



Integrating  
the Healthcare  
Enterprise

# Pathology and Laboratory Medicine Domain Update

Presented by

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- Riki Merrick, MPH – Vernetzt, LLC - Planning Committee Co-Chair

# Agenda

## Intro to IHE

## Pathology and Laboratory Medicine

### Mission and Scope

### Integration profiles:

#### PaLM TF 8.0 Final text

Laboratory Testing Workflow (LTW)  
Laboratory Device Automation (LDA)  
Laboratory Analytical Workflow (LAW) Profile  
Laboratory Point of Care Testing (LPOCT)  
Laboratory Code Set Distribution (LCSD)  
Sharing Laboratory Reports (XD-Lab)

#### Trial Implementation profiles

Inter-Laboratory Workflow (ILW)  
Anatomic Pathology Workflow (APW)  
Anatomic Pathology Report to Public Health (ARPH)  
*Anatomic Pathology Structured Report (APSR)*

#### Current Projects

Laboratory Clinical Communications (LCC)  
Laboratory Specimen Handoff (LSH)  
Specimen Event Tracking (SET)  
Transfusion Medicine Administration (TMA)  
IHE Lab Profile to US realm Lab guides Harmonization  
APSR update  
DICOM WG s collaboration to update APW  
Data element registry white paper

# Prepare to get soaked

TLA = Three Letter Acronyms and more...



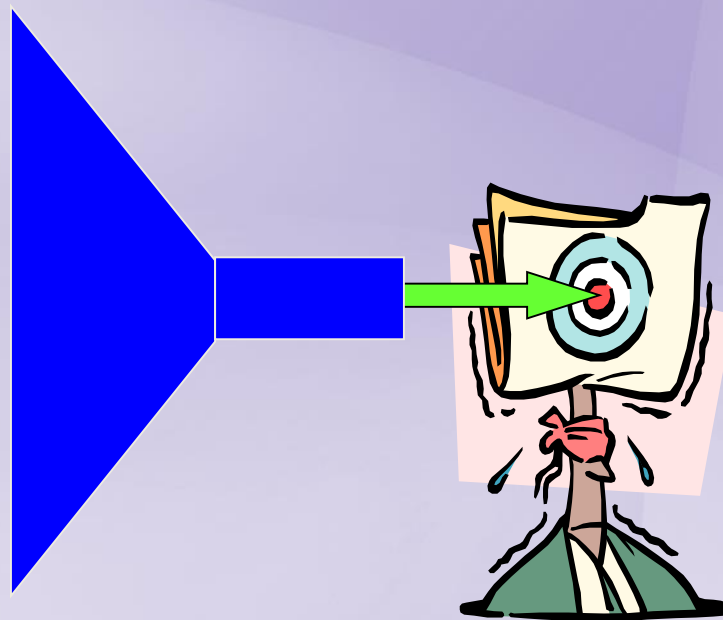
# Why IHE?

International standards represent usually the state-of-the-art and the best-of-bread blocks to build safe, interoperable, reproducible solutions of healthcare data exchange.

However ...

- ❑ They often carry a big number of options to accommodate various situations and requirements in the World.
- ❑ They hardly say how one should combine them into an e-Health solution involving multiple systems exchanging information with one another.

Base Standards

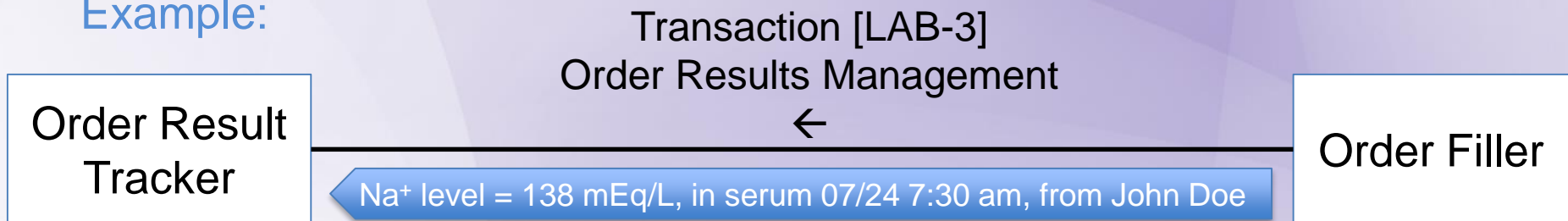


eHealth Projects

# IHE basic terms

- ❑ An **integration profile** does not impose any particular architecture of systems, nor does it constrain the applications granularity.
- ❑ It identifies functional roles with precise information exchanges responsibilities assigned to them. These functional & interoperable roles are called **Actors**.
- ❑ A functionally homogenous flow of information between two Actors is called a **Transaction**.

## Example:



This Actor could be played by:

- a computerized physician order entry (CPOE) system
- an integrated Hospital Information System (HIS)
- an enterprise repository of diagnostic results

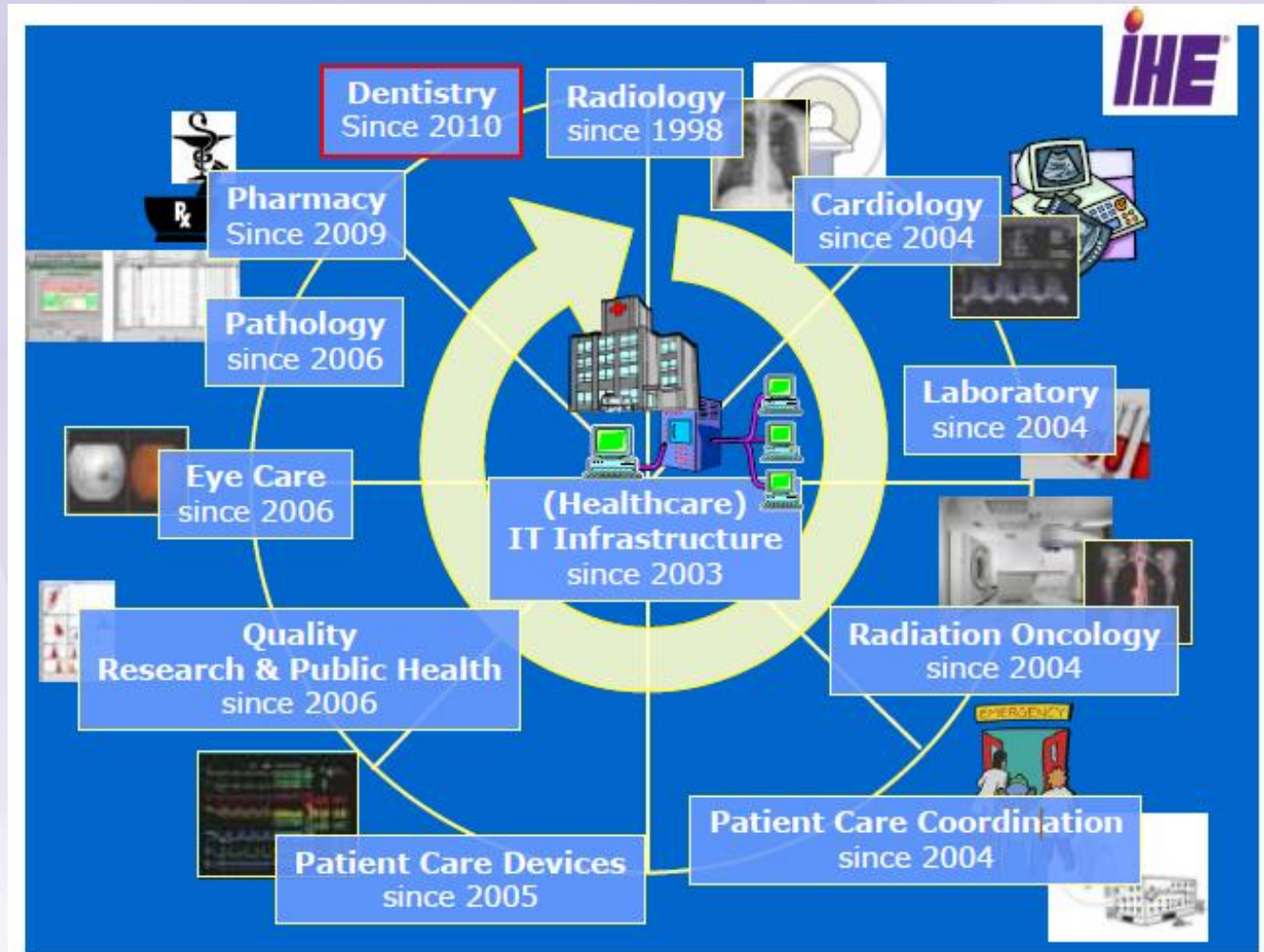


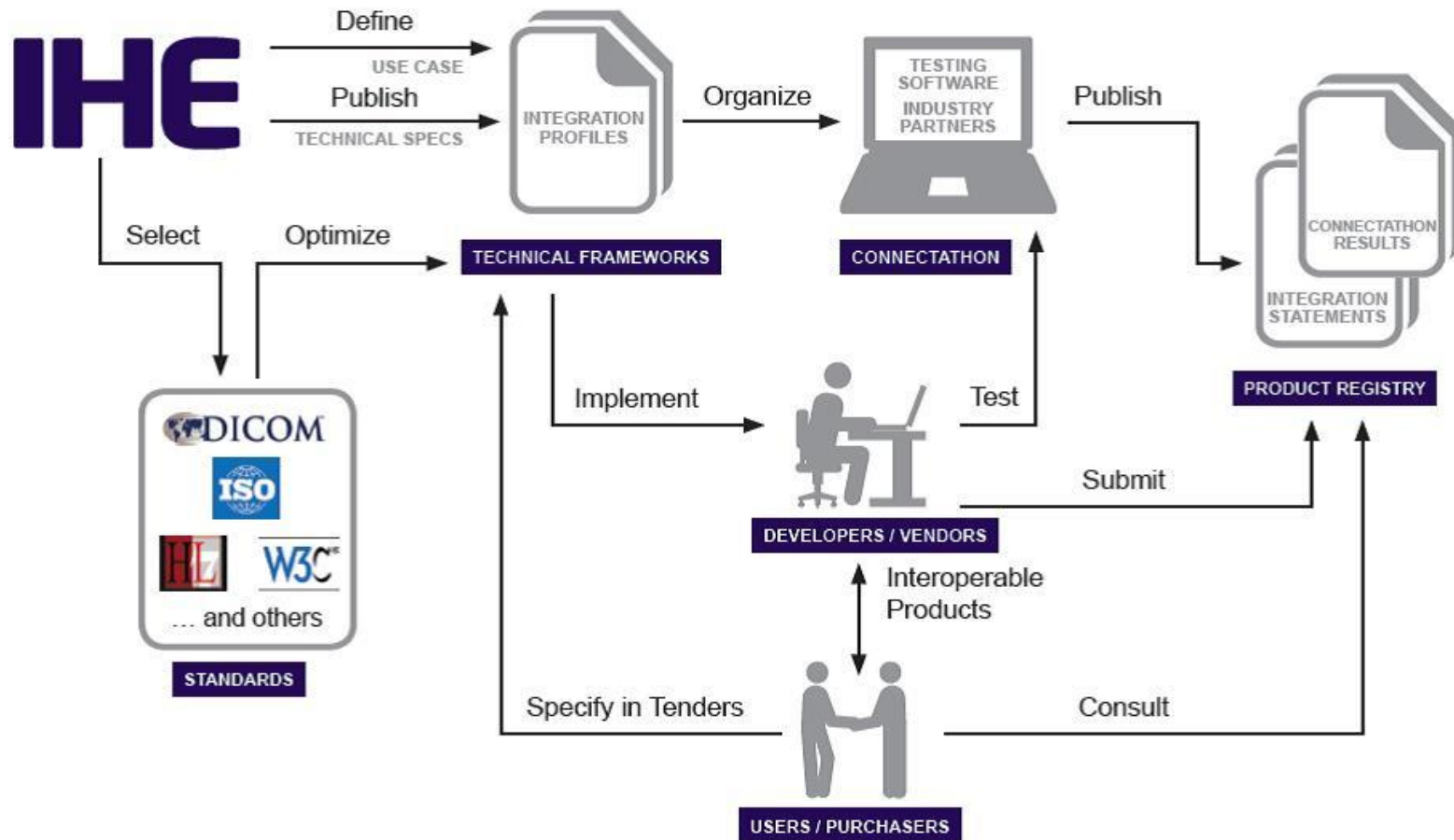
# IHE International joins healthcare professionals and IT vendors to build robust and relevant interoperability specifications.

IHE is organized per domains.

The integration profiles of a domain are assembled into the **domain Technical Framework**.

Each domain has a planning committee and a technical committee, or a single committee combining the two roles.





## Connectathons



- ❑ Week-long testing sessions organized annually per continent (Japan, North-America, Europe ...).
- ❑ Enable IT vendors to test the interoperability of their solutions with their peers.
- ❑ Accelerate the refinement of the specifications (integration profiles).
- ❑ Once finalized, the status of an Integration Profile changes from "Trial Implementation" to "Final Text", and the specification is then integrated into the domain Technical Framework.

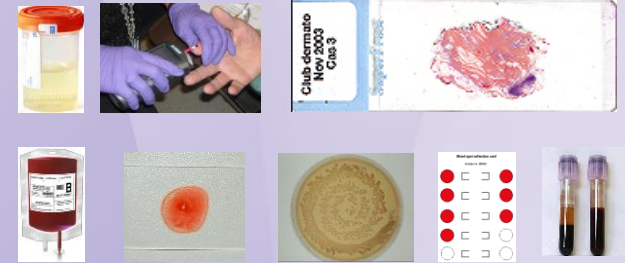
### Next Dates:

Japan: Sep 24 – 29, 2017

US: Jan 15 – 19, 2018

Europe: Apr 16 – 20, 2018





## PaLM scope covers:


- ❑ representation and exchange of digital documents, structured data, and images associated with services performed by clinical laboratories<sup>(1)</sup> and pathology laboratories<sup>(1)</sup> on in-vitro specimens collected from a patient or a non-living material;
- ❑ steering of analytical and peri-analytical automated devices;
- ❑ representation and exchange of structured data related to specimen management, long term storage (for instance in biobanks) and reuse;
- ❑ secondary use of in-vitro diagnostic observations and related clinical observations;
- ❑ representation and exchange of structured data related to the workflows of transfusion medicine around blood product receivers.

(1): Laboratory specialties in scope: clinical chemistry, hematology, coagulation, blood gas, microbiology, immunology, transfusion medicine, HLA, fertility, AMP, cytogenetic, drug monitoring, toxicology, surgical pathology, autopsy, cytopathology, image cytometry, immunohistochemistry, clinical genomics

# IT Systems in scope

- ☐ Electronic Healthcare Record Systems (EHR-S) in hospital and ambulatory care settings
- ☐ Clinical and/or anatomic pathology lab information systems (LIS)
- ☐ Public Health lab information management systems (LIMS)
- ☐ Electronic healthcare record shared infrastructures (PHR, HIE ...)
- ☐ Robotic specimen container distributors
- ☐ barcode labelers
- ☐ Robotic devices peri-analytical devices in the laboratory work area
- ☐ IVD analyzers in laboratory or on the point of care
- ☐ Middleware systems handling a set of analyzers and/or of peri-analytical devices, in laboratory or on the point of care
- ☐ Imaging modalities
- ☐ PACS and digital archive systems
- ☐ Biobank management systems
- ☐ Adverse Event tracking systems (if different from EHR-S)

# PaLM Domain Integration Profiles

 Final Text

## □ IHE PaLM Technical Framework (IHE LAB TF)

- Volume 1: Profiles & Use Cases ----- (*user view*)
  - *Laboratory Testing Workflow (LTW)*
  - *Laboratory Device Automation (LDA)*
  - Laboratory Analytical Workflow (LAW) Profile
  - *Laboratory Point of Care Testing (LPOCT)*
  - *Laboratory Code Set Distribution (LCSD)*
  - *Sharing Laboratory Reports (XD-Lab)*
- (*implementer view*)
- Volumes 2a, 2b, 2c: Transactions
- Volume 2x: Appendices - common material for Transactions
- Volume 3: Content Modules

[http://www.ihe.net/Technical\\_Frameworks/#PaLM](http://www.ihe.net/Technical_Frameworks/#PaLM)

IHE PaLM v8.0 was just published on 6/21/2017

# PaLM Domain Integration Profiles

## ❑ Supplements for Trial Implementation

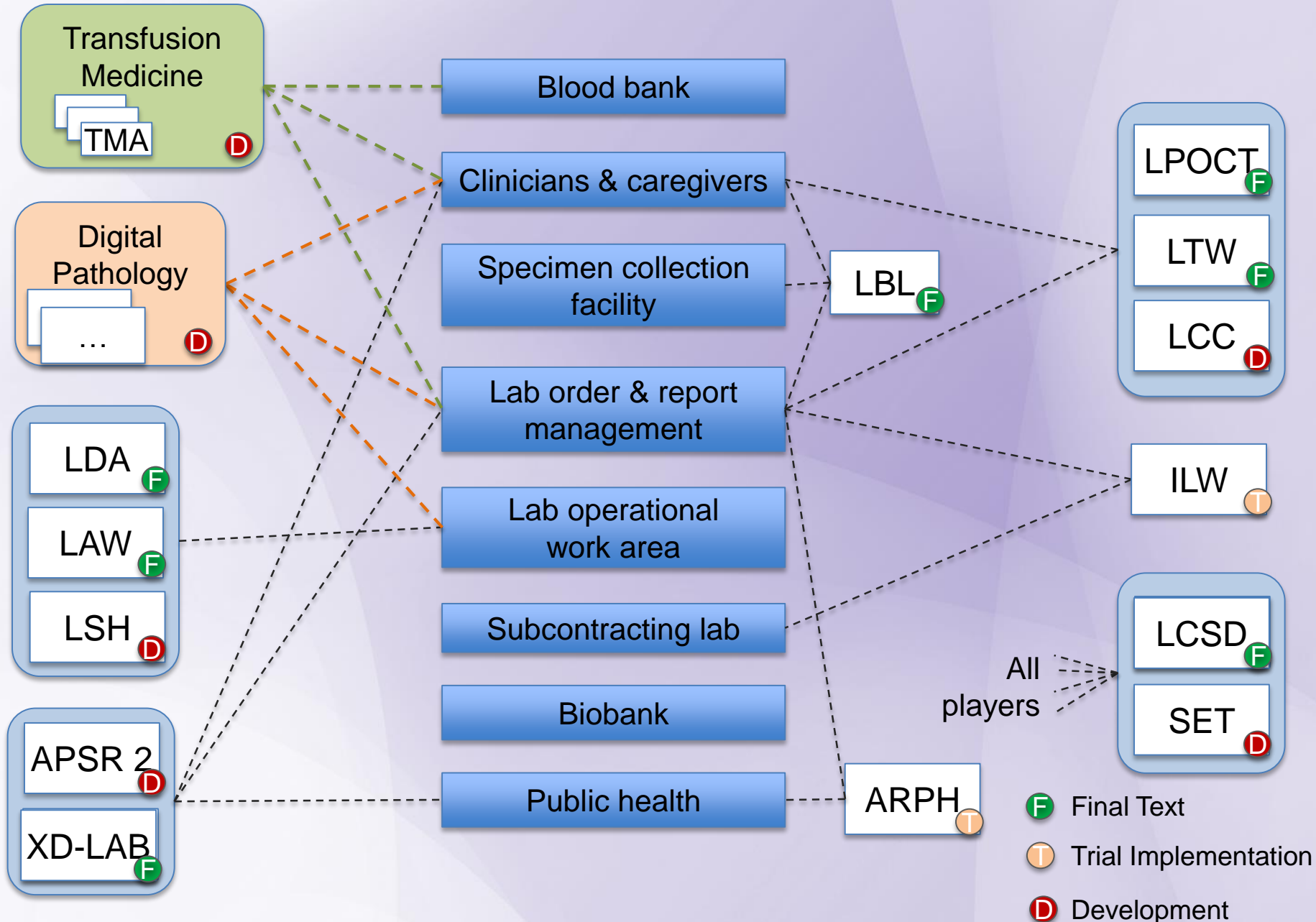
 Trial Implementation

- in LAB domain:
  - Inter-Laboratory Workflow (ILW) Profile
  - "Graphics and simple Images in Results (GIR)" option on LTW Profile
- In Anatomic Pathology Domain:
  - Anatomic Pathology Workflow (APW) in hospitals
  - Anatomic Pathology Structured Report (APSR)
  - Anatomic Pathology Report to Public Health (ARPH)

## ❑ Brief Description of Profiles developed by the PaLM Domain

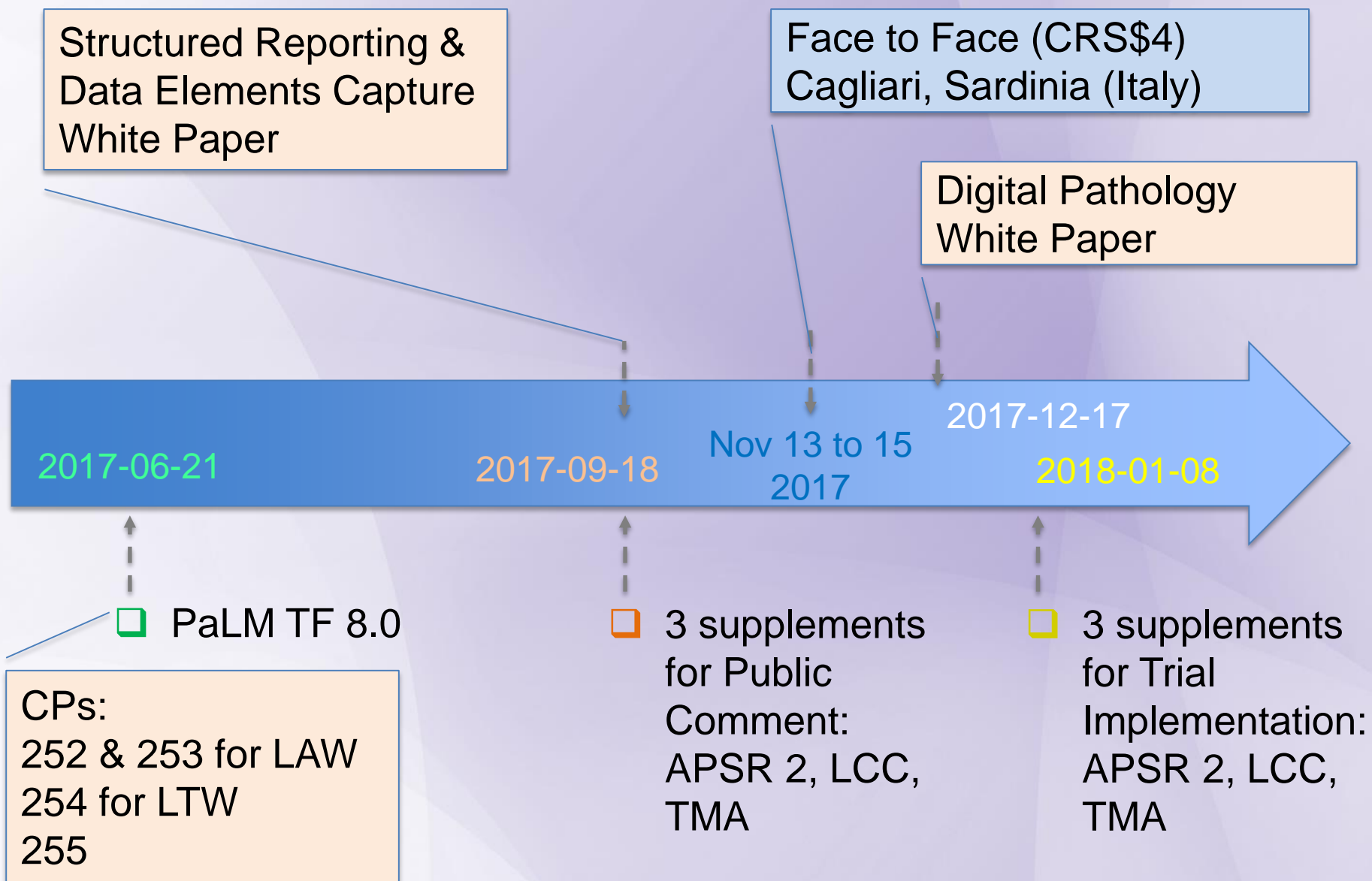
[http://wiki.ihe.net/index.php/Profiles#IHE\\_Pathology\\_and\\_Laboratory\\_Medicine](http://wiki.ihe.net/index.php/Profiles#IHE_Pathology_and_Laboratory_Medicine) .28PaLM.29 Profiles

# PaLM Profiles & players






# 2017 cycle publication schedule for PaLM



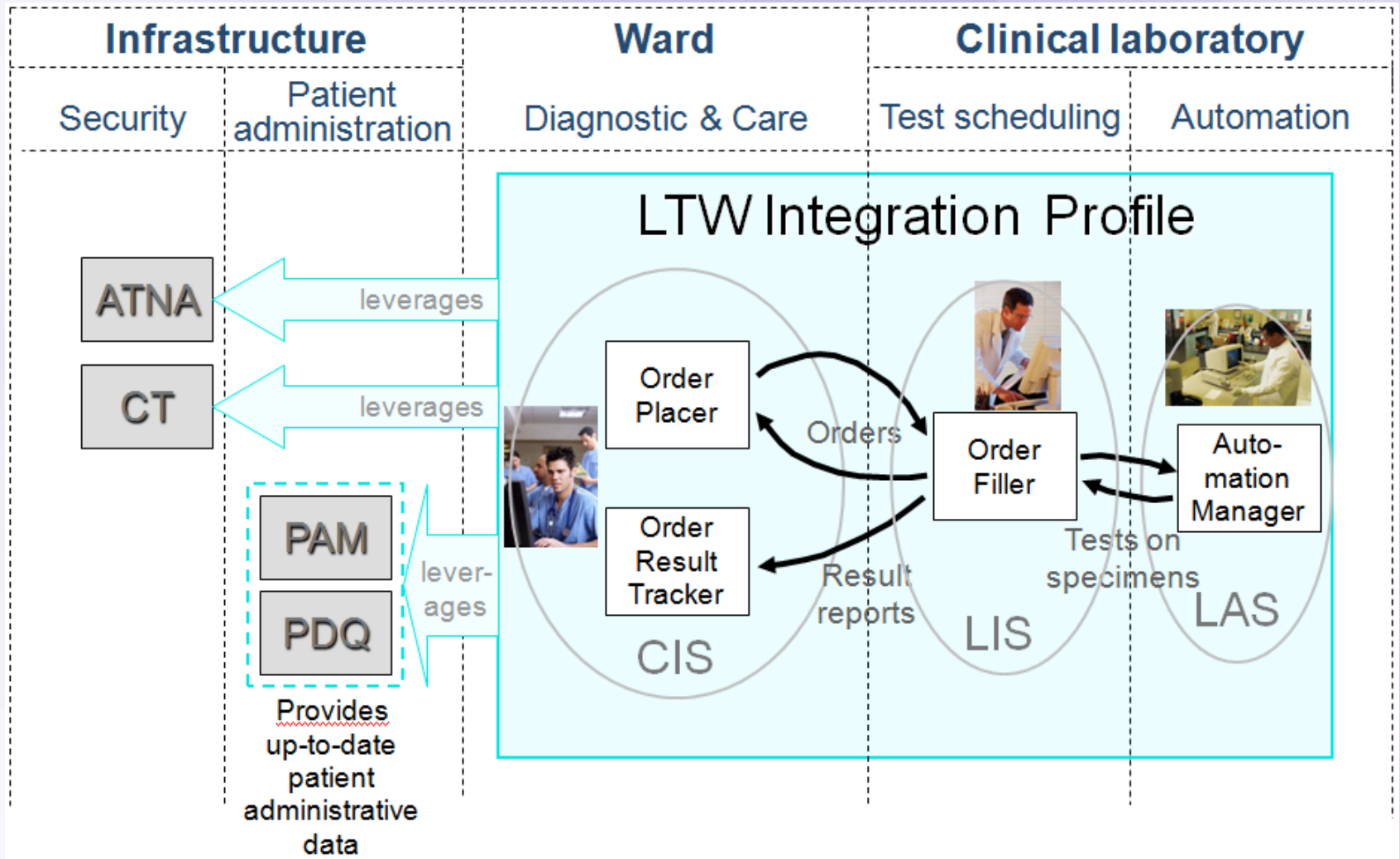
# Laboratory Testing Workflow (LTW)

## Intra-hospital data exchange

 Final Text

- Ordering, scheduling, processing, and result reporting associated with IVD tests performed by clinical labs in healthcare institutions.
- 3 major use cases:
  - Specimen collected by orderer
  - Specimen collected by lab staff
  - Specimen collected by 3rd party
- Systems involved: HIS/EMR, LIS, LAS/middlewares
- Value proposition:
  - Enhances quality of care (reduces manual copy, redundant orders, orphan or lost specimens, transcription errors).
  - Improves throughput (saves phone calls and paper reports, streamlines tests scheduling, processing, reporting).
- Standard: HL7 2.5.1

# Example of a set of systems implementing LTW



# Laboratory Point Of Care Testing (LPOCT)

**F** Final Text

- Tests on specimen performed on the point of care or on patient bedside by caregivers, under the supervision of a clinical laboratory of the institution.
- Systems involved: HIS/EMR, LIS, point of care devices and data managers.
- Value proposition:
  - Shortcut for clinicians who produce and use their results at once for a limited panel of tests.
  - Minimizes patient blood collection.
  - The supervision by a clinical lab ensures a stable level of quality of the point of care testing process.
- Combined with the **LTW** profile and with PAM or PDQ profiles.
- Standard: POCT1-A from CLSI (which includes HL7 2.5.1 ORU)

# LPOCT in combination with LTW and [PAM / PDQ]

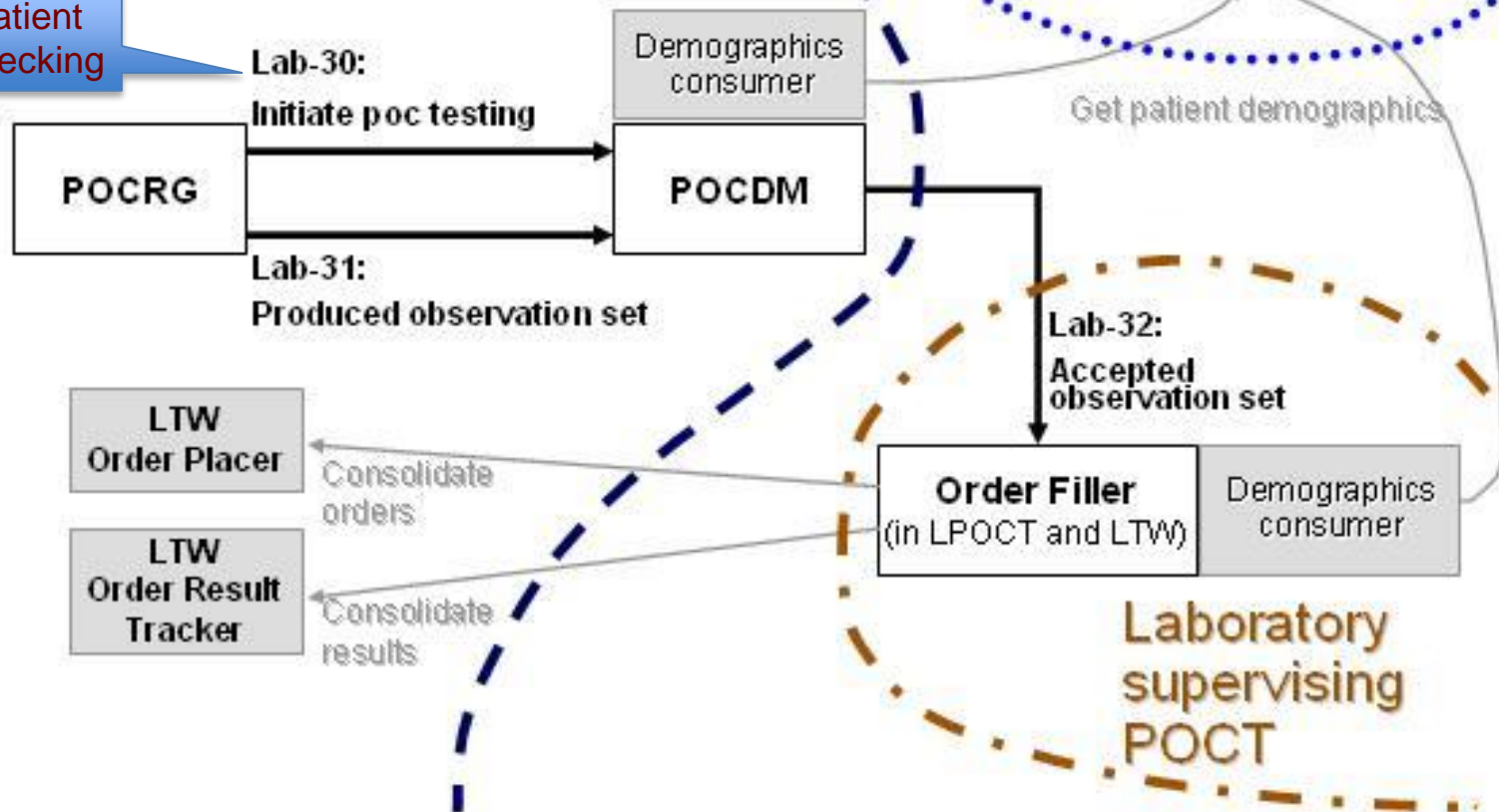
**Clinical wards**  
running point of care testing

**Patient Admin.**

PAM  
supplier


PDQ  
supplier

Option patient  
identity checking





# Robotization

 Final Text

## Lab Barcode Labeling (LBL)

- Robotized delivery and labeling of containers at blood sample collection.
- Systems involved: HIS/EMR, LIS, Robotic container selector & barcode printer.
- Value proposition:
  - Avoids selection of inadequate containers and prevents misidentification.
  - Streamlines specimen collection.
  - May be combined with LTW to let the LIS steer the printing of barcode labels performed by the CIS.

## Lab Device Automation (LDA)

- Automation of pre and post-analytical steps, such as specimen transportation, centrifugation, aliquoting, decapping, storage...
- Systems involved: middleware, pre/post-analytical devices.
- Value proposition:
  - Streamlines the operations in the lab work area.
  - Combined with LTW with the middleware playing a pivot role.

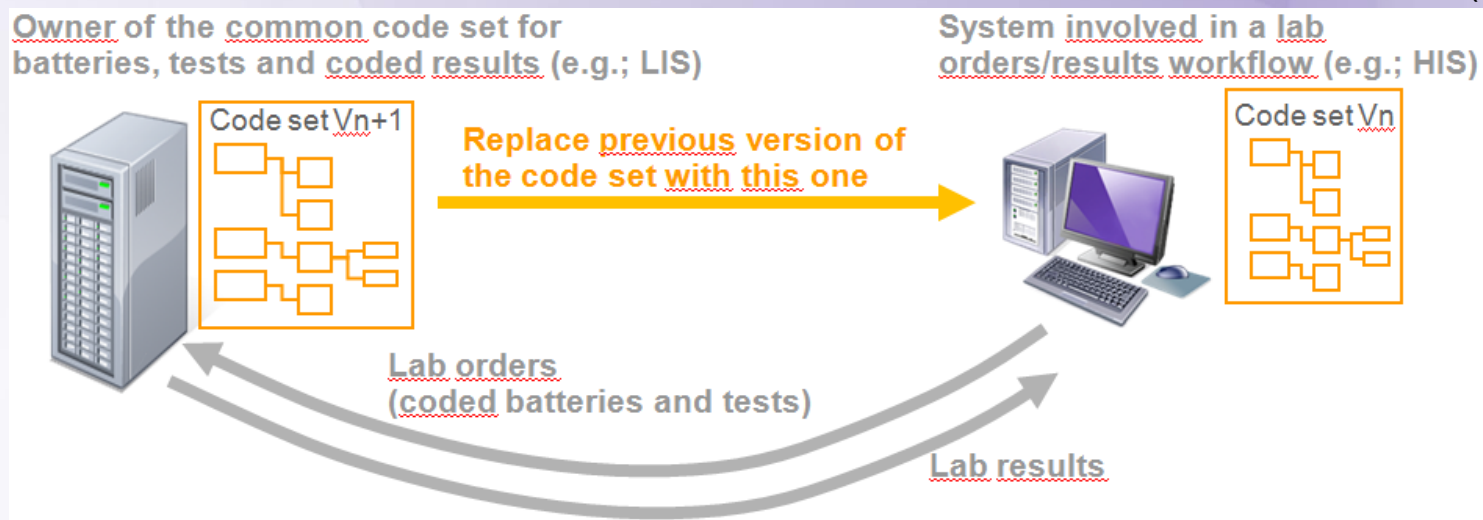
# Laboratory Code Set Distribution (LCSD)

## Synchronize test dictionaries

**F** Final Text

- Enables an application (e.g.; a LIS) owning a code set (batteries, tests and observations) to share it with other applications to further support data exchange between them.
- Systems: LIS, HIS/EMR, middleware, ...
- Value proposition
  - Reduces time of configuration of the interfaces between applications.
  - Smooths the maintenance of the interfaces over time.

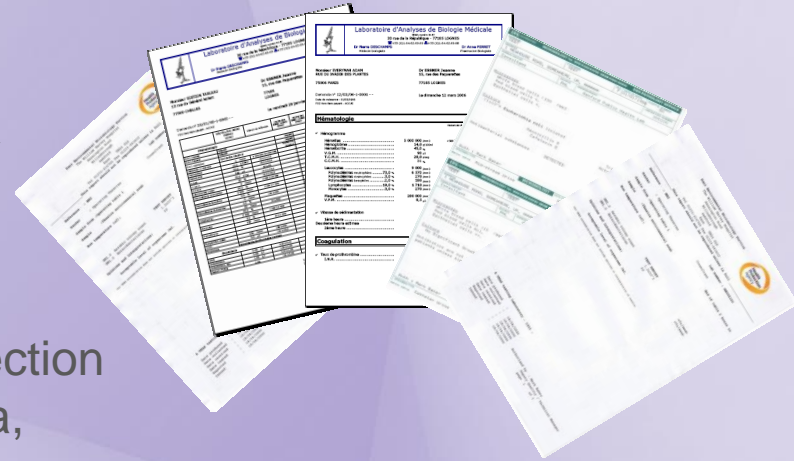
Standard:  
HL7 2.5  
Chapter 8  
(master files)



# Sharing Laboratory Report (XD-LAB)

- A unique electronic format for the exchange/sharing of lab reports.
- Systems: LIS as content creator, HIS/EMR/EHR as content consumer, HIE/PHR as document registry/repository
- Value proposition
  - Both human-readable and machine-processable: The narrative text of each section is derived from the entry of structured data, carried below it.
  - May carry reportable conditions or outbreak identification, as structured data, therefore also usable in public health.
- National standard for laboratory result reporting in Austria, Switzerland, France and Saudi Arabia
- Regionally used in North America, Europe, Middle-East, Asia

**F** Final Text



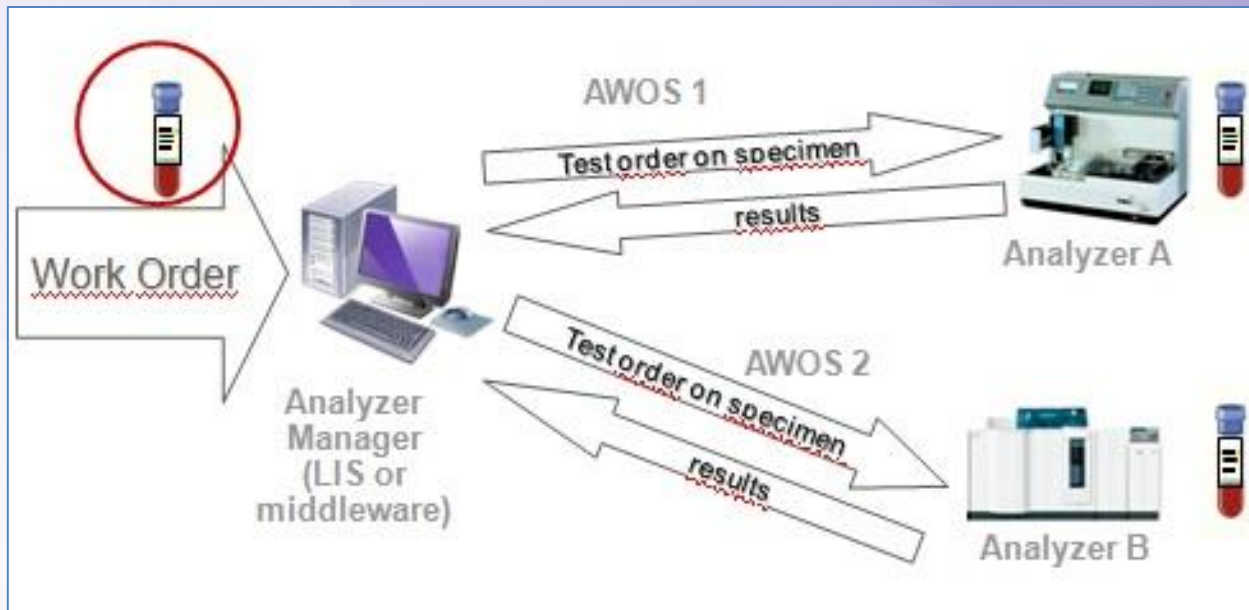
Standards:  
HL7 v3 CDA R2  
LOINC,  
UCUM

# Laboratory Analytical Workflow (LAW)

## IVD analyzers connectivity

**F** Final Text

- A multi-year joint effort of the IHE LAB Committee and the IVD Industry Connectivity Consortium (IICC)
- Purpose: exchange of information related to patient and QC test orders & their results between IVD testing systems and health informatics systems (LIS, middleware, ...)



### Analytical Work Order Step:

A panel or test to be performed on a specimen in a container, assigned to an analyzer

# LAW profile (continued)

- Value proposition:
  - Reduces complexity and variability of data exchange with IVD testing systems.
  - Simplifies installations and maintenance of connections
  - Offers analyzer vendors to declare supported options
- Standards:
  - HL7 2.5.1 + 2 pre-adoption from 2.8 & 2.9
  - LOINC recommended
  - UCUM



LIS or  
middleware

Query for  
AWOS  
[LAB-27] ↑

Analyzer Manager

AWOS  
Broadcast  
[LAB-28] ↓

AWOS  
Status  
Change  
↑ [LAB-29]



IVD testing system

Analyzer


Basis for CLSI standard: “Next Generation IVD interface = AUTO16” in 2017

LAW - IHE Conformity Assessment is available for vendor use



# Inter Laboratory Workflow (ILW)

## Exchange Data between Laboratories

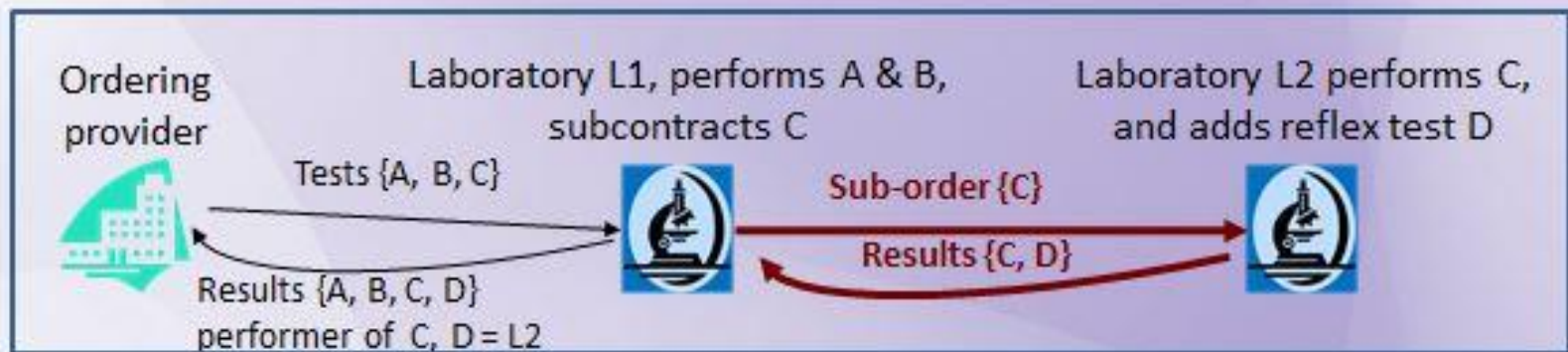
 Trial Implementation

The transmission of sub-orders and specimens from a requesting lab to a subcontractor lab performing the tests and reporting back the results

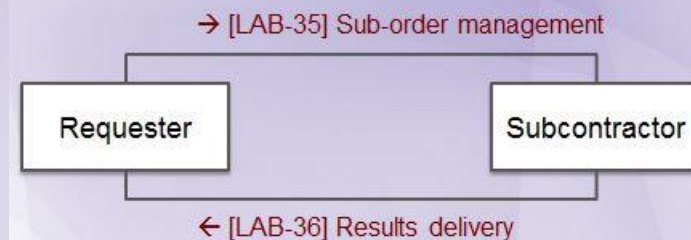
Value proposition:

Reduces complexity and variability of data exchange between labs

Simplifies installations and maintenance of connections



Standards:  
HL7 v2.5.1,  
LOINC recommended,  
UCUM



# Anatomic Pathology Workflow (APW)

## Exchange Anatomic Pathology Data in Hospitals

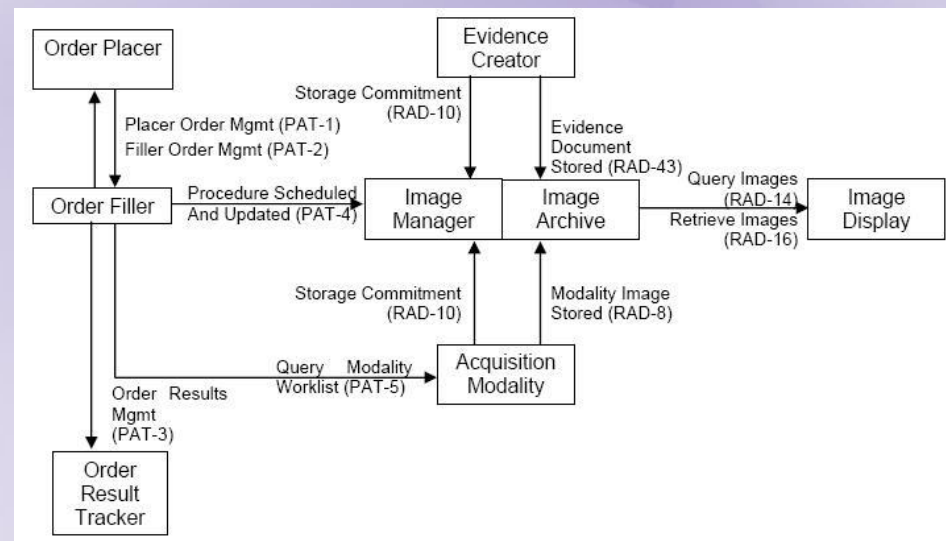
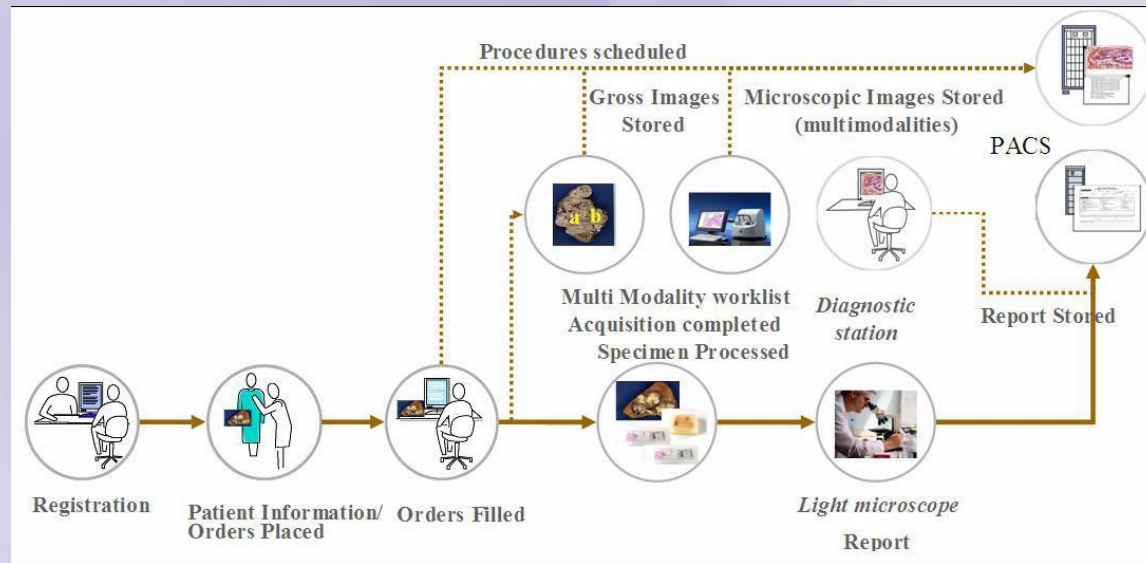
 Trial Implementation

The transmission of orders, results including imaging related aspects of the workflow in a hospital system for surgical pathology, cytology, autopsy, tissue micro array

### Value proposition:

Prevents manual data entry errors by limiting the data entry to the person generating the data, making it available to other systems

Standards:  
HL7 v2.5.1,  
LOINC,  
DICOM  
SNOMED CT



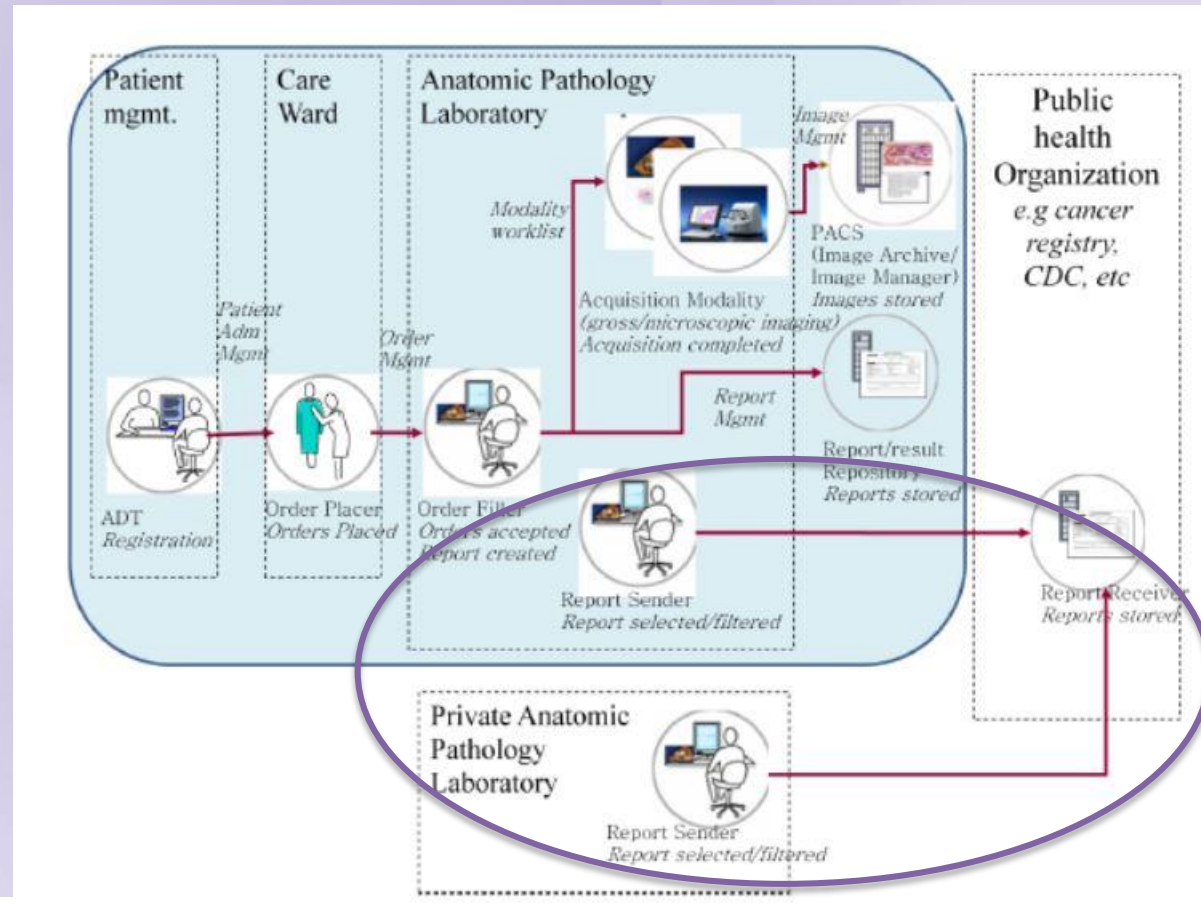
# Anatomic Pathology Report to Public Health (ARPH)

T Trial Implementation

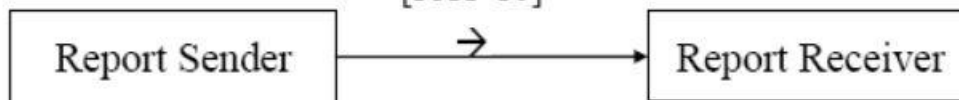
The transmission of pathology results to Public Health Agencies like cancer registries

- based on APW message, supports additional elements of public health interest
- Connectathon tested

Standards:  
HL7 v2.5.1,  
LOINC,  
DICOM  
SNOMED CT



Public Health Reporting  
[PAT-10]

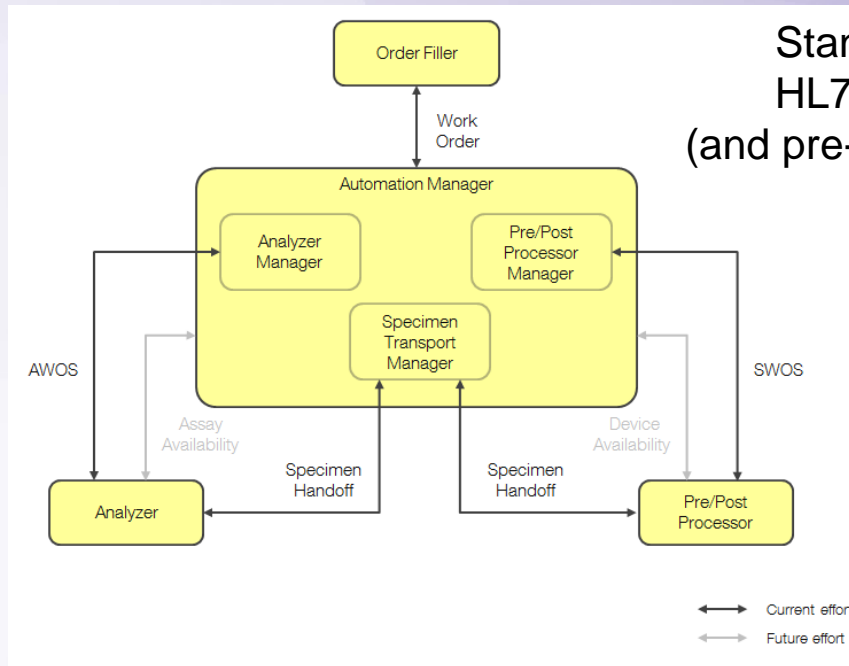


# Laboratory Specimen Handoff (LSH)

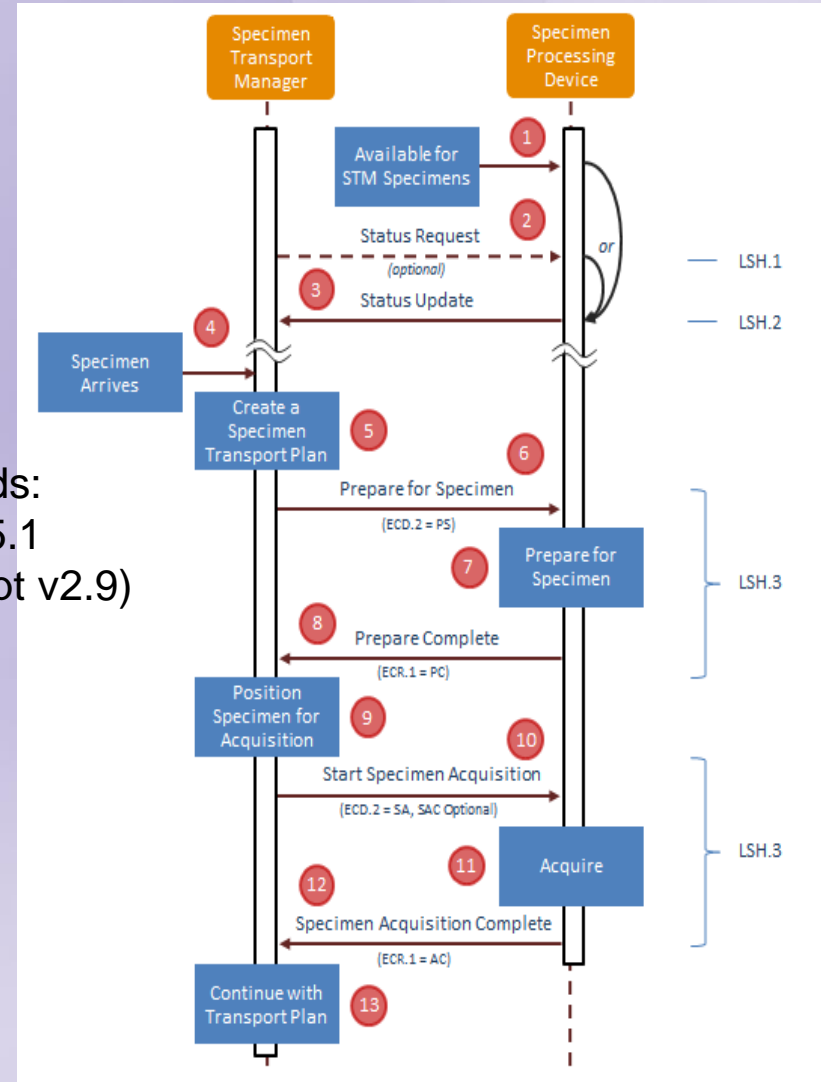
## Manage Specimen Transport Automation

**D** Development

- Provide common framework for IVD vendors to manage specimen passing in the laboratory
- Reduce design burden for Laboratory Automation Systems (LAS) and Specimen Processing Devices (SPD)



Standards:  
HL7 v2.5.1  
(and pre-adopt v2.9)

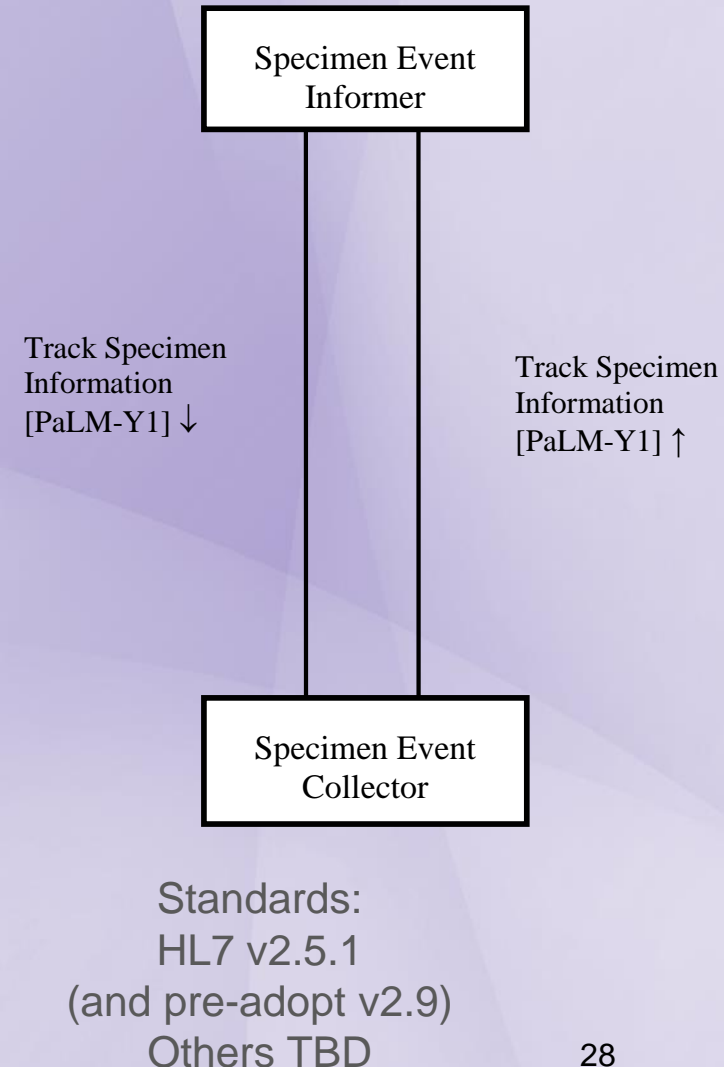


# Specimen Event Tracking (SET)

## Manage Specimen Transport Automation

 Development

- Provide common framework for IVD vendors to manage specimen passing in the laboratory in different settings (intra- and inter-organizations and facilities)
- Use cases:
  - #1 Specimen Collection Tracking
  - #2 Specimen Intra and Inter organization transfer
    - No/re-identification, reject by receiver
  - #3 Intra Laboratory IVD Specimen Tracking
  - #4 Biobank Specimen Tracking
    - Collection
    - Retrieve from biobank for testing (immediate or not)
  - #5 Specimen Derivation Tracking
- Reduce design burden for Laboratory Automation Systems (LAS) and Specimen Processing Devices (SPD)



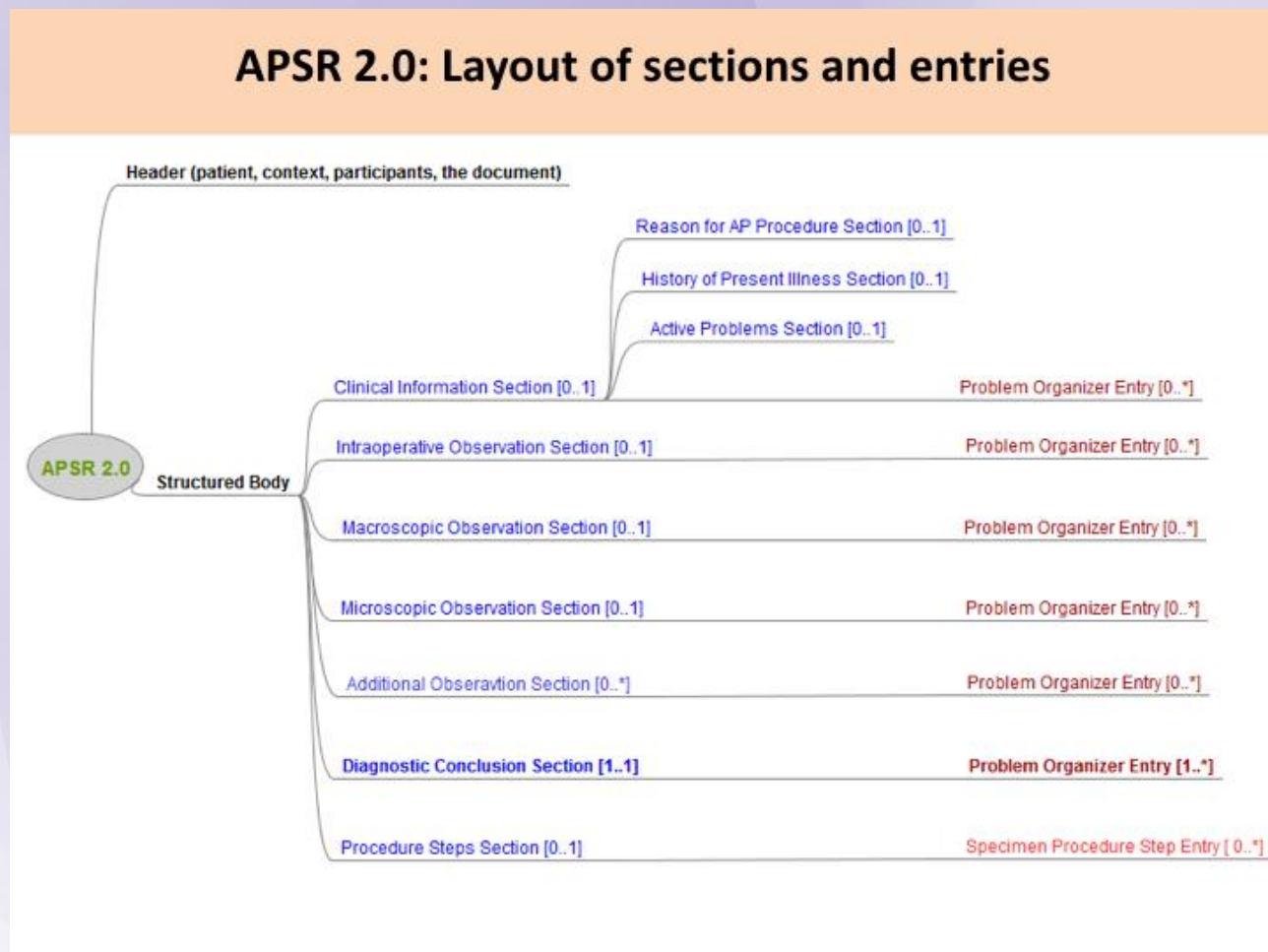


# Generalize Anatomic Pathology Structured Report (APSR 2)

**D** Development

- Create generic templates
- Enhance specimen collection section
- Created in Art-Décor tooling for better implementation experience (have conformance rule files (XML) as well as text)

Standards:  
HL7 v3 CDA R2,  
LOINC,  
DICOM  
SNOMED CT





# APSR 2 (continued)

Mediawiki view: <http://wiki.hl7.de/index.php?title=IG:Pathologiebefund>

**APSR-11 – Derivative specimens:**Specimens derived from primary specimens for ancillary studies, which may be sent to a reference lab or done in another part of the same institution, are included in the scope of this profile. The results produced on a derived specimen are included in the scope of this profile.

## VOLUME 1 - PROFILES

### 10 Anatomic Pathology Structured Report (APSR) Profile

This content profile describes an anatomic pathology structured report (APSR) as a digital document to be shared or exchanged between pathology laboratories and other care providers and institutions.

Anatomic pathology structured reports document the findings on specimens removed from patients for diagnostic or therapeutic reasons. This information can be used for patient care, clinical research and epidemiology. Standardizing and computerizing anatomy and pathology reports facilitates the exchange and reuse of the content of these reports.

This content profile describes a digital anatomic pathology report shared in a human-readable format, which may include images, and which also contains findings and observations in a machine-readable format, to facilitate the integration of these into the databases and systems that use this content.

The scope of this IHE content profile covers all fields of anatomic pathology (cancers, benign neoplasms as well as non-neoplastic conditions) as well as cytopathology.

Goldsmith, J.D., et al., "Reporting guidelines for clinical laboratory reports in surgical pathology" Arch Pathol Lab Med, 2008. 132(10): p. 1608-16, is the first source of specification for this content profile. This article delineates the required, preferred, and optional content elements.

This source is complemented by the "cancer checklists" produced by the College of American Pathologists, and by the "comptes rendus d'anatomopathologie : données minimales à renseigner pour une tumeur primitive" produced by the French society of pathology (Société Française d'Anatomopathologie). The German "Guideline Pathology / Neuropathology" (formerly TM-30) of the Sector Committee Pathology for the implementation of DIN EN ISO/EC 17020.

This profile has also benefited from the guidance on cancer AP reports provided by the North-American Association of Central Cancer Registries; some of the example snippets captured in the profile leverage the NAACCR Standards for Cancer Registries, Volume 1.

#### 10.1 APSR Actors/Transactions

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A published here.

Figure 10.1-1 shows the actors directly involved in the APSR Profile and the direction that the content is exchanged.

A product implementation using this profile must group actors from this profile with actors from a workflow or transport profile to be functional. The grouping of the content module described in this profile to specific actors is described in more detail in the "Requirements" section.

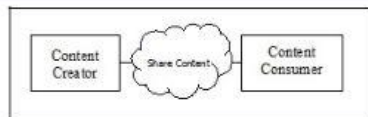


Figure 10.1-1 APSR Actor Diagram

Table 10.1-1 lists the content module(s) defined in the APSR profile. To claim support with this profile, an actor shall support all required content modules (labeled "R") and may support optional content modules (labeled "O").

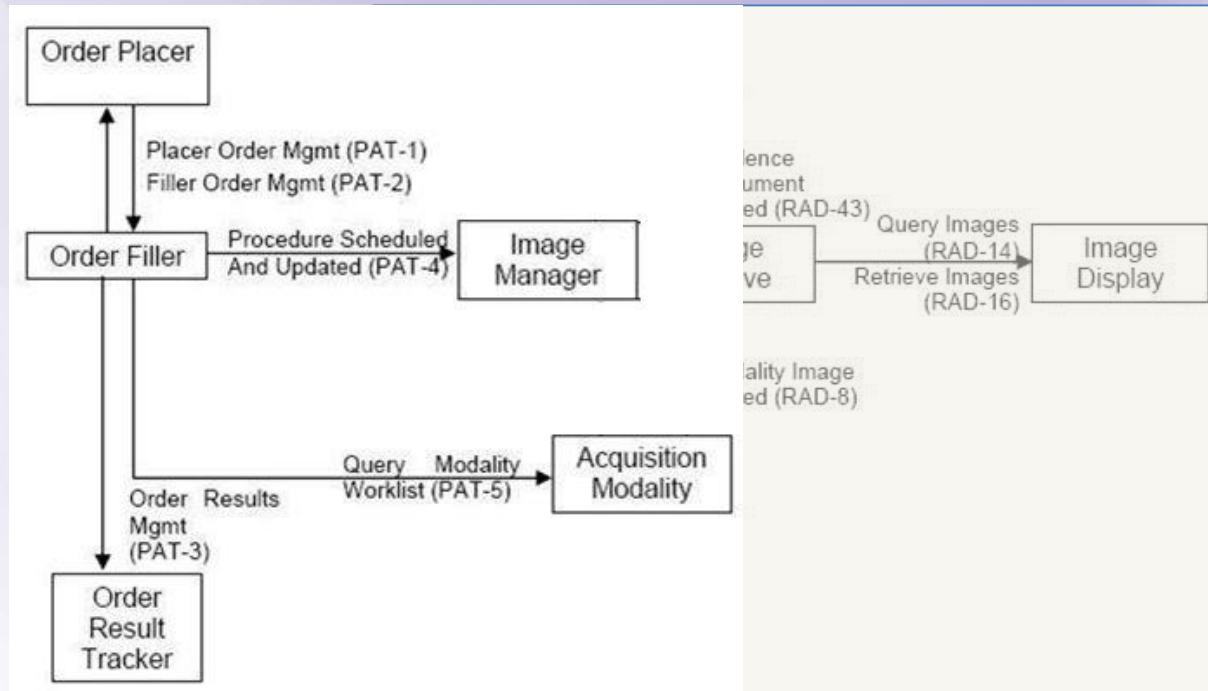
Table 10.1-1: <Profile Acronym>Profile - Actors and Content Modules

Actors	Content Modules	Optionality	Reference
Content Creator	Anatomic Pathology Structured Report 1.3.6.1.4.1.19376.1.8.1.1.1	R	PaLM TF-3: 6.3.1.2
Content Consumer	Anatomic Pathology Structured Report 1.3.6.1.4.1.19376.1.8.1.1.1	R	PaLM TF-3: 6.3.1.2

# Restructure Anatomic Pathology Workflow (APW 2)

Better integration into the PaLM Technical Framework

**D** Development



## Part 1:

Integrate with PaLM TF  
transactions LAB-1 through  
LAB-5

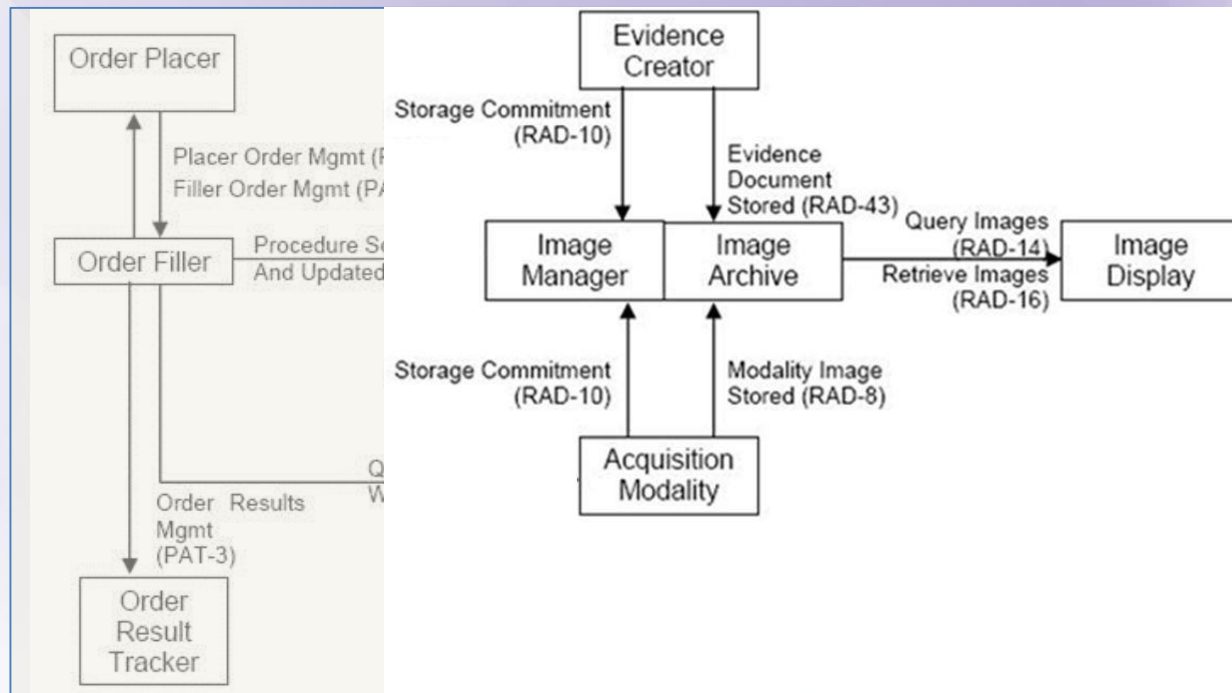
Standards:  
HL7 v2.5.1,  
LOINC,  
DICOM  
SNOMED CT



# Restructure Anatomic Pathology Workflow (APW 2)

Better integration into the PaLM Technical Framework

**D** Development



## Part 2:

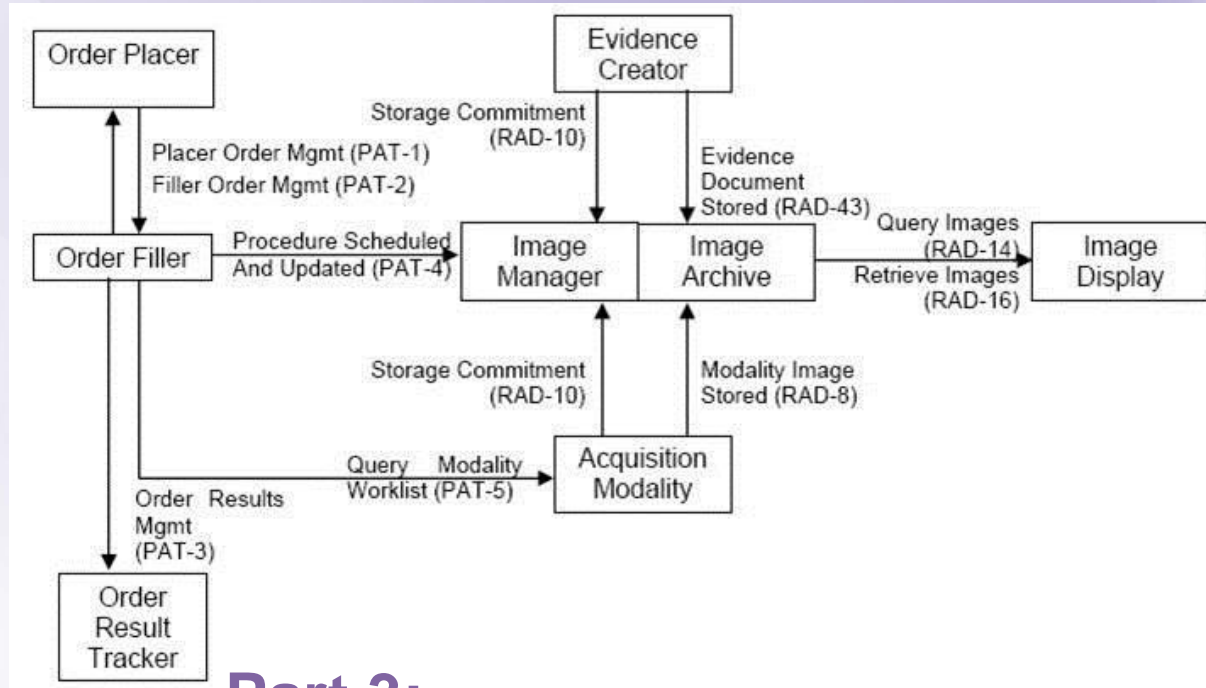
Standards:  
HL7 v2.5.1,  
LOINC,  
DICOM  
SNOMED CT

Create new laboratory  
image management  
profile under PaLM

# Restructure Anatomic Pathology Workflow (APW 2)

Better integration into the PaLM Technical Framework

**D** Development



## Part 3:

Add more laboratory image reporting capabilities in PaLM



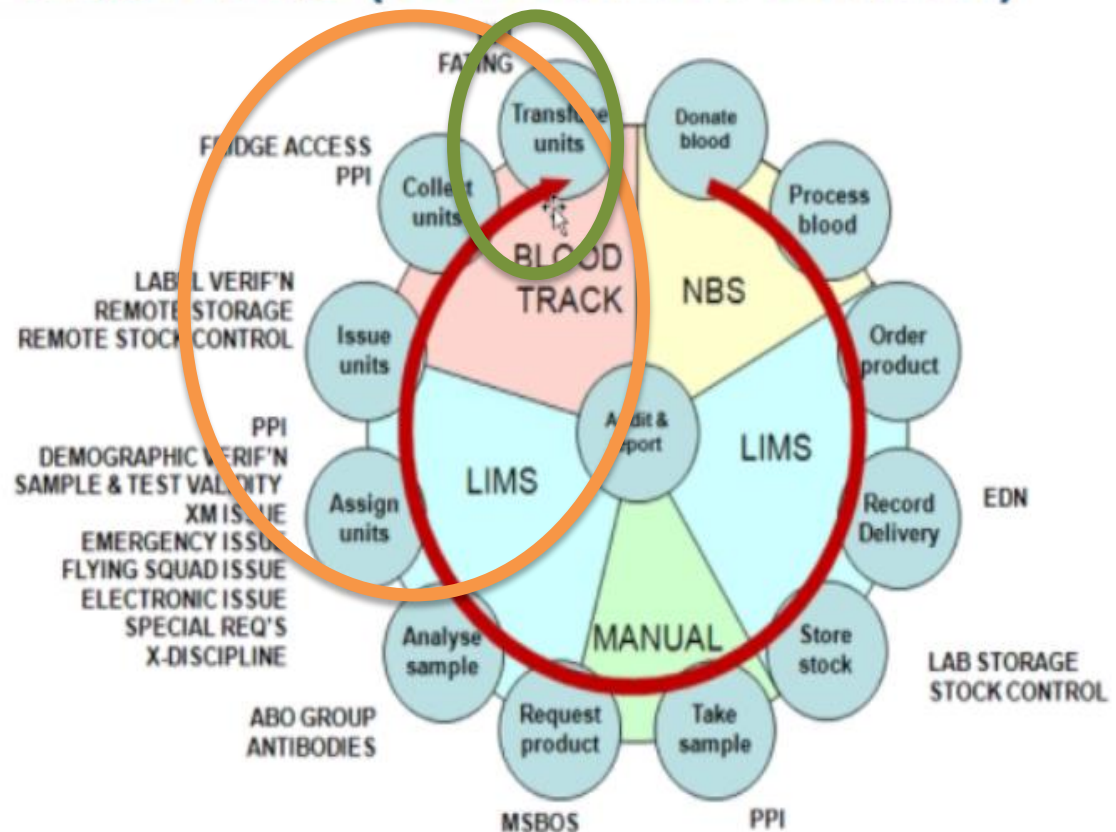
# Transfusion Medicine - Administration (TMA)

## Tracking adverse events during administration

**D** Development

**IHE** Integrating the Healthcare Enterprise

### Vein 2 Vein (USE-CASE : UK NHS)



- First in family
- Event tracking during Administration (optional patient matching verification step) = green
- Future expansion: Assigning units to collecting units = orange

Standards:  
HL7 v2.x, LOINC,  
SNOMED CT

# Current Projects

## Data Element Registry White paper

### Conveying machine understandable semantics

**Need:** reusable, well defined elements across data exchange partners for exchange of Lab reports with multiple partners for diagnostic or secondary use (Public Health, research, clinical decision support, etc.)

**Solution:** Shareable Data Element Repository that:

- Has appropriate tags, metadata, context and vocabulary binding (which could be choices of appropriate vocabulary based on country)
- Has option to capture business rules / specific guidelines for specific use cases (at the domain / organization / country / regional level) that describe data element behavior
- Is bound to specific elements in one or more data exchange format specifications
- **Next Steps**
  - White paper describing use cases and need for structured reporting interoperability
  - Call for vendors that see the benefit for content development to harmonize the format to allow for scalable (crowd sourced?) structured content development

# Current Projects

## Harmonize IHE transactions with

Laboratory Technical Workflow (LTW)  
and Laboratory Clinical Communication (LCC)

Laboratory Code Set Distribution (LCSD)

Joint HL7 Orders and Observations WG and IHE PaLM discovery project  
Gap analysis documents:

[http://wiki.ihe.net/index.php/IHE-SNI\\_Lab\\_Harmonization](http://wiki.ihe.net/index.php/IHE-SNI_Lab_Harmonization)

Next Steps:

Identify where adjustments need to be made and create CPs

## US realm lab related Implementation Guides

S&I Framework: Lab Results Interface (LRI) – HL7v2.5.1

S&I Framework: Lab Orders from EHR (LOI) – HL7v2.5.1

S&I Framework: Electronic Directory of Service(eDOS) – HL7v2.5.1

# If you want to contribute

- Apply for IHE International Organizational Membership  
Visit: [www.ihe.net/apply](http://www.ihe.net/apply) (note IP Policy)  
Approved monthly by IHE International Board  
Review IHE's 600+ Organizational Members:  
[http://www.ihe.net/governance/member\\_organizations.cfm](http://www.ihe.net/governance/member_organizations.cfm)
- Join IHE Laboratory Planning & Technical Committees  
Mailing list: <https://groups.google.com/a/ihe.net/forum/#!forum/palm>
- Non-members have limited participation:  
Review & comment during Supplement Public Comment period  
Implement IHE Profiles and test them at connectathons

# Thank you

- IHE International - [www.ihe.net](http://www.ihe.net)
- IHE Europe - [www.ihe-europe.net](http://www.ihe-europe.net)
- IHE North America/USA - <http://www.iheusa.org/>
- The complete program of educational webinars  
<http://www.iheusa.org/resources-education-webinars.aspx#webseries>
- Overview of over 100 existing IHE integration profiles  
<http://wiki.ihe.net/index.php?title=Profiles>

# Alphabet Soup

Acronym	Description
ANAPATH	Anatomic Pathology domain
ASIP Sante	Agence des Systemes d'Information Partages de Sante
ATNA	Audit Trail and Node Authentication
AWOS	Analytical Work Order Step
CAP	College of American Pathologist
CDA R2	Clinical Document Architecture Revision 2
CEN	European Committee for Standardization
CIS	Clinical Information System
CLSI	Clinical and Laboratory Standards Institute
CT	Consistent Time
DICOM	Digital Imaging and COMMunications in Medicine
eDOS	Electronic Directory of Services
EHR	Electronic Health Record
EMR	Electronic Medical Record
ETSI	European Telecommunication Standards Institute
HIE	Health Information Exchange
HIS	Health Information System
HL7	Health Level Seven
IEEE	Institute of Electrical and Electronics Engineers
IETF	Internet Engineering Taskforce
IICC	In-Vitro Diagnostics Industry Connectivity Consortium
ISO	International Organization for Standardization
IT	Information Technology
ITU	International Telecommunication Union
IVD	In-Vitro Diagnostic
JAHIS	Japanese Association of Healthcare Information Systems Industry
LAS	Lab Automation System
LCC	Laboratory Clinical Communication

Acronym	Description
LCSD	Laboratory Code Set Distribution
LDA	Laboratory Device Automation
LIS	Laboratory Information System
LOI	Lab Orders Interface
LOINC	Logical Observation Identifiers Names and Codes
LPOCT	Laboratory Point Of Care Testing
LRI	Lab Results Interface
LTW	Laboratory Testing Workflow
OASIS	Organization for the Advancement of Structured Information Standards
PAM	Patient Administration Management
PCD	Patient Care Device domain
PDQ	Patient Demographics Query
PHR	Personal Health Record
POCDM	Point Of Care Demographics Manager
POCRG	Point Of Care Result Generator
QA	Quality Analysis
S&I	Standards and Interoperability
SNOMED CT	Systematized Nomenclature of MEDicine Clinical Terms
TMA	Transfusion Medicine - Administration
UCUM	Unified Codes for Units of Measure
US	United States
W3C	World Wide Web Consortium
XD-Lab	Sharing Laboratory Reports
XDM	Cross-Enterprise Document Media Exchange
XDR	Cross-Enterprise Document Reliable Exchange
XDS	Cross-Enterprise Document Sharing