


The IHE logo consists of the letters 'IHE' in a bold, dark blue, sans-serif font. A vertical line is positioned to the right of the letters, separating them from the tagline.

**IHE**

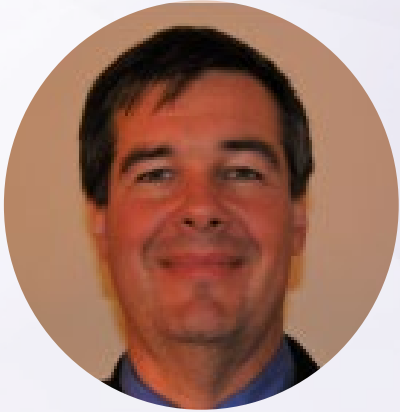
Integrating  
the Healthcare  
Enterprise

A stylized globe showing the continents of North and South America, rendered in a light purple color. It is positioned in the lower-left corner of the slide, partially overlapping the main text.

**Devices Domain: Patient Care  
Devices Work Program  
Webinar Series 2025**

# Presented by

## **Kurt Elliason**



Sr. Member Technical Staff - ICU Medical  
IHE PCD/Devices Planning Committee Co-Chair  
Pump Working Group co-lead  
IHE International Board of Directors Devices Domain Rep.

## **Rob Wilder**



Product Management Professional and Standards Consultant  
IHE PCD Planning Committee Co-Chair  
ACM Working Group co-lead

# IHE International - Overview

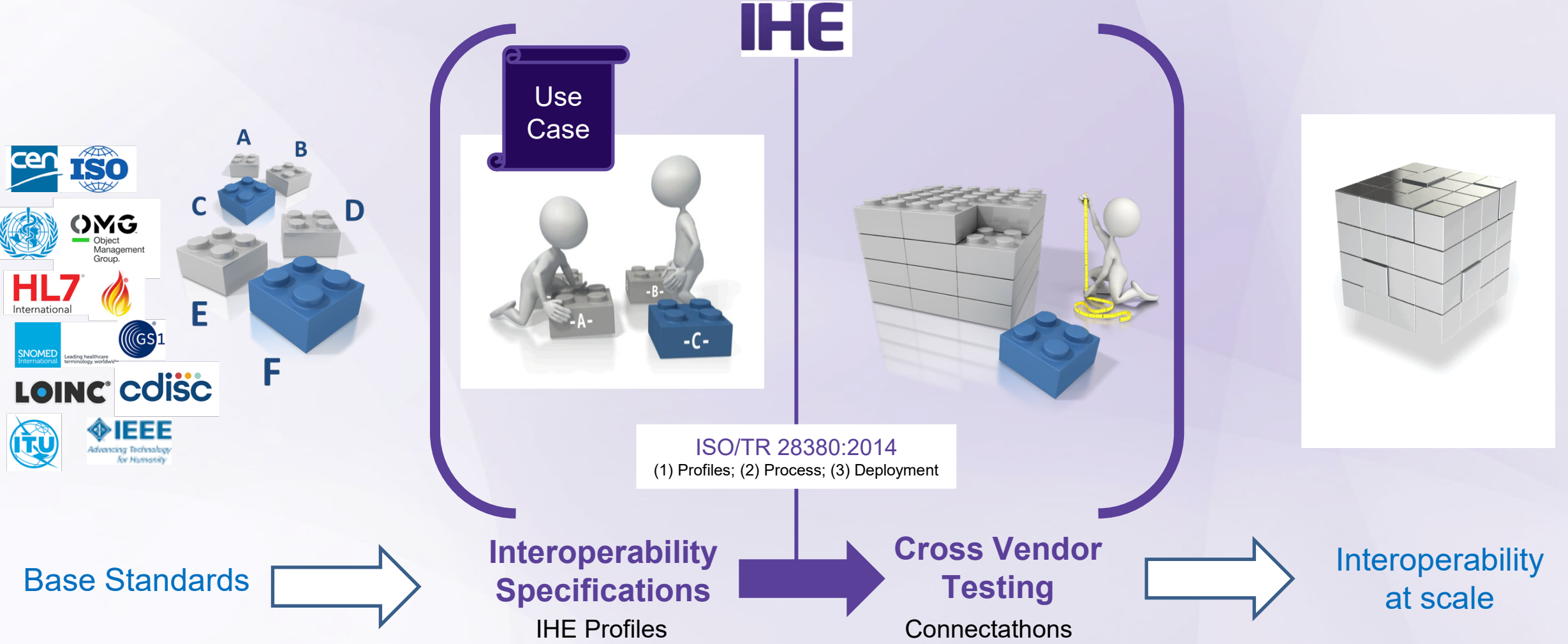
## Benefactor Members



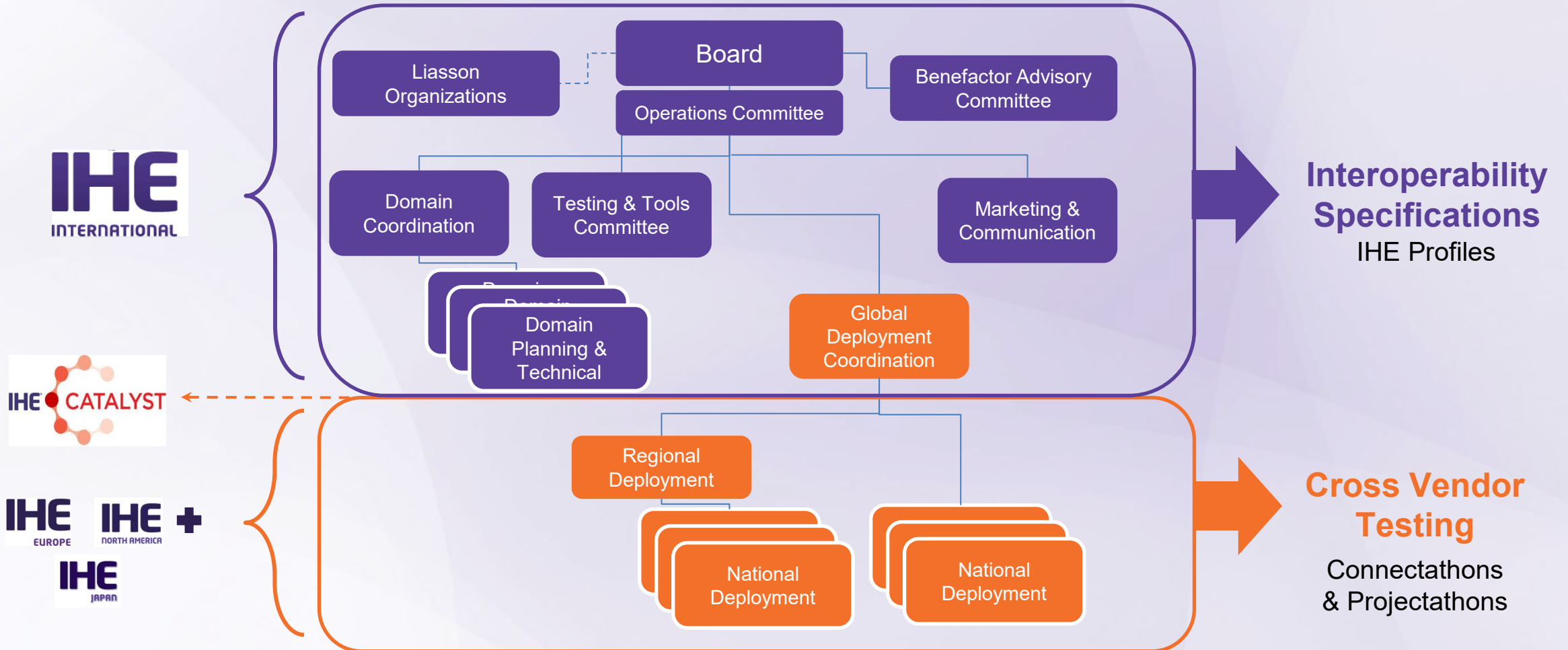
Note ASTP (US Assistant Secretary for Technology Policy) is formally ONC

- **Launched in 1999**
  - Born from collaboration by healthcare professionals and industry tech vendors.
- **Mission:** Facilitate standards into patient care devices
- **Objectives:**
  - Establish standards based “profiles” to address specific clinical needs in
  - Support more optimal patient care
  - Address clinical needs for consistent and efficient information exchange
  - Simplify the implementation of multiple products requiring interoperability in the clinical enterprise

# IHE International – The IHE Methodology



# IHE International – Organization Structure



# Devices Domain

## –Patient Care Device (PCD) Program

- Integration of medical device data from the point-of-care to information systems

## –Personal Connected Health (PCH) Program

- Focus on advancing patient/consumer-centered health, wellness and disease prevention.

## –Device Point-of-care Integration (DPI) Program

- Focus on device connectivity around a patient-centric point-of-care, including device discovery and association, data reporting, symmetric (bi-directional) communication, and external controls.

# Patient Care Device Program

- Formed:** 2005 (as the PCD Domain)
- First Profile:** 2006
- Final Text:** 2011
- Primary Focus:** Point-of-Care Medical Device integration focus
- Mission:** Enable “Out of the Box”, Reliable and interoperable solutions

## **Focuses on devices associated with patients, including...**

- Patient monitors, pumps, vital signs monitors, pulse oximetry, ventilators,
- Harmonizing terminology – nomenclature, enumerations, units of measure
- Getting alerts (alarms & advisories) to staff (clinicians, physicians, clinical engineers, IT, etc.) on local wireless, mobile, and desktop devices
- Improving infusion order safety
- Collecting and reporting data from devices for immediate access, retrospective storage and retrieval

# PCD Technical Underpinnings

- **HL7** version 2.6 baseline, with profile specifics drawing upon 2.7, 2.8, 2.9
- **ISO/IEEE** 11073 Standards
- **IEC** 60601-1-8 standards
- Wireless Communication Transfer Protocol (**WCTP**) version 1.3
- **IHE ITI domain** Consistent Time profile – Network Time Protocol

## Organizational Relationships



# PCD Program Profiles

**IDCO:** Implantable Cardiac Device Observations

**DEC:** Device to Enterprise Communication (DEC) profile

**ACM:** Alert Communication Management profile

**WCM:** Waveform support in observations and alerts (ACM and DEC)

**MEM:** Medical Equipment Management

**PIV:** Point of care Infusion Verification

**PCIM:** Point of Care Identity Management

**IPEC:** Infusion Pump Event Communications profile

**Supportive efforts:**

- **RTM:** Rosetta Terminology Management (RTM)
- **OMS:** Optimized Message Syntax (OMS)
- **NIST** Testing Tools

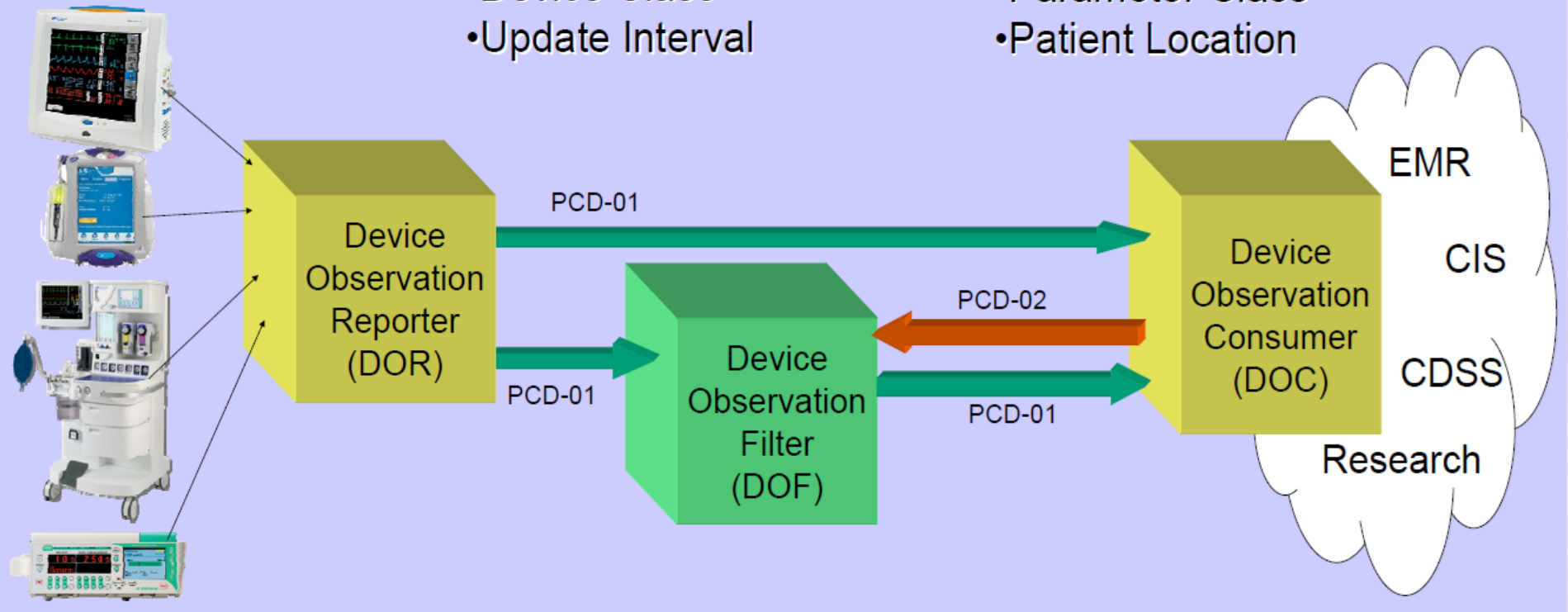
\*new profile\* Point of Care Managed Communication (PCMC)

# Device Enterprise Communications (DEC)

The DEC profile allows a consuming system (DOC) to receive patient clinical information including vitals, demographics, settings, and location from a reporting device/system (DOR).

The Subscribe to Patient Data (SPD) option allows the consumer to filter the data by:

- Medical Record #
- Device Class
- Update Interval
- Start & End Times
- Parameter Class
- Patient Location



# Alert Communication Management (ACM)

HL7 Messages  
per ACM and  
WCM profiles

Parameters, waveforms, etc.  
as evidentiary data items

Device  
Specific  
graphics



**Alert  
Reporter  
AR**

Report Alert  
PCD-04 →  
← PCD-05  
Report Alert  
Status

**Alert  
Manager  
AM**

Disseminate Alert  
PCD-06 →  
← PCD-07  
Disseminate  
Alert Status

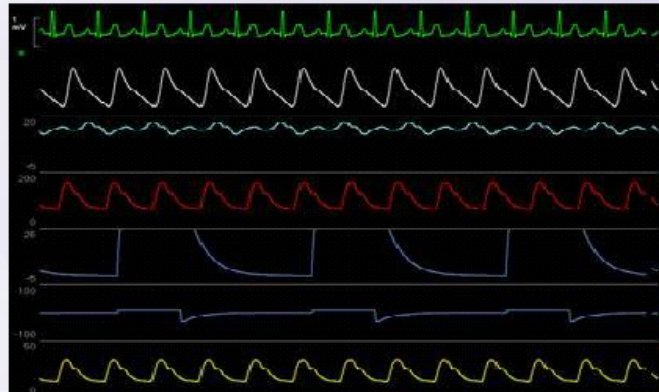
**Alert  
Communicator  
AC**



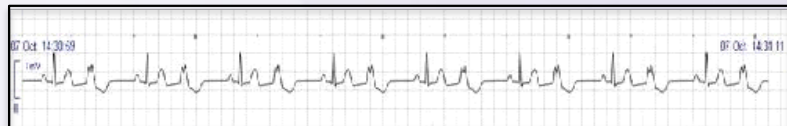
Alert Information  
Source, Phase, State, Priority  
Patient  
Location  
Instance  
Alert text  
Callback  
Timestamp  
Evidentiary data

Dissemination Status  
Instance  
Accepted by AC  
Undeliverable  
Delivered  
Read  
Accepted  
Rejected  
Cancelled  
Callback start/stop

# Waveform Content Module (WCM)



**Continuous Waveform Data**

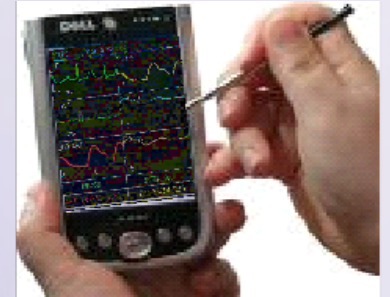
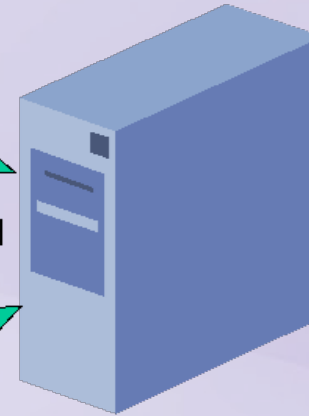


**Alarm Evidentiary Data**

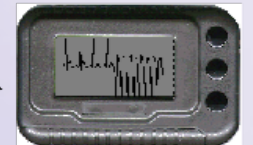
PCD-01

WCM encoded waveform

PCD-04



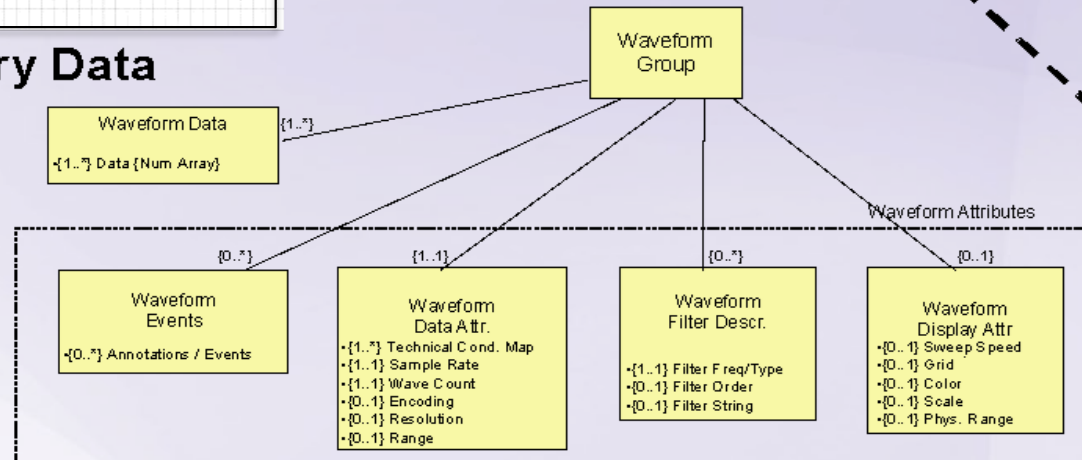
**In-Hospital Access**



**Mobile Access**



**Remote Access**



# Recent Initiatives

## Quite Hospital and Silent ICU

- **Problem:** Many audible alarm signals generated independently by many devices creates a vexing environment for caregivers and patients
- **Effects:**
  - Many non-actionable i.e. non-clinically relevant alarms
  - Patients subject to stressful noise level, hindering their healing
  - Alert fatigue and delays in treatment for caregivers



# Initiative Objectives

## Quite Hospital and Silent ICU

- Diminish alert fatigue for staff and noise level for patients
- Consolidate the audible alerting process in the patient room and the care unit
- Improved workflow for responding to common non-critical device alarms
- Enhance safety and satisfaction efforts through technology improvements
  - JACHAO 2019 NPSG 6 (Improve the safety of clinical alarm systems)
  - HCAHPS (the Hospital Consumer Assessment of Healthcare Providers and Systems) which is a required patient satisfaction survey

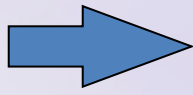
### **Silent ICU Presentation**

<https://www.youtube.com/watch?v=6sBtp5hulwg>

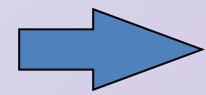
# Point of care Infusion Verification (PIV)



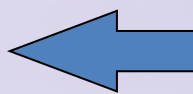
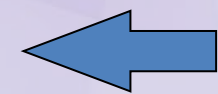
Physician's  
Order



Nurse  
Review



Pharmacist  
Review



Medication Administered



Nurse confirms 6 Rights:

- Right Patient
- Right Medication
- Right Dose
- Right Time
- Right Route
- Right Device

Infusion Pumps

BCMA to  
Pump  
(PCD-03)

Pump  
may  
provide  
data to  
EMR  
(PCD-  
01/10)

# Infusion Pump Event Communication (IPEC)

Enables reporting of clinical and operational events from an infusion pump to a Bedside Computer-assisted Medication Administration (BCMA) system or EMR.

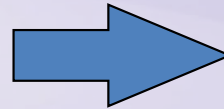
## BCMA/EMR

Prior to medication administration, nurse confirms the 6 Rights of administration using BCMA/EMR:

- Right Patient
- Right Medication
- Right Dose
- Right Time
- Right Route
- Right Device

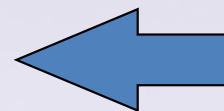
Infusion-related events are displayed, validated, and/or recorded by the clinician using the BCMA/EMR

Infusion order sent from BCMA/EMR to Pump (PCD-03)



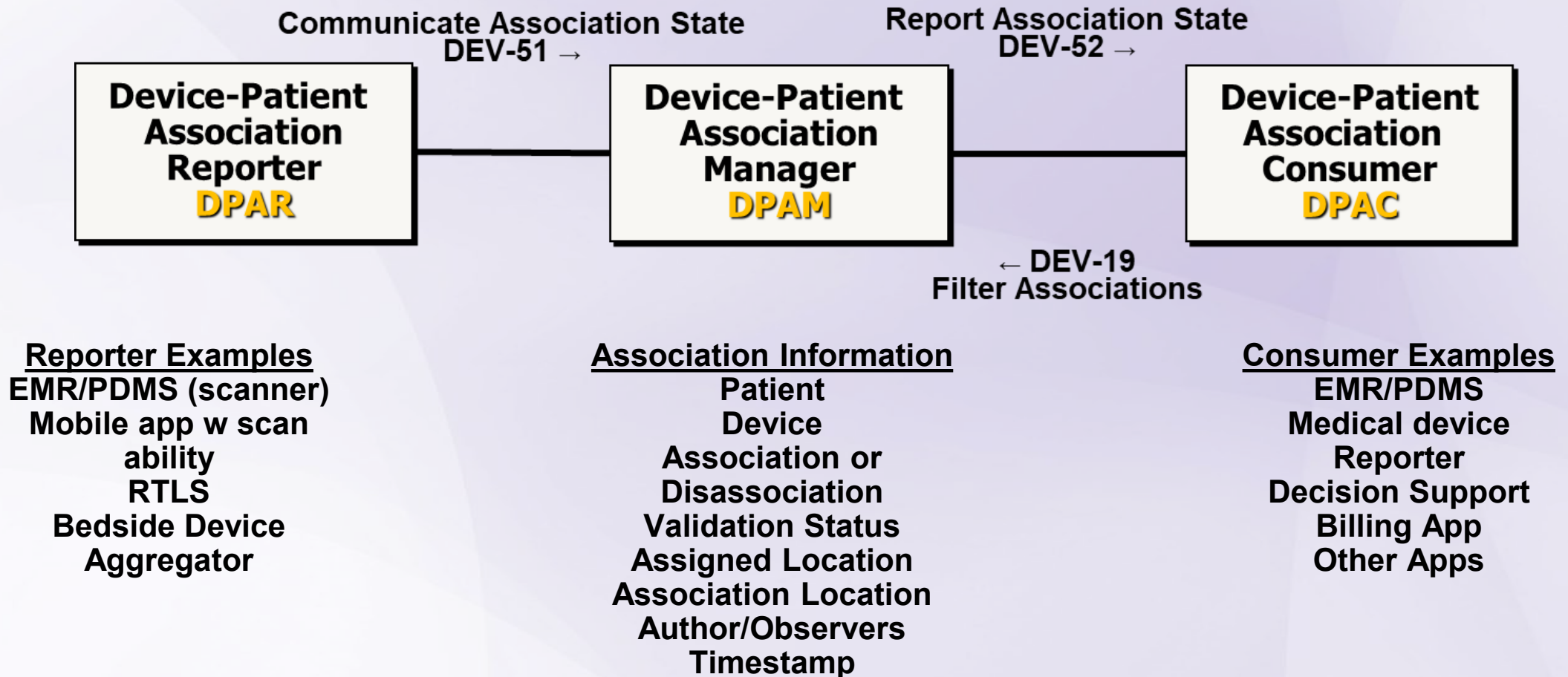
Pump provides information on infusion-related events to BCMA/EMR (PCD-10) such as:

- Delivery Start
- Delivery Stop
- Delivery Complete

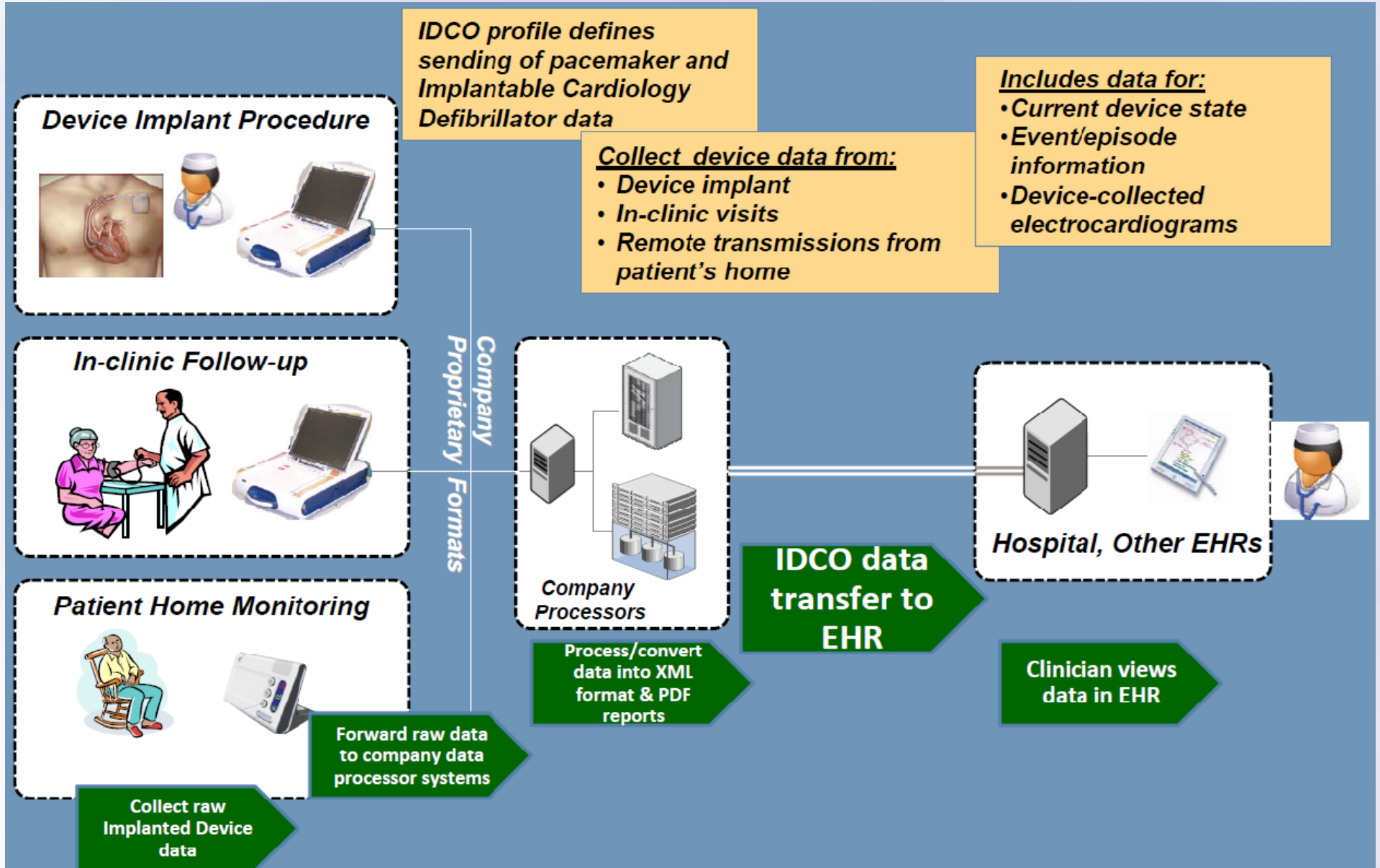


# Point of care Identity Management (PCIM)

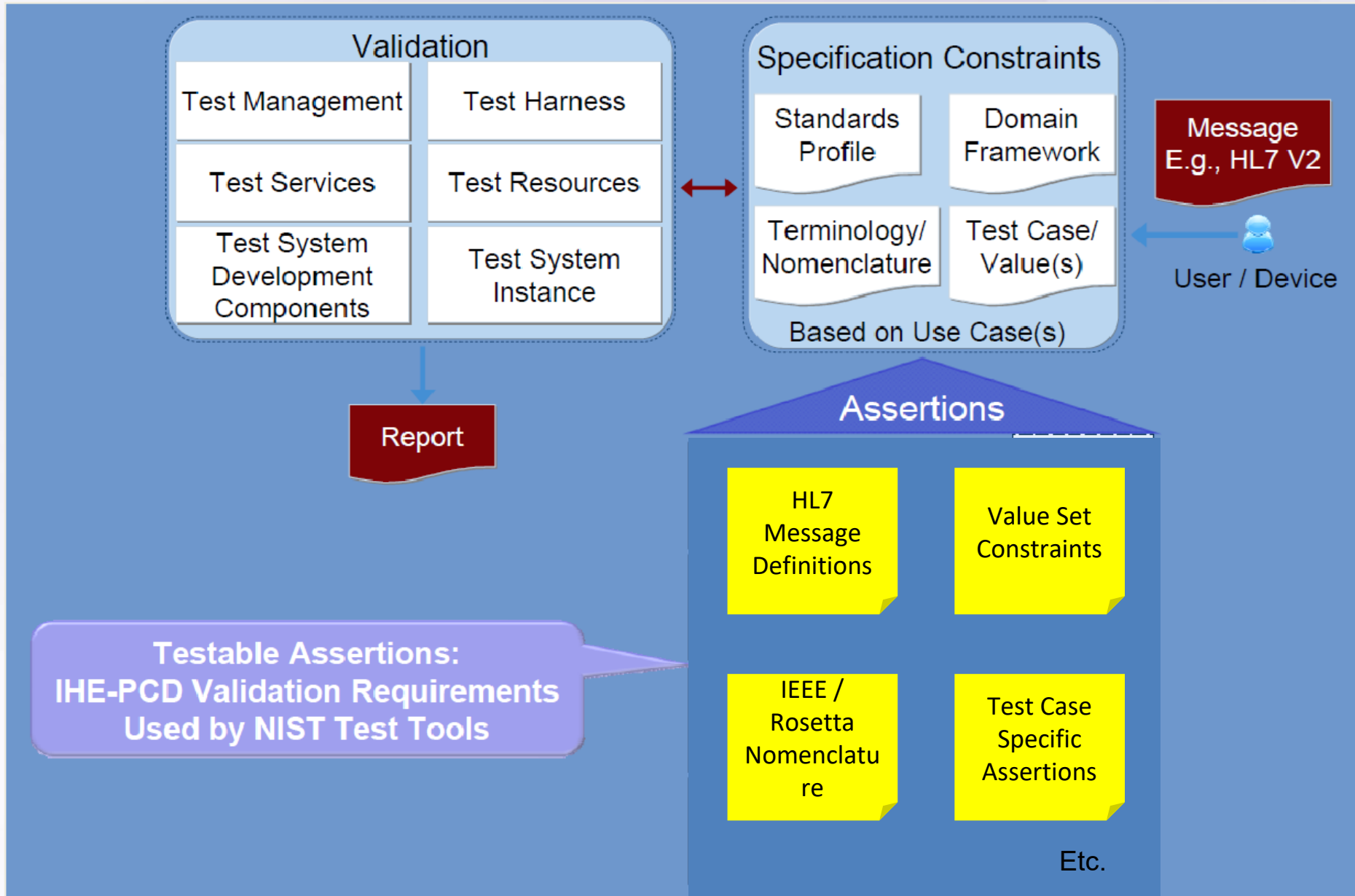
Device data stamped with patient identity and location improves safety and effectiveness.  
End-result is a reliable and interoperable device patient association source of truth



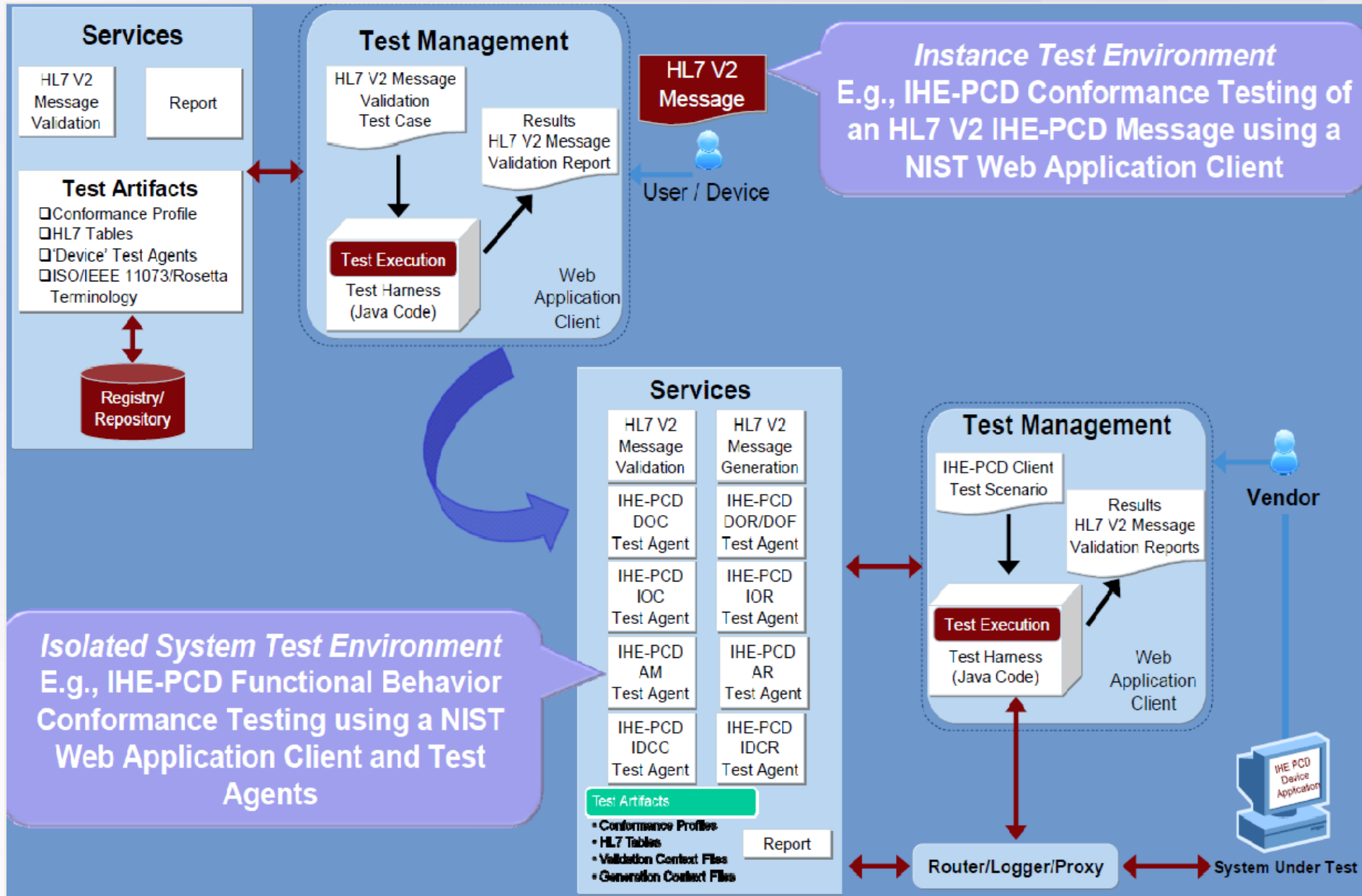
# Implantable Device - Cardiac Observation (IDCO)



# NIST Testing Tools



# NIST Testing Tools

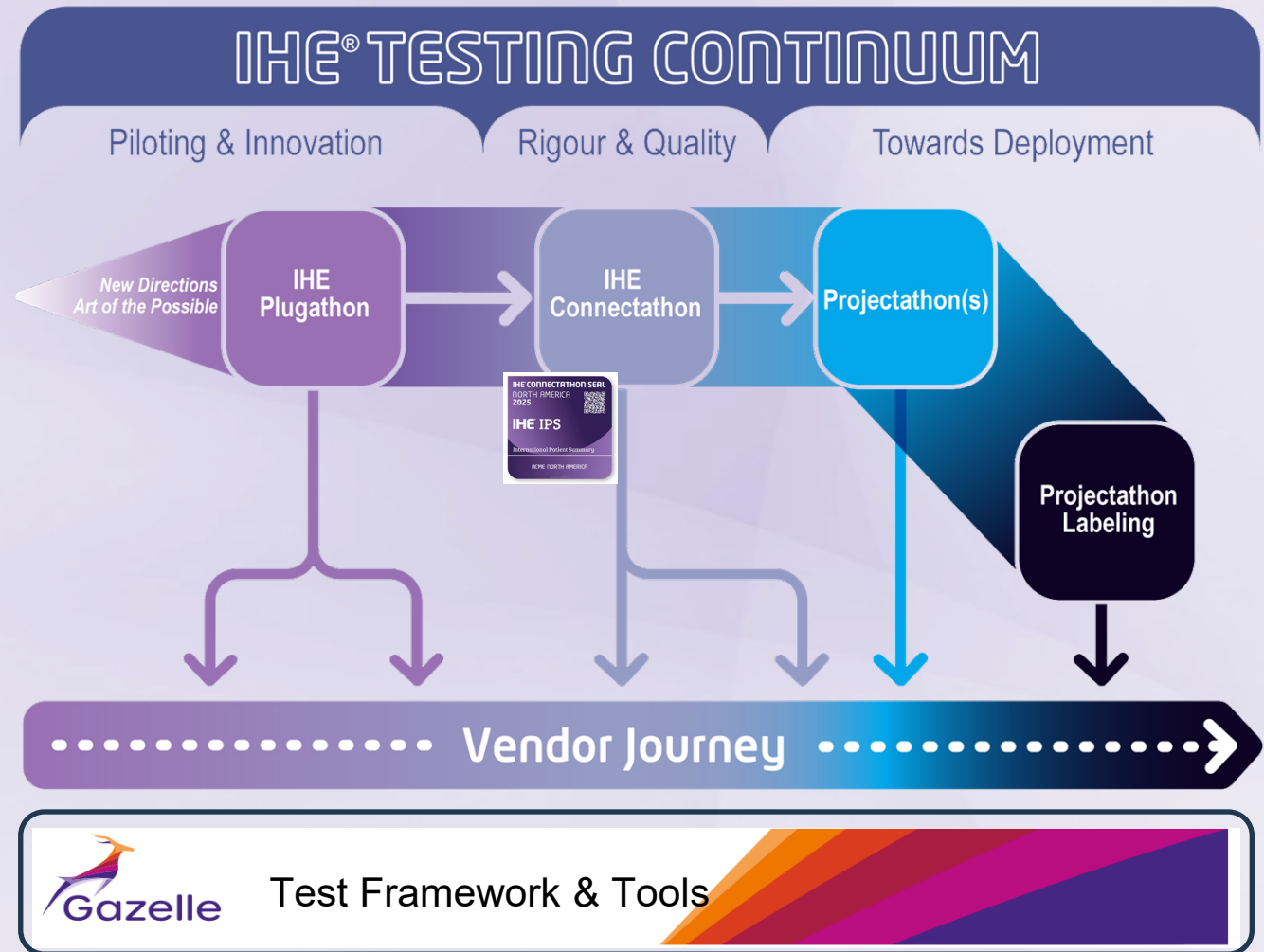


# 2025 Program Activities

- Increase interactions with end user communities and provider organizations
- Point-of-Care Identity Management(PCIM)
- Point-of-Care Monitored Communication (PCMC)
- Medical Equipment Management (MEM)
- Point of Care Infusion Verification (PIV)

# IHE International – Enabling Market Implementation

- Testing continuum enables vendor capabilities & implementation readiness
  - **Plugathons** inform specifications development
  - **Connectathons** test conformance to specifications
  - **Projectathons** are regionally focused events to guide market specific adoption
- Vendors can use Connectathon results (Seal) and Integration Statements for product labeling



# IHE International – Testing Events

## IHE Connectathons

- Twenty-six years of continuous events (>80 Connectathons held)
- IHE is the only organization in the industry that conducts this type of at-scale testing, at regular intervals, at venues around the world (North America, Europe, China, Japan, South Korea)



Domain specific: Radiation Oncology  
2025 IHE-RO Connectathon  
Erlangen, Germany Oct 13-17

# Role of Device Vendors

- **Support the Mission of IHE Devices**
  - Become an IHE member
- **Participate in PCD efforts**
  - Increased consistency and conformance – listen and be heard
- **Plant the Seed**
  - Support IHE PCD Profile based Interoperability
  - Encourage active IHE participation by vendors
- **Request customers purchase IHE PCD compliant products**
  - Provide IHE Integration Statements
  - Participate in Connectathons
  - Promote browsing of Connectathon Results and Product Registry sites
  - Participate in Interoperability Demonstrations (HIMSS)

# Role of Device Users

- **Support the Mission of IHE Devices**
  - Become an IHE member
- **Participate in PCD efforts**
  - Increased consistency and conformance – listen and be heard
- **Plant the Seed**
  - Encourage active IHE participation by users
- **Purchase IHE PCD compliant products**
  - Expect IHE Integration Statements from vendors
  - Include IHE requirements in RFI/RFP submissions
  - Look for products in Connectathon Results and Product Registry sites
  - Visit Live Interoperability Demonstrations (HIMSS)
  - Purchase commercially available PCD profile interoperable products



Integrating  
the Healthcare  
Enterprise

## Additional Resources

### –Connectathon Results

<https://connectathon-results.ihe.net/>

### –IHE Devices web site

[www.ihe.net/ihe\\_domains/devices/](http://www.ihe.net/ihe_domains/devices/)

### –Technical Framework and Supplements for Trial Implementation

[https://www.ihe.net/resources/technical\\_frameworks/#dev](https://www.ihe.net/resources/technical_frameworks/#dev)

### –IHE PCD Wiki

[https://wiki.ihe.net/index.php/Patient\\_Care\\_Device](https://wiki.ihe.net/index.php/Patient_Care_Device)

### –Tool web sites

NIST HL7 v2 Resource Portal

<https://hl7v2tools.nist.gov/portal/#/tools>

IHE Device Connectathon Testing Tool

<https://ihe-pcd.nist.gov/pcdtool/#/home>

Rosetta Terminology


<https://rtmms.nist.gov>

–To learn more about the Devices Domain, please contact the Domain Secretary at [dev@ihe.net](mailto:dev@ihe.net)

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