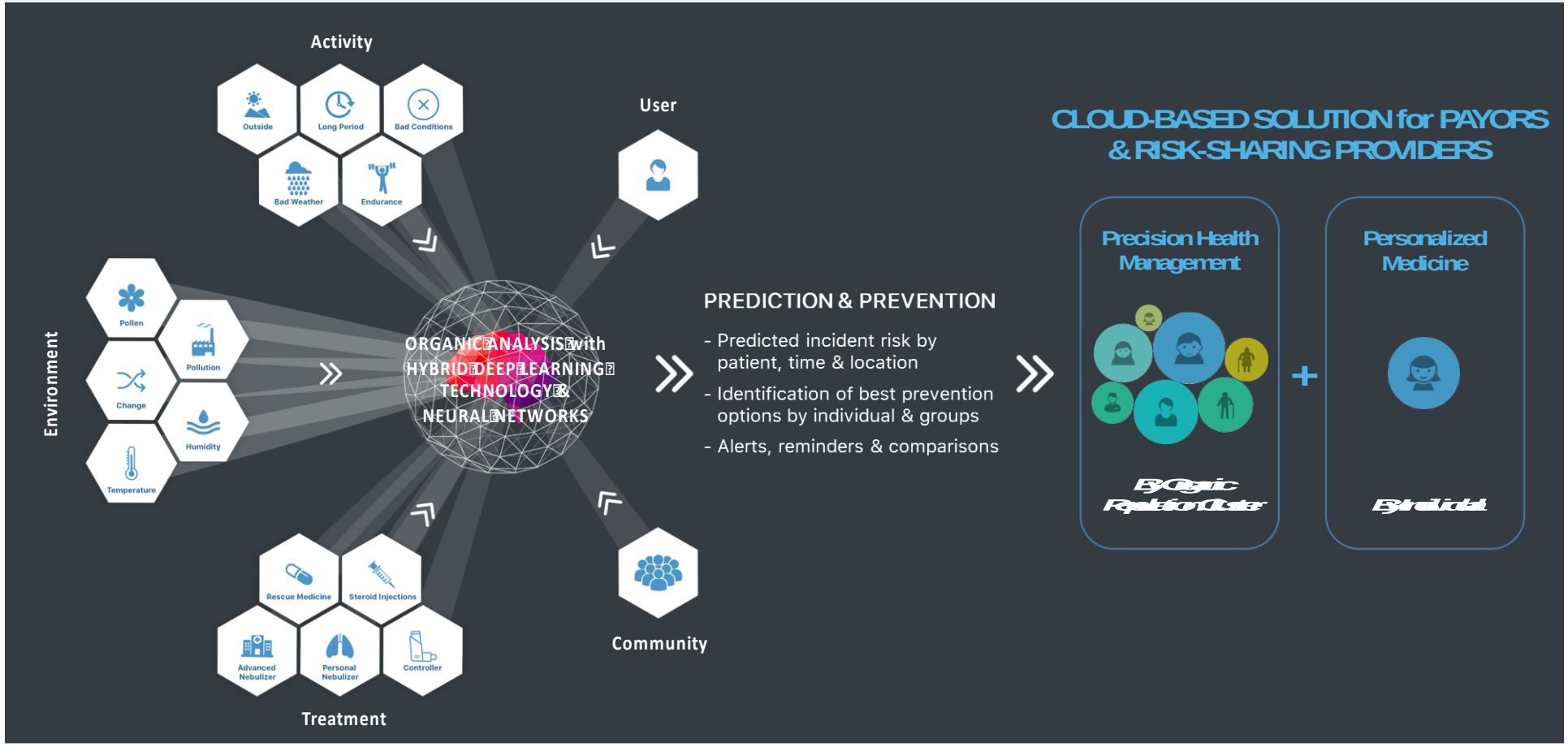
AsthmaBrain

NEURAL INTELLIGENCE SYSTEMS

REAL-TIME DATA + PERSONALIZED ANALYTICS + TIMELY ALERTS



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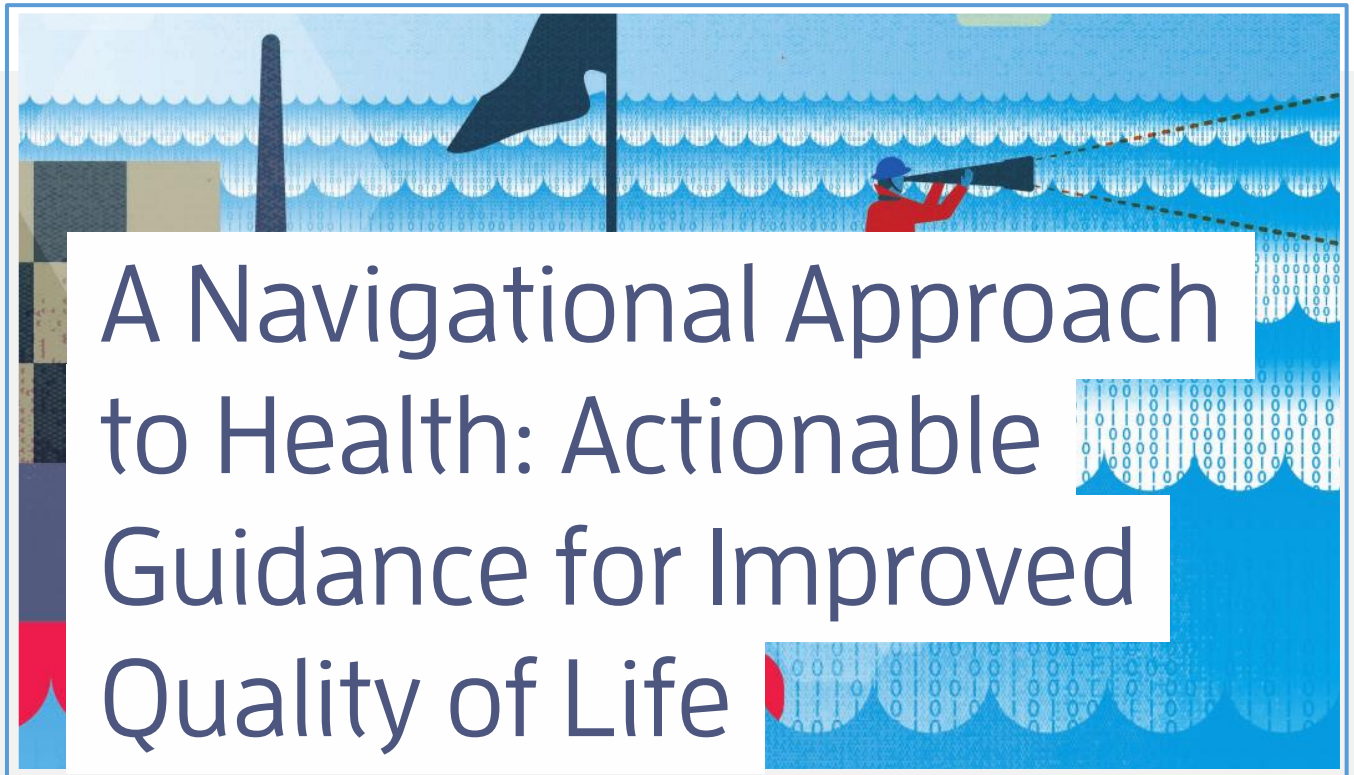

A Navigational Approach to Health: Actionable Guidance for Improved Quality of Life

Nitish Nag and Ramesh Jain, University of California, Irvine

Health and well-being are shaped by how lifestyle and the environment interact with biological machines. A navigational paradigm can help users reach a specific health goal by using constantly captured measurements to estimate how their health is continuously changing and provide actionable guidance.

COMPUTER PUBLISHED BY THE IEEE COMPUTER SOCIETY APRIL 2019

Personalized Digital Health "Navigation" vs. Precision Medicine

Consider: Personal Health "Navigator"

- What if an app could guide you to better health, similar to how GPS navigation directs you to your desired destination? Think: ***Apple / Alibaba / … "maps"***
- What if the app could use real-time information to redirect you around a disease, just as you're rerouted to avoid traffic? Think: ***Waze***
- What if the app could provide step-by-step directions to get you to your optimal health state, whether you're a young professional athlete or an old retired school teacher? Think: ***Google walking "directions"***

(Source: Dr. Ramesh Jain / UCI Institute for Future Health; https://arxiv.org/abs/1805.05402)

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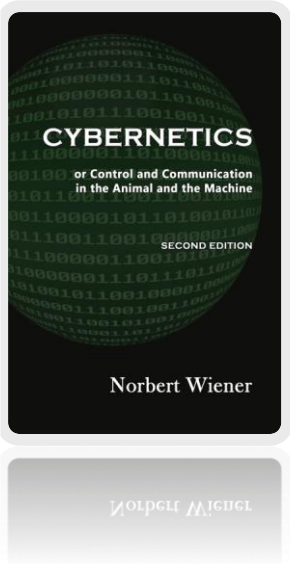
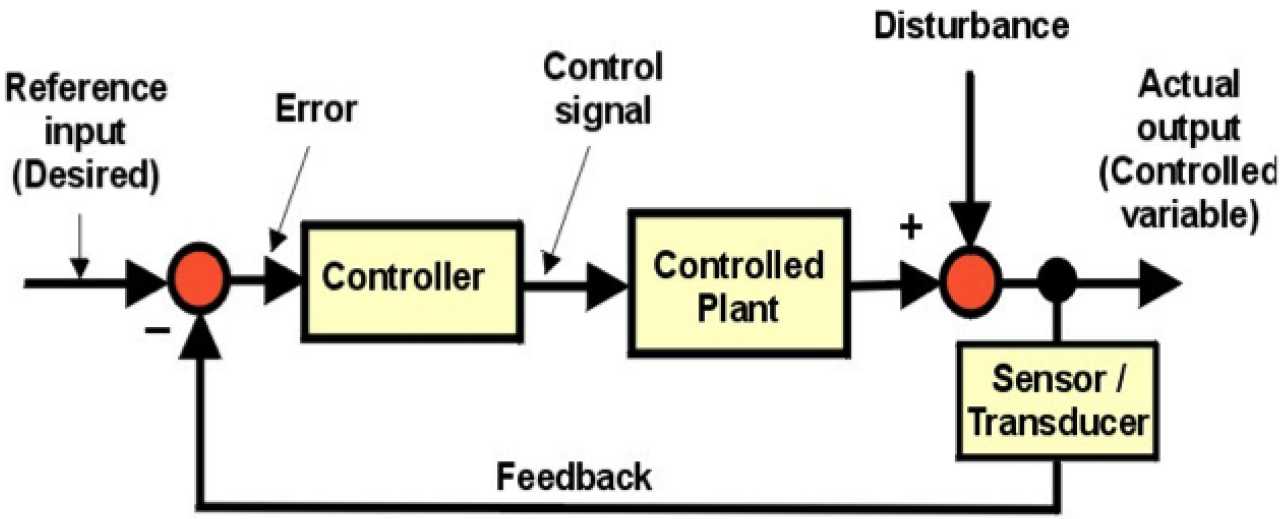
Leverage AI / ML / Cybersystems…in daily life!

Cybernetics: Feedback revolutionizes System design





Modern control theory and AI came from Cybernetics.

(Source: Dr. Ramesh Jain / UCI Institute for Future Health)

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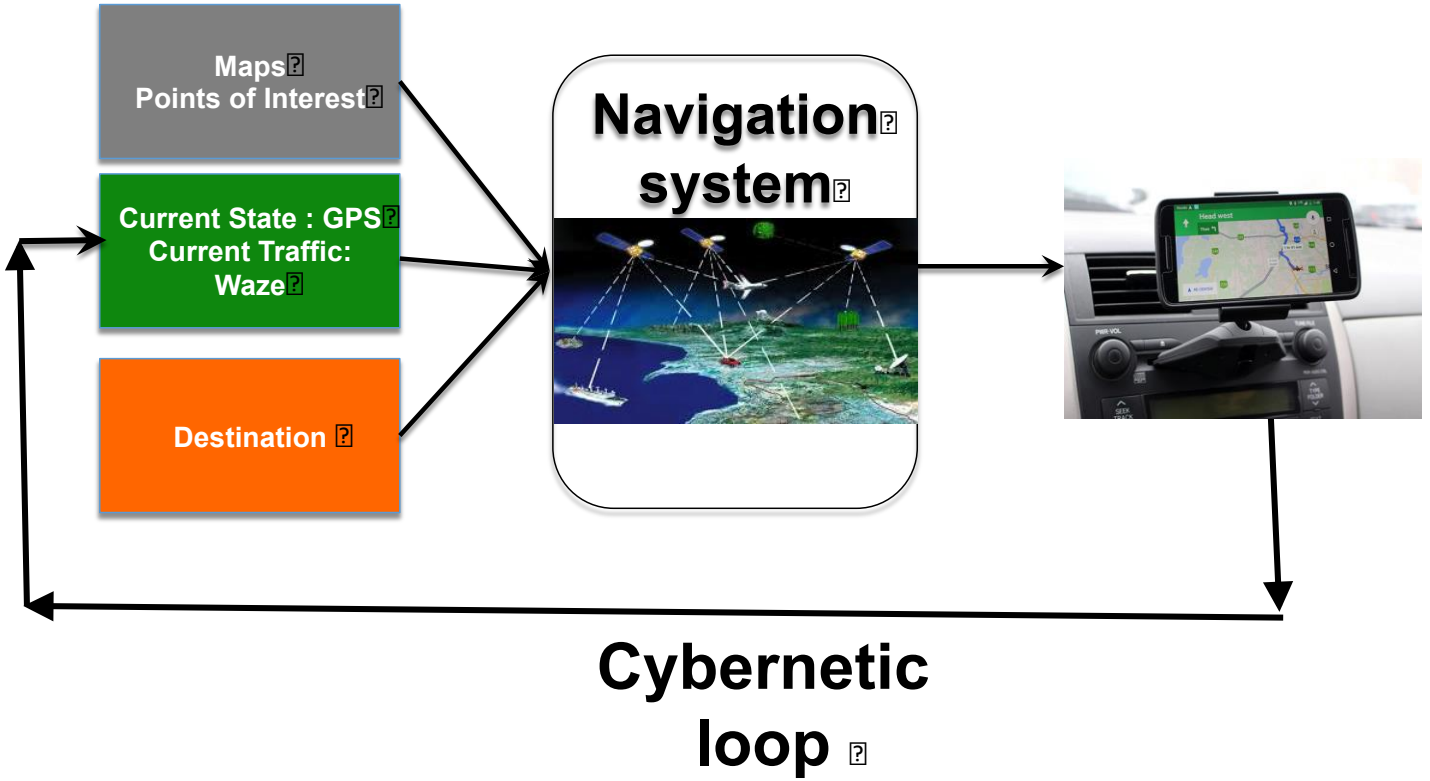
Consider modern car (and foot!) navigation

Magic Happened: Can you drive without a navigation system?



(Source: Dr. Ramesh Jain / UCI Institute for Future Health)

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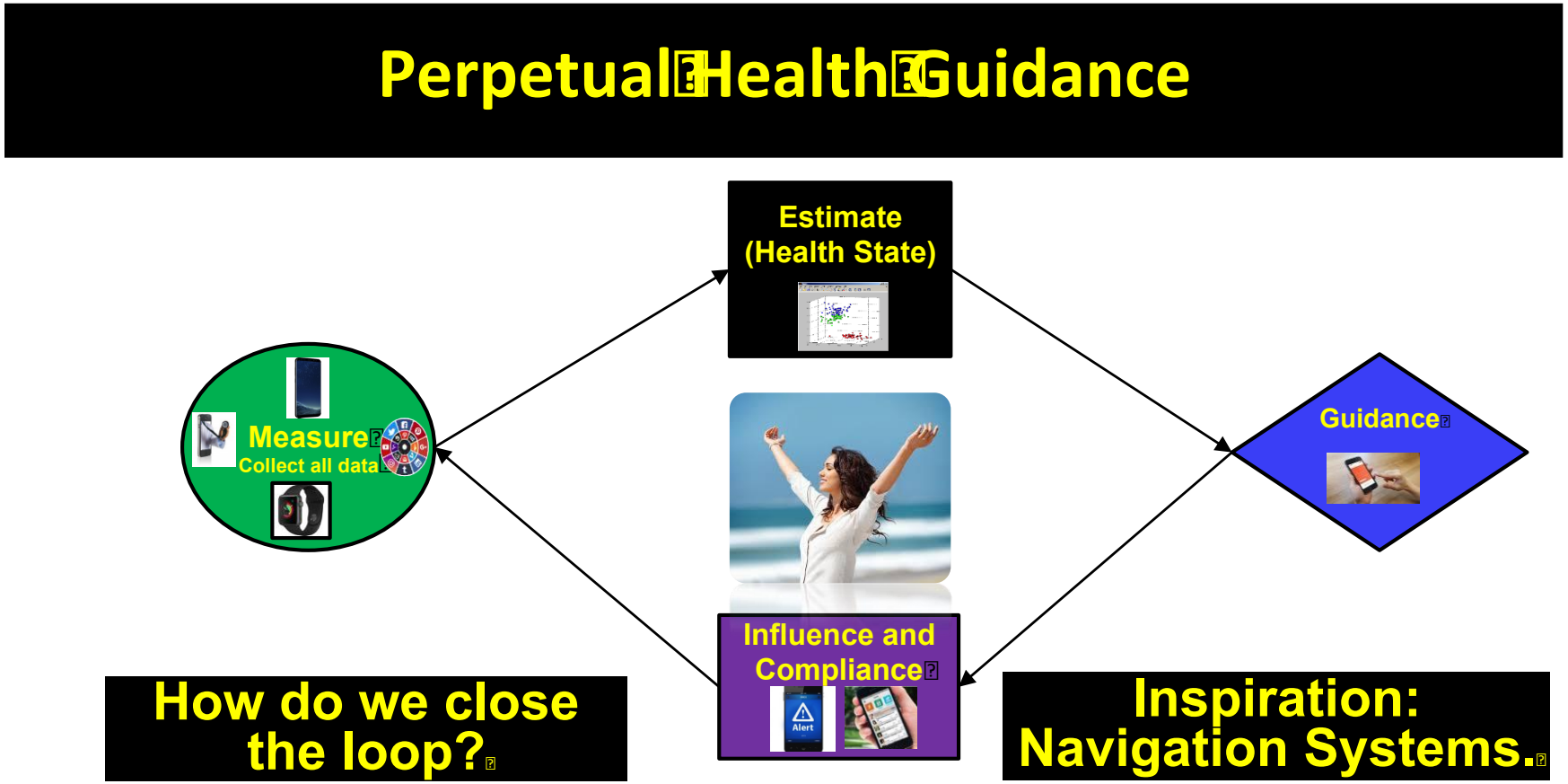
What everyone wants: *Perpetual Health!*



(Source: Dr. Ramesh Jain / UCI Institute for Future Health)

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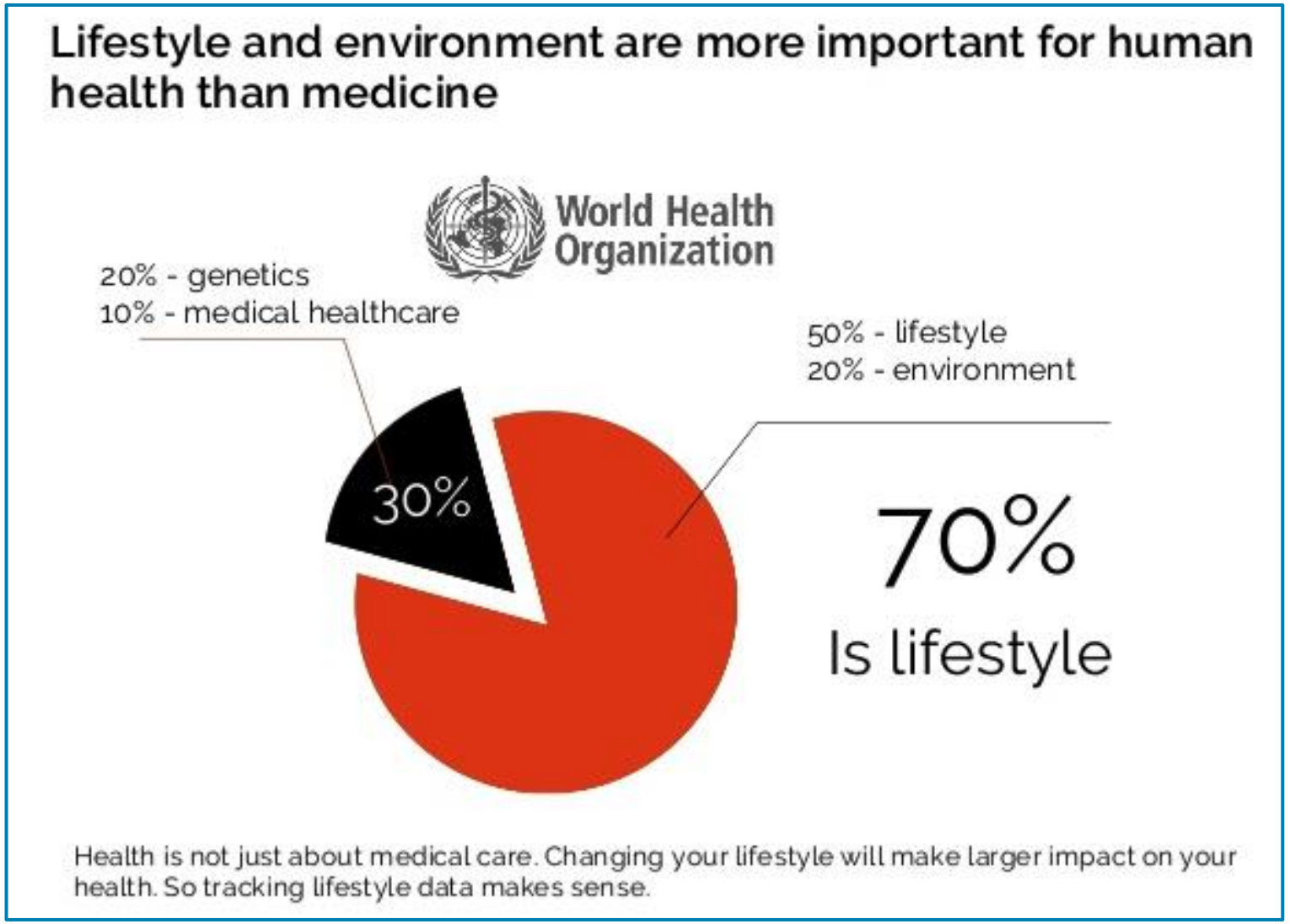
Navigational Health (Dr. Ramesh Jain / UCI)



(Source: Dr. Ramesh Jain / UCI Institute for Future Health; https://www.slideshare.net/jain49/jain-socal-himss-keynote-1805018)

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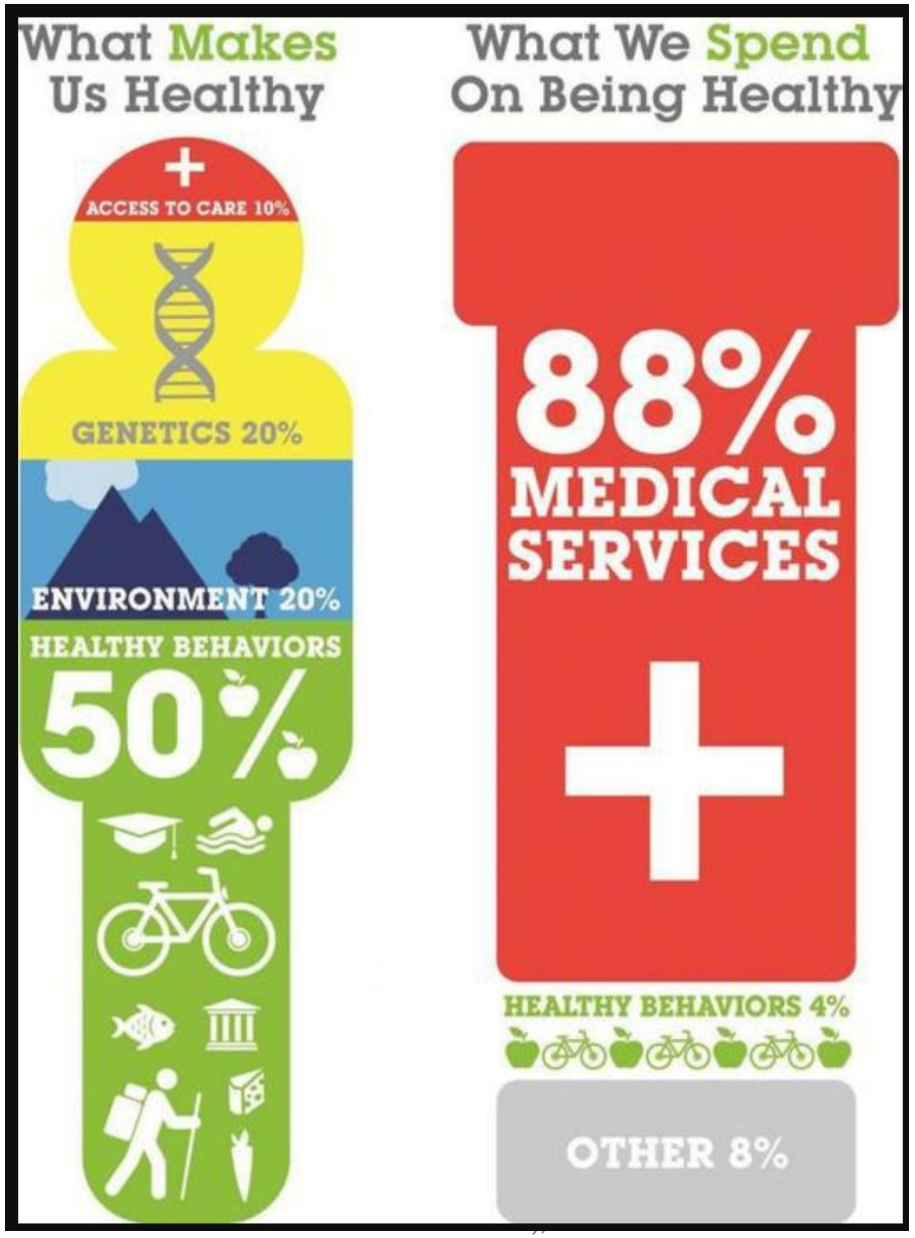
The Problem: What is Right? vs. What is Easy?



(Source: Dr. Ramesh Jain / UCI Institute for Future Health)

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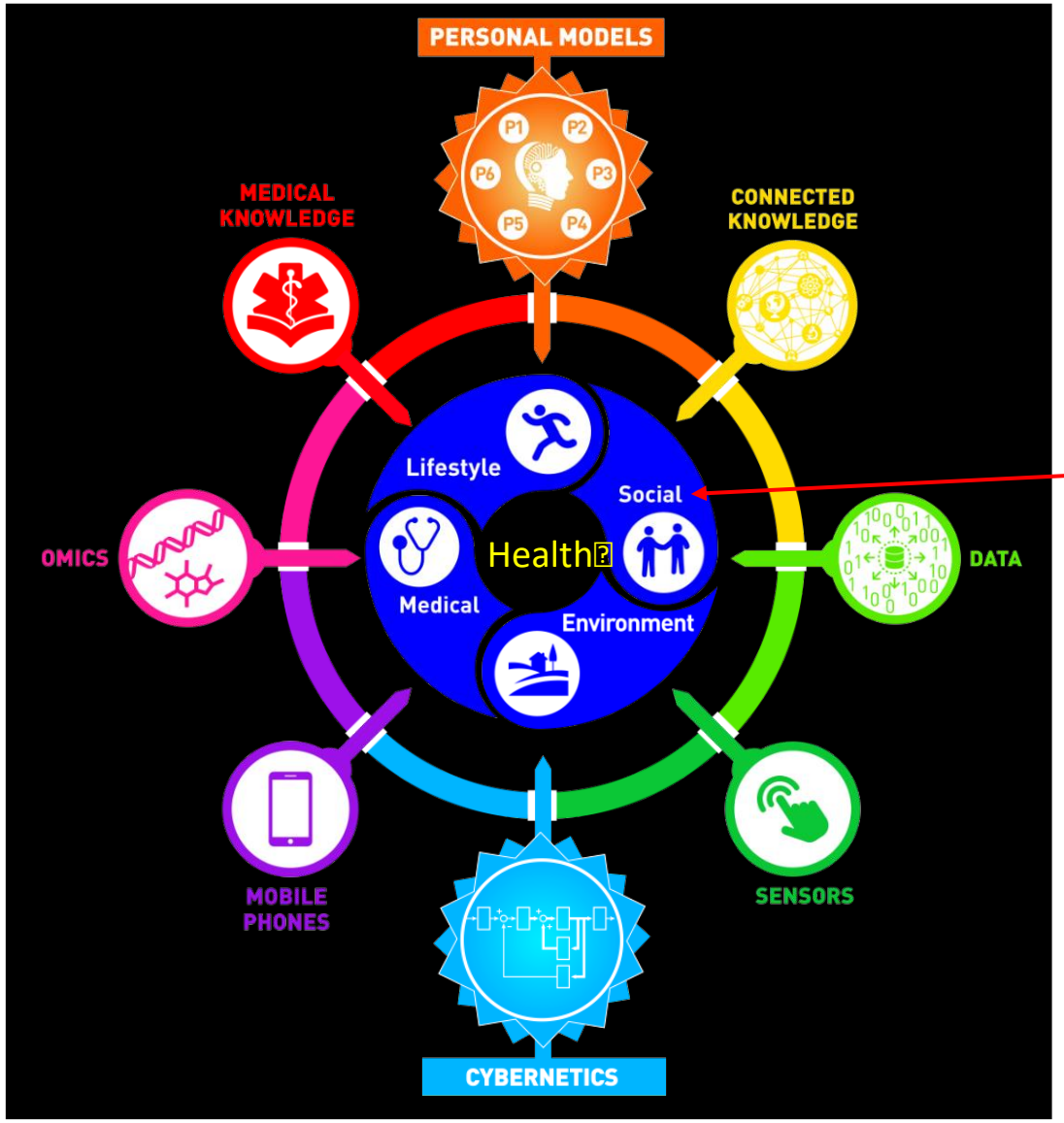
Navigational Health: A New Perspective



(Source: Dr. Ramesh Jain / UCI Institute for Future Health)

Focus on:

- Personal Models
- Cybernetics

Enter …

- ✓ Social Care Informatics
- ✓ Social Determinates of Health
- ✓ Traditional Medicines
- ✓ "Lifestyle" Informatics

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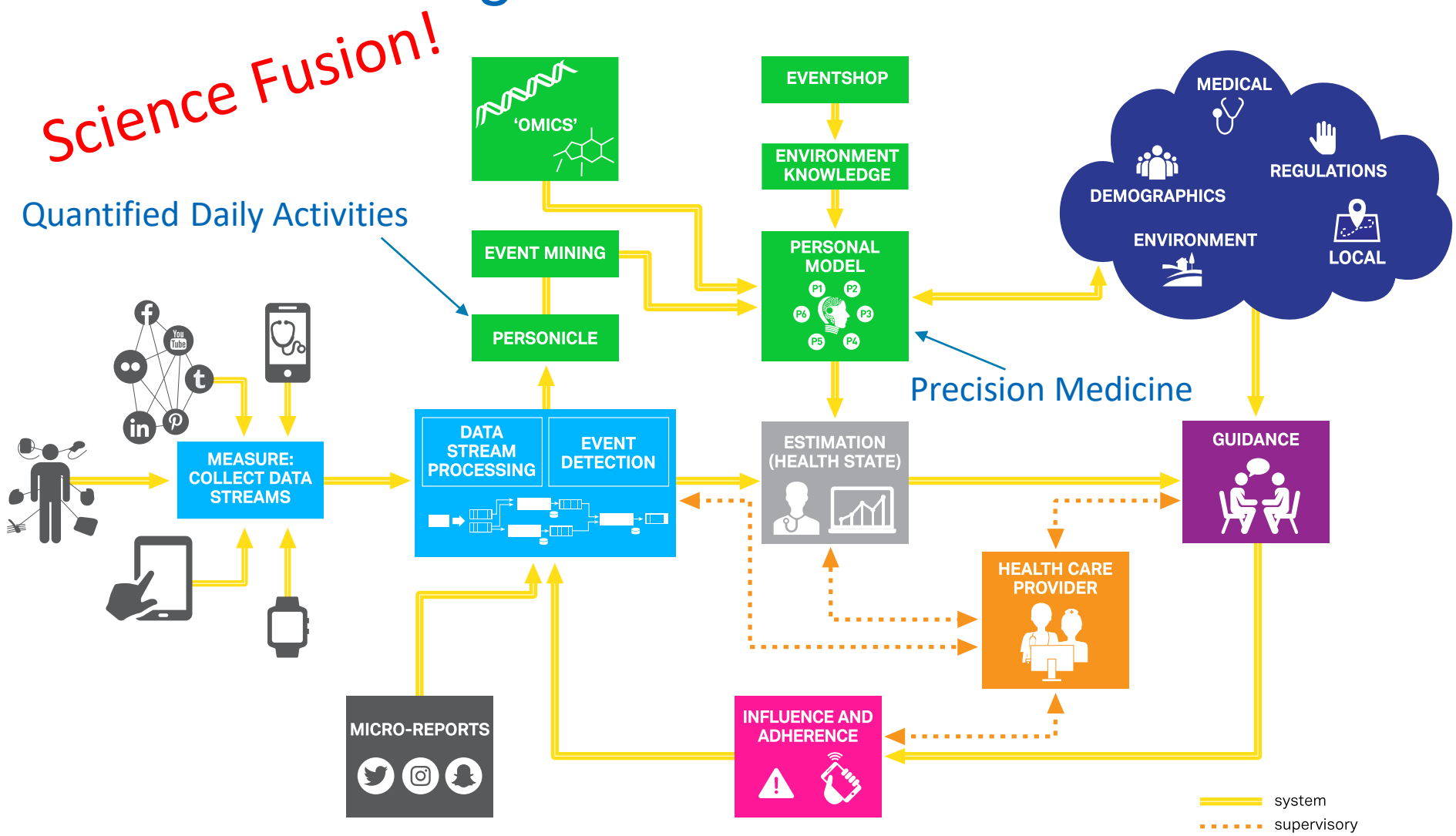
Personal Health "Navigator"



(Source: Dr. Ramesh Jain / UCI Institute for Future Health; https://arxiv.org/abs/1805.05402)

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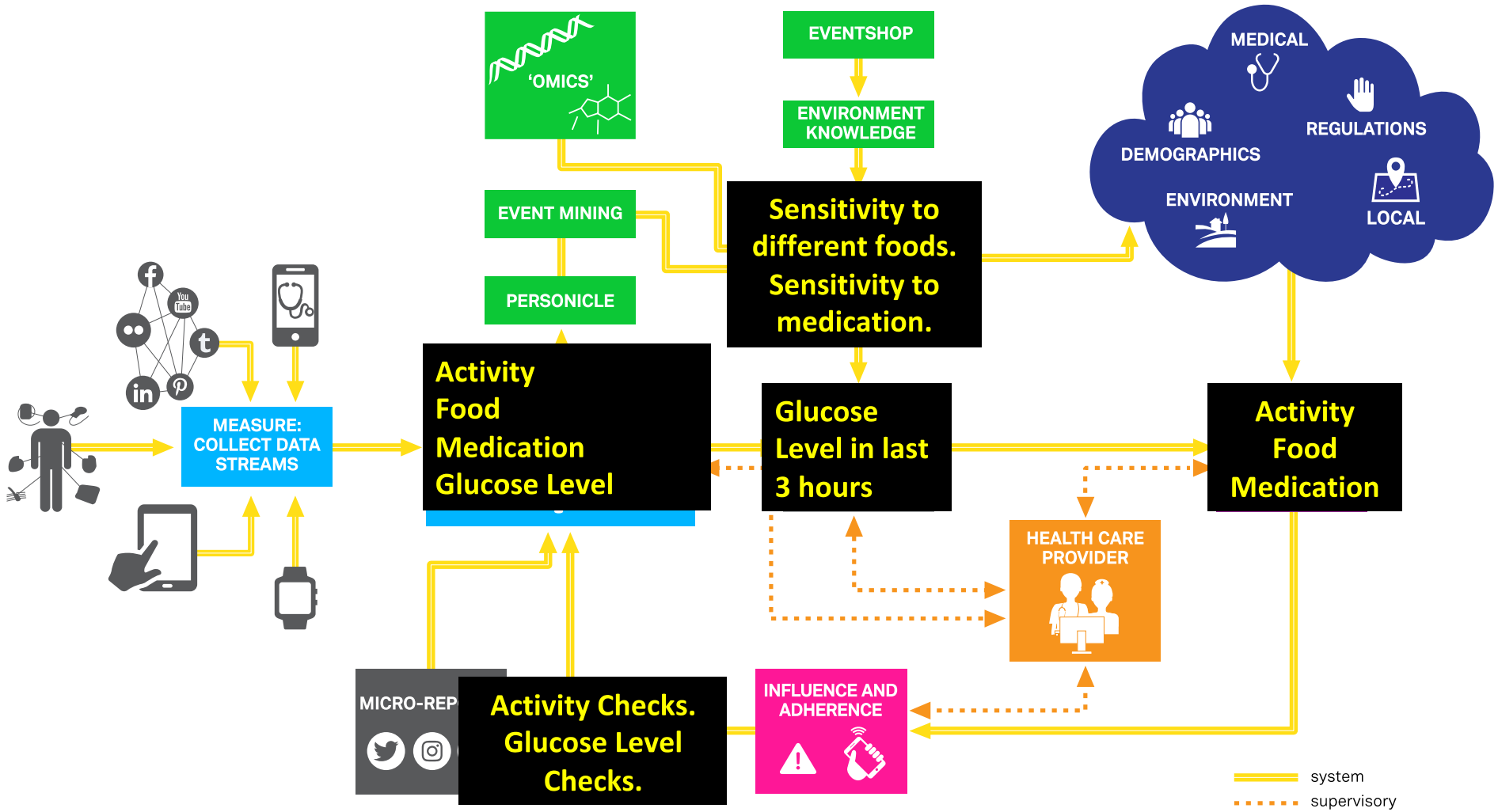
Personal Health ”Navigator”: Diabetes



(Source: Dr. Ramesh Jain / UCI Institute for Future Health)

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Dr. Ed Hammond –

Father of American Health Informatics @ Duke

In 10 years, healthcare will be increasingly delivered by robots, drones & avatars

Sophia – Ed's #1 Choice!

www.MedicalDrones.org

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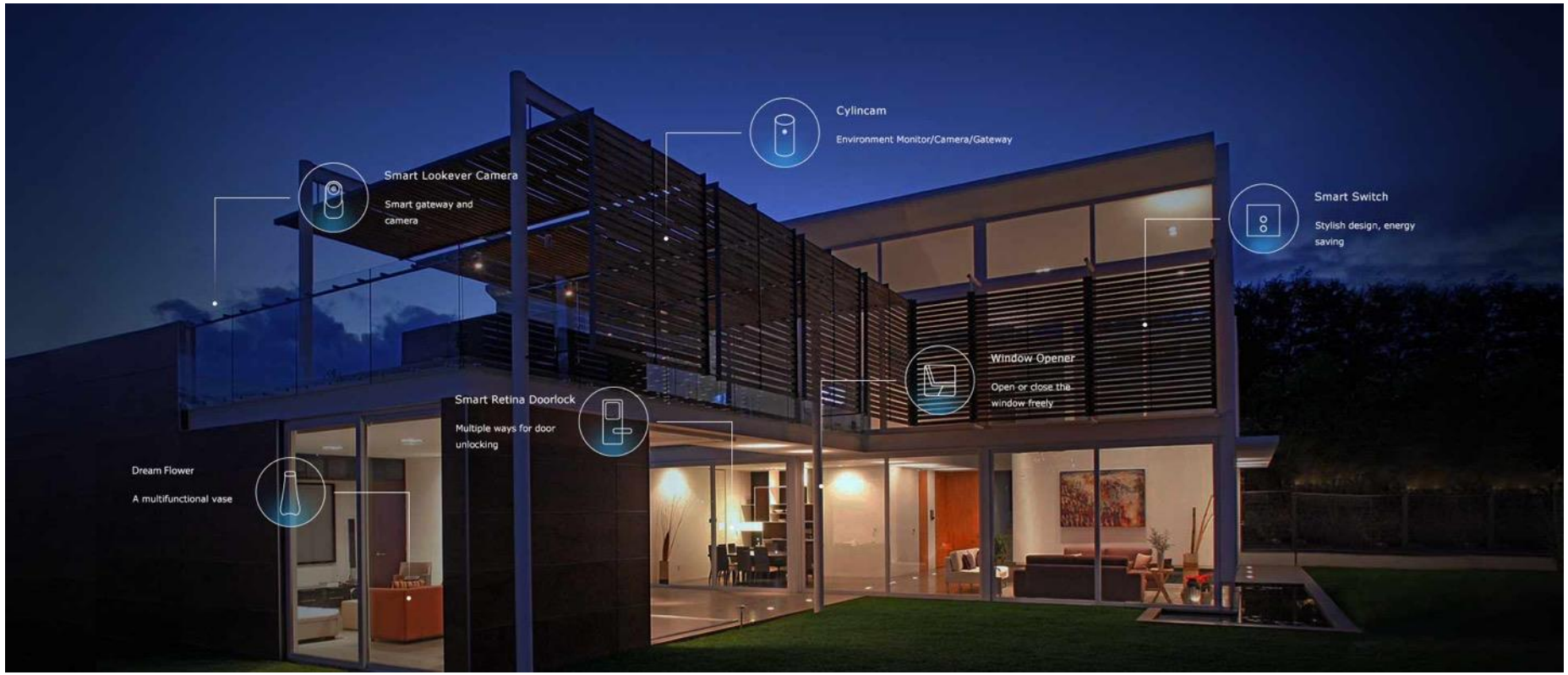
Home Automation @ Ageing in Home



Source: Gartner

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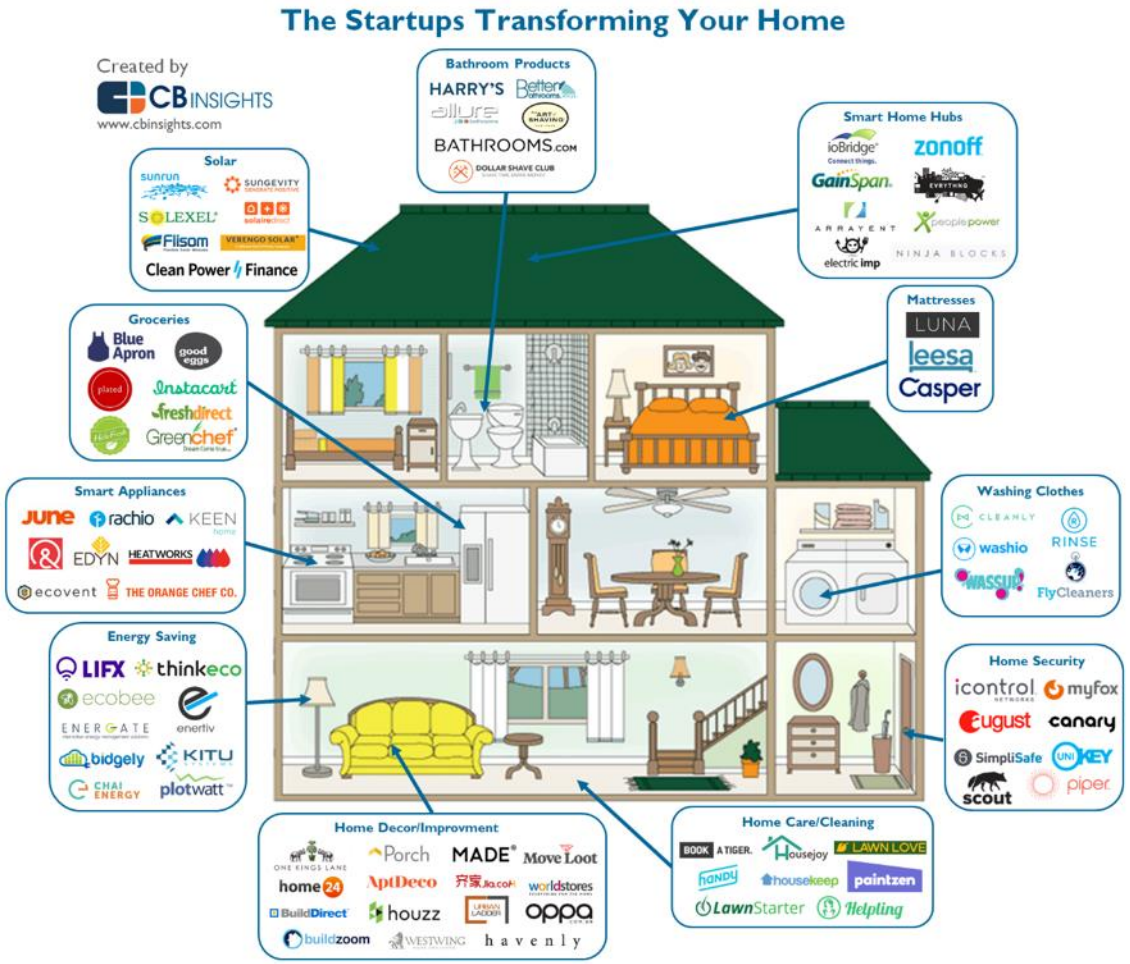
Technology & Services @ Ageing -

LASA
LEADING AGE SERVICES AUSTRALIA
The voice of aged care

LASA NATIONAL CONGRESS 2018 **EXHIBITOR LISTING**

1	Silver Memories	51	Dimple	97	Whiteley Medical
2	D+G Solutions	52	Dimple	98	Rubbermaid Commercial Products
3	Care Advantage	53	Australian College of Nurse Practitioners	99	Rubbermaid Commercial Products
6	Novis Healthcare	54	Anavar Insurance	100	WESTPAC
7	Threat Project	55	ELDAC(End of Life Directions for Aged Care)	101	Schiavello
8	Xtra AgedCare Xtra HomeCare	56	Perform HR	102	Gen-Aged Care Data
9	Molnlycke Health Care	57	Dementia Centre HammondCare	103	Foxtel
10	Atama Furniture	58	Cater Care	104	MPS Australia
11	Atama Furniture	59	Data Mobility Voice	105	Tenderlink
12	Wound Innovations	60	Interface	106	Aged Care Online
13	Painchek	61	DPS Publishing	108	Caring at Home Project
14	Workwear Group	62	HESTA	109	Capital Guardians
15	JCT Healthcare	63	HESTA	110	AON
16	Aged Care Gurus	64	Mirus Australia	111	W&L Mobile Healthcare Services
17	TSS Immigration	65	Safety and Mobility	112	Vocera Communications
18	MEDIREST	66	Emprevo	113	Health Strong
19	INS LifeGuard	67	Annecto	114	Mobile Dental Clinics Australia
20	Black Crow Designs	68	Telstra Health	115	Webstercare
21	Surecom	69	Telstra Health	116	HUR Australia
22	ACS Property Services	70	Laundry Solutions Australia	117	Dementia Care Matters
23	Beacon Energy Solutions	71	Medimap	118	Rinnai Australia Pty Ltd
24	Access Pay Salary Packaging	72	Lamson	119	Alexys
25	Sustainable Energy Solutions	73	Westpac Institutional Bank	120	Active @ Home- Partner 4 Health
26	Meaningful Ageing Australia	74	My Recruitment Plus	121	Health Management Systems
27	AUSCO Modular	75	My Recruitment Plus	122	Leecare Solutions
30	Blair Architects	76	EvacMate	123	Envigor Health Management
31	E-Tools Software	77	Hynes Legal	124	Ezi Tracker
32	TANDA	78	Zenith Insurance Services	125	Physio Corp
33	Eden in Oz and NZ	79	Encara	126	HLS Health
34	Home Instead Senior Care	80	WFS: A Workforce Software Company	127	Supply Partners
35	Lifecare Furniture	81	CareLynx	128	Bunnings Warehouse
36	Crown Furniture	82	Winc Office Max	129	Bunnings Warehouse
37	Access Health	83	Winc Office Max	130	Bunnings Warehouse
38	EBOS Group	84	Person Centred Software	131	Bunnings Warehouse
39	DOSEAID	85	Laundry Equipment Company	132	Community Data Solutions
40	LASA Online Platform Powered by UCT	86	Redstone Recruitment	133	Statcom Systems
41	The Bidet Shop	87	Alpha Care	134	Food Solutions
42	LEXIS NEXIS	88	Alpha Care	135	Next Generation Services
43	Dementia Australia	89	Healthcare Australia	136	Australian Medicines Handbook
44	Gow Gates Insurance Brokers	90	Evomed	137	AUSCO Modular
45	Autumn Care	91	Life Fitness Australia	138	Procura
46	First State Super	92	Life Fitness Australia	139	Procura
47	Riskteq	93	Avanti Care	140	Congress Dinner Table Listings
48	Zoono	94	Provider Assist	141	Congress Dinner Table Listings
49	Safe Co	95	QPS Benchmarking		
50	Frig Securities	96	Unicharm Australasia		



Source: CBInsights, www.cbinsights.com

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Questions & Answers

Medical Device Interoperability – A Brief History & Current Initiatives

for

IEEE Tech Talk: Health Electronics ~ Seattle

2022.02.22

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