

BREAKTHROUGH



SOLUTIONS

Engineers Australia CBME:

IHE Patient Care Devices (PCD) – What is REAL vs. what is a DREAM?

Adelaide – 26.11.2008

Todd Cooper, Breakthrough Solutions Foundry, Inc.

Background perspectives...

1st Device Software Dude

25+ Years Experience Architect

2nd Medical Device

ISO 13485 / GHTF...

3rd IHE “Devices” Dude

Patient Care Device (PCD) Domain

Real vs. Dream?!

...not a Clinical Dude!

What's on...

- ✓ ***Open Standards-based Interoperability: The Promise!***

Great Expectations?

IHE PCD – Provider value propositions...

- **Integrity of data** – automatic population of all information systems – reducing medical errors
- Automated systems **saves time for clinicians**
- Improved **agility** of enterprises to meet varied patient loads
- Improved **life-cycle cost** of ownership
- Automated clinical **data capture** for EHR
- Access to patient data across devices and systems so custom communication interfaces can be eliminated. **Allows for best of breed selection**

Great Expectations?

IHE PCD – Vendor value propositions...

- **Simplify** product development process
- Spend time **innovating** rather than doing infrastructure work
- Facilitate clinical decision support - innovation - **increased functionality**
- **Reduce regulatory** impact/work
- Improve patient safety - **reduce liability** - make operations easier - device aware

Great Expectations?

From ECRI: improved...

- ✓ ***Patient safety***
- ✓ ***Quality of care***
- ✓ ***Clinical workflow efficiency***

The Dream *(Cliff Notes Version)*

... fundamental value propositions:

Heterogeneity

Multiple manufacturers + multiple device modalities coexisting over a **shared infrastructure**

Semantic Comparability

Ability to respond to clinical context, compare information from different healthcare facilities, and interrogate systems across enterprises, driving clinical decision support systems with an economic business model.

Real-time Availability

Ability to provide data in a time frame appropriate to the physiologic function being measured, displayed or affected (controlled).

The Dream ... deferred...

Why has it not yet happened?

- *Incomplete standards ... but no longer the case!*
- *Uncoordinated & inconsistent demand from providers and other user stakeholders*
- *Undefined stakeholder value propositions*
- *Resources - esp. for standards-related projects*
- *Infrastructure is a hard sell: Concentrated cost
- Diffuse benefit (Dr. Brailer)*

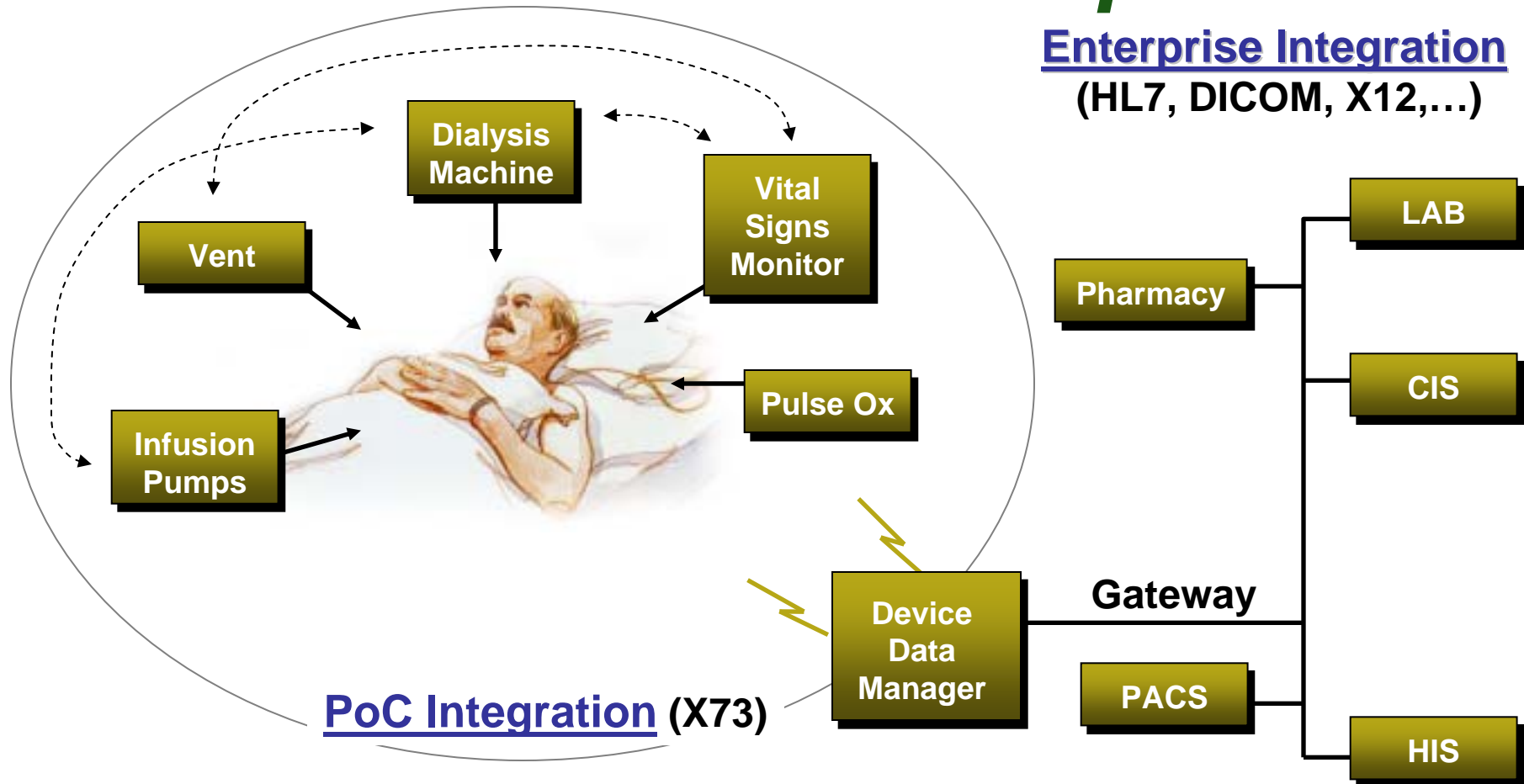
A business issue – not a lack of technology

What's on...

✓ *Key concepts ...*

PoC vs. Enterprise...

...from sensor to enterprise

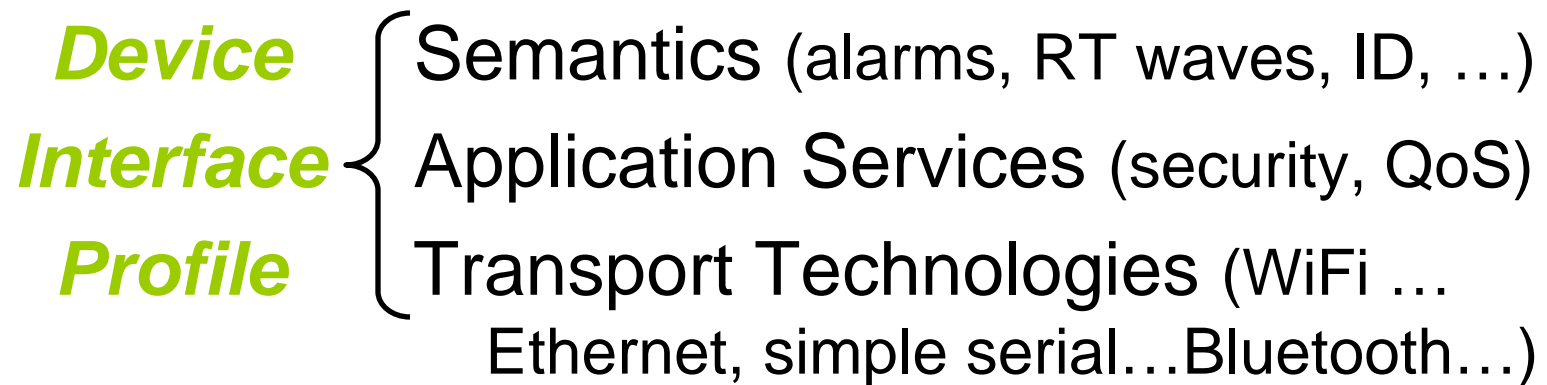


Multi-vendor environment

Requires both *semantic* & *technical* interoperability

Multi-layered Integration Profiles

Device integration involves many levels...



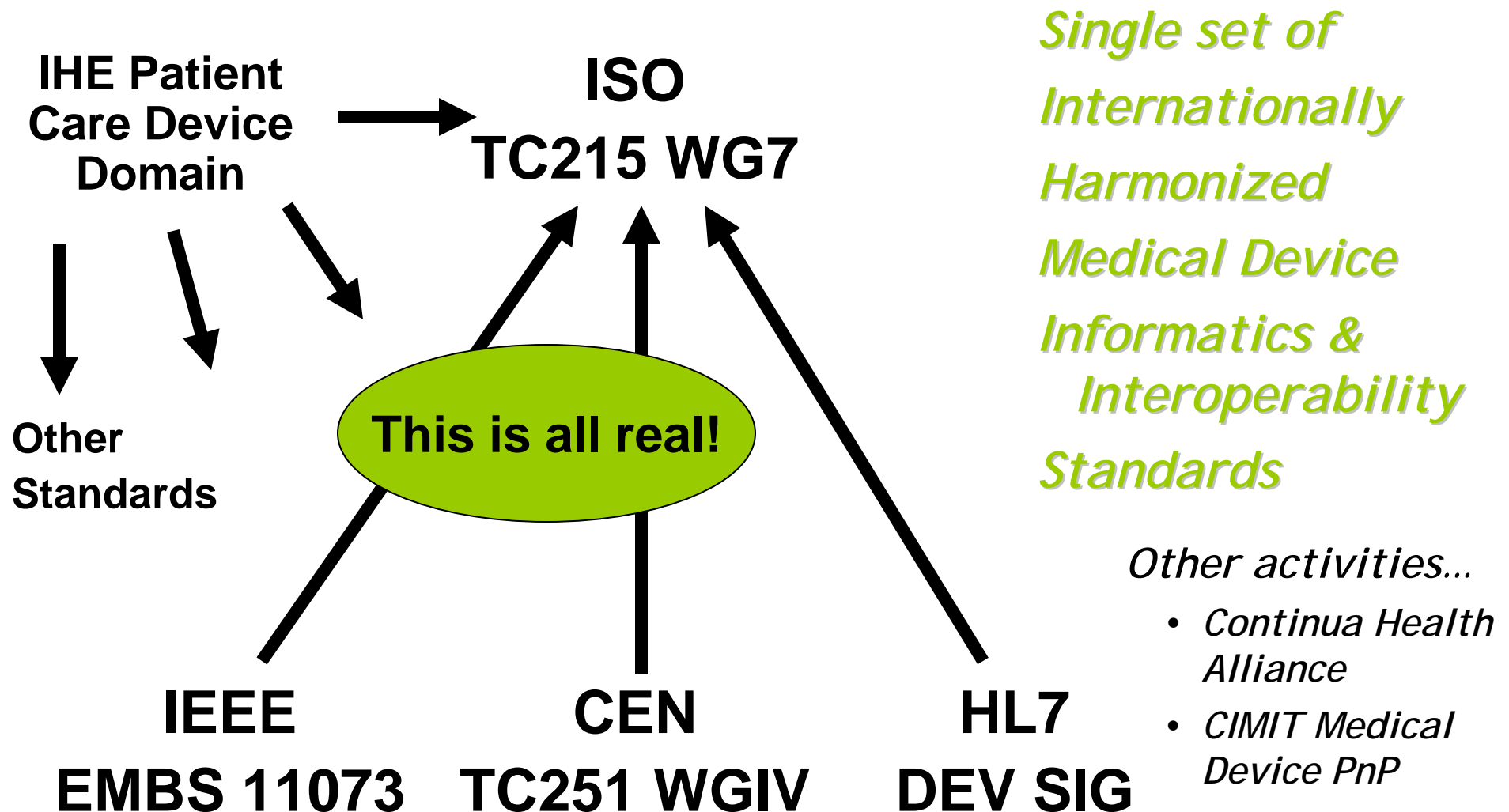
Standards-based interoperability profiles are required...from sensor to transmitter to abstract semantics!

What's on...

- ✓ *Open Standards-based Interoperability:*

SDO's on the same page!

Standards Coordination



What's on...

- ✓ *Getting the job done: IHE ... PCD*

Standards are not enough

- *Standards are ...*
 - ✓ **Foundational** - interoperability and communications
 - ✓ **Broad** - varying interpretations and implementations
 - ✓ **Narrow** - may not consider relationships between standards domains
 - ✓ **Plentiful** - often redundant or disjointed
 - ✓ **Focused** - standards implementation guides typically focus on a single standard

IHE provides a standard process for implementing multiple standards

These are increasingly real!

These are real!

Develop technical specifications

Testing at Connectathons

IHE Demonstrations

Products with IHE

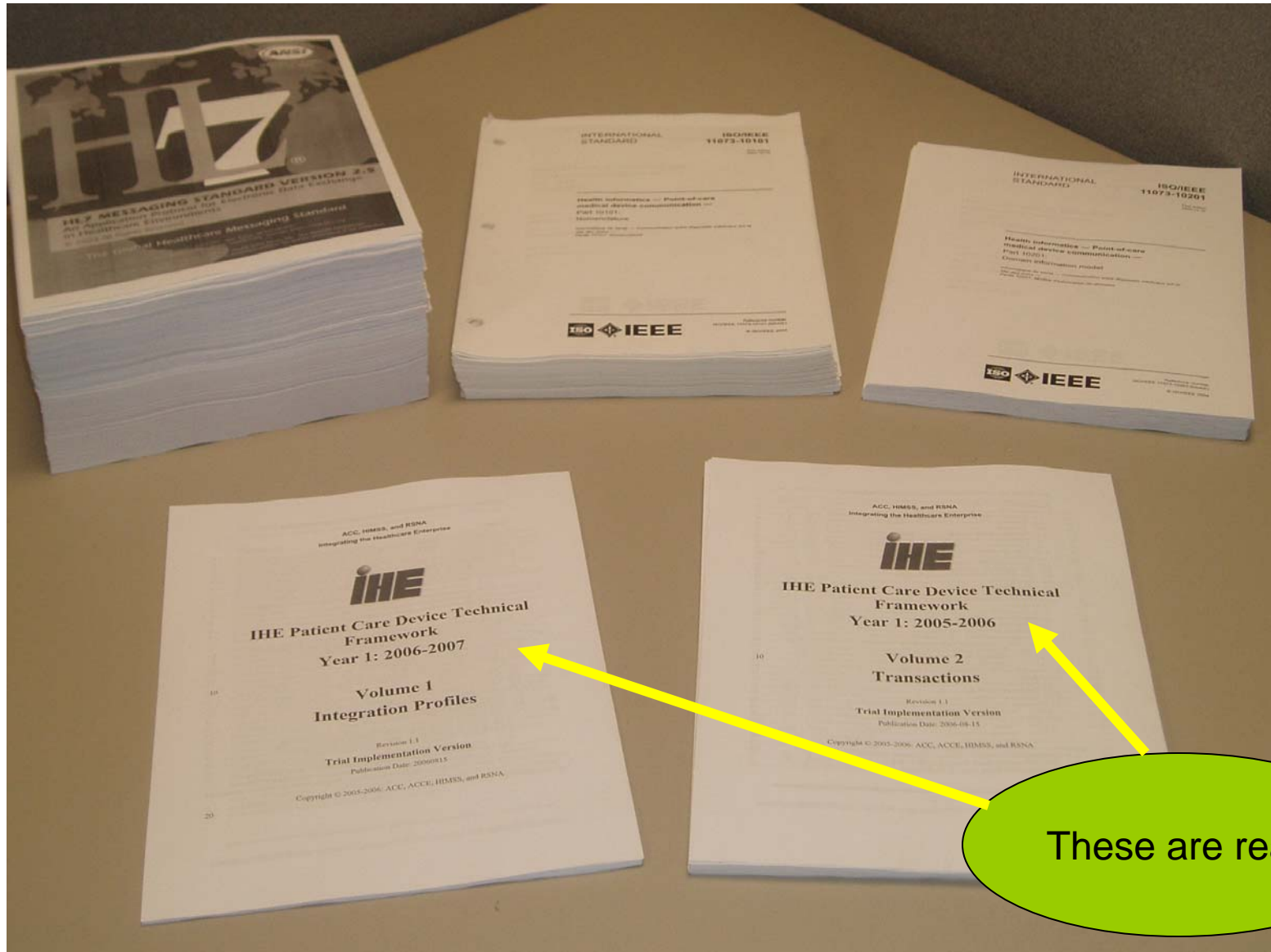
Easy to integrate products

Timely access to information

Document Use Case Requirements

Identify available standards (e.g. HL7, DICOM, IETF OASIS)

IHE PCD DEC: Simplified Specs



IHE International Board

Regional Deployment

Global Development

IHE North America

IHE Asia-Oceania

Re-org almost complete!

Japan

Taiwan

IHE Europe

Austria

France

Germany

Netherlands

Italy

Norway

Spain

Sweden

UK

Radiology

IT
Infrastructure

Laboratory

Cardiology

Patient Care
Coordination

Pathology

Radiation
Oncology

Patient Care
Devices

Eye Care

Public Health, Quality
and Research

Professional Societies / Sponsors

ACC
ACCE
ACEP

ACP
GMSI
HIMSS

RSNA
SFR
SFIL

COCIR
EAR-ECR
DRG

SIRM
BIR
EuroRec

ESC

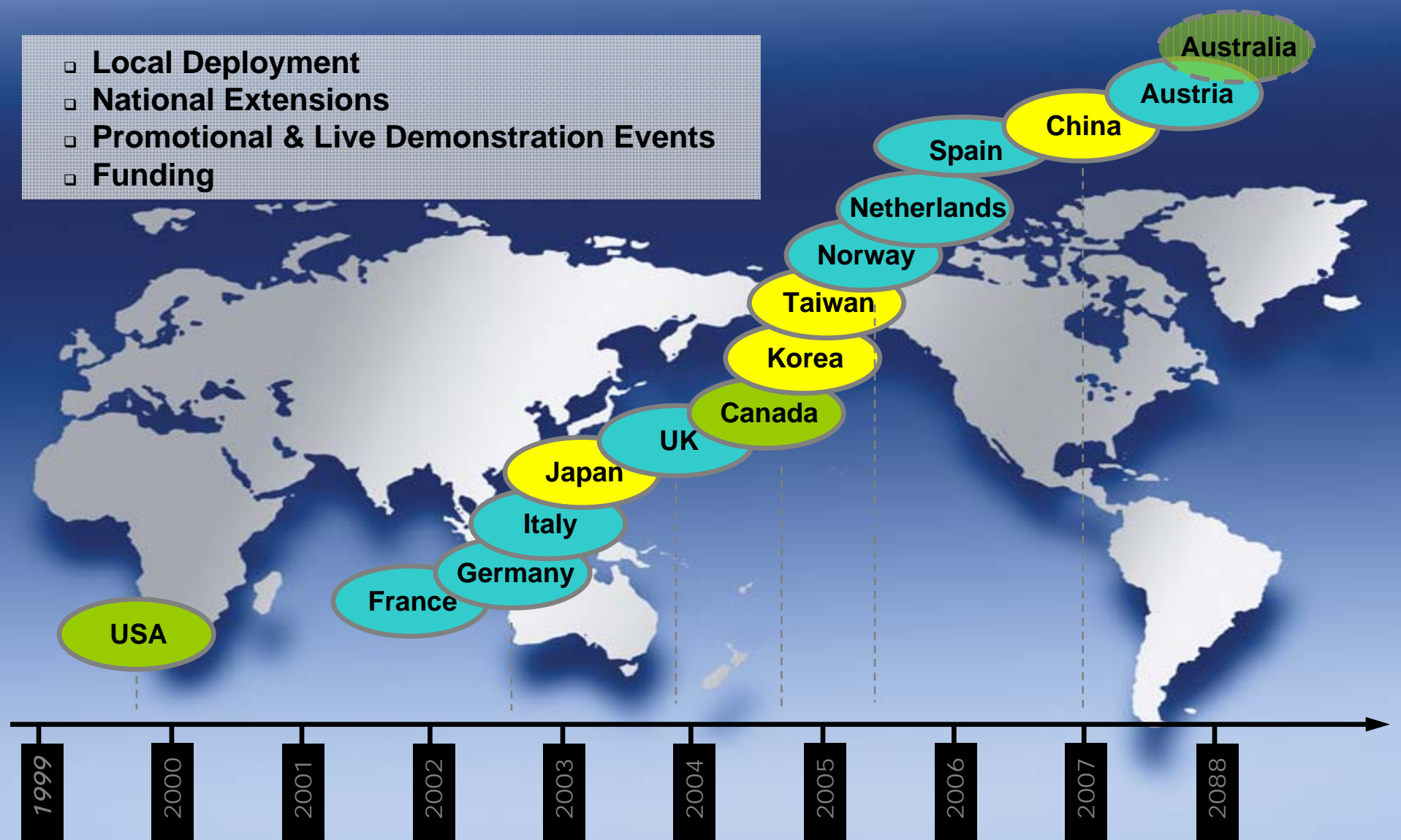
JAHIS
JIRA
JRS

METI-MLHW
MEDIS-DC
JAMI

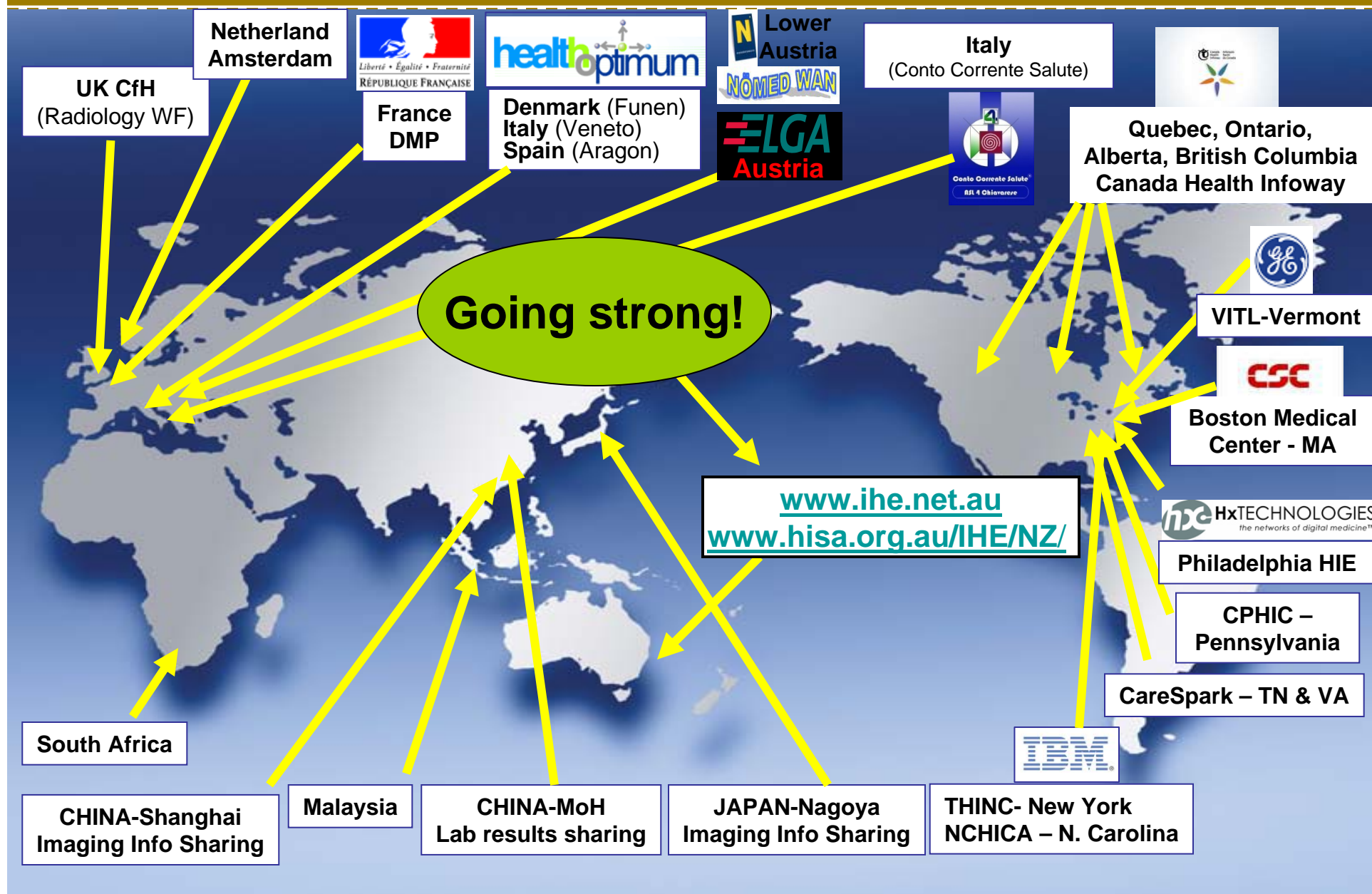
Contributing &
Participating
Vendors

International IHE Growth

- ❑ Local Deployment
- ❑ National Extensions
- ❑ Promotional & Live Demonstration Events
- ❑ Funding

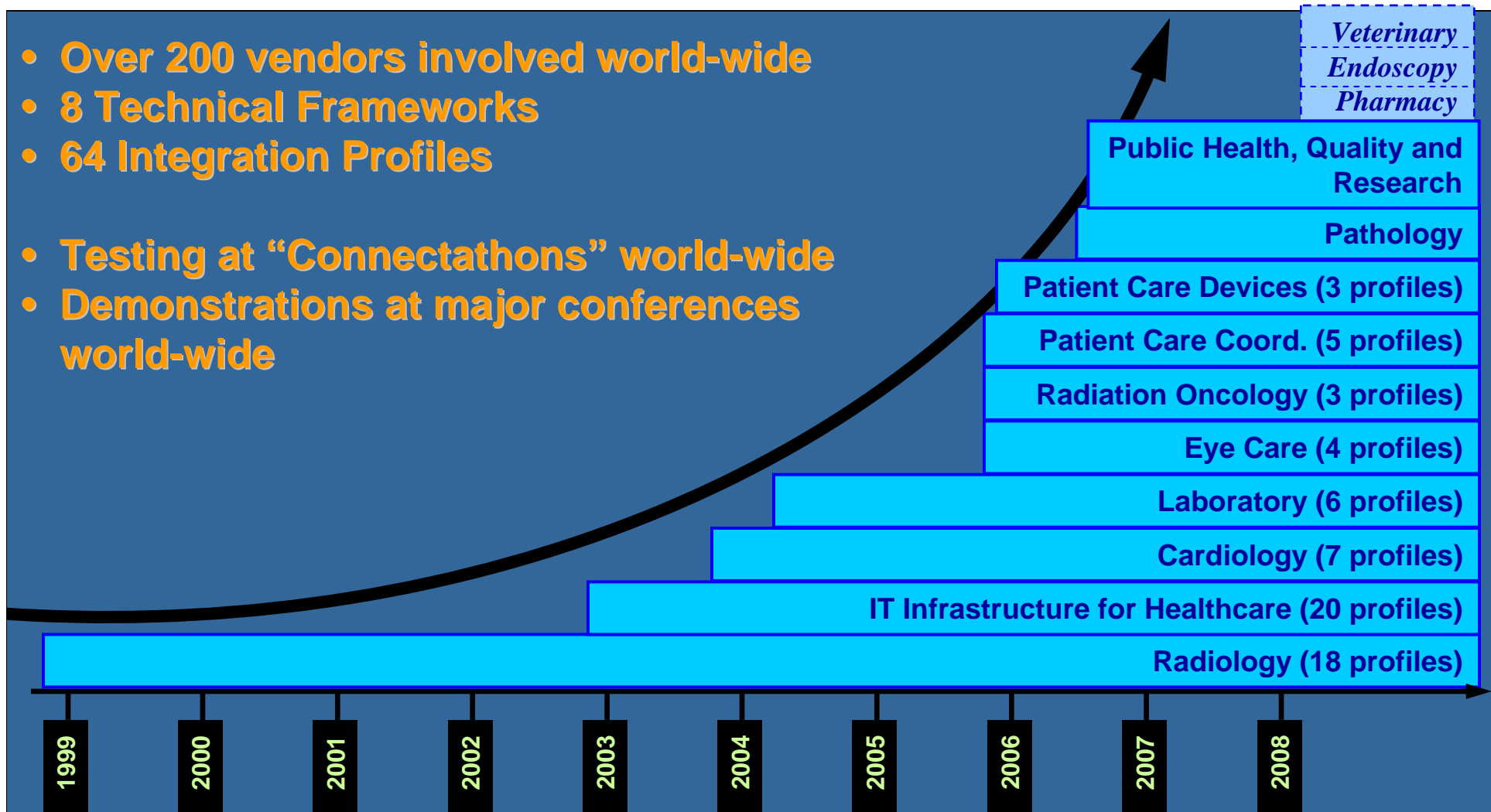


National and Regional Projects Using IHE Profiles



IHE Domain Growth

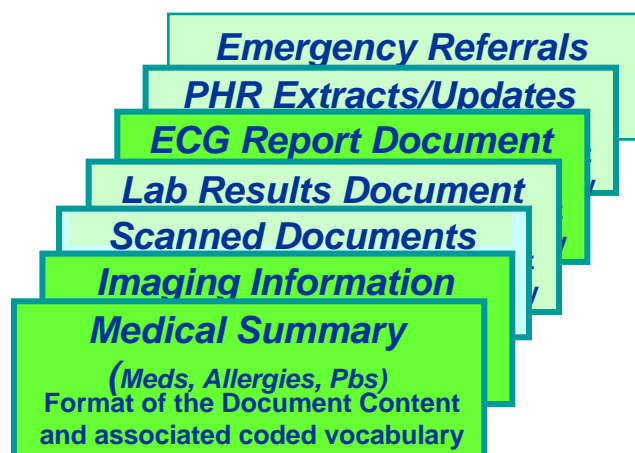
- Over 200 vendors involved world-wide
- 8 Technical Frameworks
- 64 Integration Profiles
- Testing at “Connectathons” world-wide
- Demonstrations at major conferences world-wide



IHE Profiles for Health IT Networks

What is available and has been added this cycle

Clinical and PHR Content



Health Data Exchange



Basic Patients Privacy Consents

Establish Consents & Enable Access Control

Cross-Enterprise User Attestation

User Attributes from Access Control

Document Digital Signature

Attesting "true-copy and origin"

Audit Trail & Node Authentication

Centralized privacy audit trail and node to node authentication to create a secured domain.

Consistent Time

Coordinate time across networked systems

Patient ID Mgmt

Patient Demographics Query

Patient Identifier Cross-referencing

Map patient identifiers across independent identification domains

Other

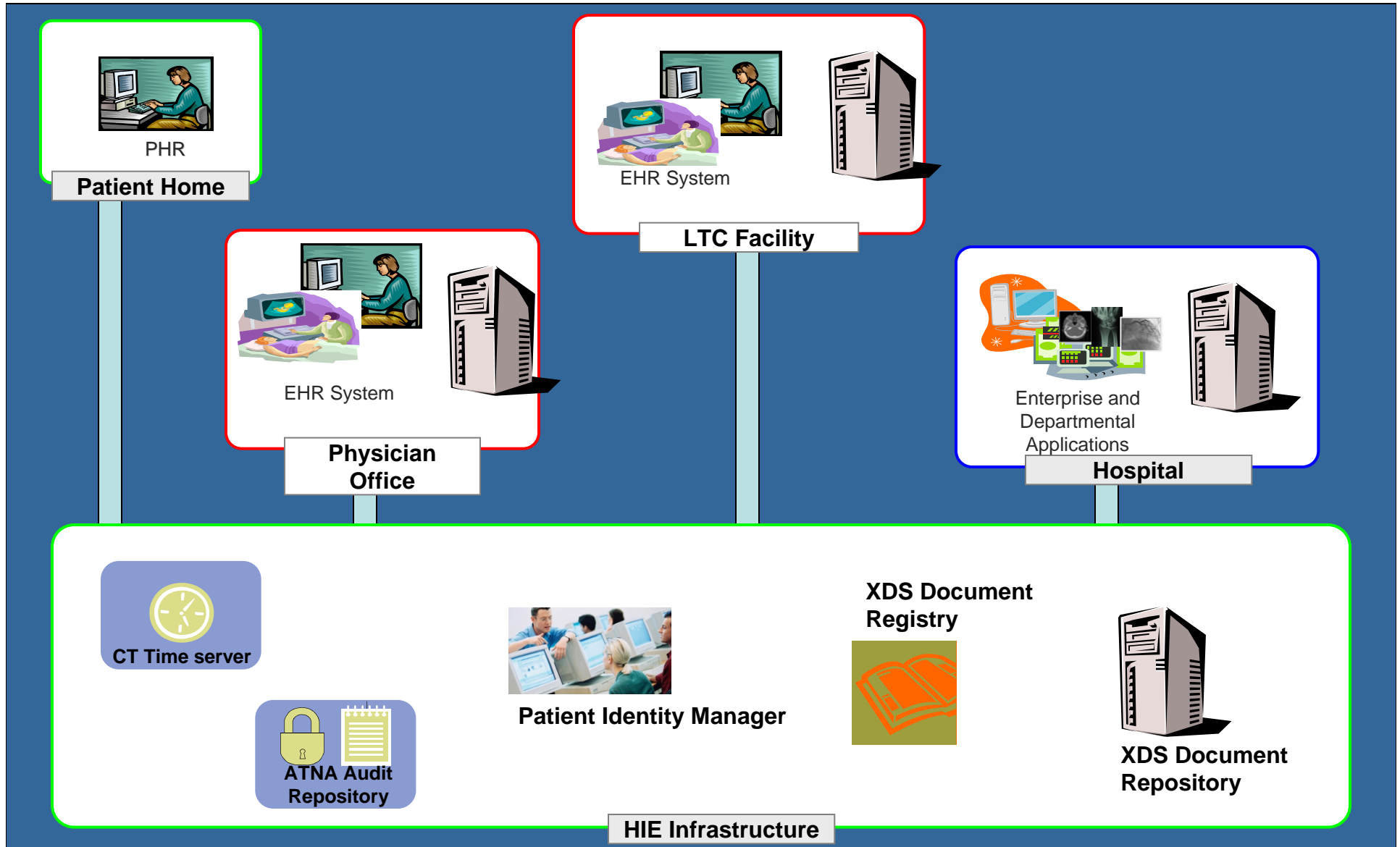
Request Form for Data Capture

External form with custom import/export scripting

Notification of Document Availability

Notification of a remote provider/ health enterprise

IHE Architecture



IHE Patient Care Devices (PCD)

IHE-PCD Charter

The Patient Care Device Domain is concerned with **Use Cases** in which at least one actor is a **regulated patient care device**. The PCD coordinates with other IHE clinical specialty based domains such as medical imaging and laboratory.

✓ **NOTE:** *Formed in 2005 & sponsored by HIMSS & ACCE*

IHE Patient Care Devices (PCD)

- **Framework Development 2007/2008**
 - Enterprise sharing of Patient Care Data (DEC)
 - Patient Identity Binding to Device Data (PIB)
 - Subscribe to Patient Data (SPD)
- **Key Objectives 2008/2009**
 - Rosetta Stone Terminology Project (RTM)
 - PCD Alarm Communication Management (ACM)
 - Point-of-care Infusion Verification (PIV)
- **Key Objectives 2009 and beyond**
 - Device Point-of-care Integration (DPI)
 - Medical Equipment Management (MEM)
 - Waveform Communication Management (WCM)
 - Query for Bulk Data (QBD)
- **Initial device classes...**
 - vital signs / physiological monitors, infusion pumps and ventilators

IHE Patient Care Devices (PCD)

- *2009 White Paper Proposals*
 - Device Point-of-care Integration (DPI)
 - Medical Equipment Management (MEM)
 - Medical Device Semantic Architecture
 - Regulatory Considerations in Deploying Systems Incorporating IHE PCD Profiles
- *IHE PCD Users Handbook*
 - What is & is not specified in PCD Profiles
 - How to assess PCD profile support
 - System verification & validation testing considerations

HIMSS '08 IHE Showcase

Leadership



GE Healthcare



Implementer



Supporter



Organizational Participants



National Institute of Standards and Technology
Technology Administration, U.S. Department of Commerce

Vendor participation
Increases every month

PCD @ HIMSS '08 IHE Showcase



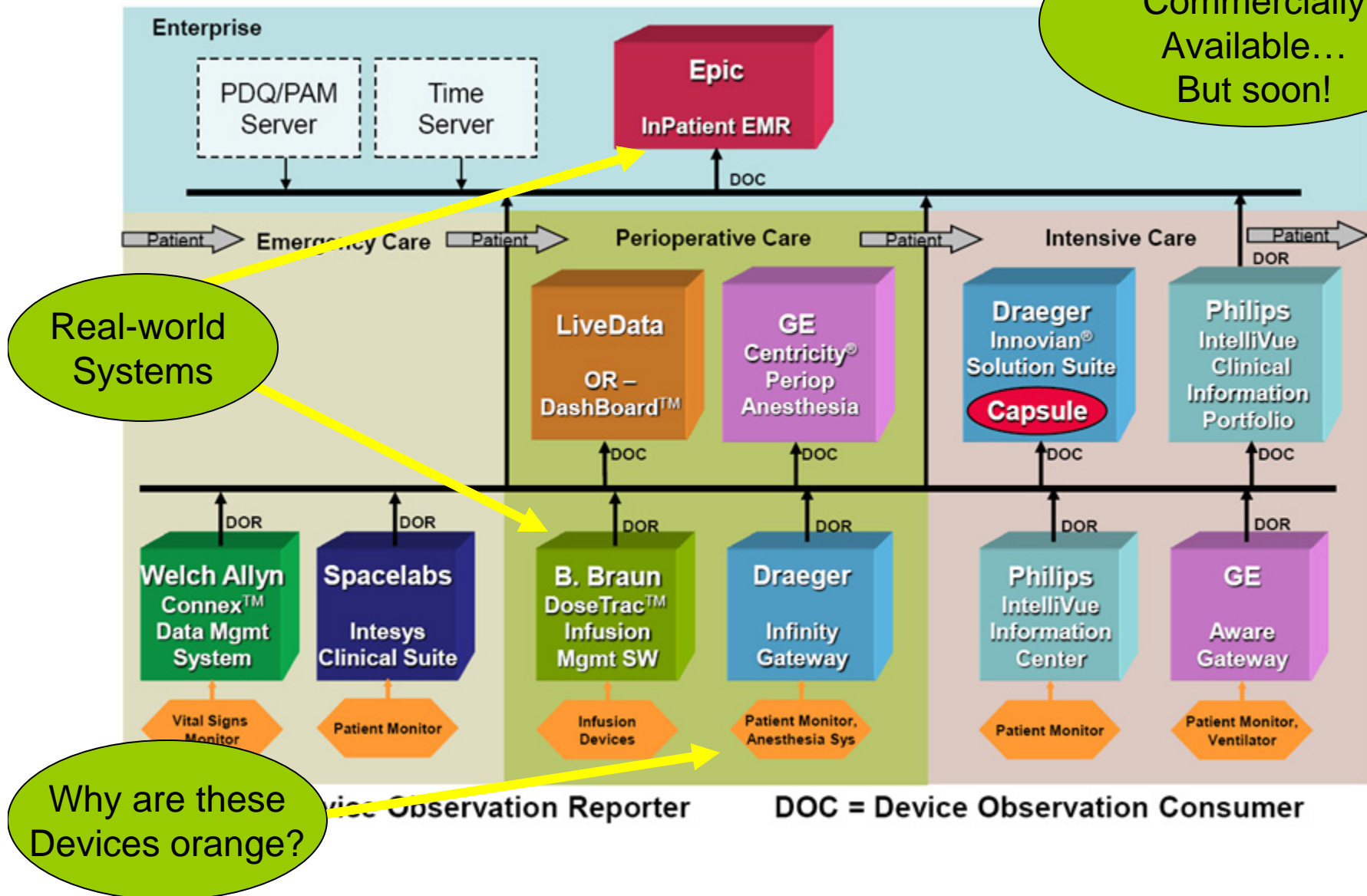
PCD @ HIMSS '08 IHE Showcase



And so did this...

PCD @ HIMSS '08 Systems

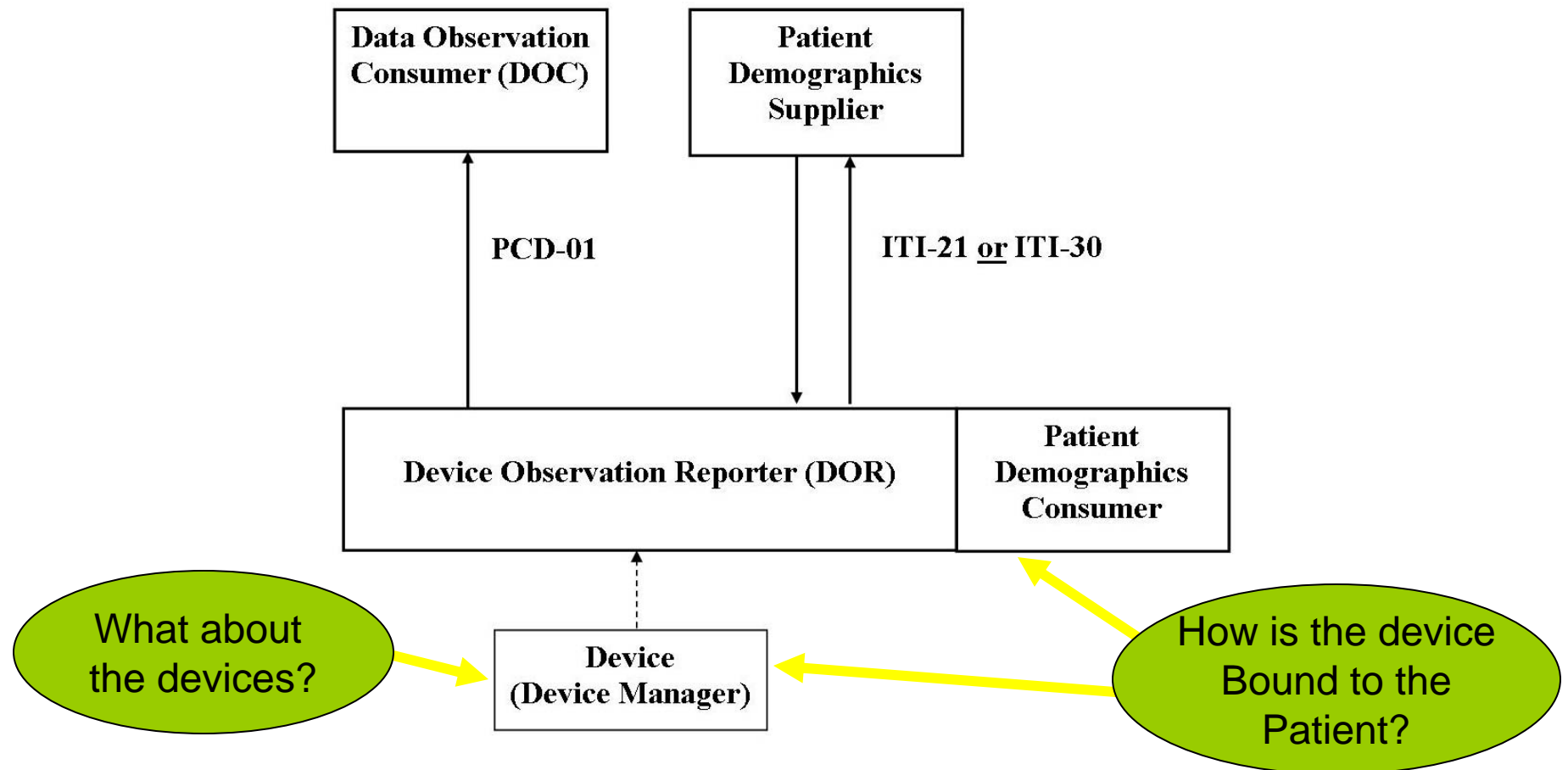
No PCD profiles
Commercially
Available...
But soon!



Why are these
Devices orange?

IHE PCD Profile: DEC w/ PIB

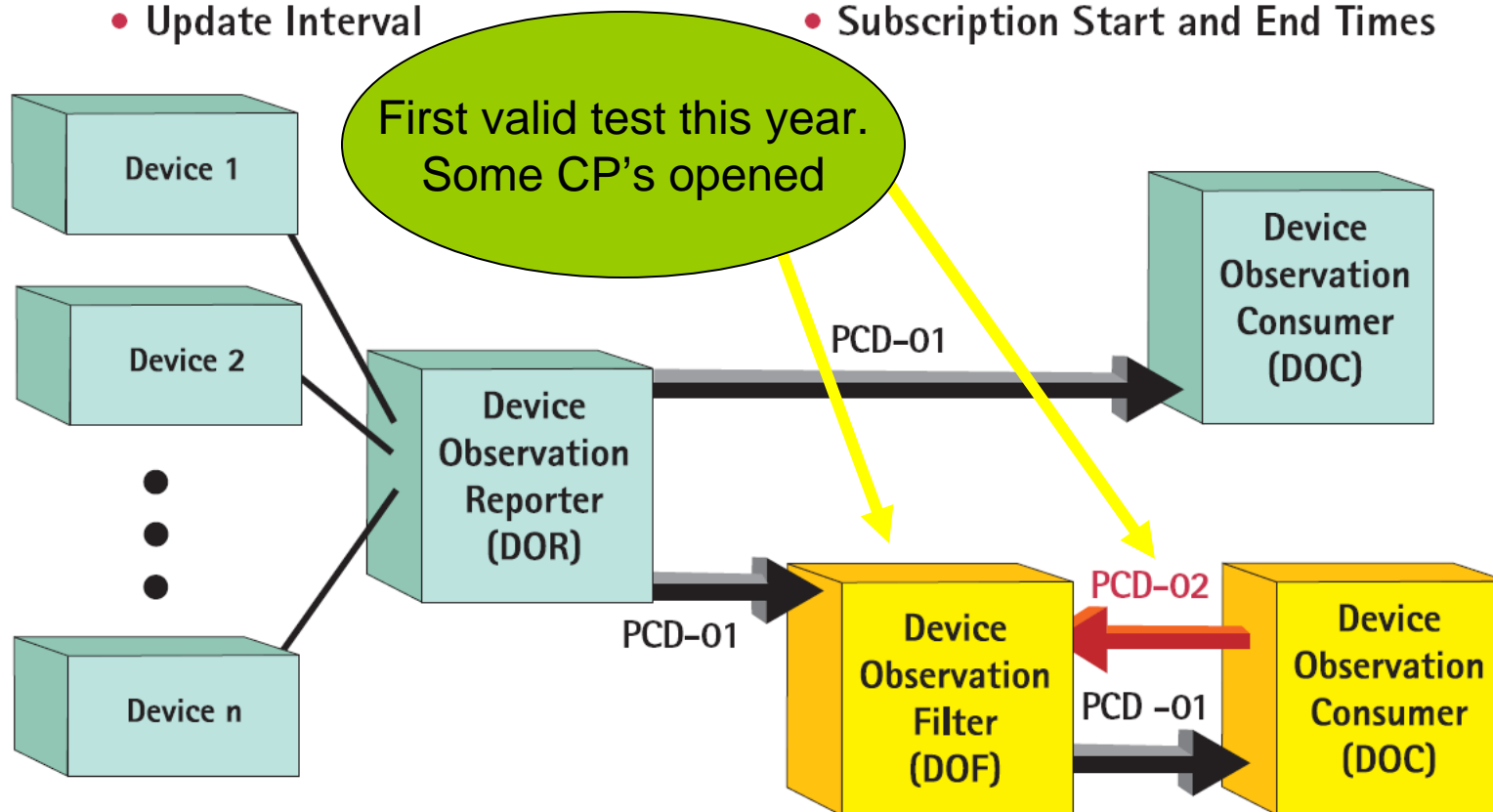
DEC with Patient Identity Binding



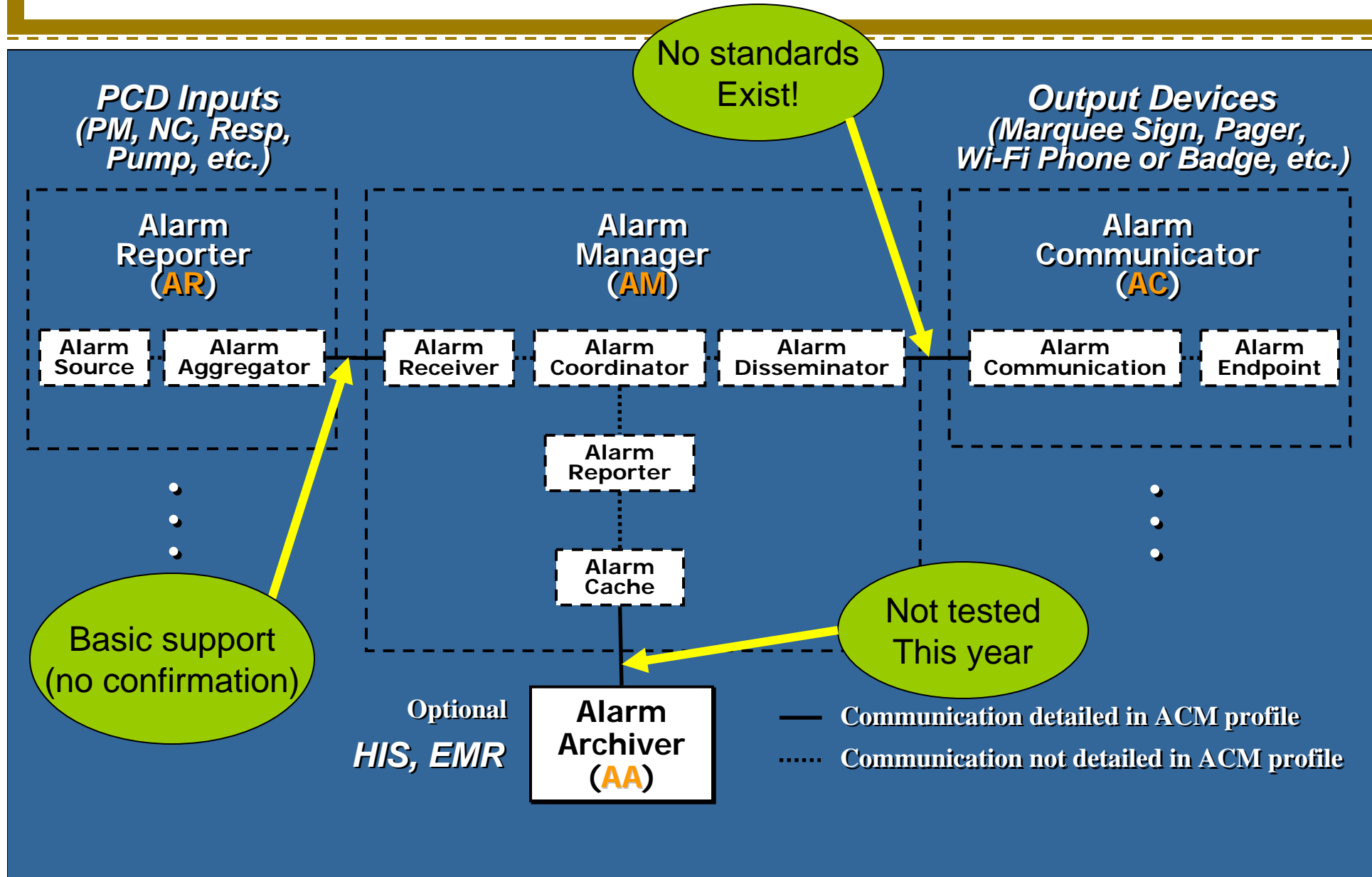
IHE PCD Profile: DEC w/ SPD

The Subscribe to Patient Data (SPD) option allows a consumer to specify a filter for PCD data using the following criteria:

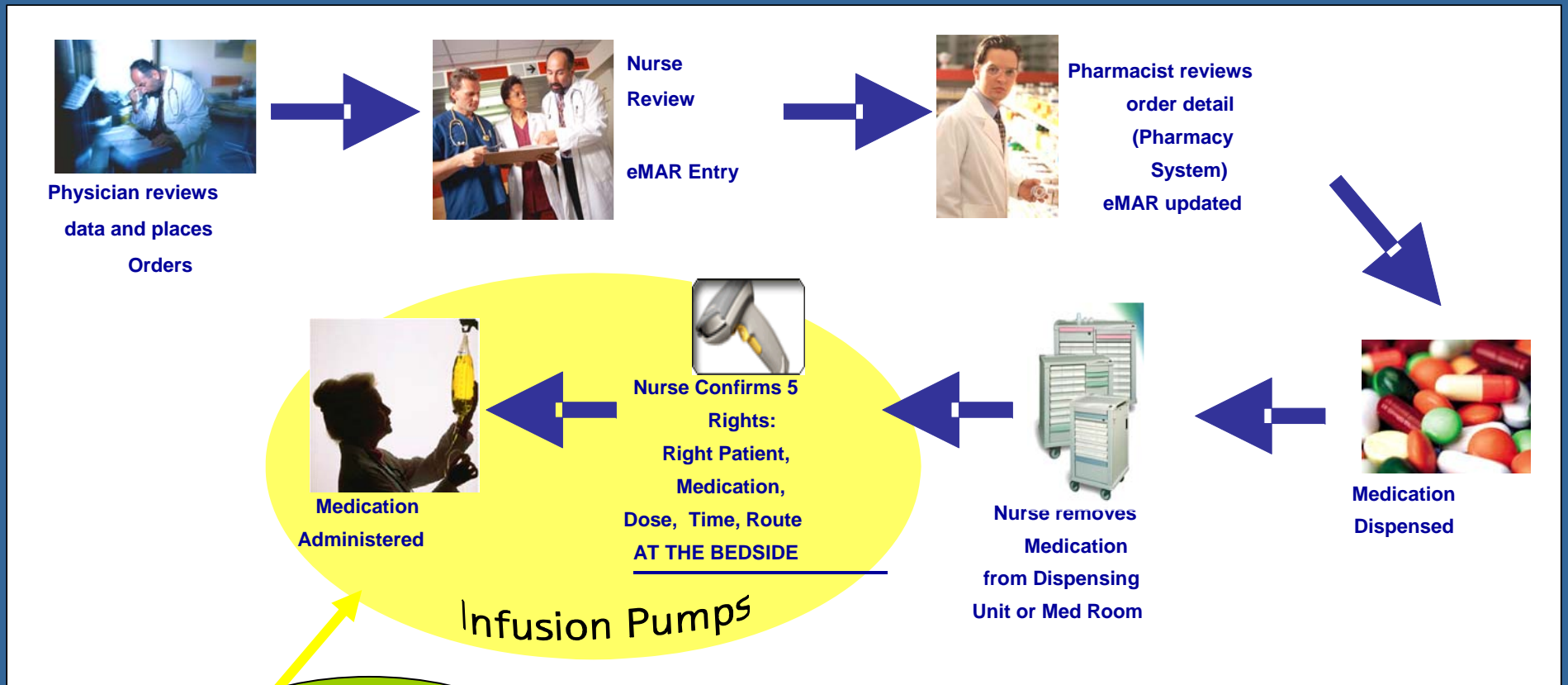
- Medical Record Number (MRN)
- Device Class
- Update Interval
- Patient Location
- Parameter Class
- Subscription Start and End Times



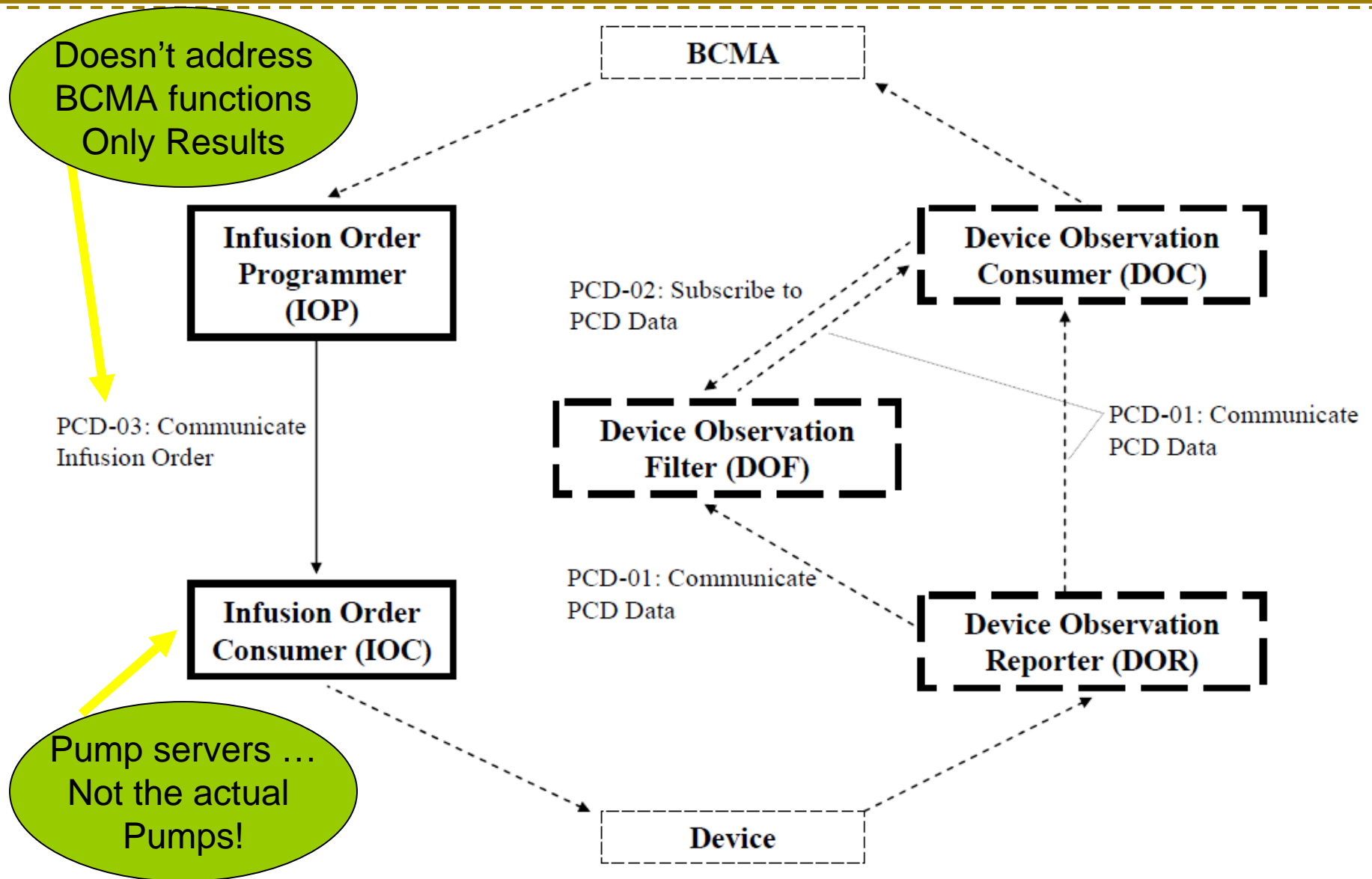
IHE PCD Profile: ACM



IHE PCD Profile: PIV



IHE PCD Profile: PIV



IHE PCD Profile: RTM

PCD ROSETTA PROJECT

Named after the Rosetta Stone, the PCD Rosetta Project maps existing and proprietary vendor parameters and units-of-measure for virtually all physiological measurements to the ISO/IEEE 11073-10101 vital signs nomenclature and related standards such as UCUM.

This will facilitate real-time interoperability between devices and systems, including FHR systems using the IHE PCD-01



PCD ROSETTA PROJECT

Creating common terminology for device connectivity

Neuromonitoring

| | | |
|-----------|-------|---------|
| Parameter | Units | Mapping |
| EEG | V | EEG |
| EMG | V | EMG |
| ECG | V | ECG |

Gas Delivery

| | | |
|-----------|-------|---------|
| Parameter | Units | Mapping |
| FiO2 | % | FiO2 |
| PEEP | cmH2O | PEEP |
| Flow | L/min | Flow |

Respiratory

| | | |
|-----------|-------|---------|
| Parameter | Units | Mapping |
| RR | 1/min | RR |
| TV | L | TV |
| VC | L | VC |

Gas Monitoring

| | | |
|-----------|-------|---------|
| Parameter | Units | Mapping |
| SpO2 | % | SpO2 |
| PaO2 | mmHg | PaO2 |
| PaCO2 | mmHg | PaCO2 |

Cardiovascular ECG

| | | |
|-----------|-------|---------|
| Parameter | Units | Mapping |
| HR | 1/min | HR |
| PRP | ms | PRP |
| PRV | ms | PRV |

Cardiovascular-Hemo

| | | |
|-----------|----------|---------|
| Parameter | Units | Mapping |
| MAP | mmHg | MAP |
| CO | L/min | CO |
| CI | L/min/m2 | CI |

Blood Chemistry

| | | |
|-----------|-------|---------|
| Parameter | Units | Mapping |
| Glucose | mg/dL | Glucose |
| HbA1c | % | HbA1c |
| Lactate | mg/dL | Lactate |

Urine Output

| | | |
|-----------|--------|---------|
| Parameter | Units | Mapping |
| UO | mL/h | UO |
| UO24 | mL/24h | UO24 |

Temperature

| | | |
|-----------|-------|---------|
| Parameter | Units | Mapping |
| Tcore | °C | Tcore |
| Tskin | °C | Tskin |

Patient Demographics

| | | |
|-----------|-------|---------|
| Parameter | Units | Mapping |
| Age | yr | Age |
| Sex | M/F | Sex |
| Weight | kg | Weight |

Infusion Pumps

| | | |
|-----------|-------|---------|
| Parameter | Units | Mapping |
| Flow | mL/h | Flow |
| Volume | mL | Volume |

Transcutaneous

| | | |
|-----------|-------|---------|
| Parameter | Units | Mapping |
| SpO2 | % | SpO2 |
| PaO2 | mmHg | PaO2 |
| PaCO2 | mmHg | PaCO2 |

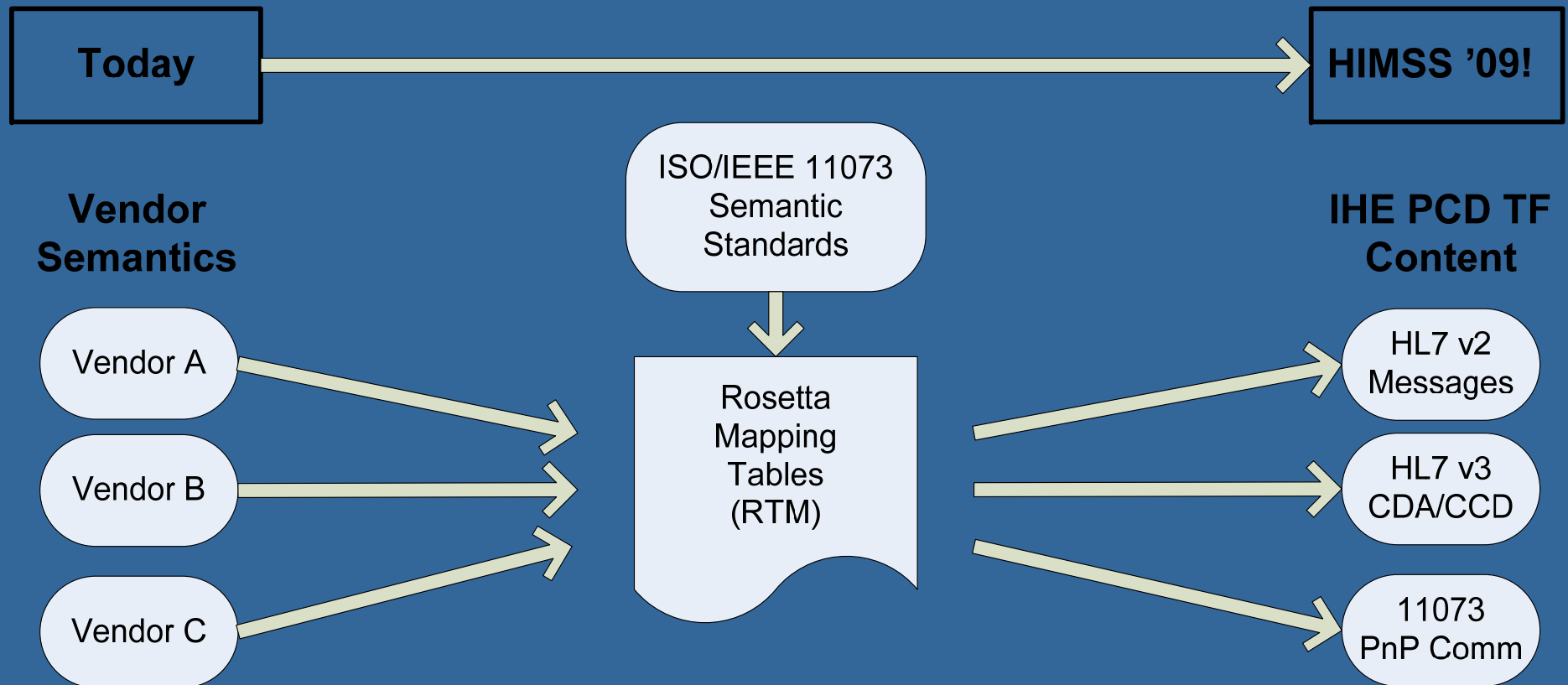
This is real +
Perhaps the most
Important work
product

IHE PCD Profile: RTM

| Group | REFERENCE_ID | Vendor_ Description | CODE | Vendor A | Vendor B | Vendor C |
|-------------|--------------------------------|-------------------------|-------|-------------|-------------|-------------|
| CVS_ECG_HR | MDC_ECG_CARD_BEAT_RATE | Heart Rate (DBR 326) | 16770 | HR | HR | HR |
| CVS_ECG_HR | MDC_ECG_CARD_BEAT_RATE_BT B | Beat-to-Beat Rate | 16778 | | | btbHR |
| CVS_ECG_HR | MDC_ECG_HEART_RATE | Heart Rate (DBR 2178) | 16770 | HR | HR | HR |
| CVS_ECG_HR | MDC_ECG_PACED_BEAT_RATE | %PACED | 16554 | %PACED | | |
| CVS_ECG_HR | MDC_ECG_TIME_PD_RR_GL | R to R Interval | 16168 | rr_time | rr_time | rr_time |
| CVS_ECG_QT | MDC_ECG_TIME_PD_QT_GL | QT interval | 16160 | | | QT |
| CVS_ECG_QT | MDC_ECG_TIME_PD_QTc | QT interval (corrected) | 16164 | | | QTc |
| CVS_ECG_RHY | MDC_ECG_ARRHY | Arrhythmia | 4410 | ARR | | |
| CVS_ECG_RHY | MDC_ECG_V_P_C_CNT | PVC rate. | 16993 | PVC/min | PVC | PVC |
| CVS_ECG_ST | MDC_ECG_AMPL_ST | ST generic label | 768 | ST | | ST |
| CVS_ECG_ST | MDC_ECG_AMPL_ST_AVF | ST lead aVF | 832 | STaVF | ST-AVF | ST-aVF |
| CVS_ECG_ST | MDC_ECG_AMPL_ST_AVL | ST lead aVL | 831 | STaVL | ST-AVL | ST-aVL |
| CVS_ECG_ST | MDC_ECG_AMPL_ST_AVR | ST lead aVR | 830 | STaVR | ST-AVR | ST-aVR |

IHE PCD Profile: RTM

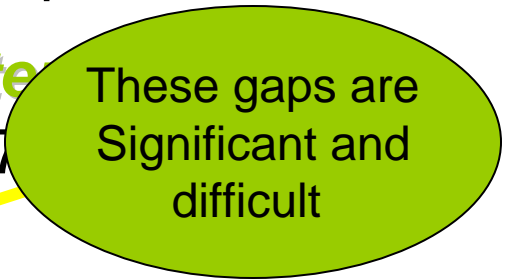
Migrating Toward True PCD Semantic Interoperability



IHE PCD Profile: RTM

2008/09 RTM development goals...

- ✓ **Expand number of numeric parameters** supported by PCD-01 from 40 today to over 400;
- ✓ **Harmonize** the use of existing nomenclature terms defined by ISO/IEEE 11073-10101;
- ✓ Specify the **units-of-measure**, **enumerated values** and **body sites** associated with **each** numeric parameter;
- ✓ Identify and **define new nomenclature terms** currently missing from the ISO/IEEE 11073 standards.

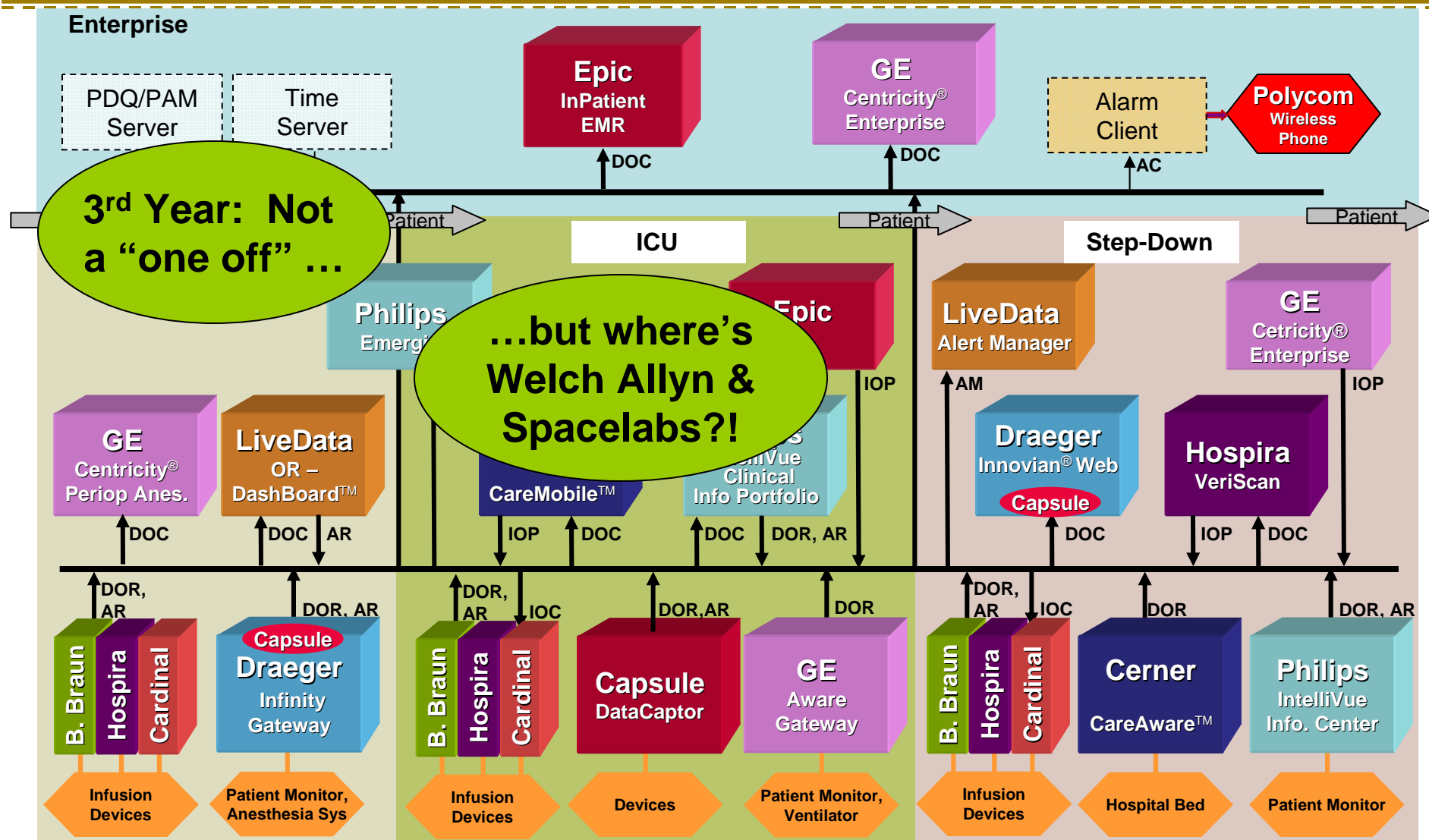


These gaps are
Significant and
difficult

NOTE: Respiratory / Ventilator terms are a major area. See

http://wiki.ihe.net/index.php?title=PCD_RTM_Ventilator

IHE PCD '09 Showcase (in process)



DOR = Device Observation Reporter / DOC = Device Observation Consumer

AR = Alarm Reporter / AM = Alarm Manager; IOC = Infusion Order Consumer / IOP = Infusion Order Programmer

IHE PCD & “ICE” / MDPnP

ASTM/WD.2 xxxxx-1 © ASTM 2008 – All rights reserved

This draft has been distributed for ASTM F29.21 Subcommittee Ballot

Comments and vote should be submitted no later than November 7, 2008.

ASTM members should submit vote and comments via the ballot site.

Non-ASTM member experts who have been invited to submit questions and comments to:

Julian M. Goldman, MD jmgoldman@mdpn.

“ICE” is still ‘out there’
This group may be
Able to road map it

draft ASTM TC F29.21 N **21**

Date: September 23, 2008

ASTM WD.2 xxxxx-1

ASTM SC F29.

- 5 **Medical Devices and Medical Systems — Essential safety requirements for**
- 6 **equipment comprising the patient-centric integrated clinical environment**
- 7 **(ICE) — Part 1: General requirements and conceptual model**
- 8 *Élément introductif — Éléments centraux — Partie 1: Titre de la partie*

✓ **ICE-PCD Analysis Committee (ICE-PAC)** – JWG underway to perform a map & gap analysis between “ICE” use case analyses, ISO/IEEE 11073 standards & the IHE DPI WG.

IHE & Continua Health Alliance



✓ ***Continua & IHE Recently announced a Memorandum of Understanding (“MoU”) to “enable and promote interoperability of healthcare devices.”***

✓ **See** http://www.ihe.net/News/ihe-continua_mou_release_2008-10-28.cfm

The MoU is signed ... joint participation in the Interoperability
But mostly “let’s
Agree to talk” HIMSS ‘09

IHE & Continua Health Alliance



Continua Use Cases

Disease Management

- Remote Patient Monitoring
 - Weight
 - Blood pressure
 - Glucose
 - Temperature
 - Spirometer data
- Wireless Network

Aging Independently

- Medication Compliance
- Assisted Daily Living
 - Bed pressure (sleep)
 - Bathroom sensor
 - Gas / water sensor
 - Emergency sensor

Health & Wellness

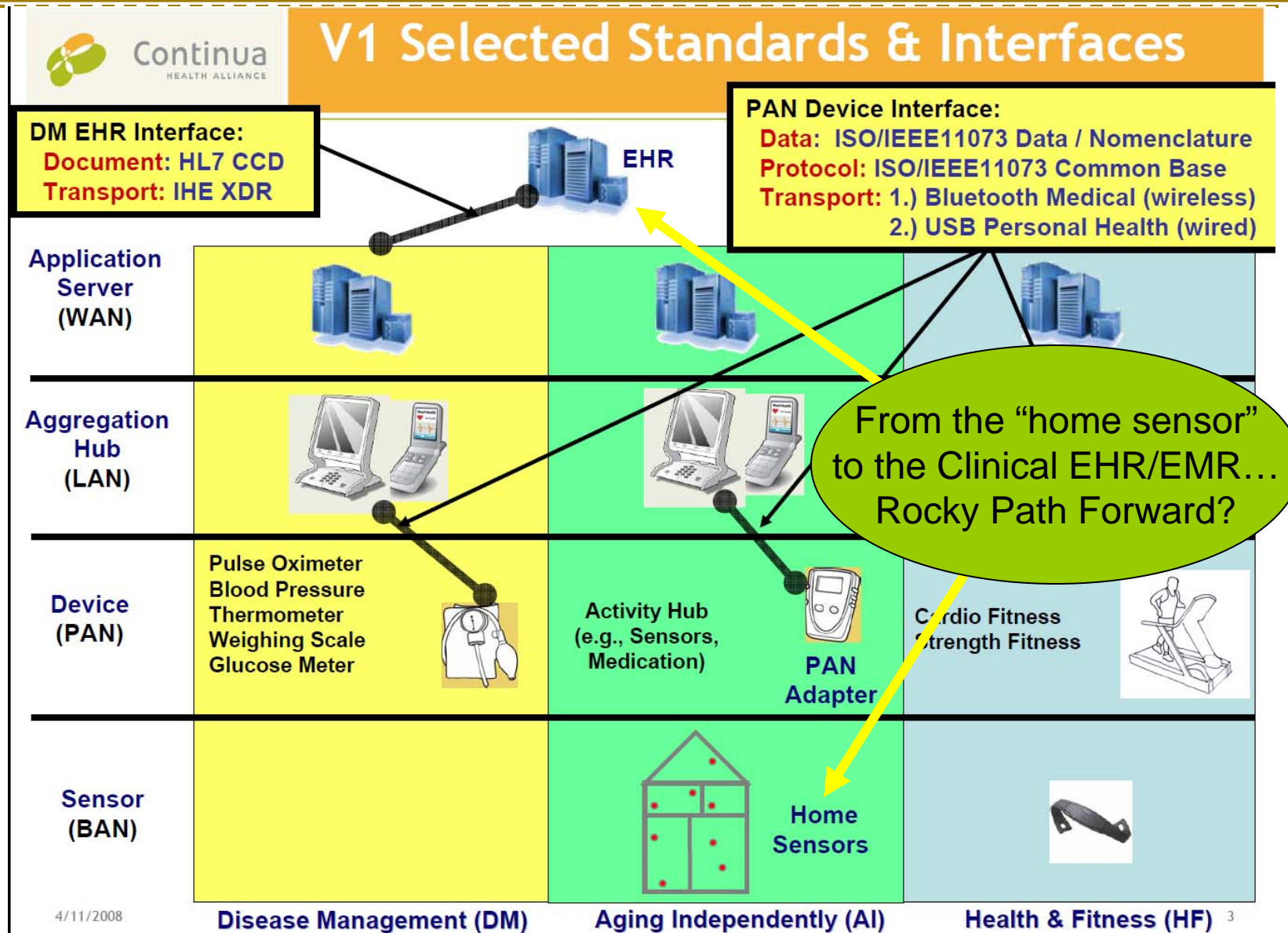
- Weight loss
- Fitness
- “Worried Well”
 - Weight
 - Blood pressure
 - Glucose
 - Cholesterol
 - Activity level
- Personal Health Records



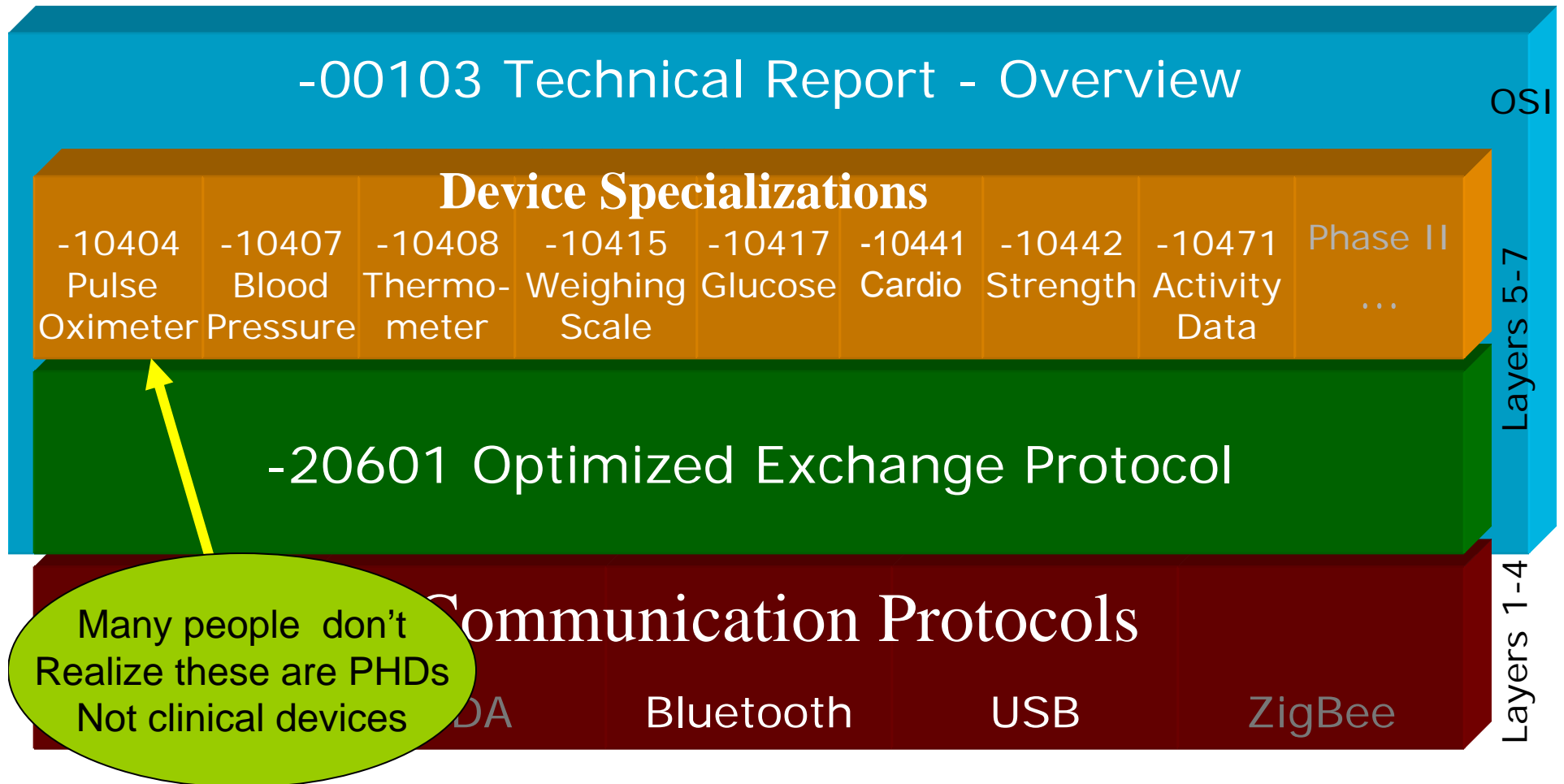
Internet



IHE & Continua Health Alliance



IEEE PHD WG & 11073 Standards



✓ **NOTE:** Optimized for **consumer-grade** personal health device applications.

And that's not all...

✓ *Beyond IHE PCD...*

Managing Integration: IEC 80001

80001 © IEC:2007

– 8 –

CD2 Rev 8 - 18 October 2008

Application of risk management for IT-networks incorporating medical devices

1 Scope

1.1 Purpose

This international standard defines the roles, responsibilities and activities that are necessary when MEDICAL DEVICES are incorporated into an IT-NETWORK, to address the KEY PROPERTIES of the IT-NETWORK incorporating a MEDICAL DEVICE:

- ✓ ***HDO's least represented & stand to be the most affected!***
- ✓ ***Status: 2nd CD Ballot scheduled 2008.11.21***
- ✓ ***Publication: FDIS Ballot scheduled 2010***

CE-IT Convergence

Currently a “hot topic” in the CE & HIT communities:

- ✓ Results from an ever *increasing interrelationship between medical technology & I.T.*
- ✓ ACCE profession: Clinical Systems Engineer
- ✓ Realizing “The Promise” requires CE-IT coordination
- ✓ IEC 80001 Process & Roles demand closer cooperation
- ✓ Easier said than done!

ECRI “Health Devices” 2008.10 provided a summary of guidance developed over a year talking with experts throughout the healthcare industry:

13 Step CE-IT Convergence Road Map!

CE-IT Community



By pooling their resources and expertise, the CE-IT Community is dedicated to:

- ✓ Fostering development of a *united voice* for IT and clinical engineering concerns and a forum for its expression
- ✓ Providing a mechanism for *developing resources, guidelines, and best practices* for the CE-IT community
- ✓ Exploring appropriate collaboration of clinical engineering/IT functions
- ✓ Developing a framework for *representing the interests* of clinical engineering and IT departments *to the broader healthcare community*

CE-IT Community



Currently organized into 5 working groups:

- ✓ Working Group #1: **Infrastructure - Wireless**
- ✓ Working Group #2: **Integration**
- ✓ Working Group #3: **Emerging Technologies**
- ✓ Working Group #4: **CE-IT Collaboration**
- ✓ Working Group #5: **Risk Management**

More information @ www.ceitcollaboration.org

Regulatory “confusion”...

- ✓ **Internationally inconsistent** determination of what is and is not a regulated medical device. **GHTF** to the rescue?
- ✓ Will the regulatory submission process migrate toward **safety cases**? This could potentially streamline the evaluation process.
- ✓ How will life-critical, dynamically configured **plug-and-play medical device systems** be ... evaluated and approved?!
- ✓ Based on IEC 80001, FDA's MDDS ... could your **hospital** be designated **a medical device manufacturer** (for in-house developed applications)? FDA response: absolutely!

“A patient shouldn’t lose their protections just because they walk through a hospital door...”

What is a medical device?

U.K. NHS’ “health software”...

prCEN ISO/TS 29321

CEN TC 251

Health informatics — Application of clinical risk management to the manufacture of health software

- ✓ **Billion's of pounds** worth of **health software** systems with no regulatory oversight.
- ✓ Requires basic quality system with **clinical risk management** + “safety cases”
- ✓ Highly ... **HIGHLY** controversial! (both SDO's & vendors)
- ✓ In the U.K. – already **proven effective in improving safety!**

Conclusion

✓ *Beyond tonight...*

What now?

To realize the Vision, HDOs must ...

- ✓ **Engage** in national & international activities such as **IHE Australia** (... or someone else will!)
- ✓ Establish a **clear vision & mission** for interoperability, starting with executive & sr. management. Back it up in contract language!
- ✓ Evaluate & anticipate **IEC 80001**
- ✓ Assess the **ECRI Road Map** and apply to your organization

and pray for...

- ✓ Improvement of the **international economy**

Contact Information

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Just in case...

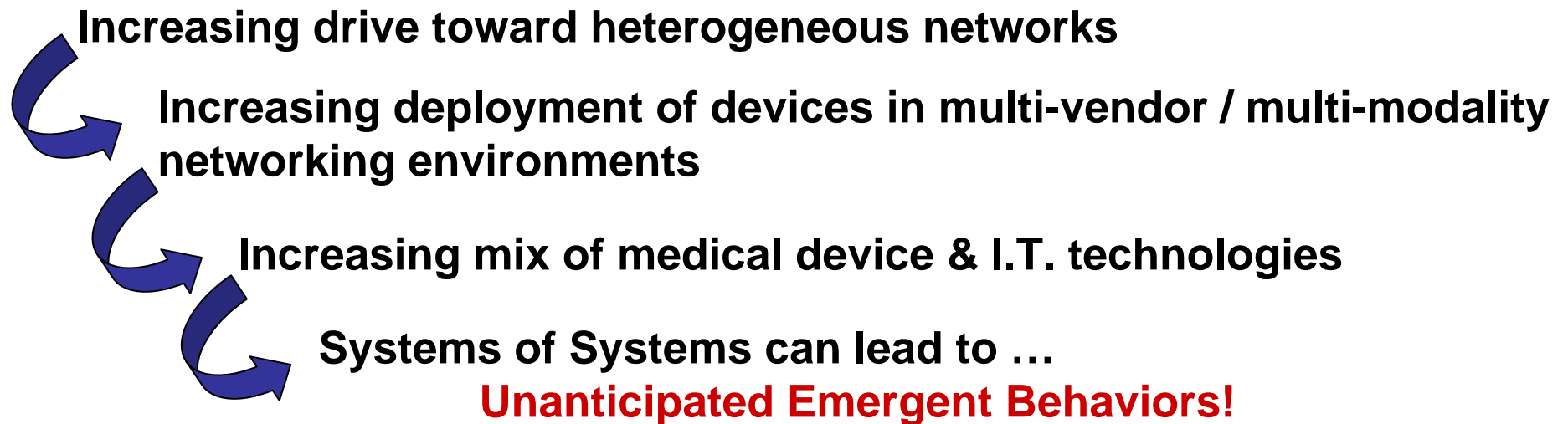
Extra Slides

What's on...

- ✓ Convergence: The Promise
- ✓ SDOs & IHE: Getting the job done!
- ✓ ***Managing Integration: IEC 80001***
- ✓ CE-IT “Convergence”:
Road map to world peace?
- ✓ Confused watch dogs...
- ✓ What now?

Managing Integration: IEC 80001

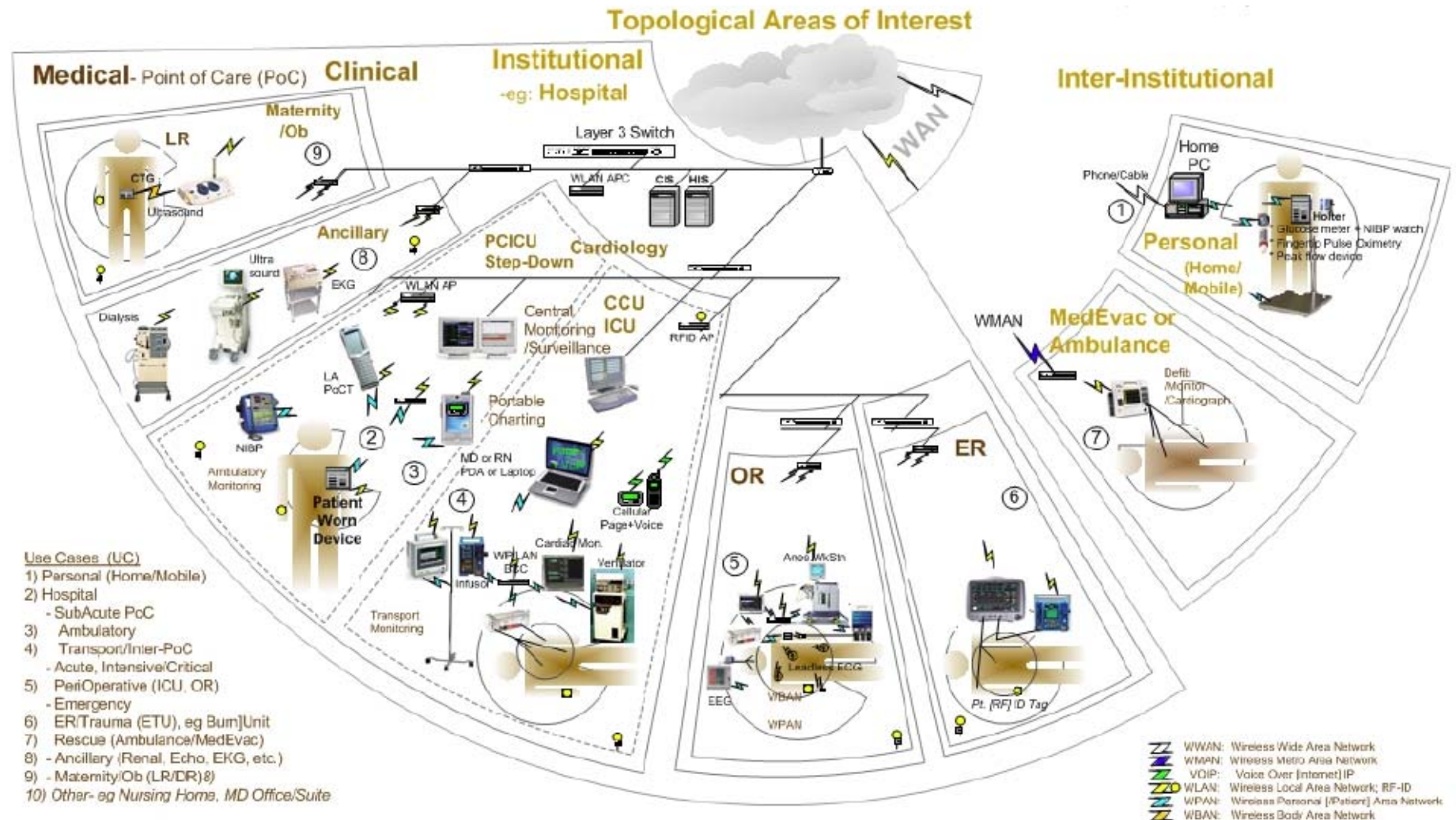
Why is IEC 80001 needed?



❖ *Proactive Federated Risk Management must be used to manage the integration of medical device & I.T. technologies*

✓ *Wireless? Can't cable around the problem!*

Managing Integration: IEC 80001



(from IEEE P11073-00101 Guidelines for the use of RF wireless technologies)

Managing Integration: IEC 80001

80001 © IEC:2007

– 8 –

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Managing Integration: IEC 80001

80001 Introduction...

“... potential problems associated with the integration of medical devices to IT-networks, including:

- **support from manufacturers** of medical devices for incorporation of their products into IT-networks, for example the availability or adequacy of information provided by the manufacturer to the operator of the IT-network;
- incorrect operation resulting from combining **medical devices** and **other equipment** on the same IT-network;
- incorrect operation resulting from combining **medical device software** and **other software** applications in the same IT-network; and
- the conflict between the need for **strict change control** of medical devices and the need for **rapid response** to an attack by malware.

*When these problems manifest themselves it frequently leads to **unintended consequences**.*”

Managing Integration: IEC 80001

80001 Scope...

“This international standard defines the **roles, responsibilities** and **activities** that are necessary when medical devices are incorporated into an IT-network, to address the **key properties** of the IT-network incorporating a medical device...”

“This standard applies throughout the **life cycle of IT-networks** incorporating medical devices.”

“This standard applies where there is **no single medical device manufacturer assuming responsibility** for addressing the key properties of the IT-network incorporating a medical device.”

“This standard applies to both **responsible organizations** and **medical device manufacturers** for the purpose of **comprehensive risk management**.”

Managing Integration: IEC 80001

80001 Key Properties...

“Risk management should be applied to address the **balance of the following key properties** appropriate for the IT-network incorporating a medical device:

- ✓ **safety**;
- ✓ **effectiveness** (effective treatment of the patient using the information exchanged and also enhanced effectiveness of the responsible organization due to the exchange of information);
- ✓ **data and system security**; and
- ✓ **interoperability**

Inappropriate balance of these properties is interpreted as a **hazard to a patient** or to the responsible organization's **mission**.

Managing Integration: IEC 80001

80001 core components...

- ✓ **Roles & Responsibilities**
- ✓ **Risk Management Life Cycle (process)**
- ✓ **Supporting Documentation**

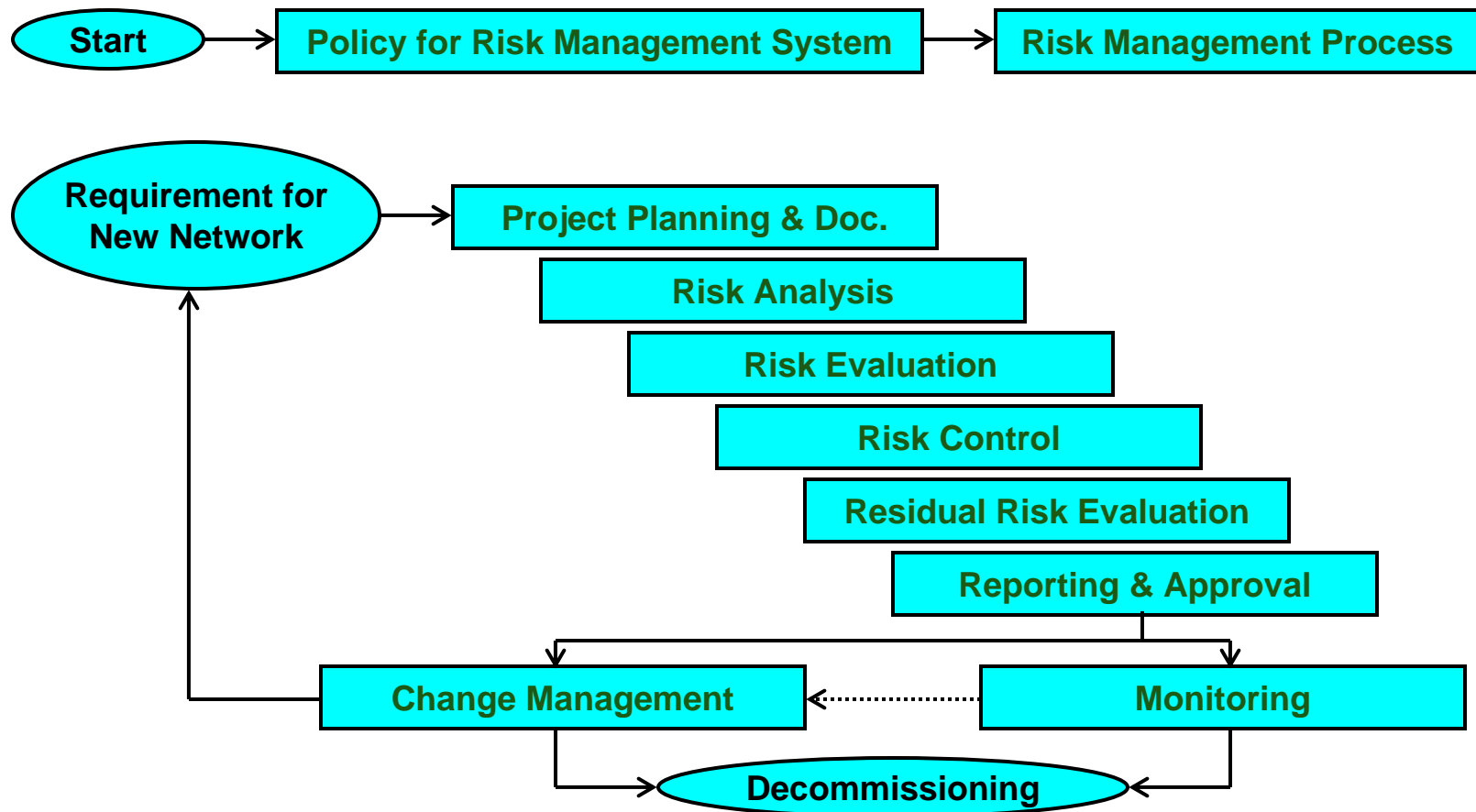
Managing Integration: IEC 80001

80001 Roles & Responsibilities...

- ✓ **Responsible Organization**
- ✓ **Top Management**
- ✓ **Medical IT-Network Risk Manager**
- ✓ **Medical IT-Network Maintainer**
- ✓ **Medical Device Manufacturer(s)**
- ✓ **IT Technology Providers (non-MDMs)**
- ✓ **Risk Management Team**

Managing Integration: IEC 80001

Risk Management Life Cycle...



Managing Integration: IEC 80001

Supporting Documentation...

✓ **Responsibility Agreement (contract)**

- ☐ **MDM Residual Risk Documentation**
- ☐ **Intended Use of MD (on IT-Network)**
- ☐ **Required Performance / Configuration**
- ☐ **...**
- ☐ ***Summary of info from MDM for Responsible Org. to perform it's risk management process!***

Managing Integration: IEC 80001

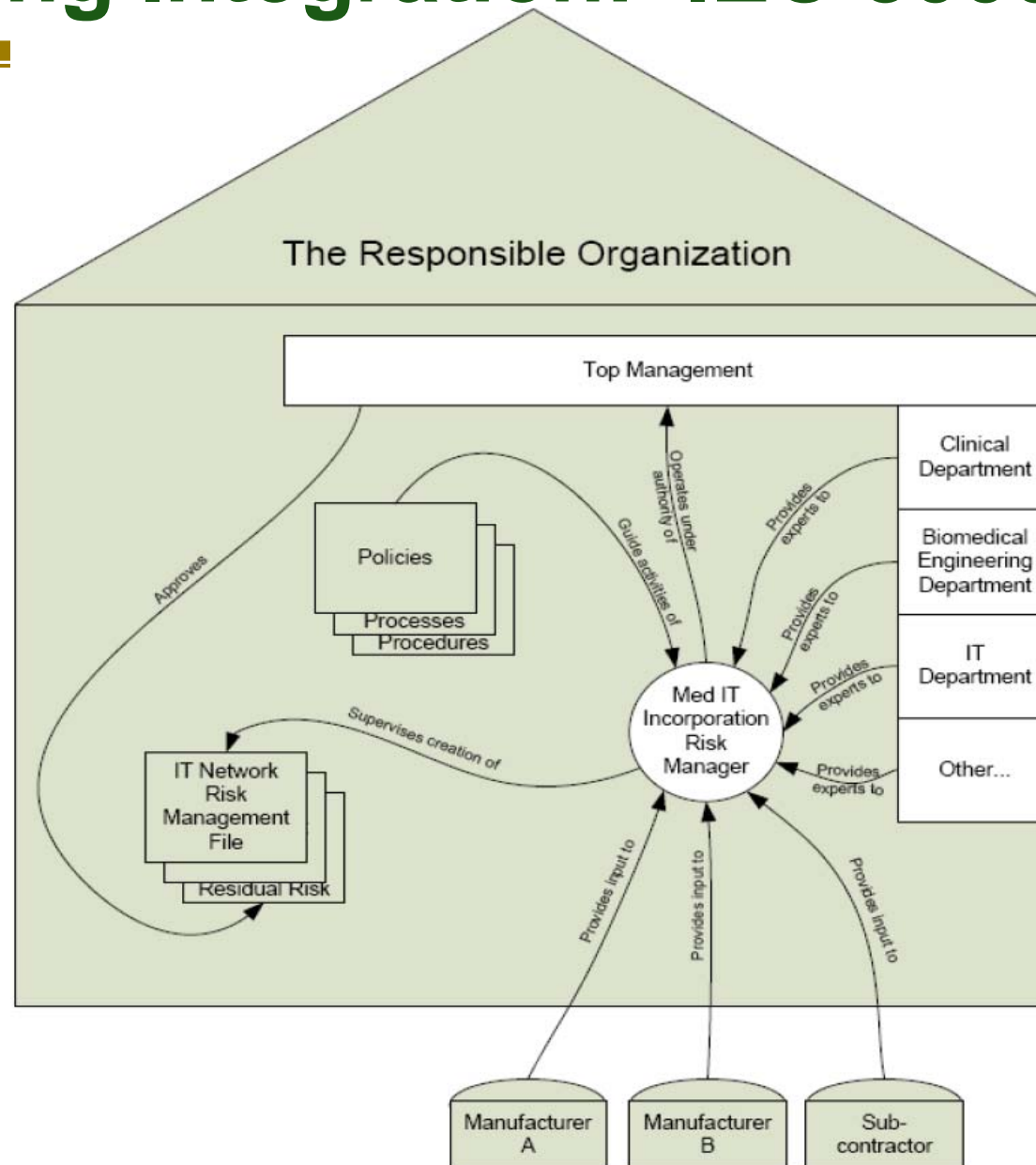
Supporting Documentation...

✓ **Medical IT-Network Risk Management File**

For each identified hazard, traceability to:

- ☐ **Risk Analysis**
- ☐ **Risk Evaluation**
- ☐ **Risk Control Measures Implementation & Verification**
- ☐ **Residual Risk Assessment Acceptability & Approval**
- ☐ **...**

Managing Integration: IEC 80001



Managing Integration: IEC 80001

Beyond The Process...

- ✓ ***Rapid*** follow-on guidance development
- ✓ ***Network Classification*** guidance
- ✓ Application to ***Wireless Networks***
- ✓ Medical IT-Network Risk Manager / Maintainer = ***ACCE “Clinical Systems Engineer”*** ?

What's on...

- ✓ Convergence: The Promise
- ✓ SDOs & IHE: Getting the job done!
- ✓ Managing Integration: IEC 80001
- ✓ ***CE-IT “Convergence”:
Road map to world peace?***
- ✓ Confused watch dogs...
- ✓ What now?

CE-IT Convergence

Currently a “hot topic” in the CE & HIT communities:

- ✓ Results from an ever *increasing interrelationship between medical technology & I.T.*
- ✓ ACCE profession: Clinical Systems Engineer
- ✓ Realizing “The Promise” requires CE-IT coordination
- ✓ IEC 80001 Process & Roles demand closer cooperation
- ✓ Easier said than done!

ECRI “Health Devices” 2008.10 provided a summary of guidance developed over a year talking with experts throughout the healthcare industry...

CE-IT Convergence: ECRI Road Map

"Coping with Convergence - A Road Map for Successfully Combining Medical and Information Technologies",

Health Devices 2008 Oct; 37(10): 293 - 304.

#1: Ensure That You Have a Strategic Vision

- ✓ Without a clearly communicated **vision** and **mission** – from the highest levels of the organization – there is no hope of convergence.

#2: Establish Strong Leadership

- ✓ **Executive & Sr. Management** must support convergence
- ✓ People & Resources & Schedule & Mission...

#3: Foster Relationships

- ✓ Major **cultural differences** between CE & HIT communities
- ✓ **Mission-Critical** vs. **Life-Critical** focus
- ✓ Cross train / cross assign / joint partnership projects etc.

CE-IT Convergence: ECRI Road Map

#4: Ensure That Decisions Are Patient-Centric

- ✓ **Primary focus** on areas that most directly affect patient care:
improved safety and **quality**
- ✓ Establish **metrics** early in the process

#5: Make Clinical Work Processes a Priority

- ✓ **"Involve clinicians in decision making"** - Easier said than done!
- ✓ Must understand and address workflow and how these systems are integrated into care delivery. (Peter the Urologist)

#6: Understand the Life Critical Nature of the Medical Data Being Exchanged

- ✓ Know what is communicating with what and the **criticality** of the exchanges
- ✓ Identify – design for – and monitor **Quality of Service** requirements
Note: it's not just bandwidth!

CE-IT Convergence: ECRI Road Map

#7: Approach Projects with a Systems-Based Methodology

- ✓ Devices & IT systems often developed & tested in isolation
- ✓ Systems of Systems:
 - Emergent Behaviours / Unintended Consequences!
- ✓ Sloane 2007 ESPM-ABEC Conference "**Systems of Systems Engineering - New Skills & Tools for the 21st Century CE**"
- ✓ IEEE Systems of Systems Engineering Council w/ Healthcare Focus

#8: Purchase Wisely

- ✓ "Standardize on converging technology vendors & applications" – Usually the first to be given up during the acquisition process...
- ✓ Include IHE compatibility statements (new **yellow** / **green** / **blue** designations will help identify profile & testing maturity.
- ✓ Participate in "**MD FIRE**" (http://mdpnp.org/MD_FIRE.php) contract language development
- ✓ At least move in the direction of open standards-based convergent technologies

CE-IT Convergence: ECRI Road Map

#9: Protect the Security of Medical Information

- ✓ Ensure appropriate confidentiality, integrity & availability (**CIA**)
- ✓ Note: many medical devices do not require **1st link security**.
- ✓ Software patches/updates: Who applies them & when?
- ✓ FDA “Cyber security” guidance
- ✓ HIMSS “Medical Device Security Survey” (**MDS²**) Forms

#10: Carefully Plan Your Wireless Enterprise

- ✓ ***"Wireless technology promises the right information to the right people at the right time anywhere within the hospital."*** Wow!!!
- ✓ Systems must coexist - can't wire around this problem
- ✓ ***Wireless is not a "best fit" for all applications*** – esp. life critical

#11: Understand Software Issues

- ✓ Realize software has unique & real problems to be managed
- ✓ ***Incident reporting*** & updated version integration? (Regulated or not...)
- ✓ ***Support support support*** ... nail down in the contracting language
- ✓ Company track record & survivability.

CE-IT Convergence: ECRI Road Map

#12: Perform Risk Analyses on Converging Technologies

- ✓ Per *IEC 80001*...
- ✓ How did this get so far down the list?!

#13: Develop a Plan for the Future

- ✓ *Multi-year focus*
- ✓ Establish *prioritized strategy* for achieving mission
- ✓ Address entire *system life cycle* – not simply initial deployment

NOTE: The Health Devices article has far more detailed information; a copy can be obtained from www.ecri.org.

CE-IT Community



By pooling their resources and expertise, the CE-IT Community is dedicated to:

- ✓ Fostering development of a *united voice* for IT and clinical engineering concerns and a forum for its expression
- ✓ Providing a mechanism for *developing resources, guidelines, and best practices* for the CE-IT community
- ✓ Exploring appropriate collaboration of clinical engineering/IT functions
- ✓ Developing a framework for *representing the interests* of clinical engineering and IT departments *to the broader healthcare community*

CE-IT Community



Currently organized into 5 working groups:

- ✓ Working Group #1: **Infrastructure - Wireless**
- ✓ Working Group #2: **Integration**
- ✓ Working Group #3: **Emerging Technologies**
- ✓ Working Group #4: **CE-IT Collaboration**
- ✓ Working Group #5: **Risk Management**

More information @ www.ceitcollaboration.org

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- ✓ *Confused watch dogs...*
- ✓ What now?

What is a medical device?

GHTF Definition...

Any **instrument**, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, **software**, material or other similar or related article, **intended by the manufacturer to be used**, alone or in combination, for human beings for one or more of the specific purpose(s) of

- **diagnosis, prevention, monitoring, treatment or alleviation of disease**,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

(From GHTF - Global Harmonization Task Force.)

What is a medical device?

Role of “standalone software”?

2007.09 Updated European Medical Device Directive

It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device.

... but there has been considerable discussion regarding the definition of “general purpose” *health software* and systems!

What is a medical device?

U.K. NHS' “health software”...

prCEN ISO/TS 29321

CEN TC 251

Health informatics — Application of clinical risk management to the manufacture of health software

- ✓ **Billion's of pounds** worth of health software systems with no regulatory oversight.
- ✓ Requires basic quality system with **clinical risk management** + “safety cases”
- ✓ Highly ... **HIGHLY** controversial! (both SDO's & vendors)
- ✓ In the U.K. – already **proven effective in improving safety!**

What is a medical device?

FDA proposed MDDS...

2008.02 FDA: “Medical Device Data System”

- ✓ Clarifies systems that *transfer, store, retrieve & display medical device data* need no PMA if...
 - Only used by healthcare professionals
 - Device does not perform irreversible data compression
 - No altering of the function or parameters of connected devices
- ✓ However as *Class I devices* they do have to ...
 - Register as a medical device
 - Good Manufacturing Practice (GMP)
 - Subject to Medical Device Reporting (MDRs)
- ✓ When in doubt ... submit 513(g)!

Other regulatory issues...

- ✓ **Internationally inconsistent** determination of what is and is not a regulated medical device. **GHTF** to the rescue?
- ✓ Will the regulatory submission process migrate toward **safety cases**? This could potentially streamline the evaluation process.
- ✓ How will life-critical, dynamically configured **plug-and-play medical device systems** be ... evaluated and approved?!
- ✓ Based on IEC 80001, FDA's MDDS ... could your **hospital** be designated **a medical device manufacturer** (for in-house developed applications)? FDA response: absolutely!

“A patient shouldn’t lose their protections just because they walk through a hospital door...”

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Just in case...

Extra Extra!

Slides

What's on...

- ✓ **Convergence: The Promise**
- ✓ **SDOs & IHE: Getting the job done!**
- ✓ **Managing Integration: IEC 80001**
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