

Interoperability standards and impact on procurement

Charles Parisot Mgr Interop Standards & testing, GE Healthcare
IHE-Europe Steering Committee
Co-Chair, IHE IT Infrastructure Planning



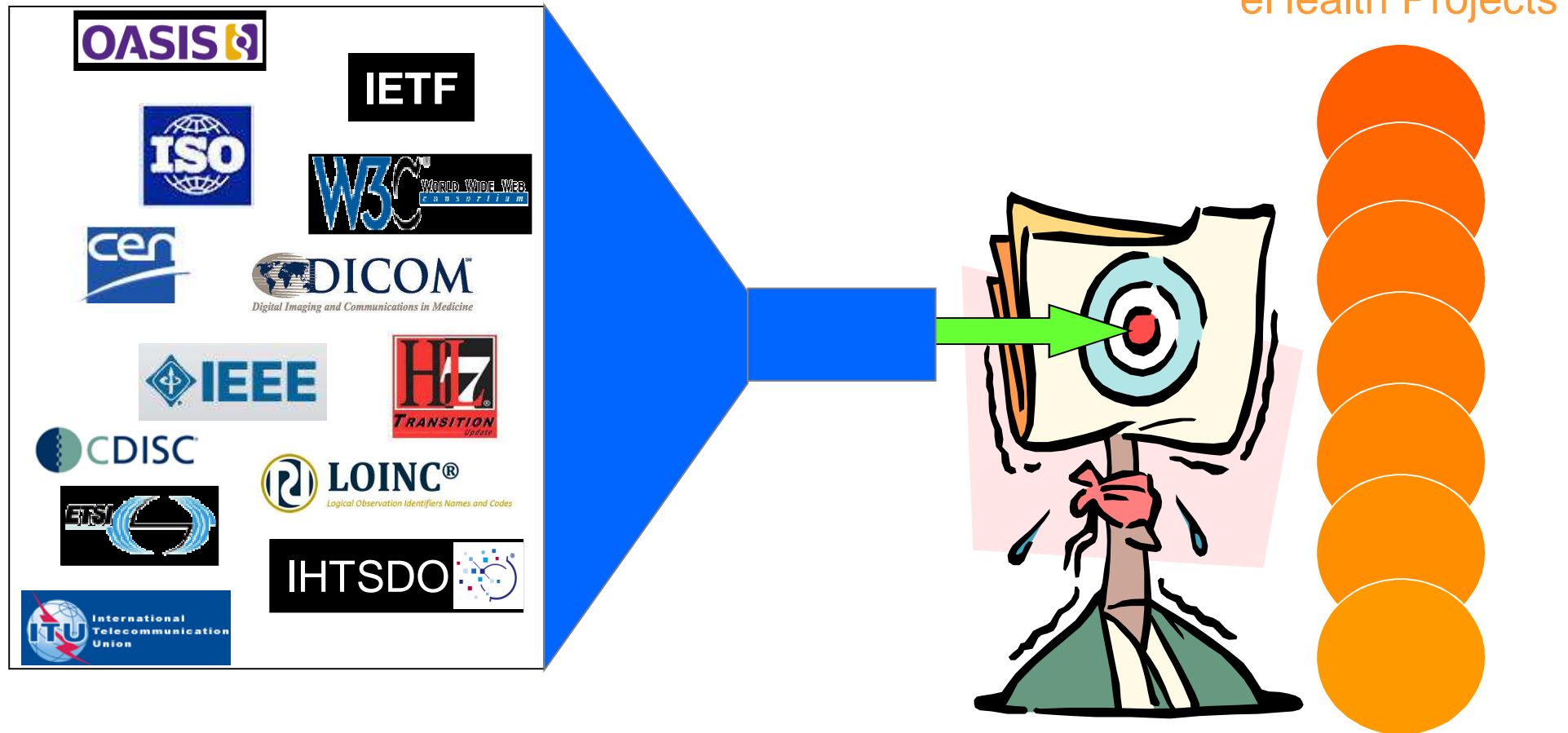
Session Objectives

- Interoperability is hard and when ignored results in significant delays, costs and conflicts
- The good news: industry and users have “streamlined” standards for interoperability, for both *personal* and *clinical* medical device data
- This is great help, but needs some attention
- What about conformance testing ?
- What this means to you ...

Interoperability: Major Cause of Health IT project failures

Base Standards

eHealth Projects



Health Interop. Standards: Ignore & Face
Consequences

Interoperability: Major Cause of Health IT project failures

Base Standards



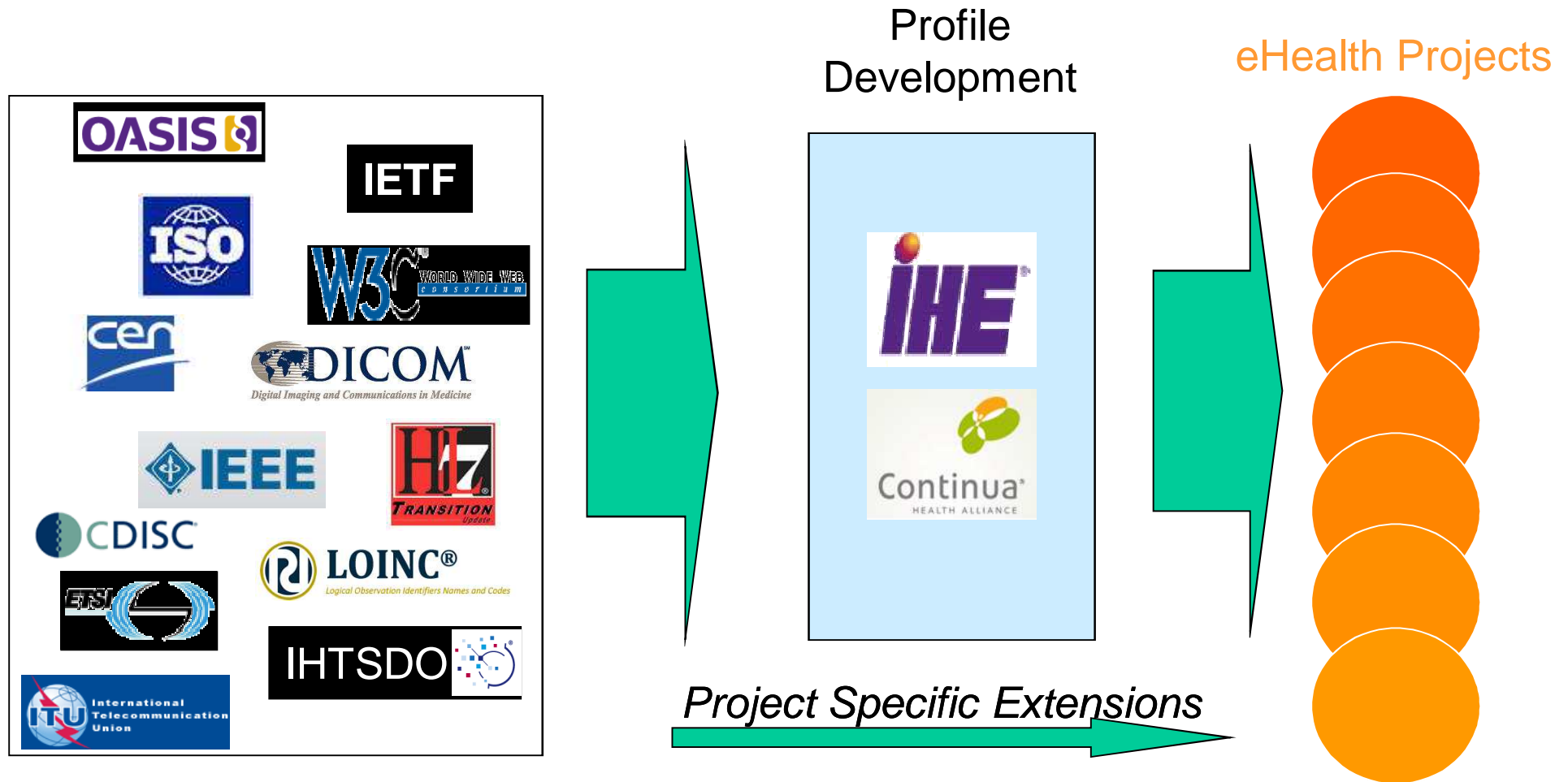
eHealth Projects



Health Interop. Standards. Chaos with projects choice

?

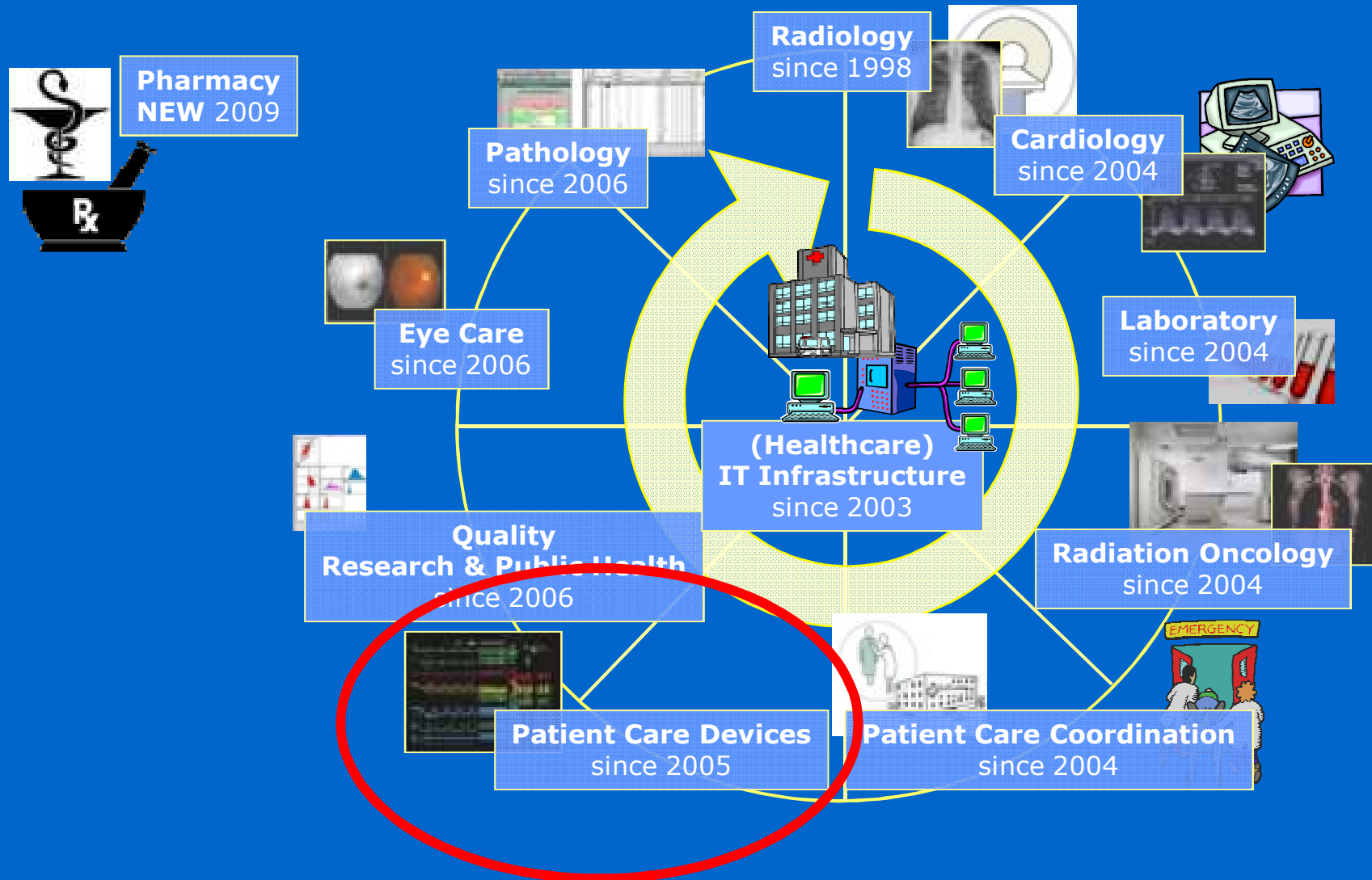
Interoperability: From a problem to a solution



Profiling Organizations Are Established

The IHE Development Domains

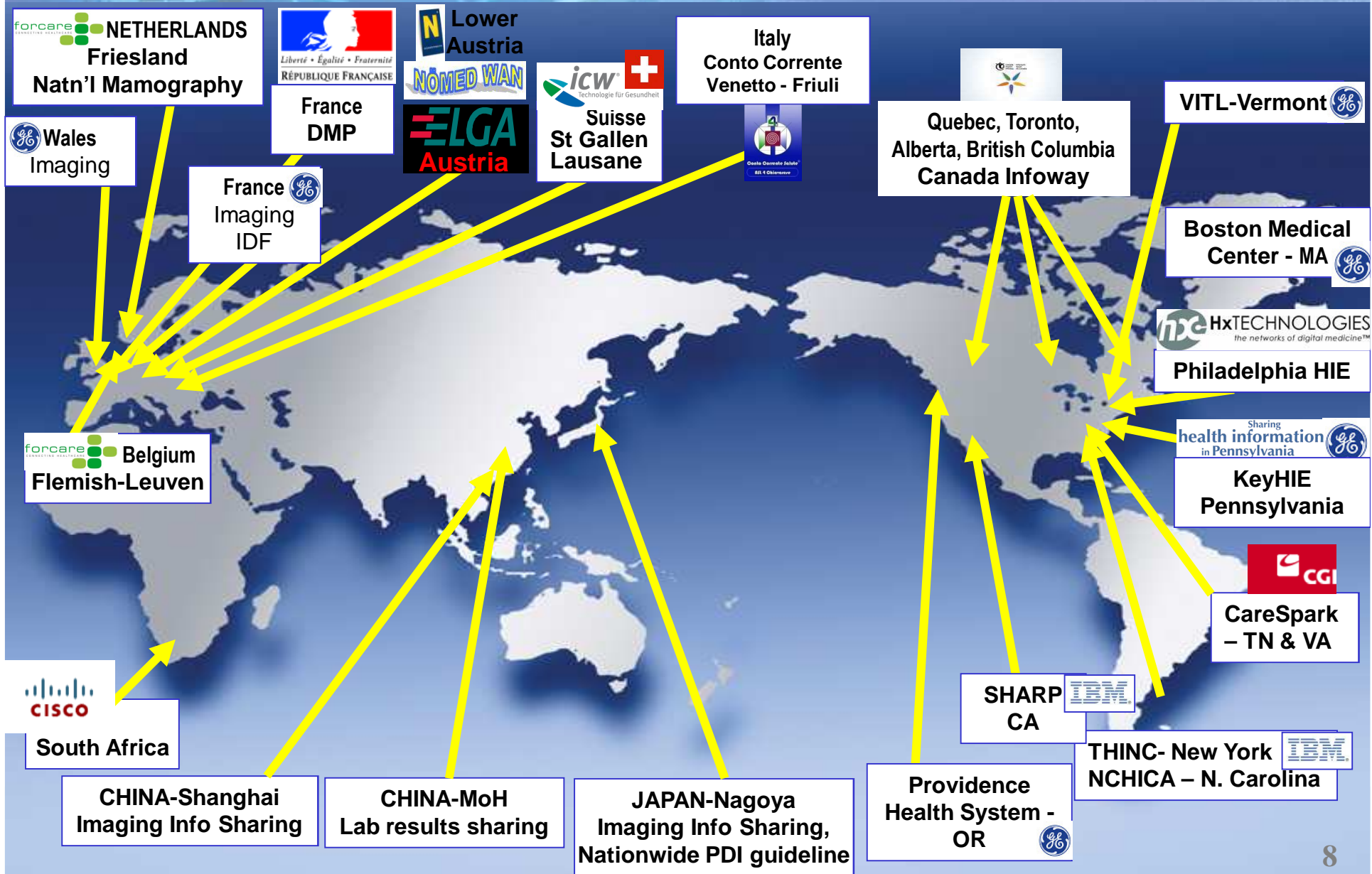
12 Years of Steady Evolution 1998 – 2010



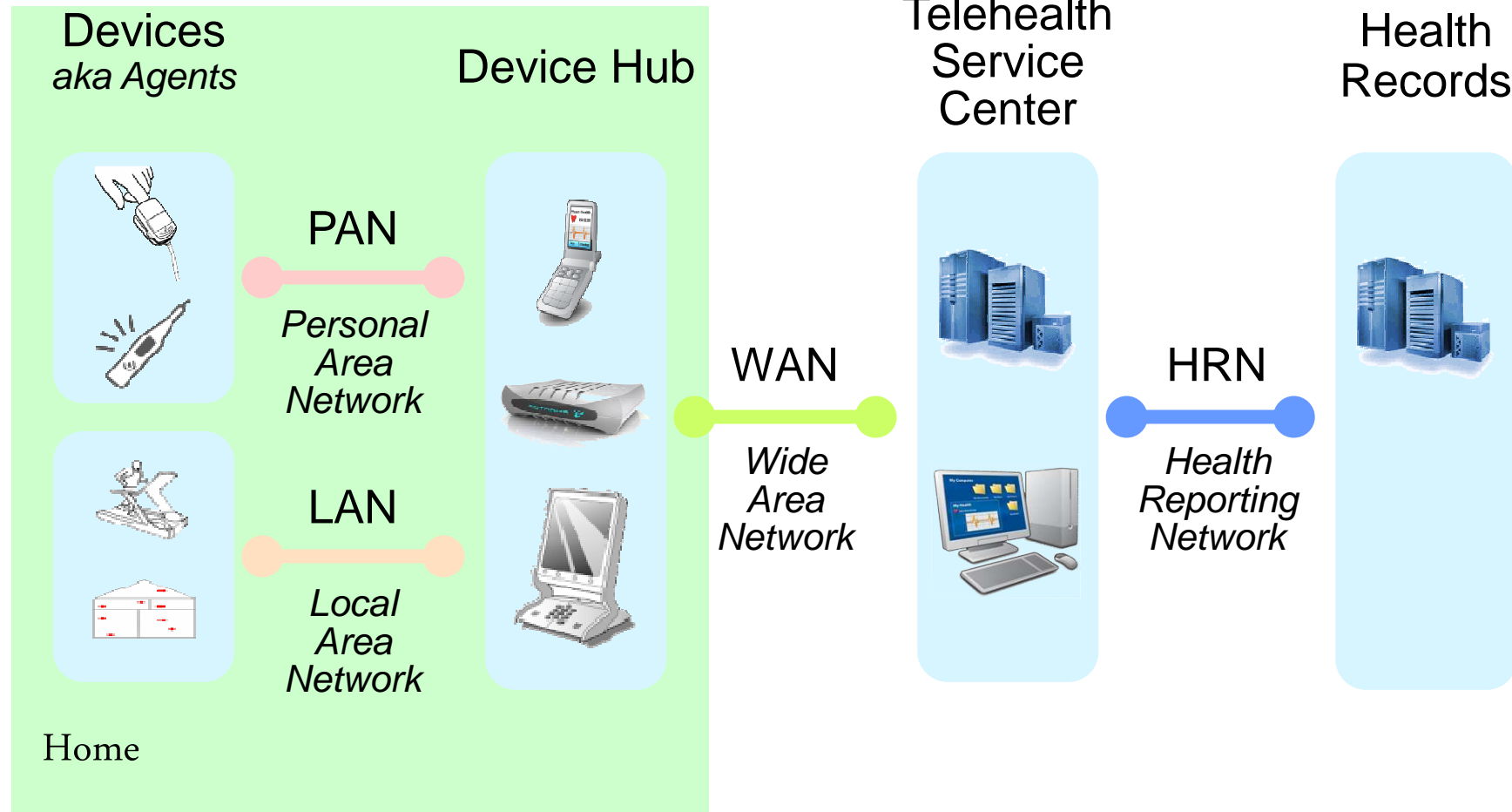
What is IHE, how much adopted ?


- Over 300 Members, solved and tested a number of healthcare interoperability problems.
- An open, multi-stakeholder collaborative to accelerate stds based interoperability
- The European Commission and eHealth Interop Mandate 403: endorses IHE process
- ISO Health Informatics: TR28380 Global Standards Adoption – IHE Process and Profiles
- Widespread adoption of IHE Profiles by National and Regional Projects around the world: USA, Europe, Asia
- Home Health: CONTINUA and IHE work together.
- 12 Country European epSOS Project (IHE-Europe hosting Industry Team, performing testing).

IHE, Global Standards-Based Profiles Adopted in National & Regional Projects



Remote Monitoring Connectivity Framework





Convergence over the WAN – *personal and clinical medical device data*



Continua®
HEALTH ALLIANCE

iHE® *changing the way healthcare*
www.ihe.net *connects*



Two great organizations ...

... *collaborating rather than competing*

Do the same thing the same way

- a temperature is a temperature, no matter where it is taken
- *so why not send the data the same way!*

Share best practices ...

- learn from each domain, *clinic to personal* and *personal to clinic*
- use the same protocols, documentation and conformance tooling
- achieve a critical mass, *and others will join ...*

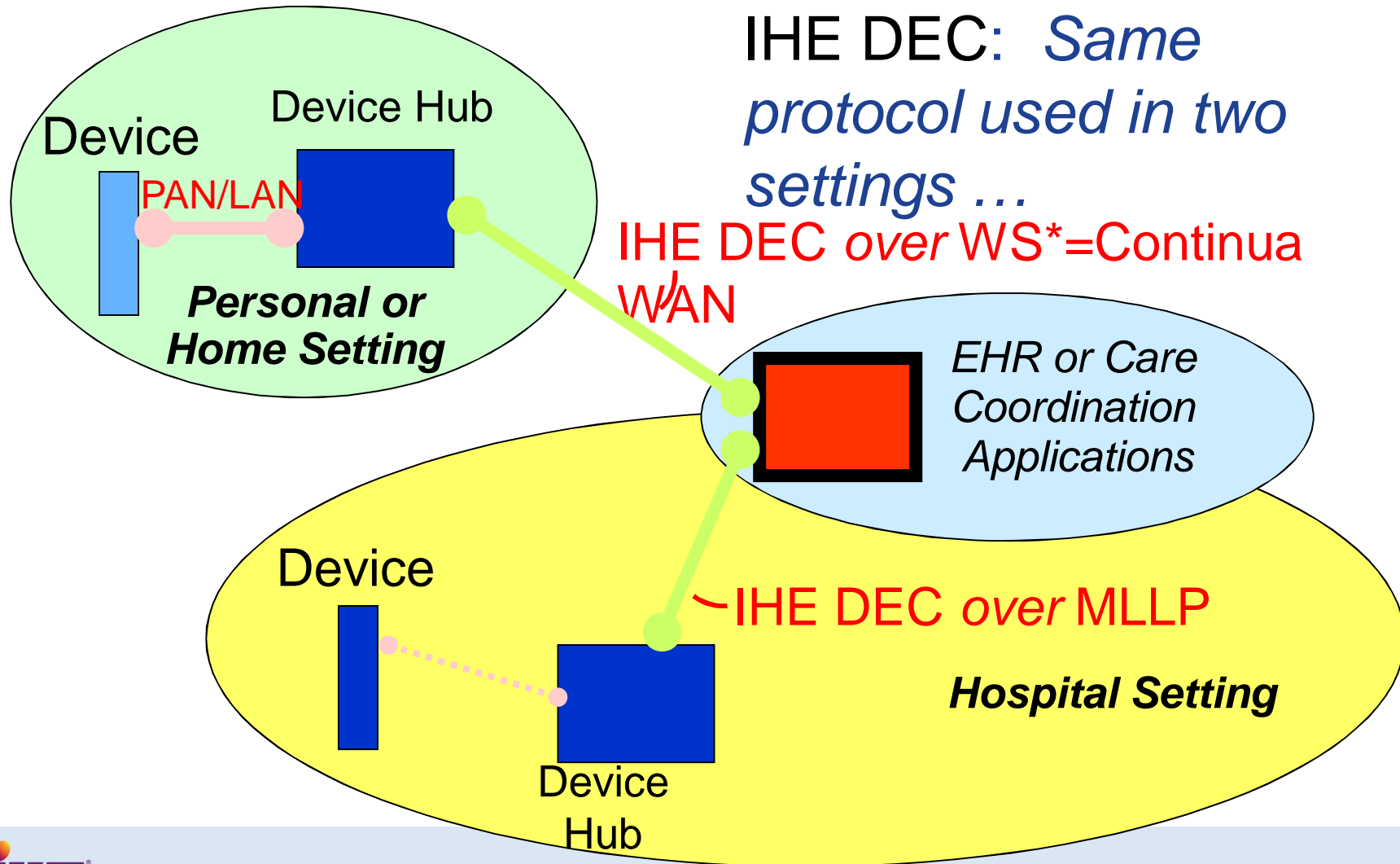
... to the benefit of the clinicians and patients we serve.


- cross-diffusion of devices used in personal, home or clinic settings
- facilitate use of more advanced devices at home

.....and makes the hospital CIO happy with the same interface for import of device data in EHR !

Personal and Clinical Device data

Why should they be exchanged differently?





Looking at some interoperability standards “under the cover”

...Actually we do not have to dive at that level !



&



did it for us !

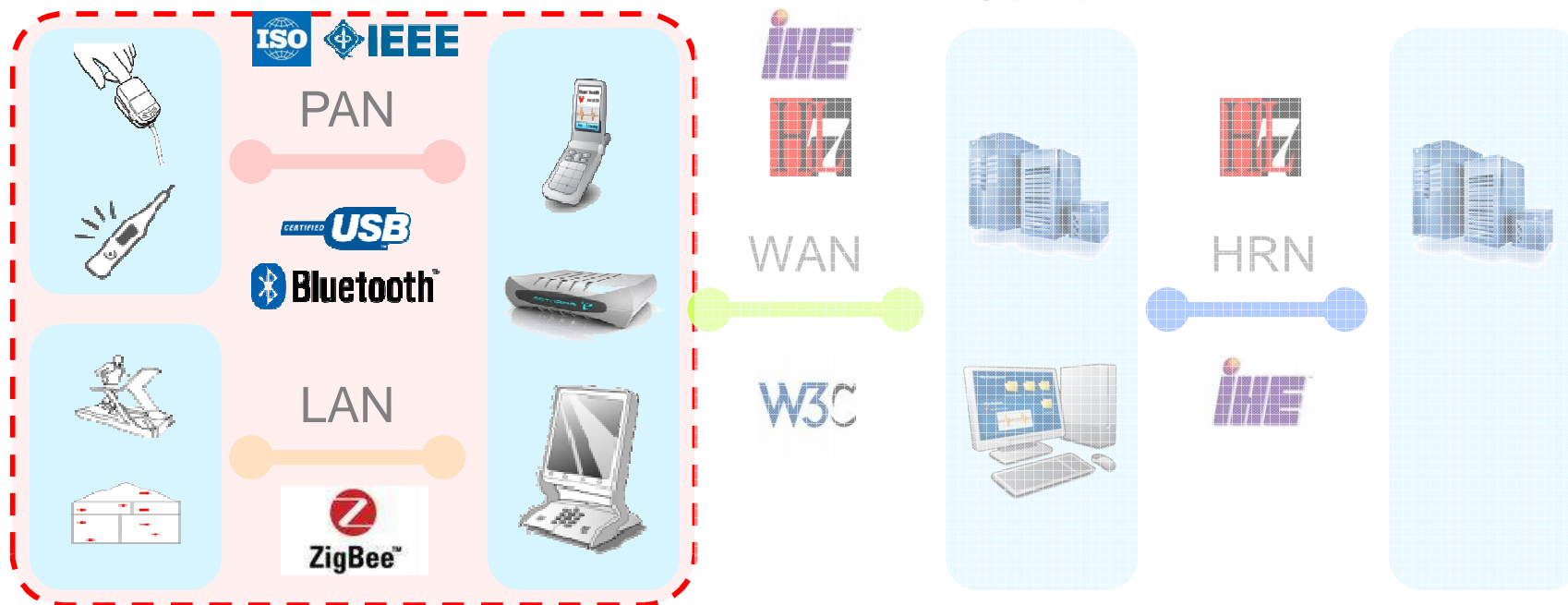
End-to-End Connectivity Standards

Devices
aka Agents

Aggregation
Manager

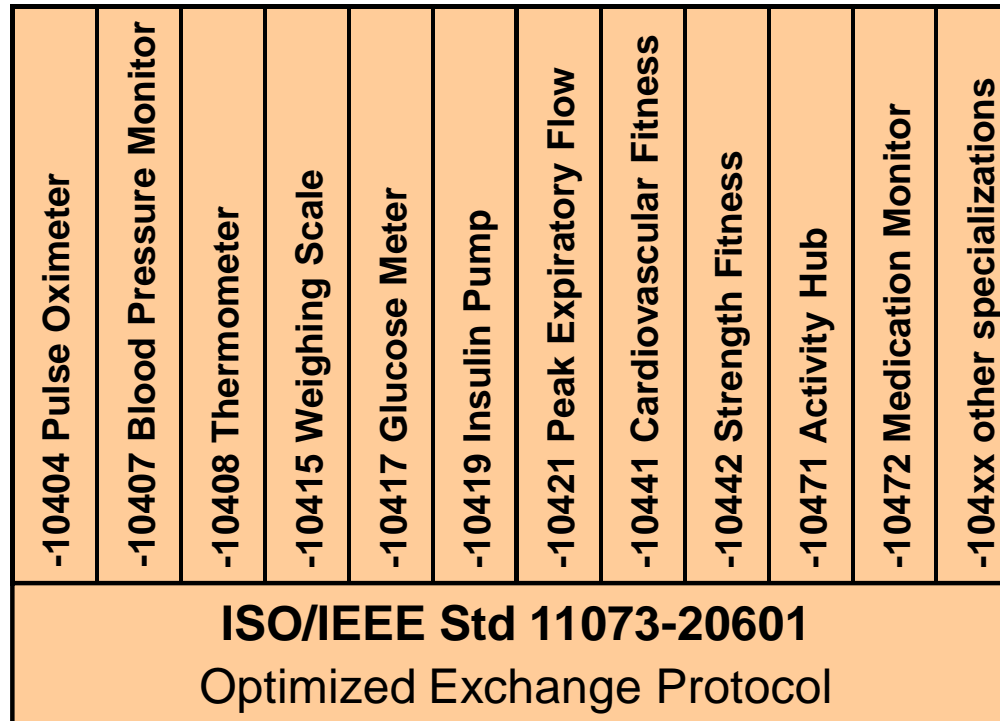
Telehealth
Service
Center

Health
Records



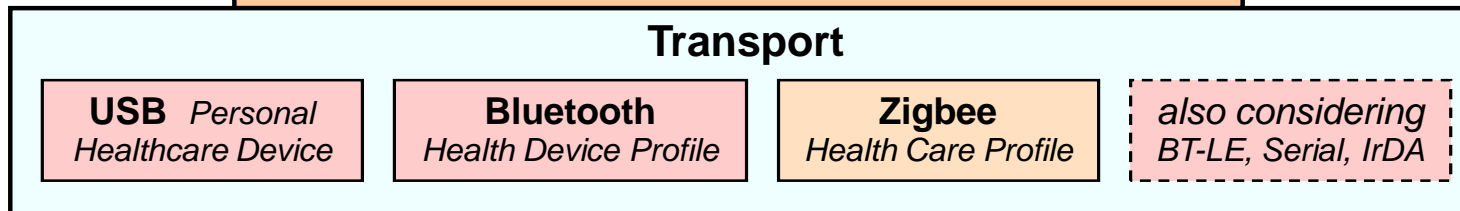
IEEE 11073 PHD Communication

ISO/IEEE Std 11073-104xx Device Specializations



Device Specializations

Data Exchange Protocol



End-to-End Connectivity Standards

Devices
aka Agents

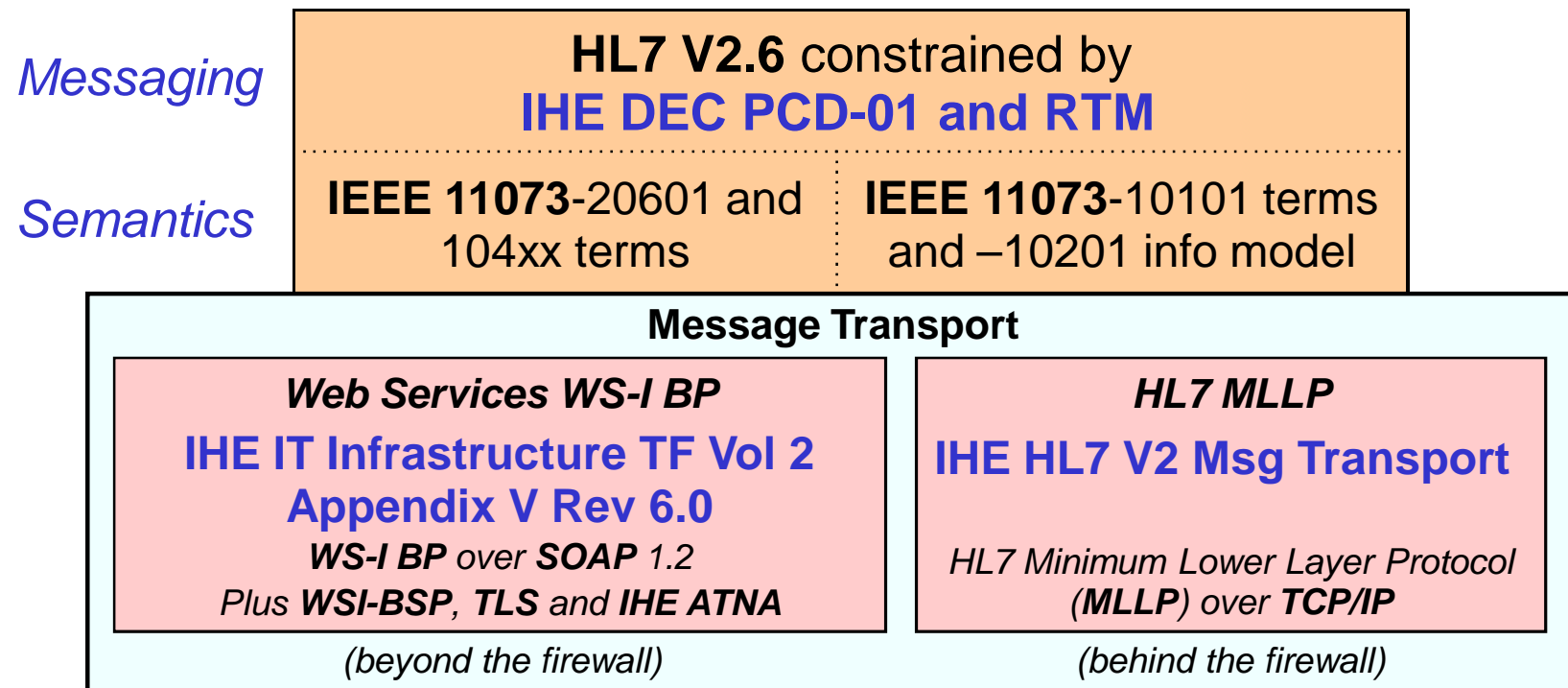
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Continua WAN and IHE DEC



IHE and Continua WAN V1.5 Security Guidelines

Requirement	Guidelines	WAN	IHE
Data Confidentiality	WS-I BSP v1.0 <ul style="list-style-type: none"> • TLS protocol v1.0 (RFC 2246) • AES cipher (RFC 3268) 	M	✓ O
Data Integrity	WS-I BSP v1.0 <ul style="list-style-type: none"> • TLS protocol v1.0 (RFC 2246) • SHA1 hash (RFC 3174) 	M	✓ O
Authorization Information Exchange	WS-I BSP v1.0 <ul style="list-style-type: none"> • WS-Security Header Only • SAML v2.0 token 	M	✓ Consistent with IHE XUA
Auditing	IHE ATNA Auditing <ul style="list-style-type: none"> • Section 3.20, ITI-TF6-Vol2a 	mV2 ¹	✓

M Mandatory 'shall' **R** Recommended **O** Optional

✓ Guideline is aligned with IHE

mV2¹ IHE ATNA Auditing may become mandatory in a later version, e.g. V2

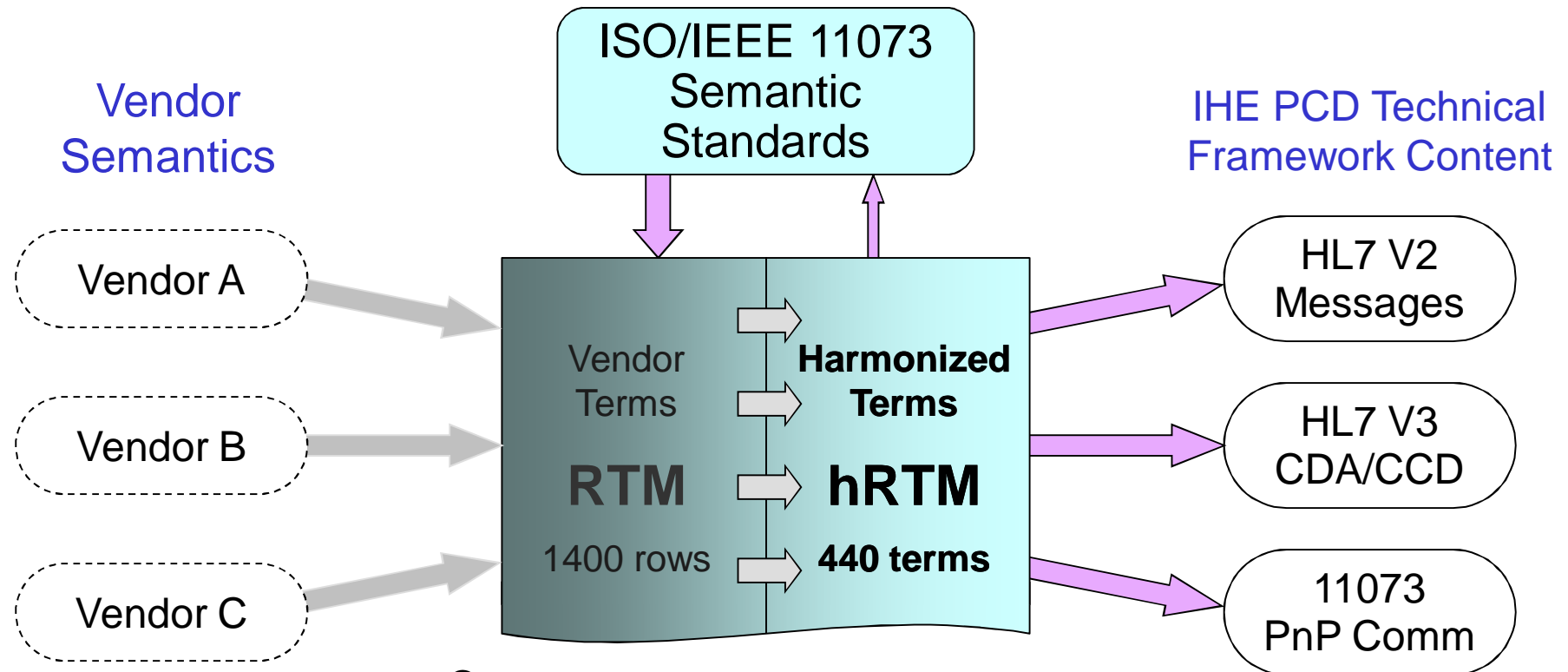


Semantic Interoperability

Objective:

- Communicate medical device data using a single **unified nomenclature** and **semantic model** that can be **rigorously defined** and **enforced** to facilitate safe and effective plug-and-play interoperability.

IHE PCD Rosetta Terminology Management



- Open consensus process
- Observation identifiers *and* co-constraints
- New terms incorporated into standards
- hRTM used for conformance testing

IHE PCD Harmonized Rosetta (hRTM)

Specifies for each IEEE 11073 **REFID observation identifier**:

- the 11073 MDC and UCUM **units-of-measure**
 - includes dimensional analysis to ensure correct ‘units-math’
- **enumerated values** and **measurement sites**
- numeric **codes**, where appropriate

An extract from the hRTM is shown below:

Group	REFID	DIM	UOM_MDC	UOM_UCUM
CVS_ECG_HR	MDC_ECG_HEART_RATE	T-1	MDC_DIM_BEAT_PER_MIN	{beat}/min {beats}/min 1/min /min
CVS_ECG_ST	MDC_ECG_AMPL_ST_I	ML2I-1T-3 ML2I-1T-3	MDC_DIM_MILLI_VOLT MDC_DIM_MICRO_VOLT MDC_DIM_MILLI_M#	mV uV (added by scripting rule) mm# (voted “off-the-island”)
GASMON_AA_ENFL	MDC_CONC_ENFL_ET	L3L-3 LMT-2L-2 LMT-2L-2	MDC_DIM_VOL_PERCENT MDC_DIM_KILO_PASCAL MDC_DIM_MMHG	%{vol} kPa mm[Hg]

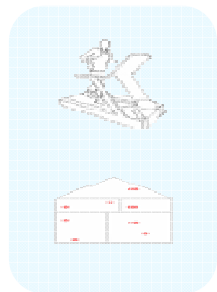
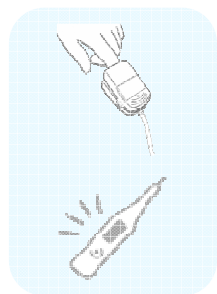
Available at http://wiki.ihe.net/index.php?title=PCD_Profile_Rosetta_Terminology_Mapping

hRTM Highlights

- Unified semantics and semantic model are essential prerequisites for **safe and effective interoperability** between devices and systems.
- The hRTM **rigorously defines** what may be sent and informs recipients of what they may expect to receive. For each **observation identifier**, the hRTM specifies the **units-of-measure**, **enumerated values**, **measurement sites** and other co-constraints.
- The hRTM is based on the **ISO/IEEE 11073 standards** and leverages and extends that work by using an **open consensus process**.
- The hRTM is **publicly available** for IHE PCD clinical devices and will be available shortly for IEEE 11073 personal health devices.
- The hRTM **supports message conformance testing frameworks** that can be used for both **clinical** and **personal** health devices.

End-to-End Connectivity Standards

Devices
aka Agents



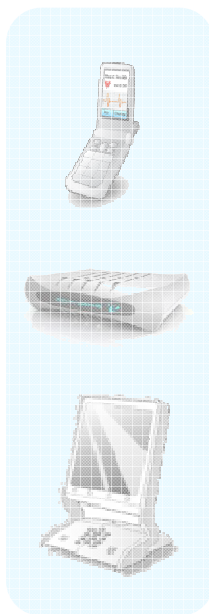
PAN



LAN



Aggregation
Manager



WAN

W3C

Telehealth
Service
Center



Health
Records

Health Reporting Network (HRN) Interface

Messaging

Semantics

HL7 Implementation Guide for CDA R2:
Personal Healthcare Monitoring Report, Release 1

HL7 Clinical Document Architecture CDA R2 –
Continuity of Care Document (CCD)

SNOMED, LOINC, UCUM *and IEEE 11073 as required*

Transport: Document Exchange

IHE XDR

*IHE Cross-Enterprise
Document Reliable Interchange
MTOM, SOAP 1.2 / HTTP*

(direct communication)

IHE XDM

*IHE Cross-Enterprise
Document Media Interchange
ZIP format / S-MIME or media*

(email, media)



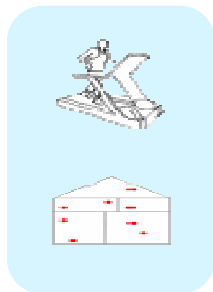
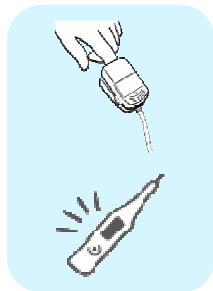
Interoperability Procurement Recommendations

Personal Devices Connectivity Procurement

Which Interface: e.g. PAN, LAN, WAN, HRN

Which Device Data: e.g. Glucose Meter

Devices
aka Agents



PAN

**Continua
PAN 1.0
or 1.5**

LAN

**Continua
LAN 1.5**

Device Hub



WAN

**Continua
WAN 1.5**

Telehealth
Service Center



HRN

**Continua
HRN 1.0
or 1.5**

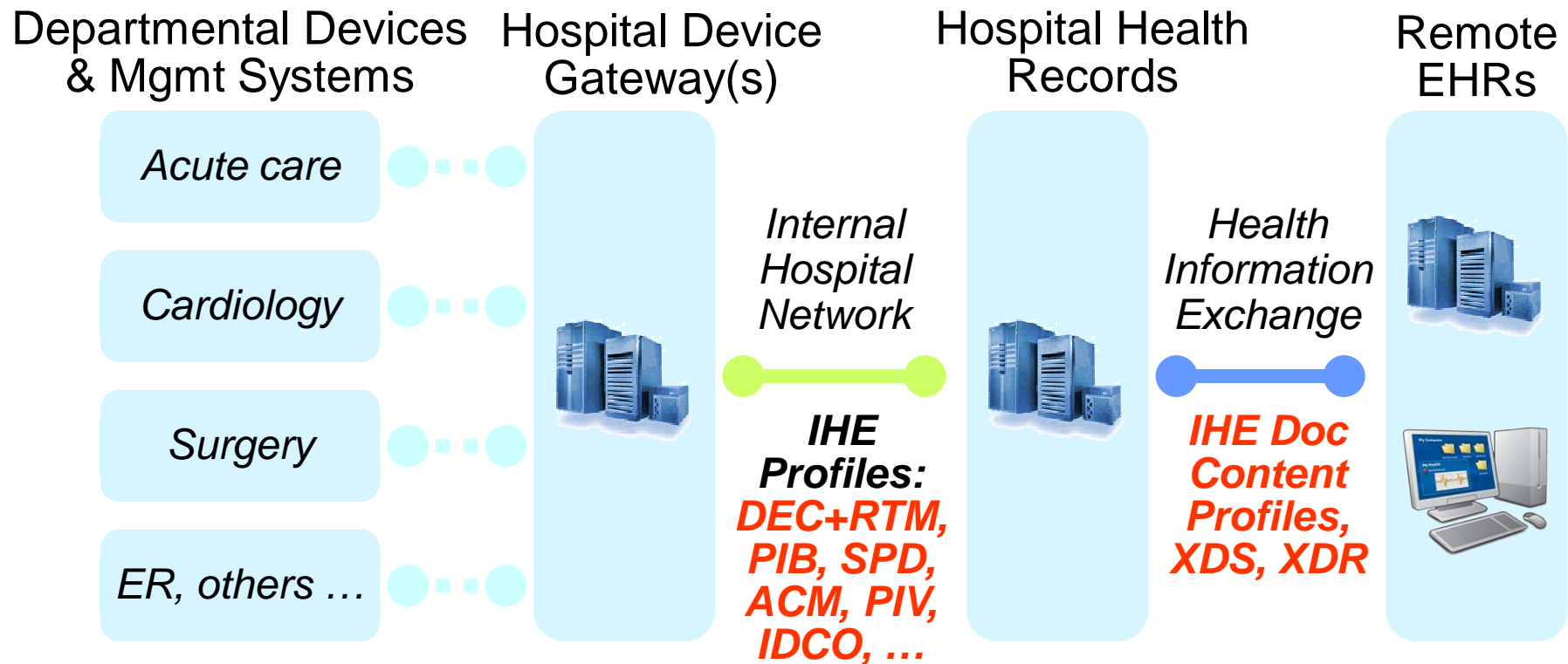
Health
Records



Note: Continua expects to finalize the V1.5 Guidelines in June/July 2010.
Continua has a comprehensive certification program for all supported interfaces.

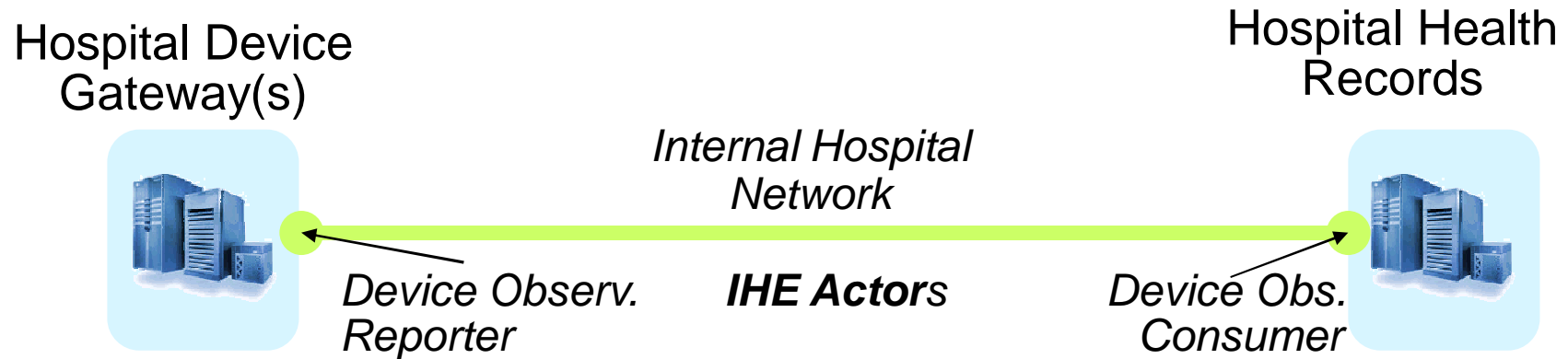
Clinical Devices Connectivity Procurement

*Which Profile and Actor: e.g. DEC as Observation Source
Which Device Data Group (Device): Pick a row from hRTM*



Note: IHE Profiles shown above have been conformance tested at US & EU Connectathon; IHE DEC and RTM are to be published as 'final text' in June/July 2010.

Clinical Devices Connectivity Procurement



IHE Profiles:

DEC+RTM:

Device Enterprise Com.

Rosetta Terminology (pick one or more rows)

ACM:

Alarm Communication Mgt

...(See IHE PCD Technical Framework Volume 1).

For each systems procured:

- 1 - Specify the Profile/Actors to be supported (saves pages of detailed specs)
- 2 - Ask for the IHE Integration Statement (declares Profile/Actors supported)
- 3 - Ask for a voluntary declaration that the Actor/Profile implemented tested at a Connectathon
- 4 - Place contractual commitments to fix non-compliance to IHE Profile Specifications claimed

Concluding Remarks

- **Want to interface personal devices to your EHR or Care Coordination System ?**
→ *Continua Implementation Guidelines*
- **Want to interface clinical devices to your EHR ?**
→ *IHE Patient Care Device Profiles*
- **Want to share personal device monitoring data between EHRs, PHRs and Care Coordination Systems ?**
→ *IHE XDS/XDR/XDM + for clinical doc content XPHR/PHM*

Consistent specifications, implemented, tested at IHE Connectathons, CONTINUA certification.

Demonstrated at Interoperability Showcases (HIMSS, WoHIT)

For further information



Integrating the Healthcare Enterprise

IHE Web: www.ihe.net PCD Web: www.ihe.net/pcd and www.accenet.org/ihe

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

PCD Getting Started: http://wiki.ihe.net/index.php?title=PCD_Getting_Started

PCD Users' Handbook: <http://www.ihe.net/Resources/handbook.cfm>



Continua Health Alliance

Web: <http://www.continuaalliance.org>

Continua Wiki: http://en.wikipedia.org/wiki/The_Continua_Health_Alliance

Continua Overview Presentation, Video, Flyers:

<http://www.continuaalliance.com/about-the-alliance.html>



National Institute of Standards and Technology

Web: <http://www.nist.gov>

Medical Devices: <http://www.nist.gov/medicaldevices>



Conformance Testing

*How do we get from
'plug-and-pray'
to
'plug-and-play' ?*

NIST Conformance Testing

NIST has the following mission in regards to Health IT Interoperability Standards:

- *Ensure* health IT standards are *complete* and *robust*,
- *Establish* a health IT standards *testing infrastructure* that supports effective industry consensus standards development processes, and
- Provide the U.S. healthcare IT industry and federal activities with robust *conformance* and *interoperability testing*.

IHE and NIST Collaboration

- IHE and NIST have an had active collaboration for the past six years, with a strong focus on the IHE PCD profiles.
- NIST supports IHE PCD HL7 V2 message conformance testing, including syntax and semantics, with the latter constrained by hRTM.
- NIST is establishing a framework for IHE PCD covering increasing complexity over the next five years, including support for virtual and face-to-face connectathons as well as year round testing.
- Other collaboration and development, beyond IHE PCD:
 - ISO/IEEE 11073 Standard (X73): Medical Device Communication
 - ISO/IEEE 11073 Personal Health Devices (X73_PHD)

Visit <http://www.nist.gov/medicaldevices>

Questions?





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www.ihe.net *connects*

WWW.IHE.NET