Inside IHE: Pathology and Laboratory Medicine Webinar Series 2018

Presented by

- Raj Dash, MD, Duke - Planning Committee Co-Chair
- Riki Merrick, MPH – Vernetzt, LLC - Planning Committee Co-Chair

Agenda

- Intro to IHE Pathology and Laboratory Medicine (PaLM) / Mission and Scope
- Summary of all Integration profiles
- Highlighting of New Trial Implementation profiles
  - Anatomic Pathology Structured Report (APSR) 2.0
  - Laboratory Clinical Communications (LCC)
  - Transfusion Medicine Administration (TMA)
- Current Projects
  - Specimen Event Tracking (SET)
  - Digital Pathology (collaboration with DICOM WG 26 to update Anatomic Pathology Workflow (APW)

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.
IHE helps put those together for specific use cases (profiles)

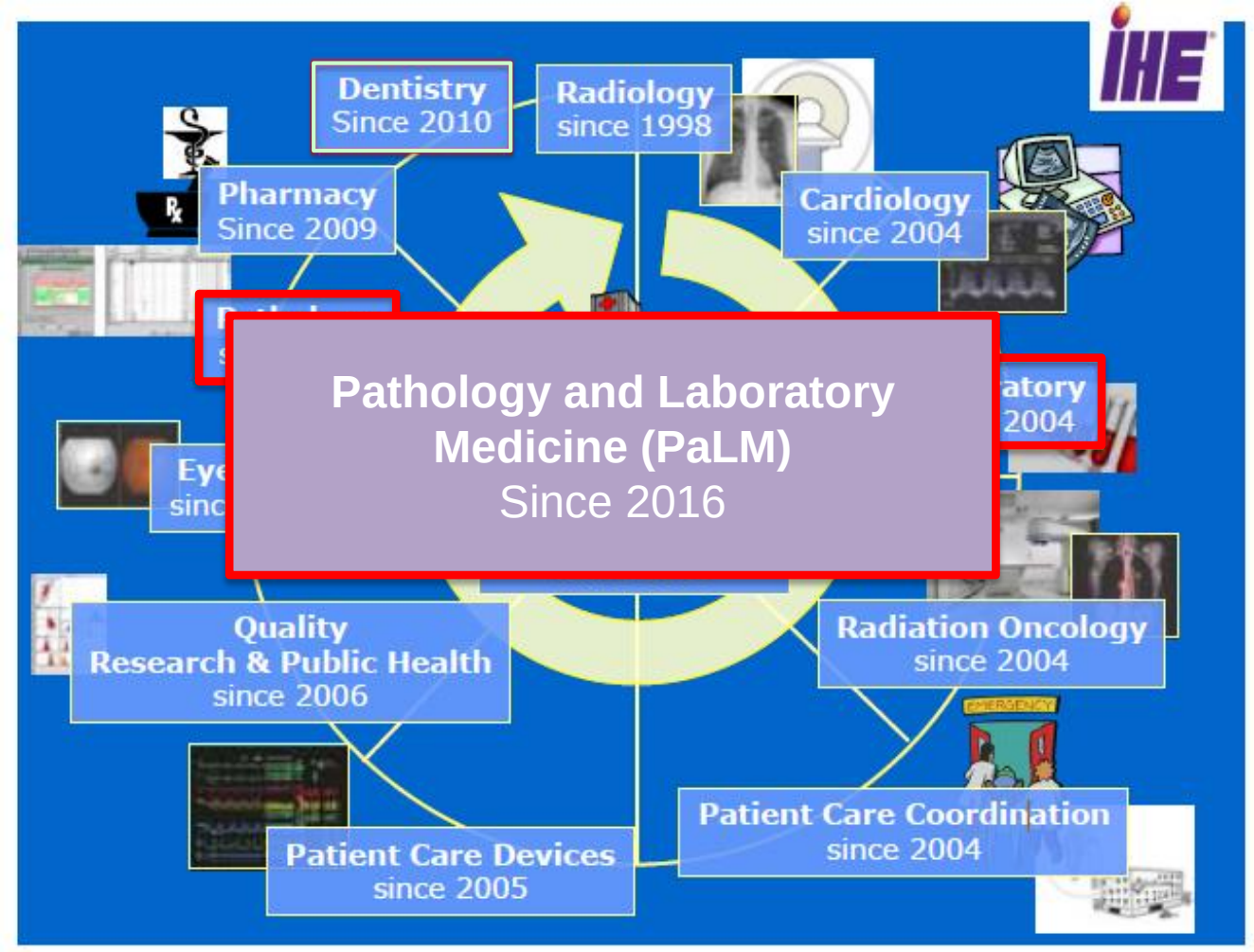
- For a good introduction to IHE see this video: https://youtu.be/Cz5B5KOoDuw

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: Oct 15-19, 2018
US: Jan 21-25, 2019
Europe: Apr 8-12, 2019

IHE Integrating the Healthcare Enterprise

PaLM scope covers:

- representation and exchange of digital documents, structured data, and images associated with services performed by clinical laboratories(1) and pathology laboratories (1) 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 distributers
- 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

F 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

IHE PaLM v9.0 was sent to publishing 6/21/2018

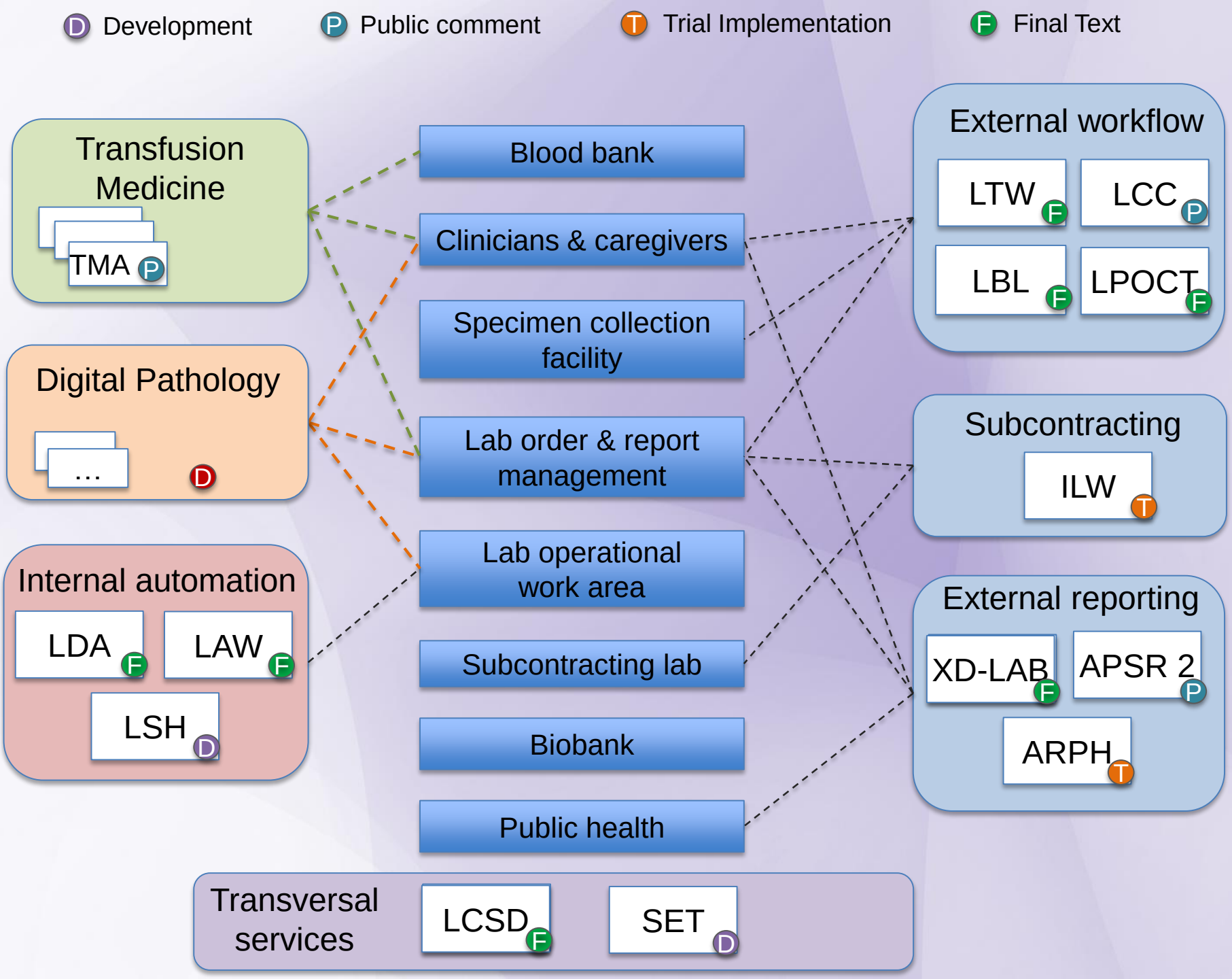
PaLM Domain Integration Profiles

Trial Implementation

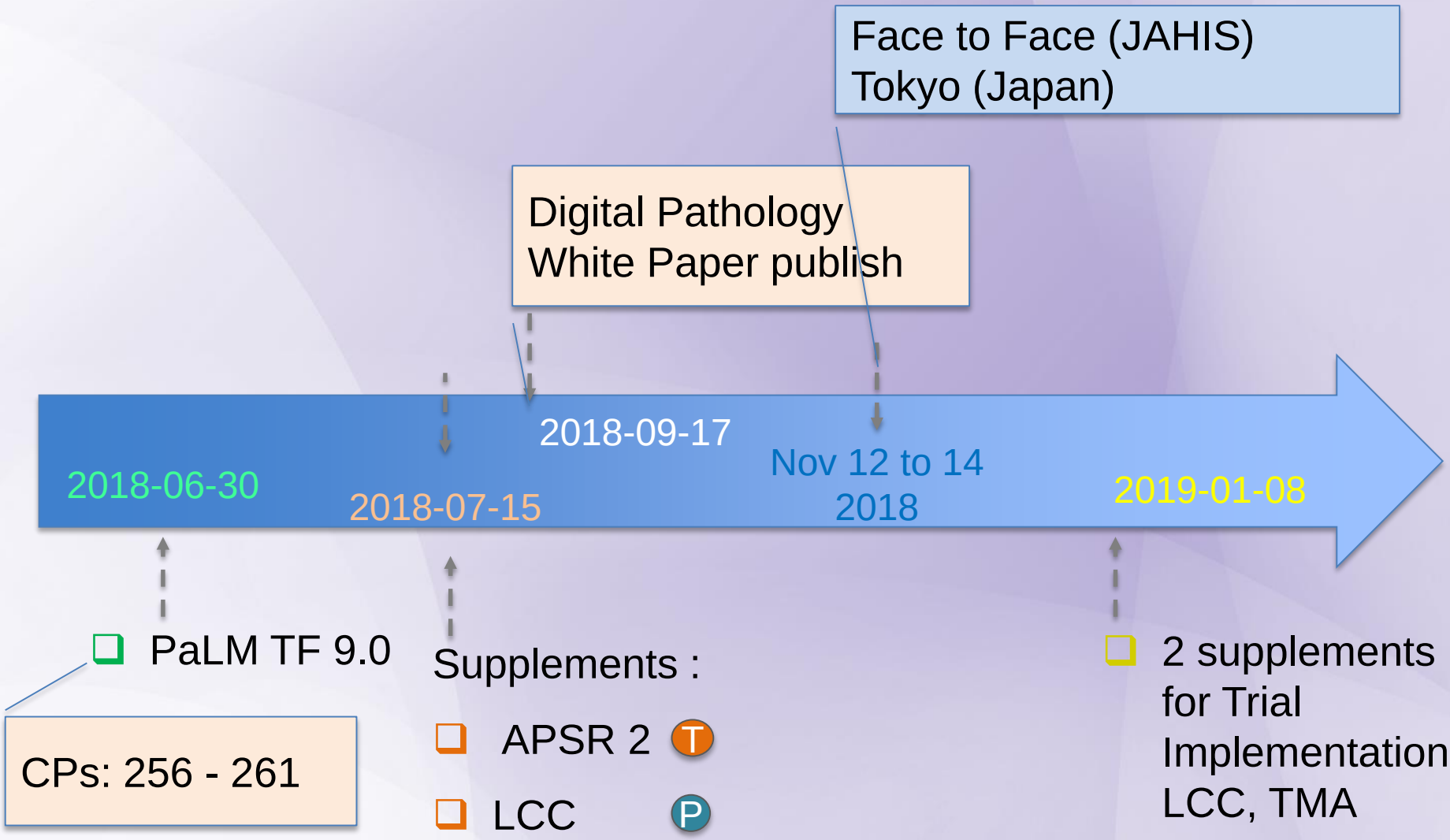
- Supplements for Trial Implementation
  - in LAB domain:
    - Inter-Laboratory Workflow (ILW) Profile
    - "Graphics and simple Images in Results (GIR)" option on LTW Profile
  - In Anatomic Pathology Domain:
    - Anatomic Pathology Workflow (APW) in hospitals
    - Anatomic Pathology Structured 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_.28PaLM.29_Profiles


D Development
P Public comment
T Trial Implementation
F Final Text
Transfusion Medicine
TMA P
Digital Pathology
… D
Internal automation
LDA F
LAW F
LSH D
Blood bank
Clinicians & caregivers
Specimen collection facility
Lab order & report management
Lab operational work area
Subcontracting lab
Biobank
Public health
External workflow
LTW F
LCC P
LBL F
LPOCT F
Subcontracting
ILW T
External reporting
XD-LAB F
APSR 2 P
ARPH T
Transversal services
LCSD F
SET D

2018 cycle publication schedule for PaLM



Newly Published Supplements

Laboratory Clinical Communication LCC

Enhance Communications for Orders

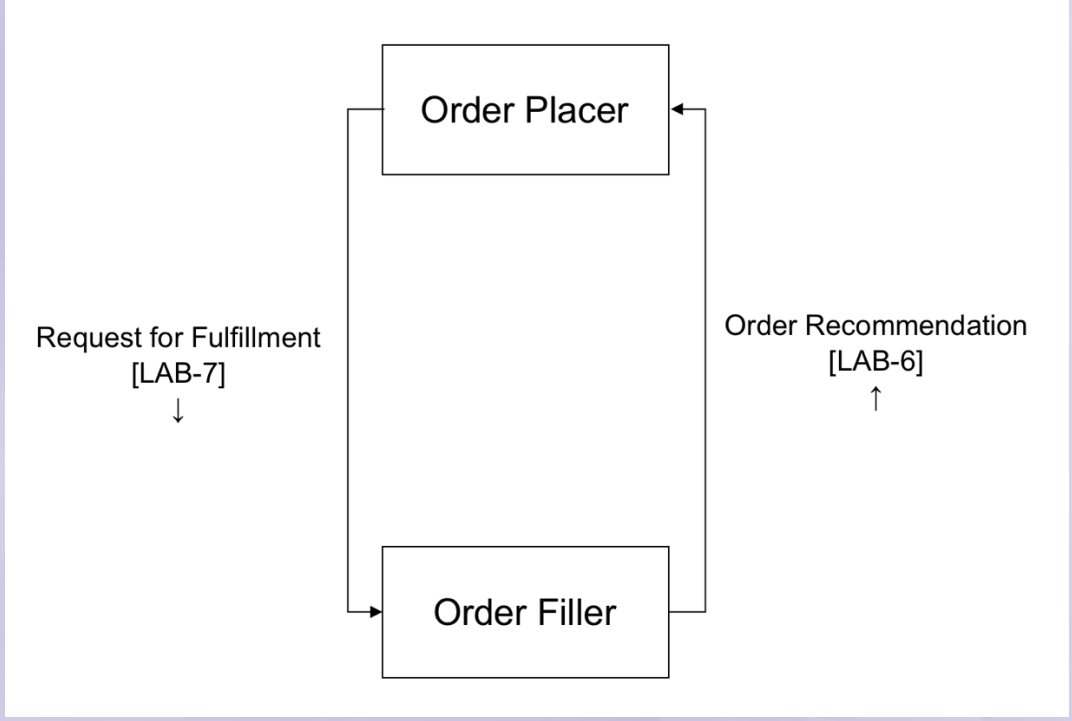
Trial Implementation

- Works together with existing profiles:
  - Laboratory Testing Workflow (LTW)
  - Inter-Laboratory workflow (ILW)
- LAB-6:

Filler can recommend to replace or supplement orders, placer can accept or reject recommendations

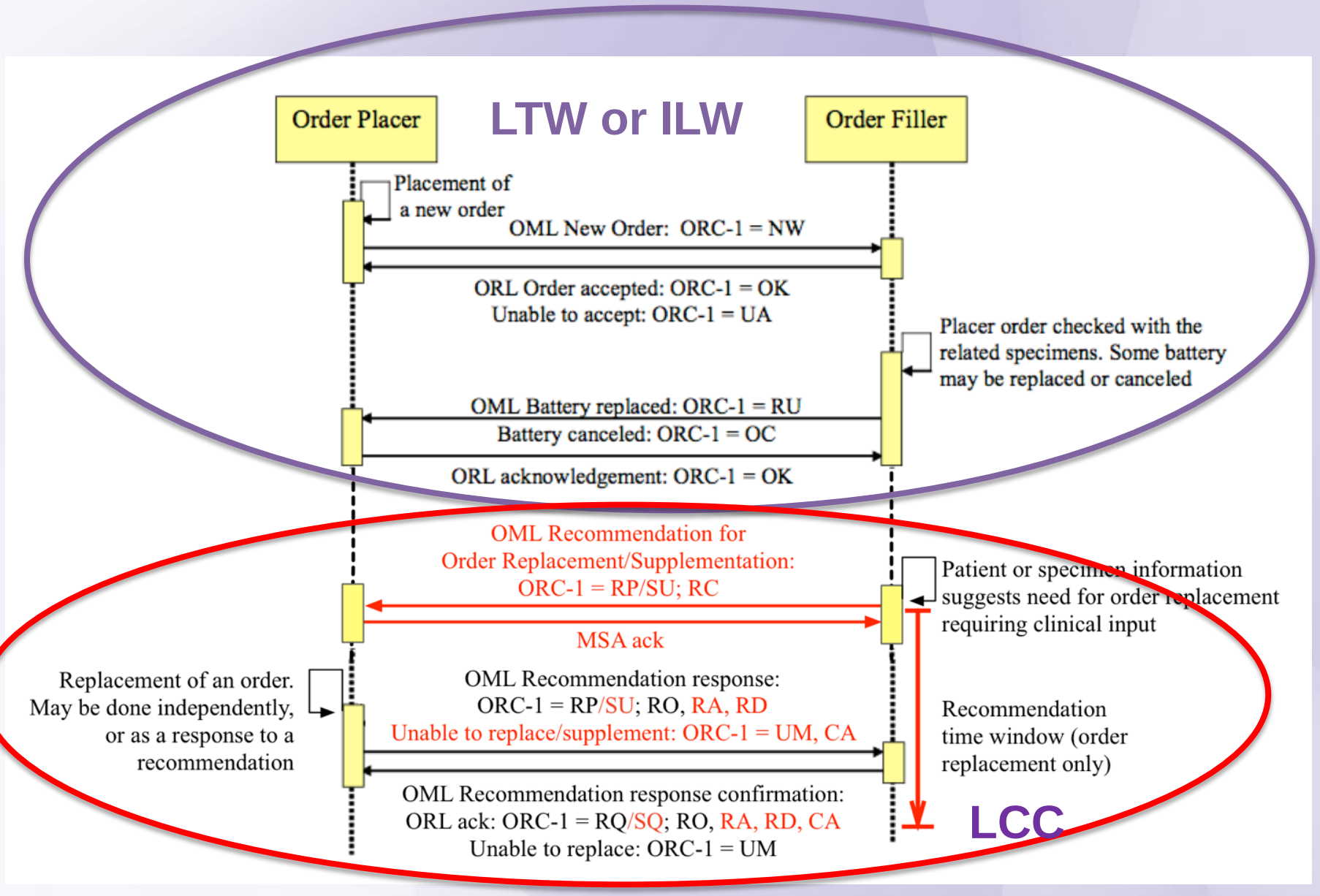
- LAB-7

Placer can request specific results to be re-examined

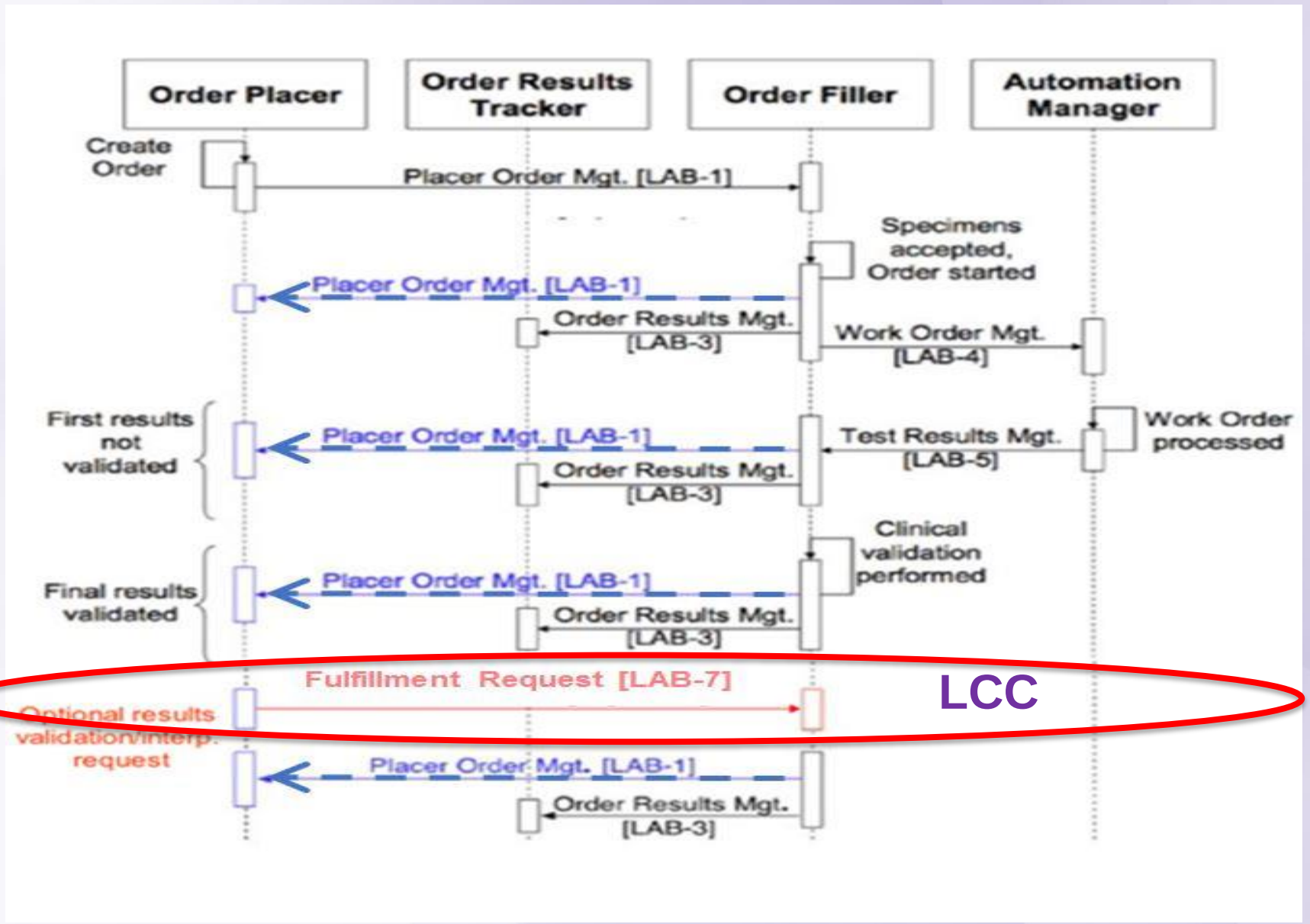


Standards: HL7 v2.5.1 and HL7v2.9

LAB-6


Order Placer
LTW or ILW
Order Filler
Placement of a new order
OML New Order: ORC-1 = NW
ORL Order accepted: ORC-1 = OK
Unable to accept: ORC-1 = UA
Placer order checked with the related specimens. Some battery may be replaced or canceled
OML Battery replaced: ORC-1 = RU
Battery canceled: ORC-1 = OC
ORL acknowledgement: ORC-1 = OK
OML Recommendation for Order Replacement/Supplementation: ORC-1 = RP/SU; RC
Patient or specimen information suggests need for order replacement requiring clinical input
MSA ack
Replacement of an order. May be done independently, or as a response to a recommendation
OML Recommendation response: ORC-1 = RP/SU; RO, RA, RD
Unable to replace/supplement: ORC-1 = UM, CA
Recommendation time window (order replacement only)
OML Recommendation response confirmation: ORL ack: ORC-1 = RQ/SQ; RO, RA, RD, CA
Unable to replace: ORC-1 = UM
LCC

LAB-7

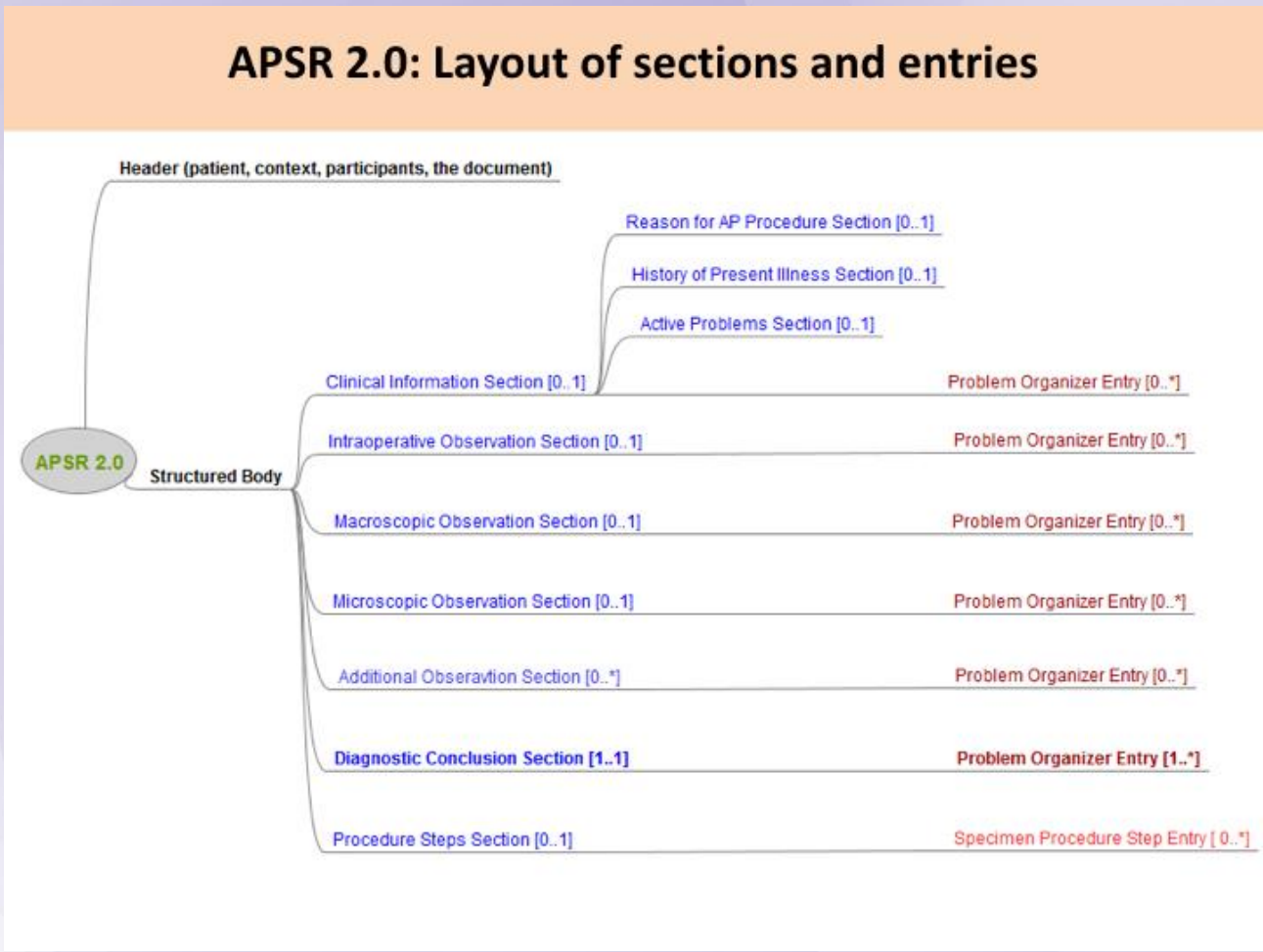

Order Placer
Order Results Tracker
Order Filler
Automation Manager
Create Order
Placer Order Mgt. [LAB-1]
Specimens accepted, Order started
Placer Order Mgt. [LAB-1]
Order Results Mgt. [LAB-3]
Work Order Mgt. [LAB-4]
First results not validated
Placer Order Mgt. [LAB-1]
Test Results Mgt. [LAB-5]
Work Order processed
Order Results Mgt. [LAB-3]
Clinical validation performed
Final results validated
Placer Order Mgt. [LAB-1]
Order Results Mgt. [LAB-3]
Fulfillment Request [LAB-7]
LCC
Optional results validation/interp. request
Placer Order Mgt. [LAB-1]
Order Results Mgt. [LAB-3]

Anatomic Pathology Structured Report
APSR 2.0

Generalize Anatomic Pathology Structured Report

Trial Implementation

- 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)

- Art Décor view

Template *Anatomic Pathology Structured Report Content Module* 2014-05-13 11:57:57

Id	1.3.6.1.4.1.19376.1.8.1.1.1	**Effective Date**	valid from 2014-05-13 11:57:57
Status	Draft	**Version Label**	2.0
Name	AnatomicPathologyStructuredReportContentModule	**Display Name**	Anatomic Pathology Structured Report Content Module

▸ Description

Context	Pathname /
Label	PaLM Suppl. APSR 2.0-3: 6.3.1.1 APSR clinical document content module
Classification	CDA Document Level Template
Open/Closed	Open (other than defined elements are allowed)
Associated with	▸ Associated with 14 concepts
Used by / Uses	▸ Used by 1 transaction and 0 templates, Uses 19 templates
Relationship	Specialization: template 2.16.840.1.113883.10.12.1 (*2005-09-07*)
Example	▸ example for use case #1

Expand All | Collapse All | Search by name

Item	DT	Card	Conf	Description	Label
▾ hl7:ClinicalDocument		1 .. 1	M		PaLM Su 6.3.1.1 docume
@classCode	cs	0 .. 1	F	DOCCLIN	
@moodCode	cs	0 .. 1	F	EVN	
		Associated with concepts: psr-dataelement-58 Anatomic Pathology Structured Report APSR			
▾ hl7:templateId	II	1 .. 1	M	This element is identifying the set of constraints applied to the CDA R2 standard by this IHE specification of a AP report. The following templateId SHALL be present and valued as follows to indicate compliance with the APSR 2.0 content module specification.	PaLM Su 6.3.1.1 docume
@root	uid	1 .. 1	F	1.3.6.1.4.1.19376.1.8.1.1.1	
hl7:realmCode	CS CWE	1 .. 1	M	This element SHALL be present and is valued from the RealmOfUse [2.16.840.1.113883.1.11.11050] subset, within the VocabularyDomainQualifier value set. In the international context of this profile used as it is without any further extension, the realm code SHALL be <realmCode code="UV"/> (universal). Whenever a national extension has been defined and is used, the realm code SHALL identify this national extension.	PaLM Su 6.3.1.1 docume
▾ hl7:typeId	II	1 .. 1	M	This element is a technology-neutral explicit reference to the standard CDA R2. It SHALL be present and valued as follows: ClinicalDocument/typeId@root = "2.16.840.1.113883.1.3" (which is the OID for HL7 Registered models); ClinicalDocument.typeId@extension = "POCD_HD000040" (which is the unique identifier for the CDA, Release Two Hierarchical Description).	PaLM Su 6.3.1.1 docume
@root	uid	1 .. 1	F	2.16.840.1.113883.1.3	
@extension	st	1 .. 1	F	POCD_HD000040	
▾ hl7:id	II	1 .. 1	M	ClinicalDocument/Id SHALL be present. It represents the unique instance identifier of the clinical document. The combination of the root and extension attributes SHALL provide a globally unique identifier, in accordance with CDA R2, without further constraints.	PaLM Su 6.3.1.1 docume
@root	uid	1 .. 1	R	Here the OID for PAT exemplary instances, in practice the OID of the LIS	
@extension	st	1 .. 1	R	Here a hypothetical document ID, most often derived from the accession number	
	Constraint			A report may have several successive revisions over time, in case corrections or complements are provided by the custodian after the initial release of the report. The unique id of the current revision of the report is carried by the id element, and is composed of • id@root, which SHALL be an OID, • and optionally id@extension, which can be any string so that the concatenation of the two attributes root and extension provide a globally unique id, which identifies this release of the report.	

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 s

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 anatomi 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 databas 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

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 pathol 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, Volun

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 "Require

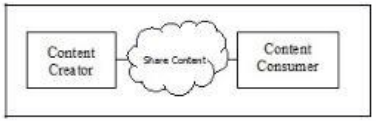


Figure 10.1-1 APSR Actor Diagram

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

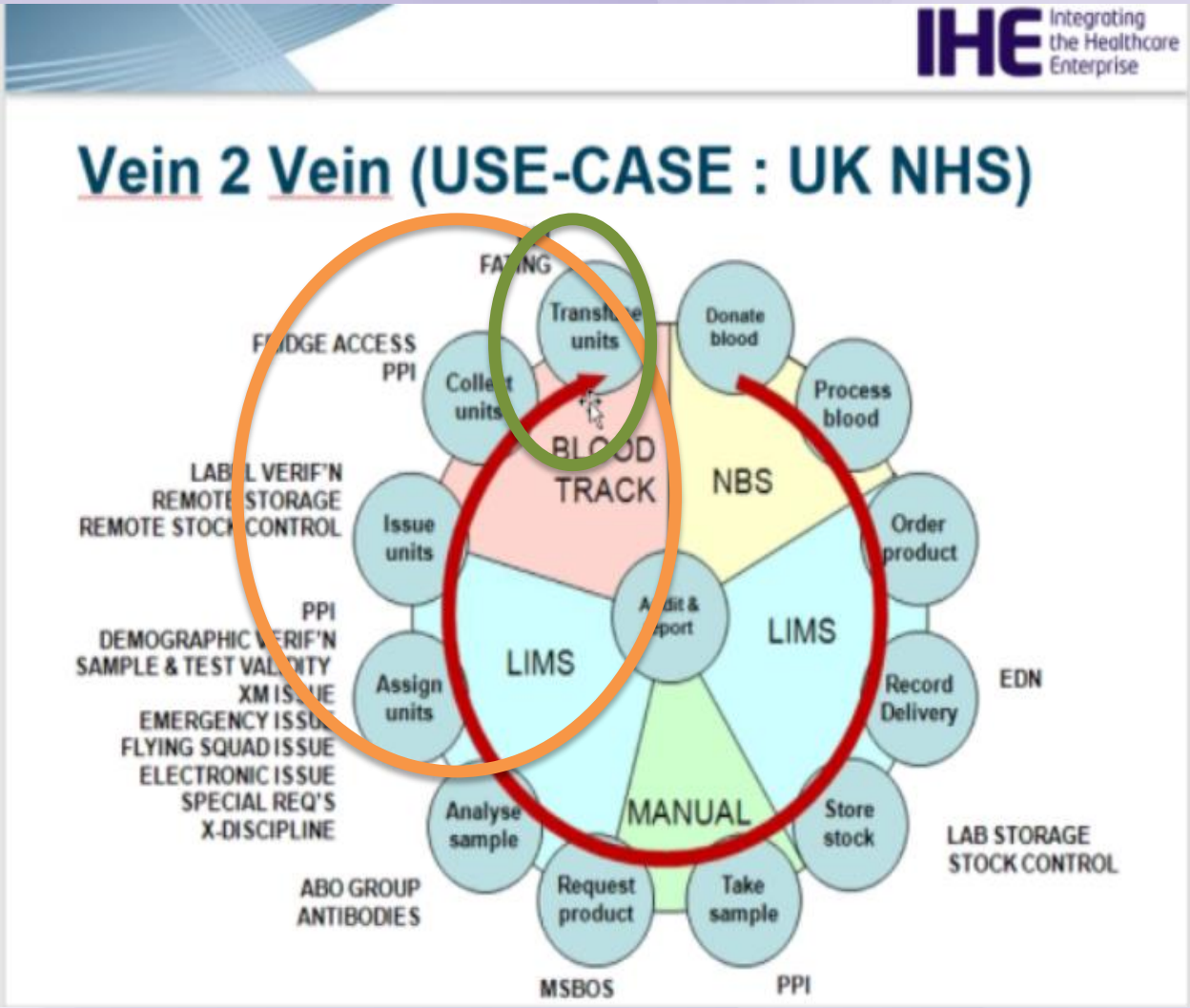
Actors	Content Modules	Optionality	Reference
Content Creator	Anatomic Pathology Structured Report 1.3.6.1.4.1.19376.1.8.1.1.1	R	PaLM TF-3: 6.3.1.2
Content Consumer	Anatomic Pathology Structured Report 1.3.6.1.4.1.19376.1.8.1.1.1	R	PaLM TF-3: 6.3.1.2

Transfusion Medicine – Administration (TMA)

Tracking Adverse Events During Transfusion Administration

Trial Implementation

- 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

WE NEED YOUR HELP

- For more detail and to access the TMA as published for comment:

http://ihe.net/uploadedFiles/Documents/PaLM/IHE_PaLM_Suppl_TMA_Rev2.0_PC_2018-04-27.pdf

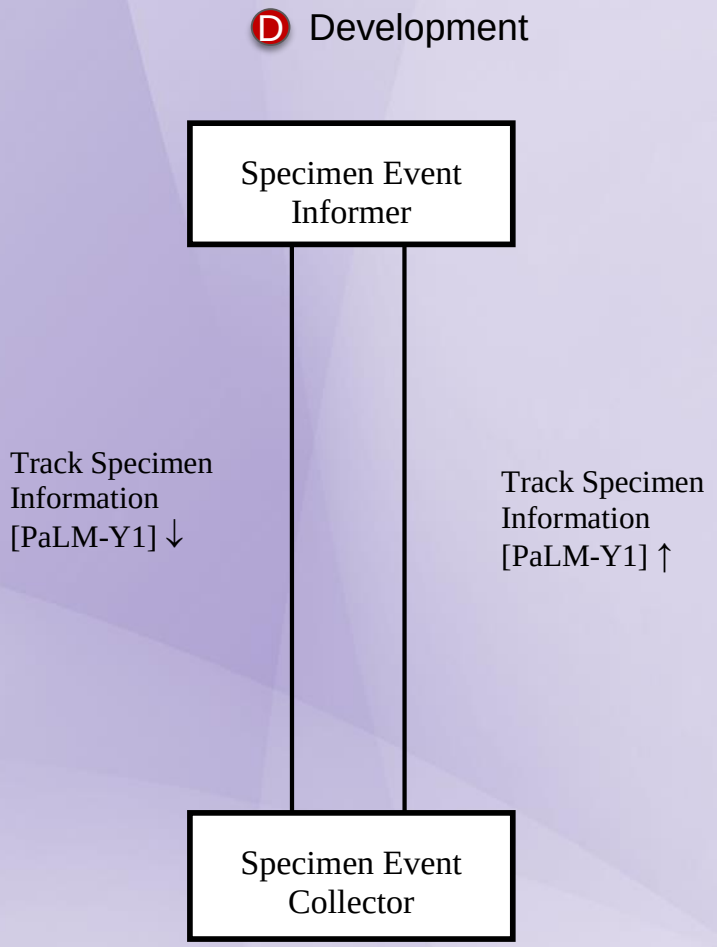
- We are looking for stakeholders interested in testing this in connectathons (applies to ALL PaLM profiles)
- We are planning more elements of the Transfusion Medicine life cycle and would like input from stakeholders

Current Work

Specimen Event Tracking (SET)

Manage Specimen Transport Tracking

- 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)



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

WE NEED YOUR HELP

- For more detail and to access current work on SET http://wiki.ihe.net/index.php/Specimen_Event_Tracking

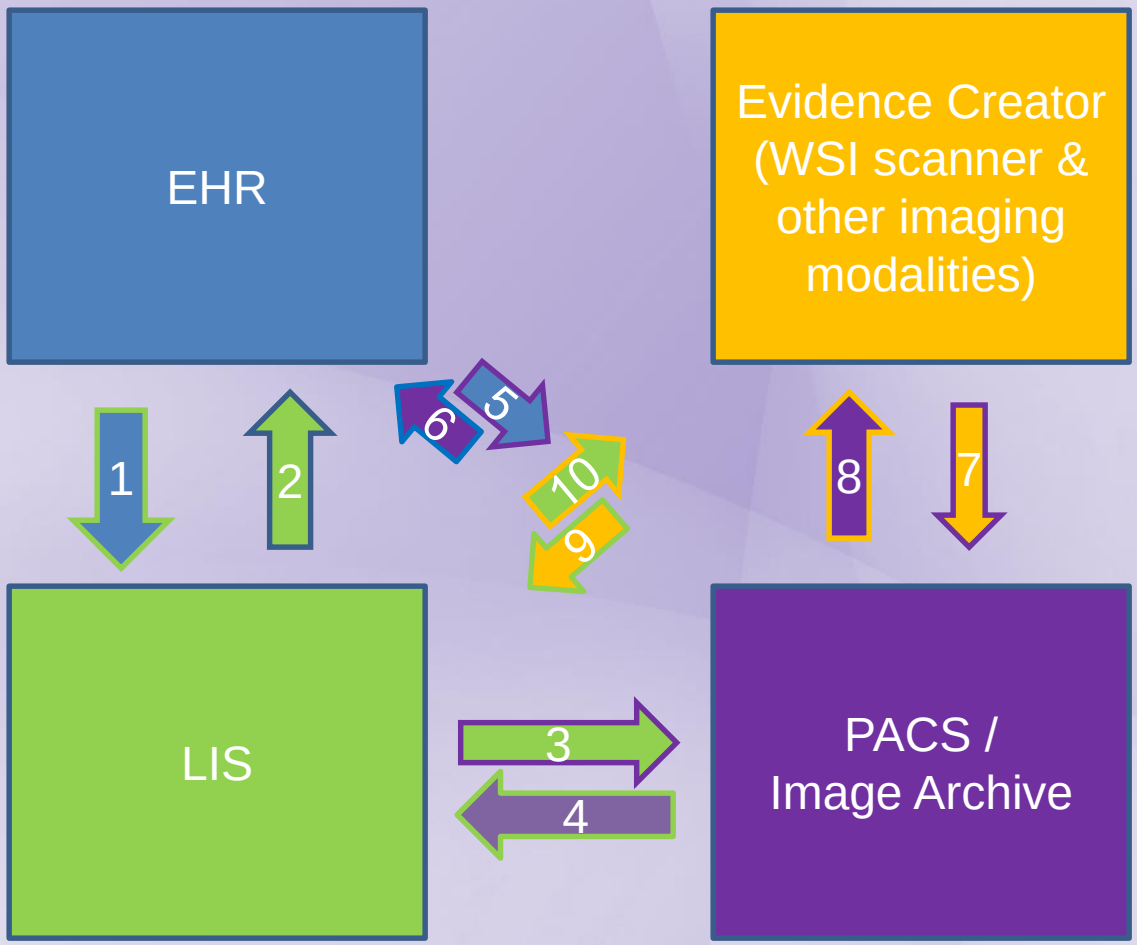
- Working on data element matrix (defining all the elements for each of the different tracking steps
- Working on defining message structure(s) for tracking steps with the same data requirements
- Verifying all tracking steps covered

Evolve Anatomic Pathology Workflow to Accommodate Digital Pathology

- DICOM WG26 and IHE PALM collaboration
- Anatomic pathology workflow reimagined with incorporation of image digitization
- Use cases established with initial effort focused on profile to support image acquisition
  - Primary diagnosis and secondary consultation use cases will take priority
- First white paper to be released Fall 2018 and first profile to be published December 2018

Example: actors, workflow, transactions in Digital Pathology

1. EHR sends case order with one or more specimens
2. LIS sends case results (diagnosis)
3. LIS requests stored image(s) for specimen
4. Archive returns image(s)
5. EHR requests all images for case (not likely?)
6. Archive returns image(s)
7. Creator sends images for storage
8. Archive acknowledges image(s) stored
9. LIS receives events as creator acquires, completes, modifies digital asset
10. LIS acknowledges / approves creator transaction



WE NEED YOUR HELP

- For more detail and to access current work on Digital Pathology

  https://wiki.ihe.net/index.php/APW-EDM_White_Paper
- Review use cases
- Review draft white paper, comment on focus of initial effort, and associated actors and transactions
- Identify how you would recommend prioritization of future efforts as part of a long term road map
- Identify which vendor partners in your organization would benefit from being involved and help us reach out to them!

If you want to contribute

- Apply for IHE International Organizational Membership
  - Visit: www.ihe.net/apply (note IP Policy)
  - Approved monthly by IHE International Board
  - Review IHE's 200+ Organizational Members:
  - 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

http://www.valuesbasedleader.com/wp-content/uploads/2013/12/iStock_TimeIsNow_SmallCrop.jpg

Thank you

- IHE International - www.ihe.net
- IHE Europe - 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