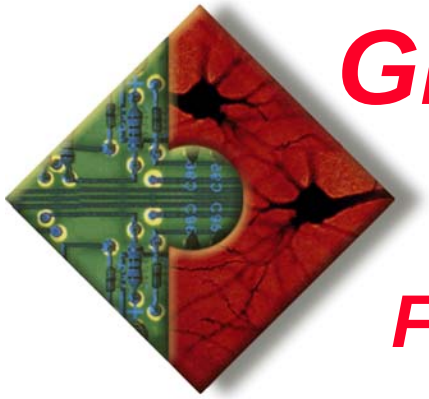

Global Health Information Workshop

Fall '10 EMBS Annual Conference

Buenos Aires, Argentina

The Integration of Medical Devices

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Elliot Sloane's Bio Brief

- 35+ years in the medical technology and IT/HIT fields, as a technology/engineering expert and consumer/safety advocate
  - Biomedical and Clinical Engineering core
  - Information Systems and Sciences doctorate
- 25 years as a CIO, COO, CTO, CRO in the medical technology industry (ECRI Institute & MEDIQ, Inc)
- 10+ years in business schools, MIS, CS
- Since Nov, 2009 ***Health Systems Engineering Program Director and Research Professor*** at Drexel University, Philadelphia, USA
  - Received recent NSF grant for Health IT Curriculum and Certification
  - Developing one of the first university-based Wireless Medical Device Interoperability Laboratory for teaching and research
  - Specializations: electronic health records, medical devices, privacy, security, and patient safety, wireless in healthcare, and related technical standards and policies

Full Disclosure

- I have no direct or indirect economic interest in, nor derive economic benefit or support from, any medical device or electronic health record software company
- I hold or have held uncompensated board/member/chair roles with multiple non-profits, including ACCE, AHTF, CHIRP, IEEE EMBS, and RFID in Health Consortium, and with Standards Development Organizations including ANSI, IEEE-SA, IHE International, and IHE USA
- I do provide consulting services to US gov't, the World Health Organization, and other government, educational, and non-profit agencies
- I am also the founder and president of a US non-profit agency called the *Center for Healthcare Information Research and Policy (CHIRP)*
- I am co-chair of the IHE International Standards program, and the EMBS Sponsor for the ISO/IEEE 11073.x Standards program

Presentation Outline

- The Evolution of “Medical Devices” to “Medical Device System of Systems (SoS),” and the Interoperable Medical Device Environment
- Global Medical Device Interoperability Standards
- Opportunities, Consequences, Outcomes, and Challenges

Evolution of Medical Devices to Medical Device Systems of Systems (SoS)

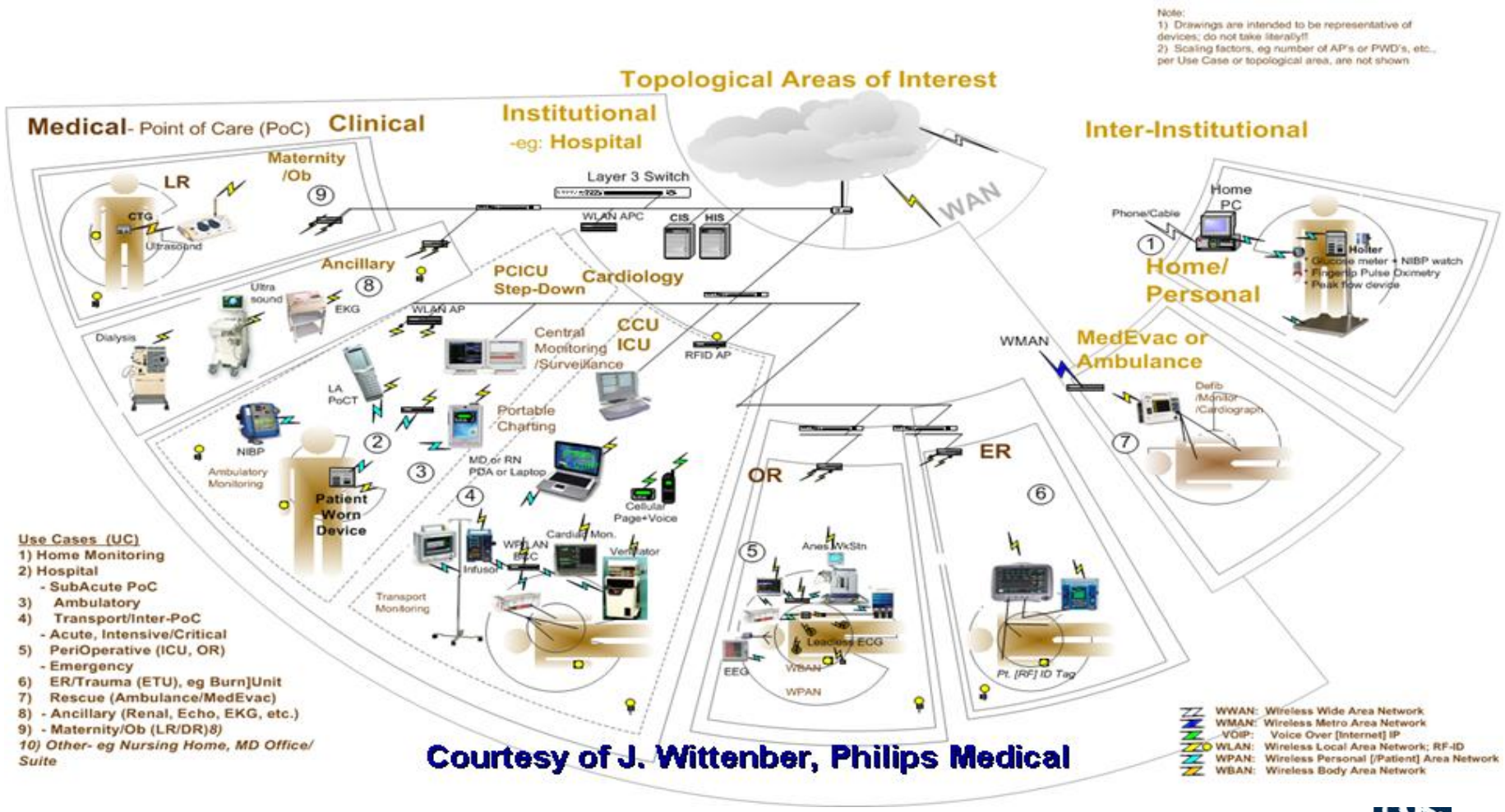
- 1950's – 1970's
  - Almost all individual devices, analog I/O, no standards
- 1970's
  - Mid-1990's some single-brand SoS, like an HP or Philips Central Nursing Station or a GE PACS (RS-232 serial data interface)
- Mid-1990's on
  - Emergence of PC networks, and shift of medical device data to LANs
- 2004 onward
  - Global standards drive towards multi-vendor, multi-product interoperable device standards for flexible and complex SoS configuration/reconfiguration
- 2010 onward (eHealth, mHealth, uHealth, pHealth)
  - Global medical device and electronic health record (EHR) interoperability at the Point of Care (bedside, home, mobile)

A Wireless Medical Systems Map

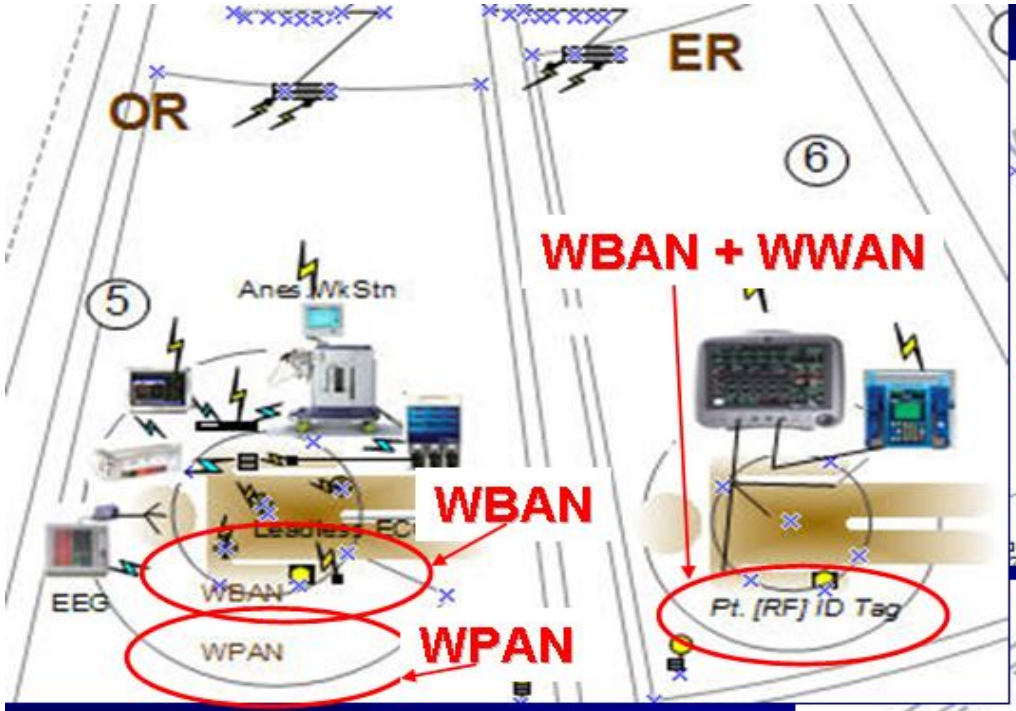
Medical Device Semantics and Communication Modalities Use Cases

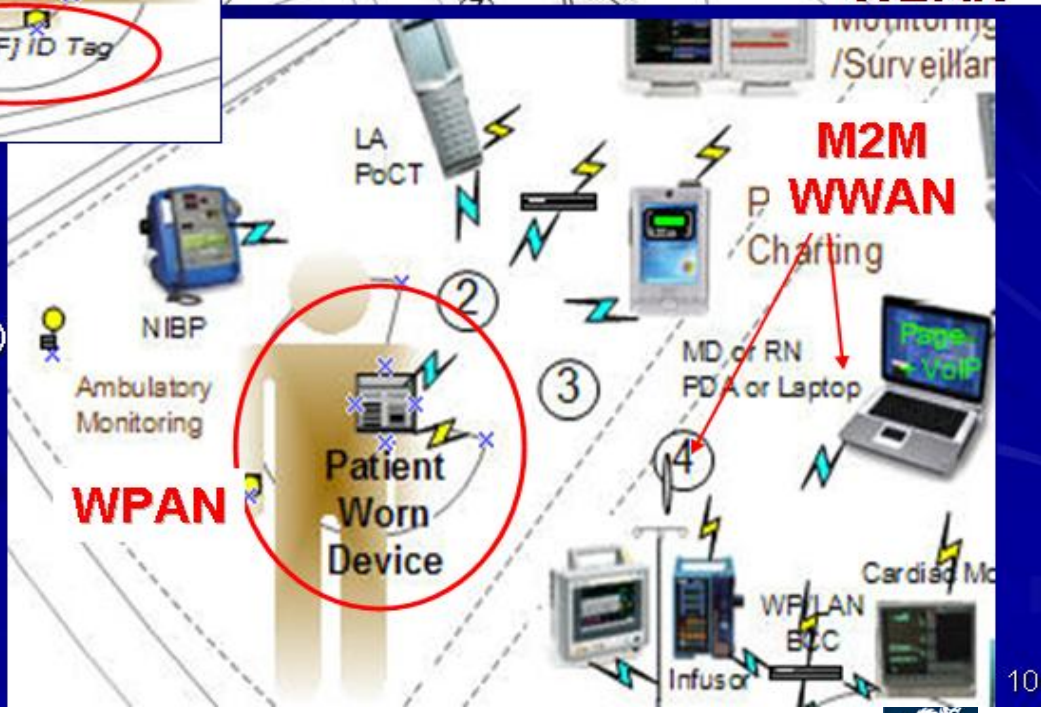
IEEE 11073.x and IEEE 802.x Standards At Work

22July10 Rev 4a



Courtesy of J. Wittenber, Philips Medical





Wireless medical system networks

- Body Area Network (ZigBee)
- Personal Area Network (Bluetooth)
- Wide Area Network (Wi-Fi)
- Metropolitan Area Network
  - Cellular
  - Wi-Max (4G)
  - 3G

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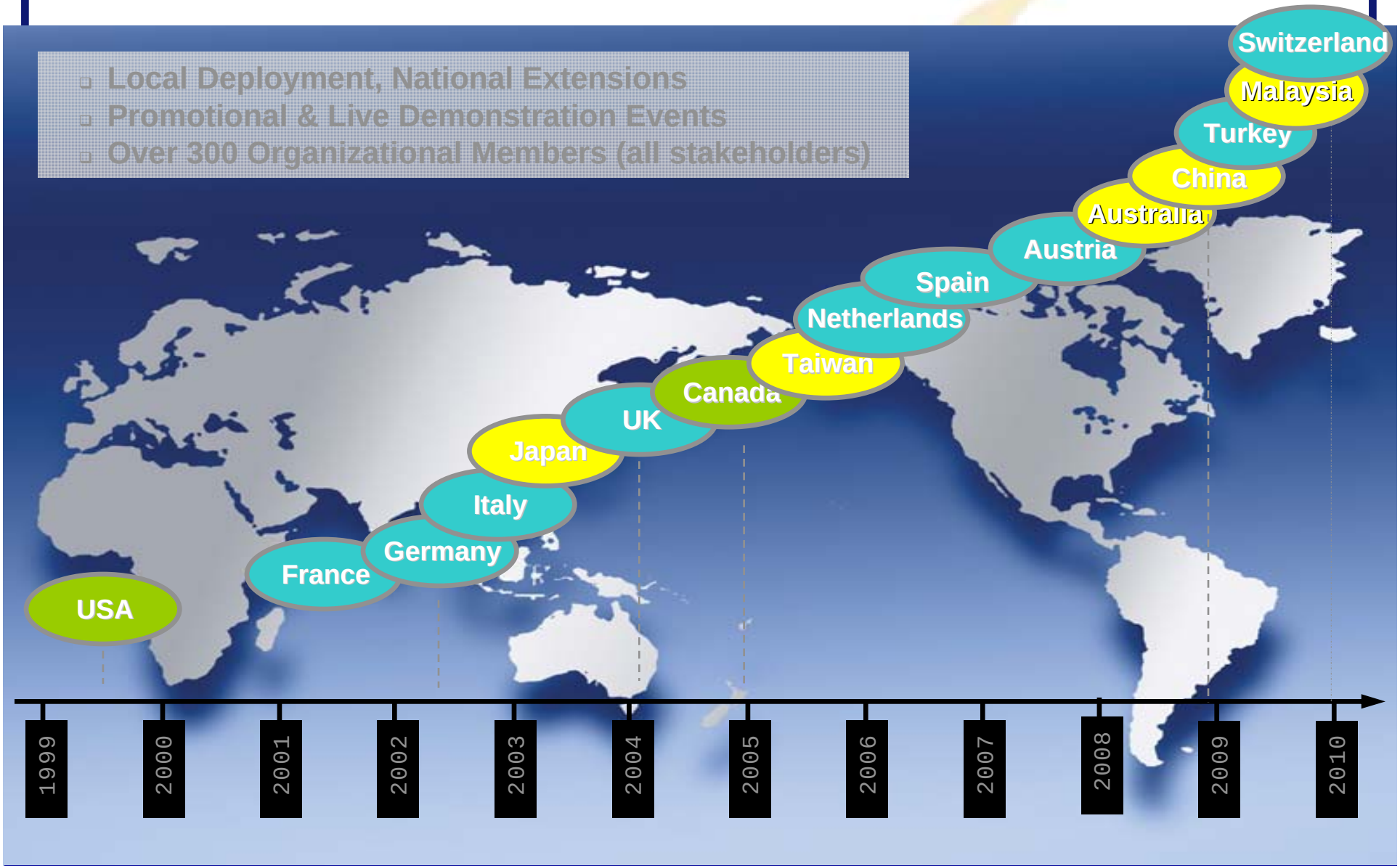
Common elements of the Medical Device SoS enviroment

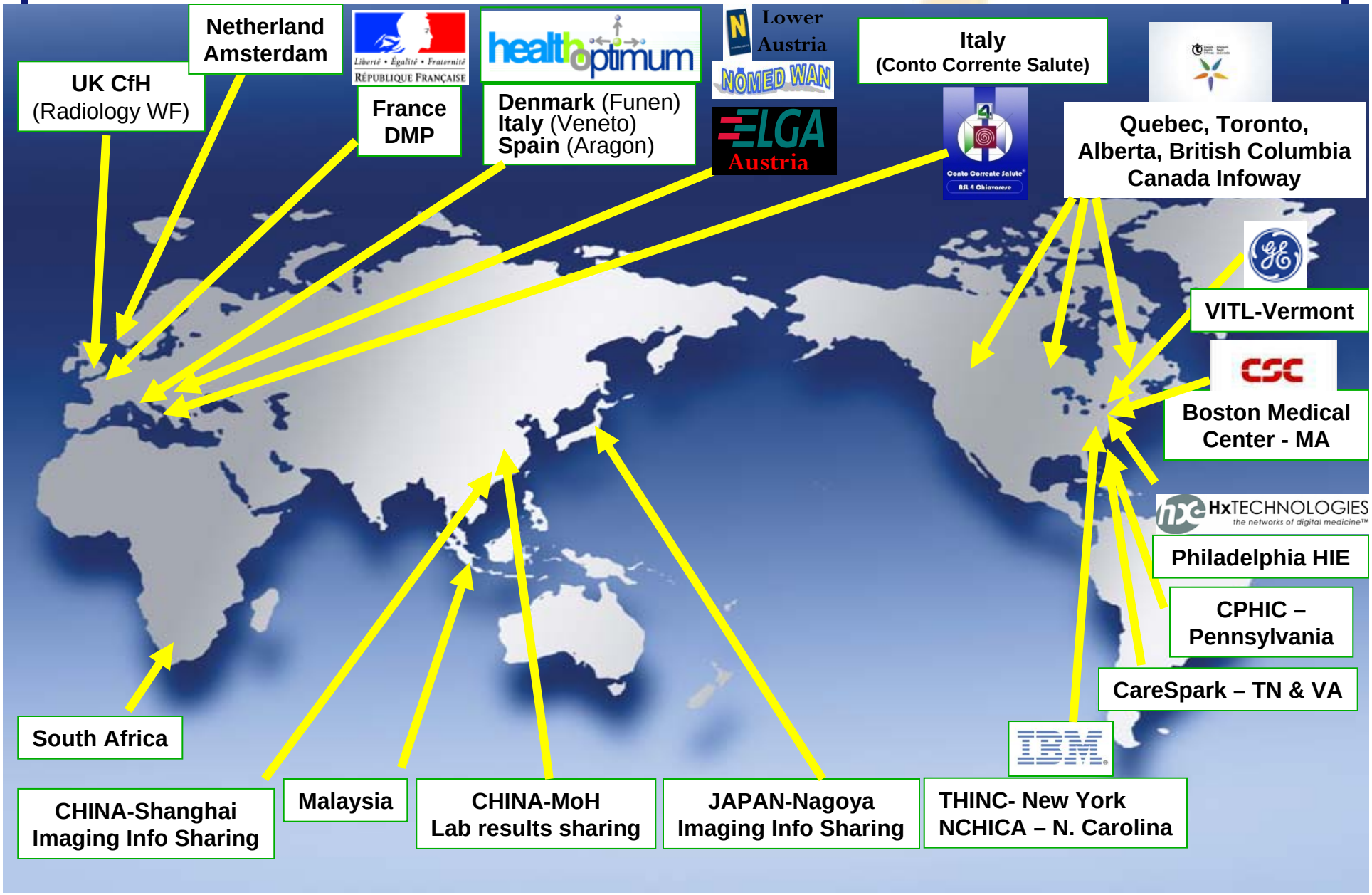
- Today, almost 100% Ethernet (IEEE 802.3) and/or WiFi (IEEE 802.11 a/b/g/n) based
  - Rapidly evolving to wide- and metropolitan-area networks (WAN and MAN) for mobile health (mHealth) using IEEE 802.11n/m, 3G and 4G cellular
- Rapid global uptake of ISO/IEEE 11073.x medical device semantic interoperability standards for data structure and content
- Rapid global uptake of open-source Integrating the Healthcare Enterprise (IHE) Electronic Health Record *AND* IHE Patient Care Device (IHE-PCD) data interchange standards

International Adoption of IHE

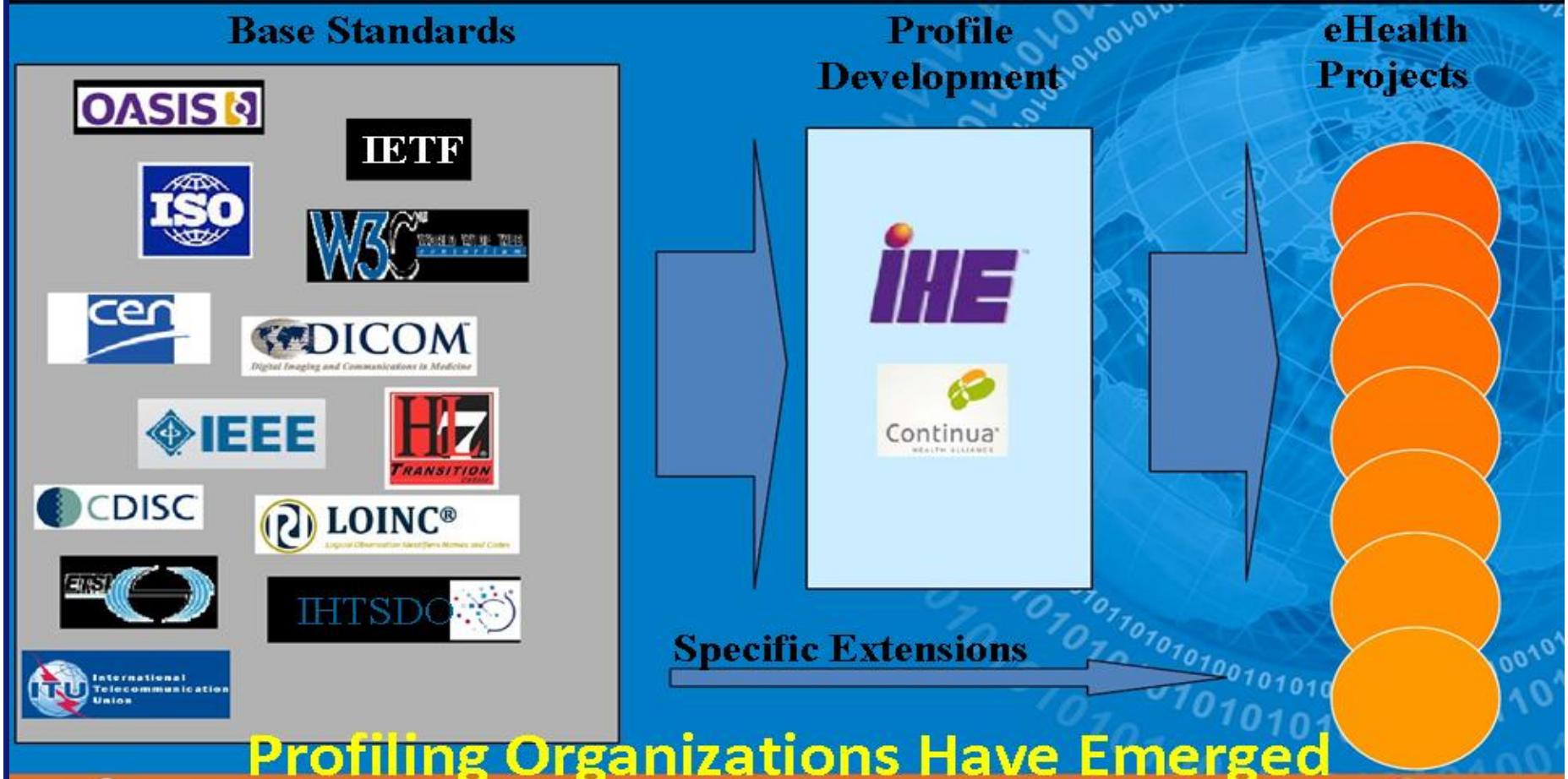


Pragmatic global standards harmonization + best practices sharing

National and Regional Projects Use IHE Profiles



Interoperability: From a Problem to a Solution



Profiling Organizations Have Emerged

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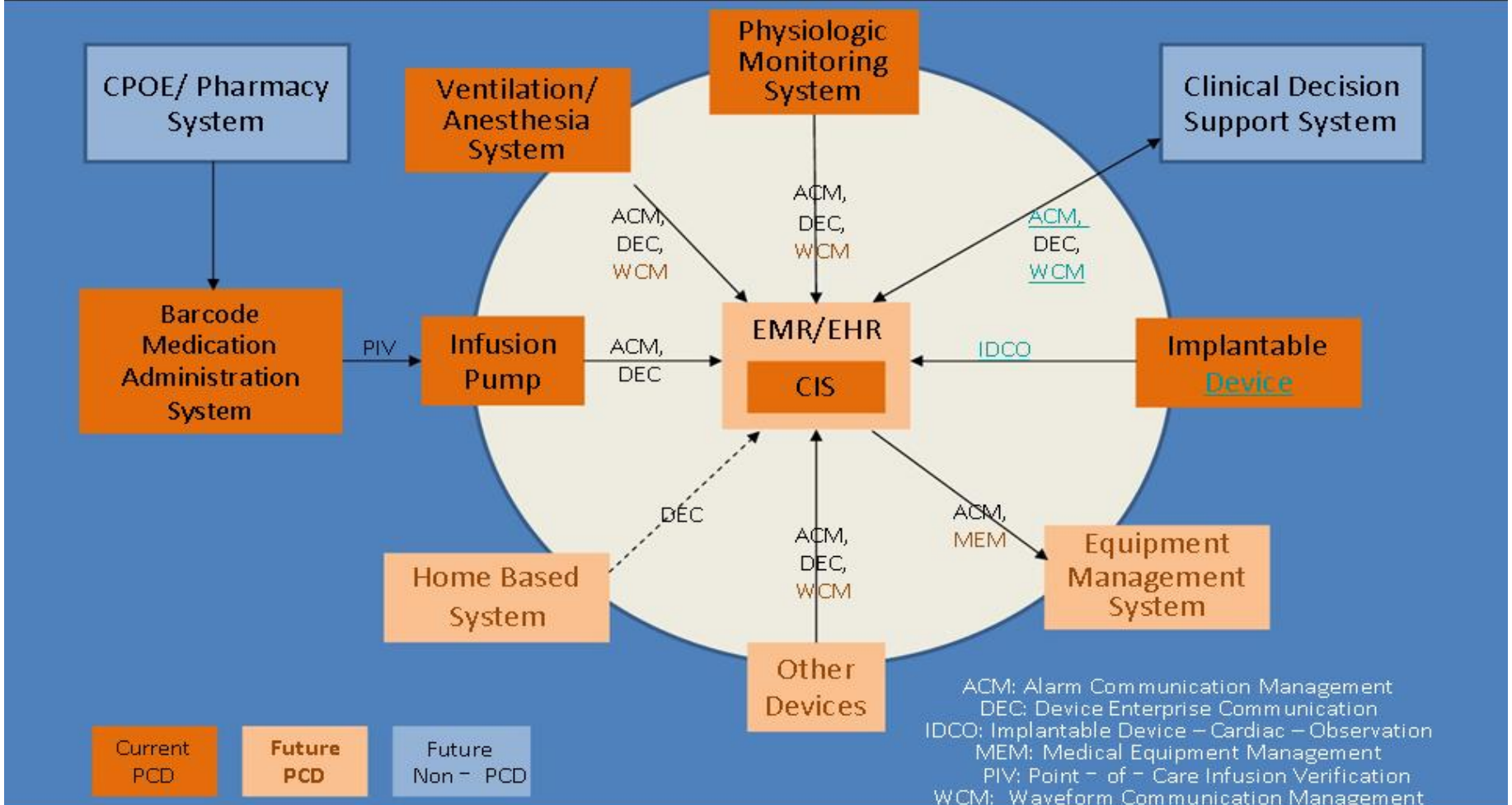
IHE PCD – Profile Overview



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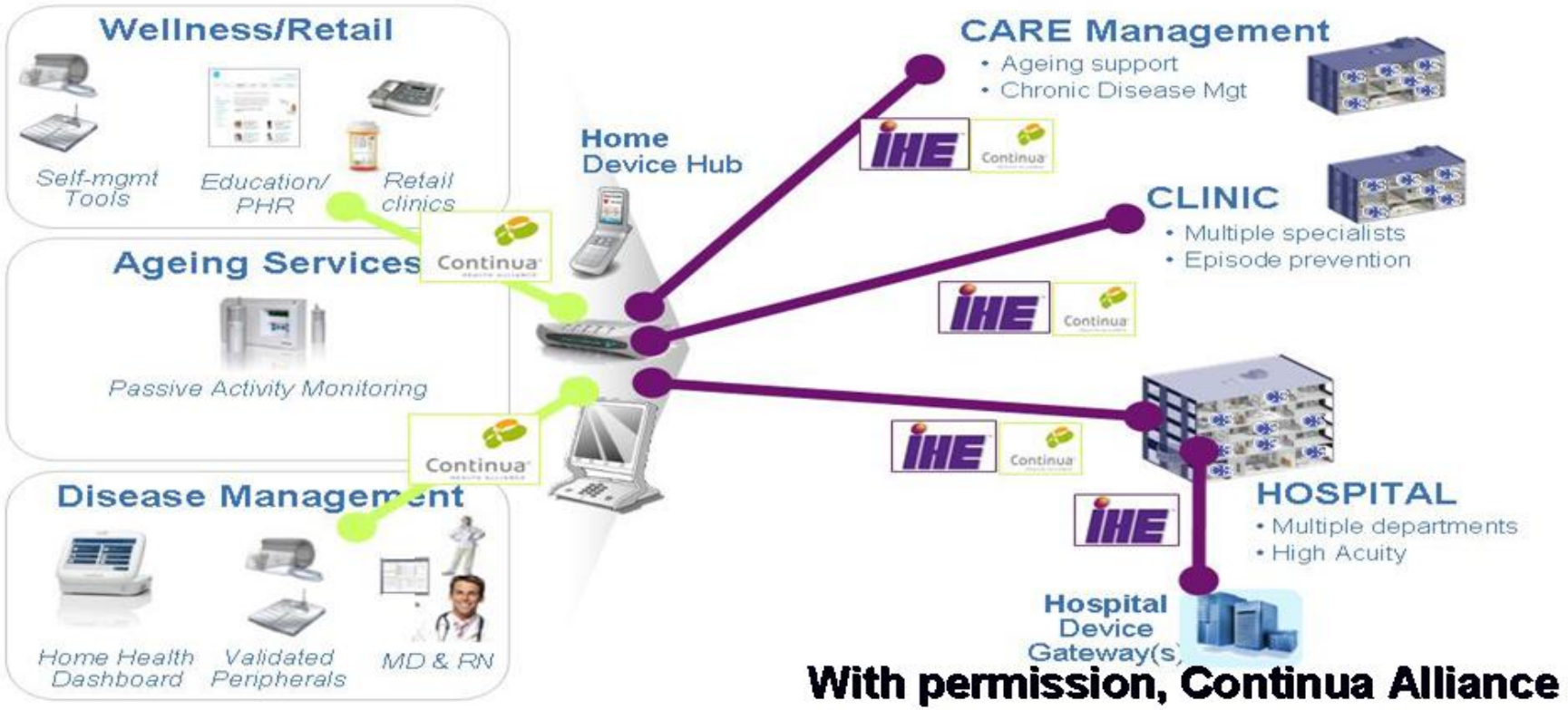
Beginning this Fall, a single data interface architecture can be used by all Continua Personal Health Devices, all IHE-PCD Medical Devices, and all IHE EHRs!

Home health – Key connection Standardized

*IHE and CONTINUA have agreed to support the **a single common IHE DEC profile** for feeding **home device** data and clinical device data into health records*

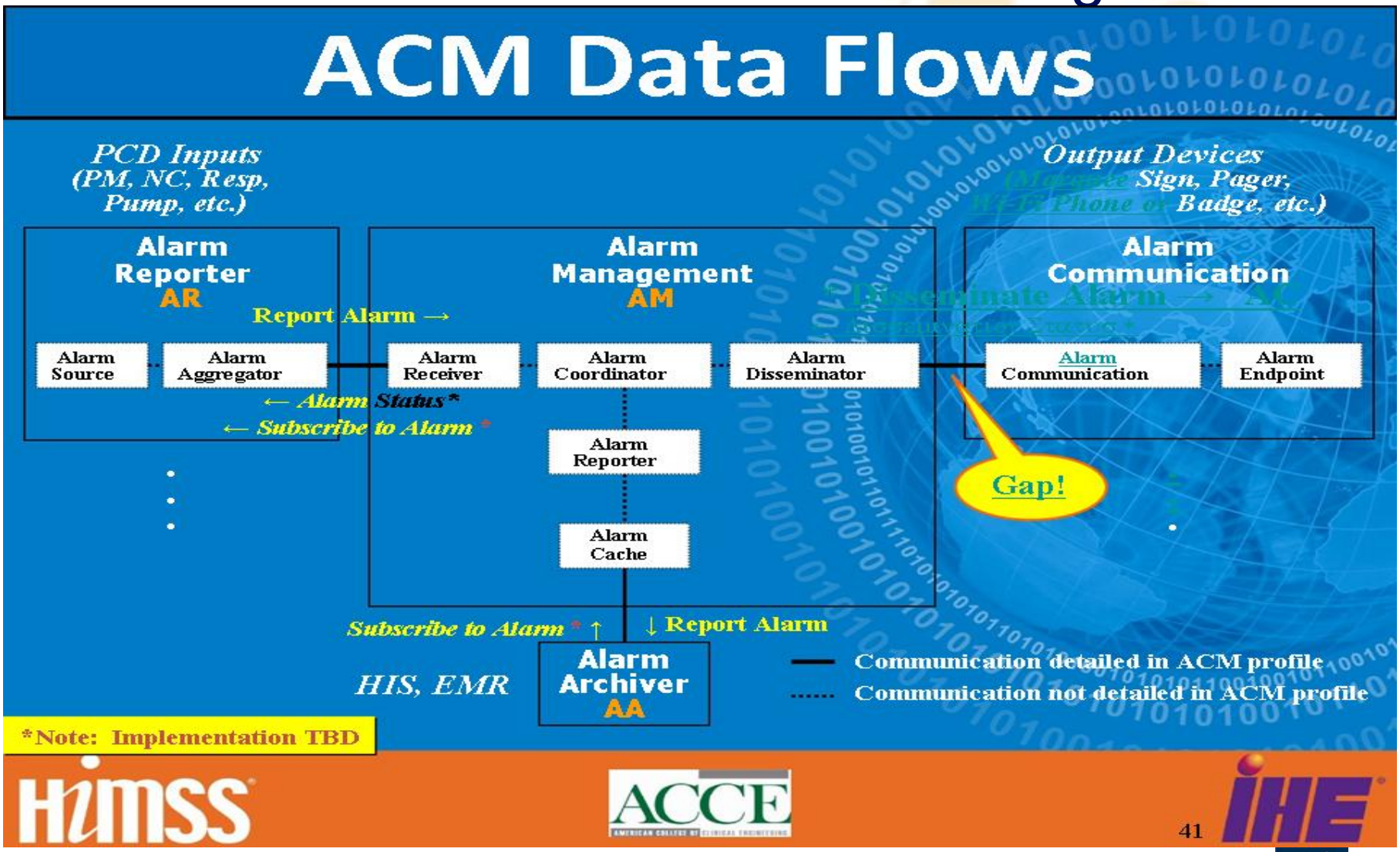


With permission, Continua Alliance

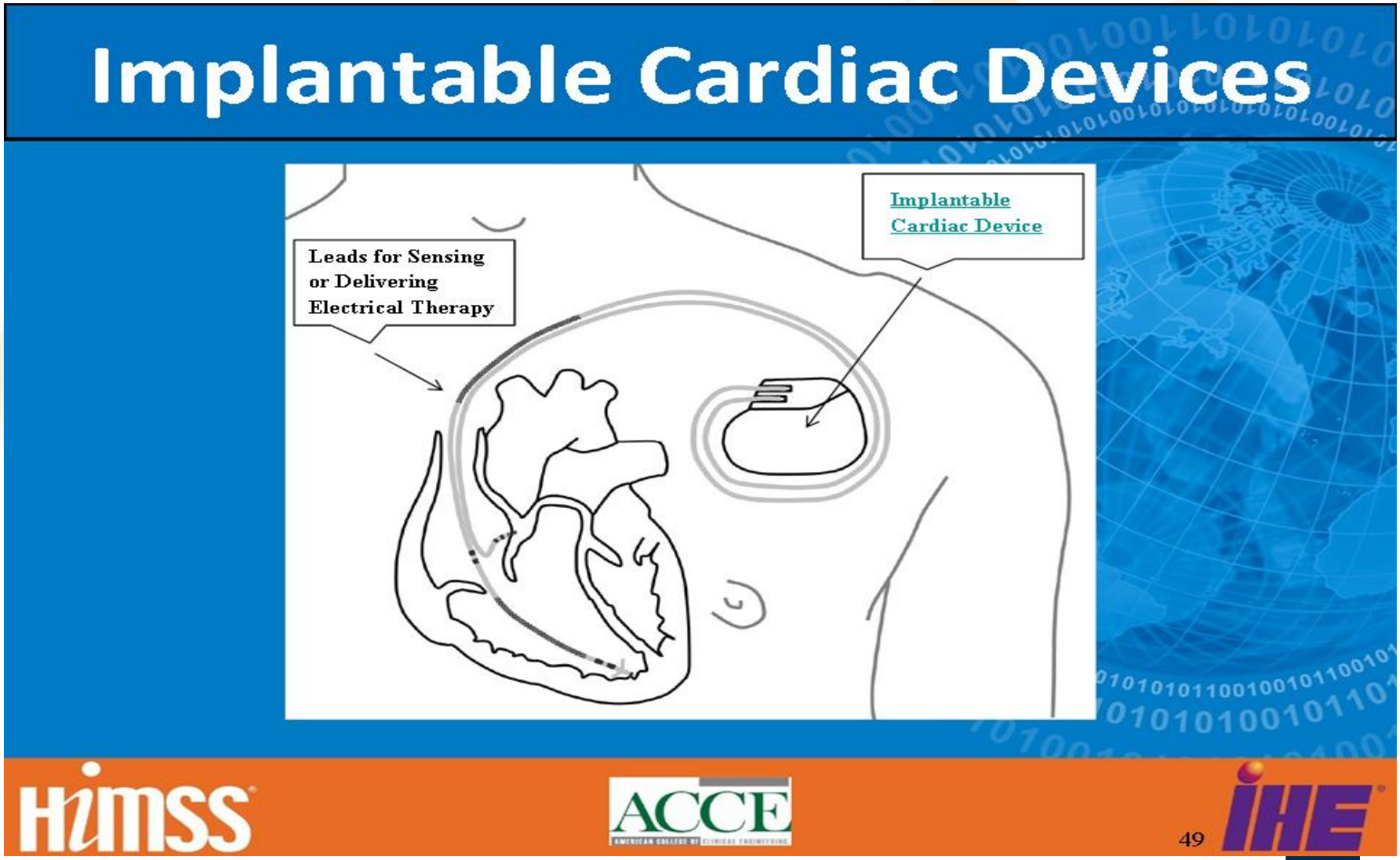
IHE-PCD and Continua "live" in two different but overlapping worlds

- *Continua* – "**Personal Health Devices**" non-regulated personal appliances, non-life-critical settings like home, car, gym, simple data sets
  - Personal wellness status, chronic illness home care
- *IHE-PCD* – Full-on clinical devices and applications, from home chemotherapy through intensive care, implanted devices, and surgery
  - Becoming MUCH more mobile, including relative acute care management at the home
- *Both products must co-exist in the home, with overlapping missions, different price-points*

e.g., IHE has to tackle life-critical, real time Alarm Communication Management



e.g., IHE-PCD has to tackle implants



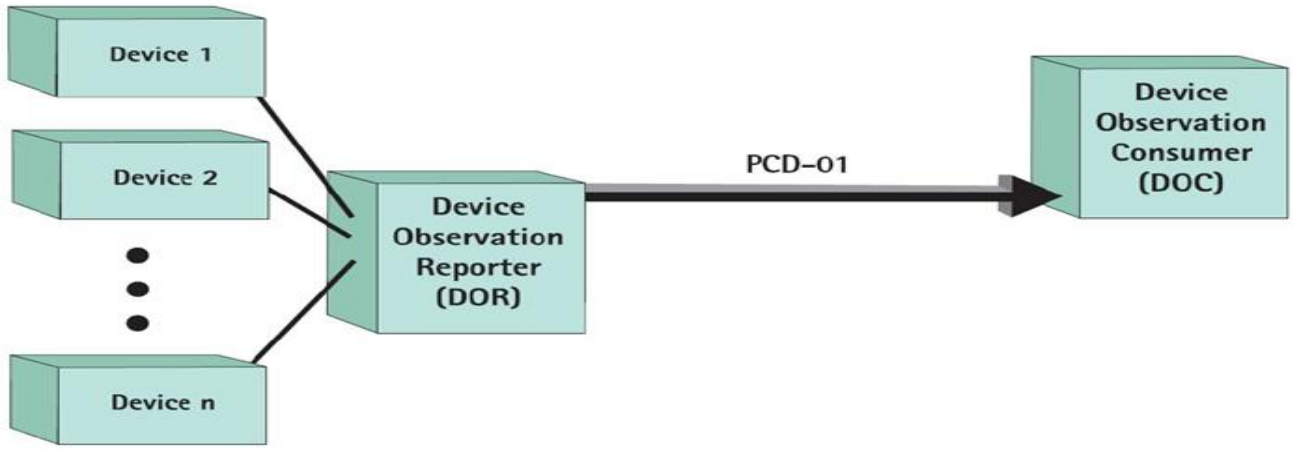
Profiling has emerged as a POWERFUL enabler

- IHE's and Continua's "Integration Profiles" take myriad "base standards" such as DICOM, ICD9/10, HL7, or IEEE and "*CONSTRAINS THE OPTIONALITIES*"
  - e.g., Each standard has a different (or many different) coding choices and data structure locations for Date and Time
  - An Integration Profile ***specifies the SOLE option*** to be used for each standard AND ***specifies a SOLE Global Standard*** for "Universal Timekeeping" (typically "internet time")

e.g., IHE-PCD and Continua-WAN have adopted the same "DEC" profile to enable interoperability

Device to Enterprise Comm. (DEC)

The Device to Enterprise Communication (DEC) profile allows a consuming device to receive patient clinical information including vitals, settings, demographics and location from a reporting device.



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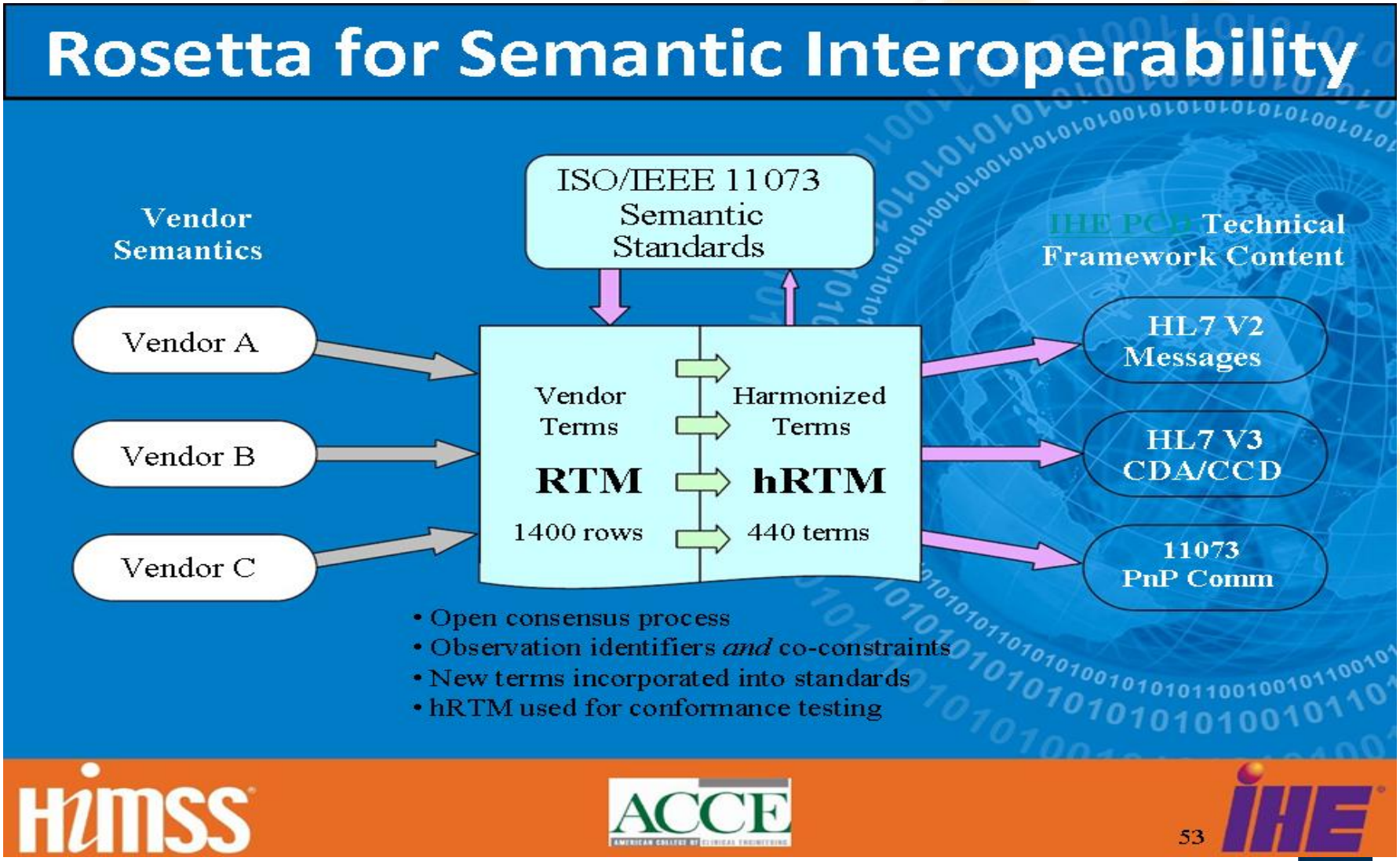
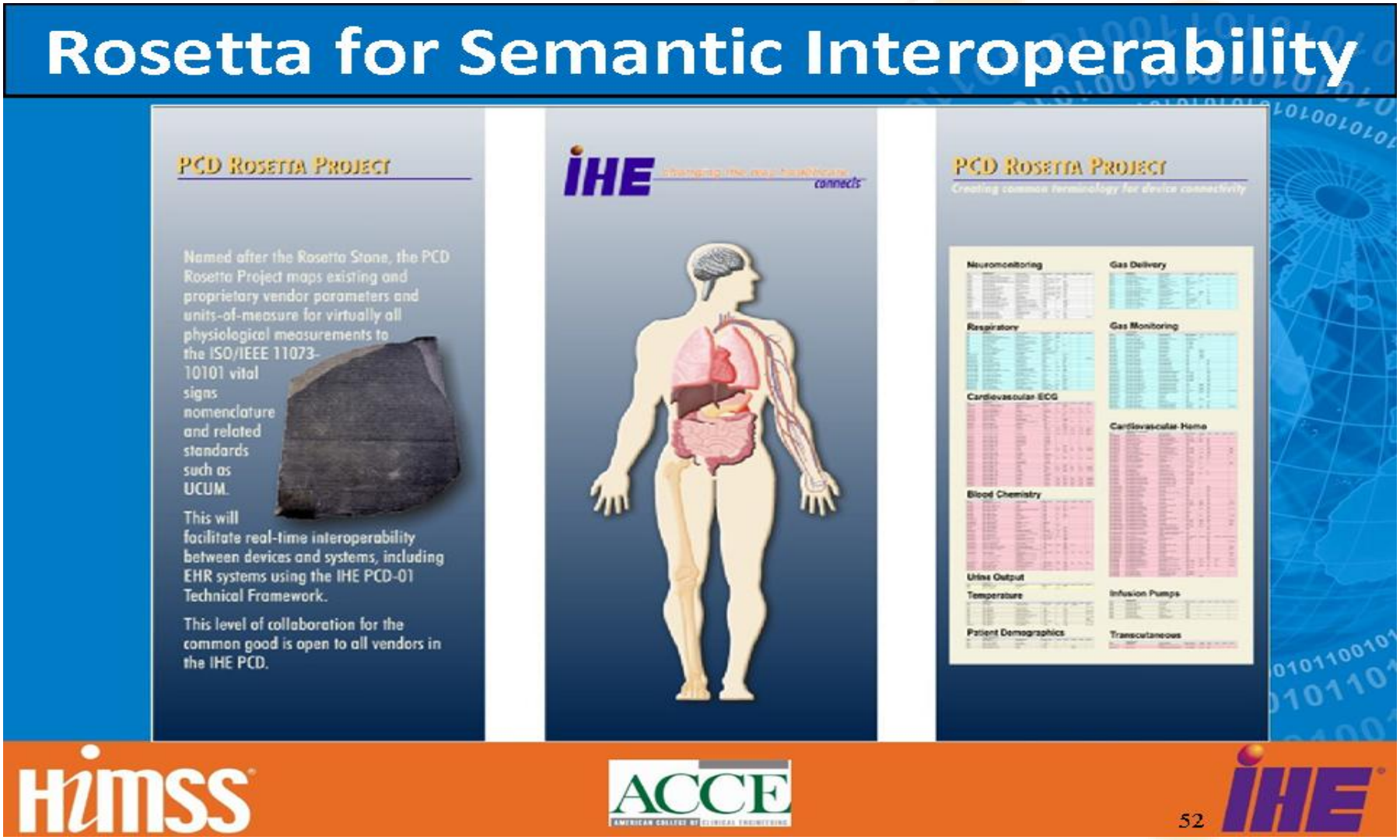
The EMBS IEEE 11073.x standards are foundational to both Continua and IHE



IHE's *Rosetta Project* maps ALL vendor clinical coding to each other via IEEE 11073



IHE Rosetta Project

- Now over 400 columns of vendor-specific mappings of clinical variables and globally-harmonized UCUM units of measurements
  - e.g., Every brand of ECG monitor, EHR, or IV pump can “know” the kinds of data that other branded products might send, and can therefore translate that information correctly
  - This is ESSENTIAL for life-critical data preservation, interpretation, and, ultimately, closed-loop multi-vendor systems

All IHE and IHE-PCD profiles are FREE to download and use

- www.IHE.net and www.IHE.net/PCD

- Continua Alliance profiles are proprietary, and require membership in the Community

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Opportunities

- Flexible, multi-vendor interoperable medical device solutions can finally be considered for deployment to facilitate telemedicine, eHealth, and mHealth as well as acute care, in-hospital deployment
  - *Human data entry will be minimized, freeing up valuable physican, nurse, and caregiver time AND reducing errors!*
- Asset management (procurement, deployment, maintenance) will become easier and easier as more interoperable products come to market
- The Electronic Medical Record systems will begin to share timely and accurate data regionally and nationally
  - **Personalized Health and Wellness, Pervasive Healthcare (pHealth), and Ubiquitous Healthcare (uHealth) can emerge.**
  - **Personal, national, and global quality of care, clinical outcomes, and overall population health will become easier to see and manage in real time!**

Consequences and Challenges

- Interoperable systems are relatively complex and have many hidden interdependencies
  - When one system or sub-system fails, many systems may fail too
  - Risk assessment and risk acceptance strategies need to emerge for planning and commissioning such systems
    - The ICT exposures, for example, are significant. Consider, e.g., if a single virus or worm enters such systems!
    - Wireless, though it provides essential mobility and point of care interventions, is vulnerable to interference and privacy breaches

There are many System of Systems Engineering (SoSE) Challenges

- e.g., Verification and Validation of SoS is relatively new field of research
- "Emergent Behaviors," i.e., unanticipated human-system interactions and effects are a new class of "unintended consequences" that DEFINE SoSE research
  - e.g., people with complex implants are now traveling on airplanes and are being asked to shut off their wireless interfaces!
- Clinical Engineering needs a whole new toolkit!

New Medical Device SoSE Challenges

- Regulation is going to be tough.
  - Where does the medical device end? The box itself, the interface, the network, the sub-system? Who/what is regulated?
  - Software engineering comes to the forefront, including Software Development Life Cycles (SDLC) including Agile and Extreme methods, Change Management, and State Machine Programming
  - IEC 80001 is a Risk Management strategy that harnesses the hospitals and the vendors together, but who is really responsible??
  - Security management of homogeneous, open, interoperable, and interdependent systems is going to present challenges!
    - On the other hand, relatively autonomous sub-systems might be more robust… *but only if designed that way.*

Help take on one challenge: Facilities for Wireless Medical System and Interoperability Testing are needed

This field will continue to evolve, and contemporary teaching and research resources do not exist.

I intend to provision an initial Wireless Medical Device Interoperability Laboratory this winter at Drexel University's School of Biomedical Engineering, Science and Health Systems.

Quite frankly, MANY more are needed around the world to support R&D in this important area properly.

We will be glad to collaborate with YOU to set up your own!

Presentation Review

1. The Evolution of “Medical Devices” to “Medical Device System of Systems (SoS),” and the Interoperable Medical Device Environment
2. Global Medical Device Interoperability Standards
3. Opportunities, Consequences, Outcomes, and Challenges

Resources

- www.CEITCollaboration.org
- www.ContinuaAlliance.org
- www.HITSP.org
- www.IHE.net
- www.IHE.net/PCD
- http://standards.ieee.org/getieee802/

For further information:

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or just Google™ me!!

I will be glad to send you a copy of this presentation.

Thank you.