VIENNA 2025 JUNE 23/27

IHE EUROPE CONNECTATHON®

What's new in IHE PaLM?

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1

What's New in IHE **P**athology **a**nd **L**aboratory **M**edicine

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Please keep your microphone muted

Questions during the session? Please use the chat box. We will address the questions in the second part of the webinar

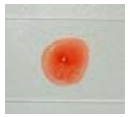
Note that this webinar will be recorded and made available on IHE-Europe Youtube channel. Slides will be available on Connectathon webpage

Agenda

1. Overview of the PaLM domain
2. Current work
3. Profiles for June Connectathon update
4. Q&A

The PaLM domain scope

- Exchange of digital assets (data, documents, images) associated with services performed on specimens by clinical laboratories(1) and pathology laboratories(1);
- analytical and peri-analytical automation;
- representation and exchange of structured data related to specimen management, long term storage (for instance in biobanks) and reuse;
- secondary use of laboratory observations and related clinical observations;
- Interoperable workflows of transfusion medicine targeting 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

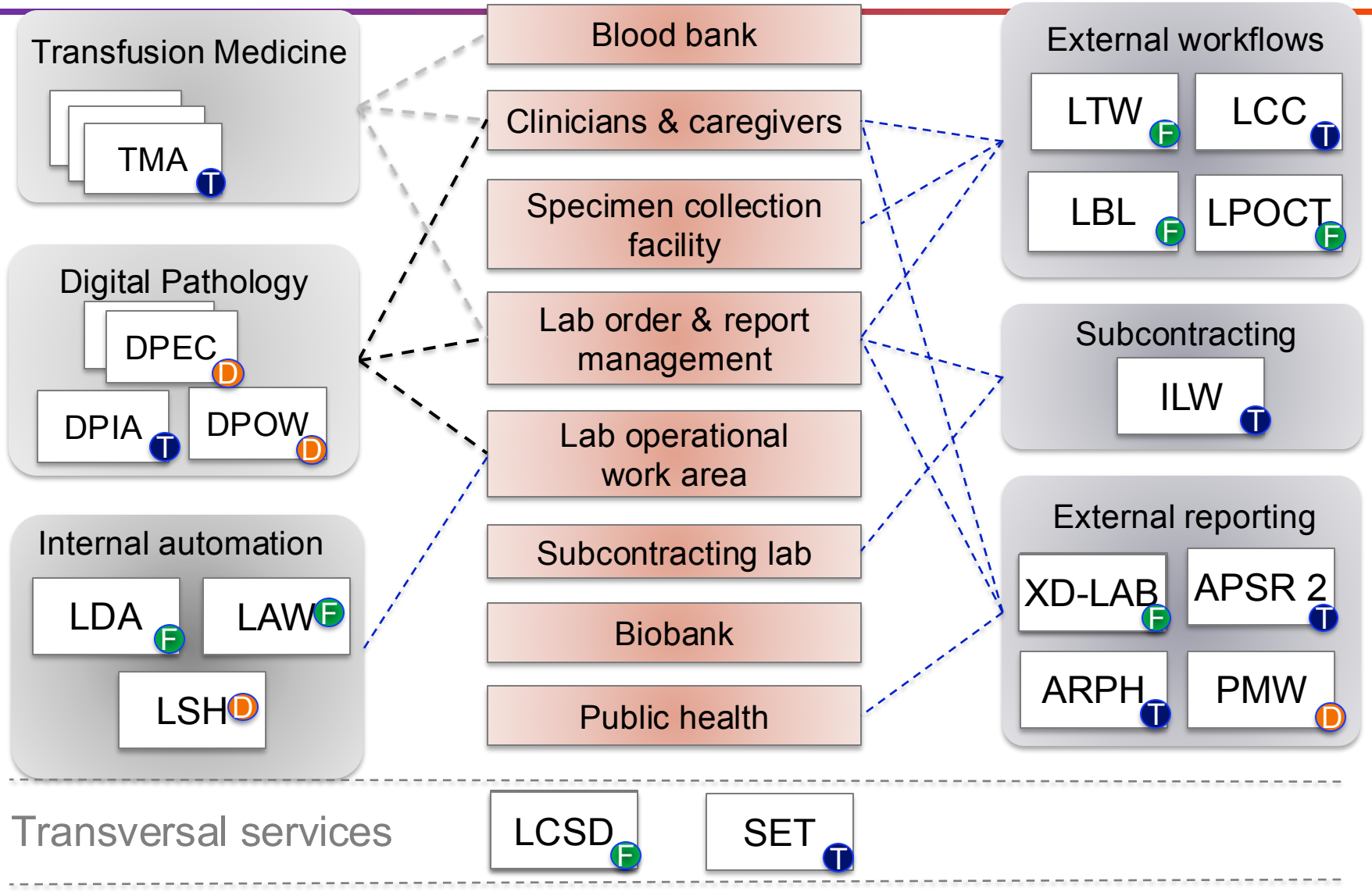
ihe_domains/ihe_pathology_and_laboratory_medicine/

IT Systems in PaLM

- ❑ EHR & EMR systems in hospital and ambulatory care settings
- ❑ Clinical and 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 for specimen containers
- ❑ Analytic and peri-analytical robotic devices in lab work area
- ❑ Point-of-care analytical devices
- ❑ Middleware systems steering automation
- ❑ Imaging modalities
- ❑ PACS and digital archive systems
- ❑ Biobank management systems
- ❑ Blood bank management systems
- ❑ Adverse Event tracking systems

- (F) Final text
- (T) Trial implementation
- (D) Development

PaLM profiles



PaLM TFs – Rev. 11

Released in April 2024, includes several CPs, with some important changes for LAW profile

Vol 1: Actors and supported transactions for all profiles
Vol 2a: Laboratory Testing Workflow (LTW) and Laboratory Device Automation (LDA)
Vol 2b: Laboratory Analytical Workflow (LAW)
Vol 2c: Laboratory Point Of Care Testing (LPOCT) and Laboratory Code Set Distribution (LCSD) and Laboratory Specimen Barcode Labeling (LBL)
Vol 2x: Common segment definitions
Vol 3: Sharing Laboratory Reports (XD-LAB)

Current Work

Laboratory Specimen Handof (LSH)

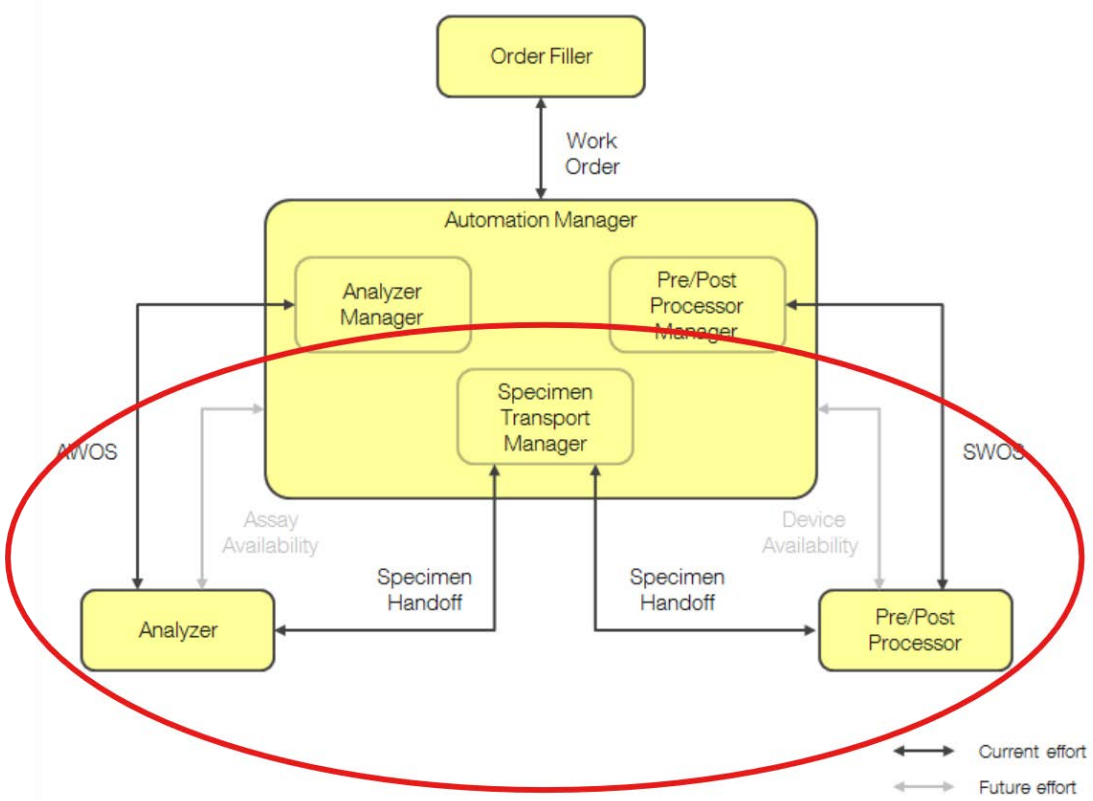
Defines workflows for specimen handoff between Laboratory Automation System (LAS) and Specimen Processing Devices (SPD)

2 use cases:

- Single-Specimen Point-in-Space Acquisition
- Single-Specimen Container Transfer

- Systems involved: LAS, SPD, Analyzer, Specimen Transport Manager

1. Reduced design burden for Specimen Processing Devices
2. Reduced design burden for the laboratory automation systems to which SPDs are attached
3. Comprehends handoff pitfalls that may not be apparent to an individual development team
4. Provide a generally accepted foundation upon which the industry can build

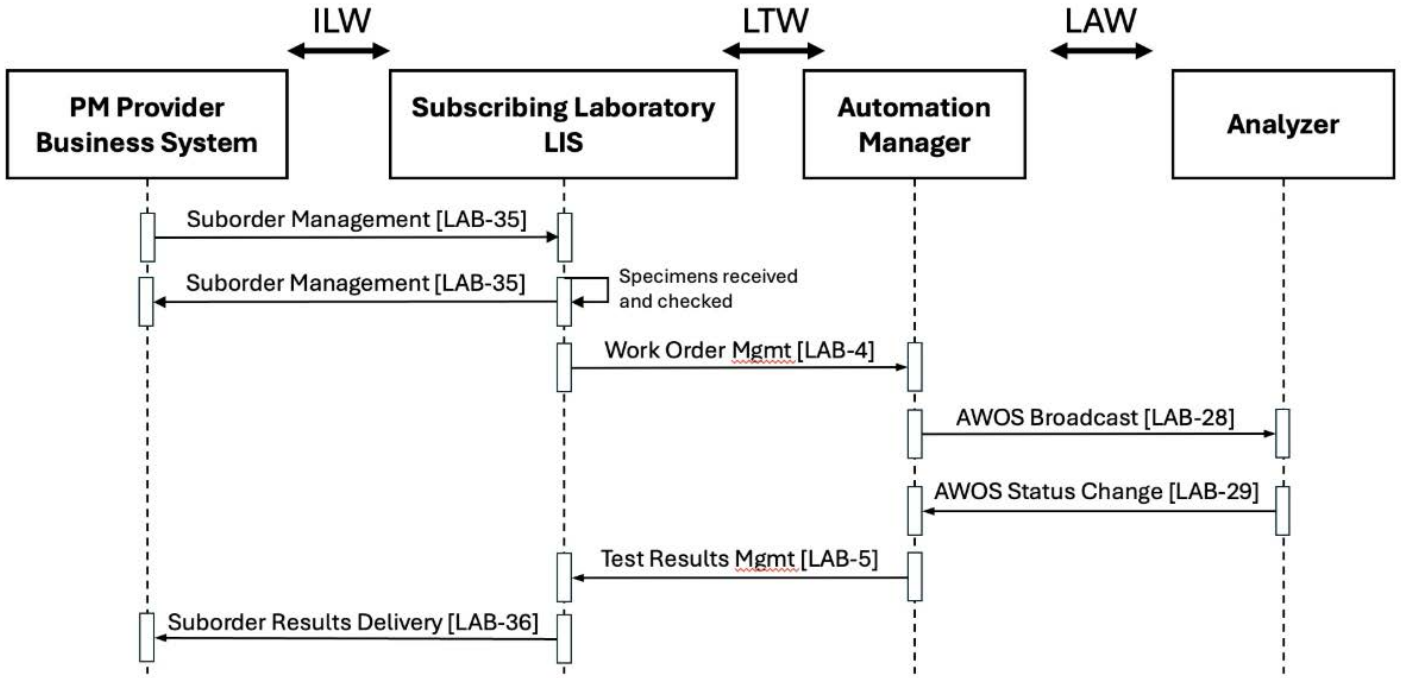


Performance Management Workflow (PMW)

workflow and content for messages that communicate orders and results for tests that are carried out to evaluate the technical performance of laboratories

Use case: Ordering and resulting for external organization, including the internal transactions

- Systems involved: Proficiency Testing Provider, LIS, LAS/middleware/Analyzer
- evaluates the technical performance of laboratories



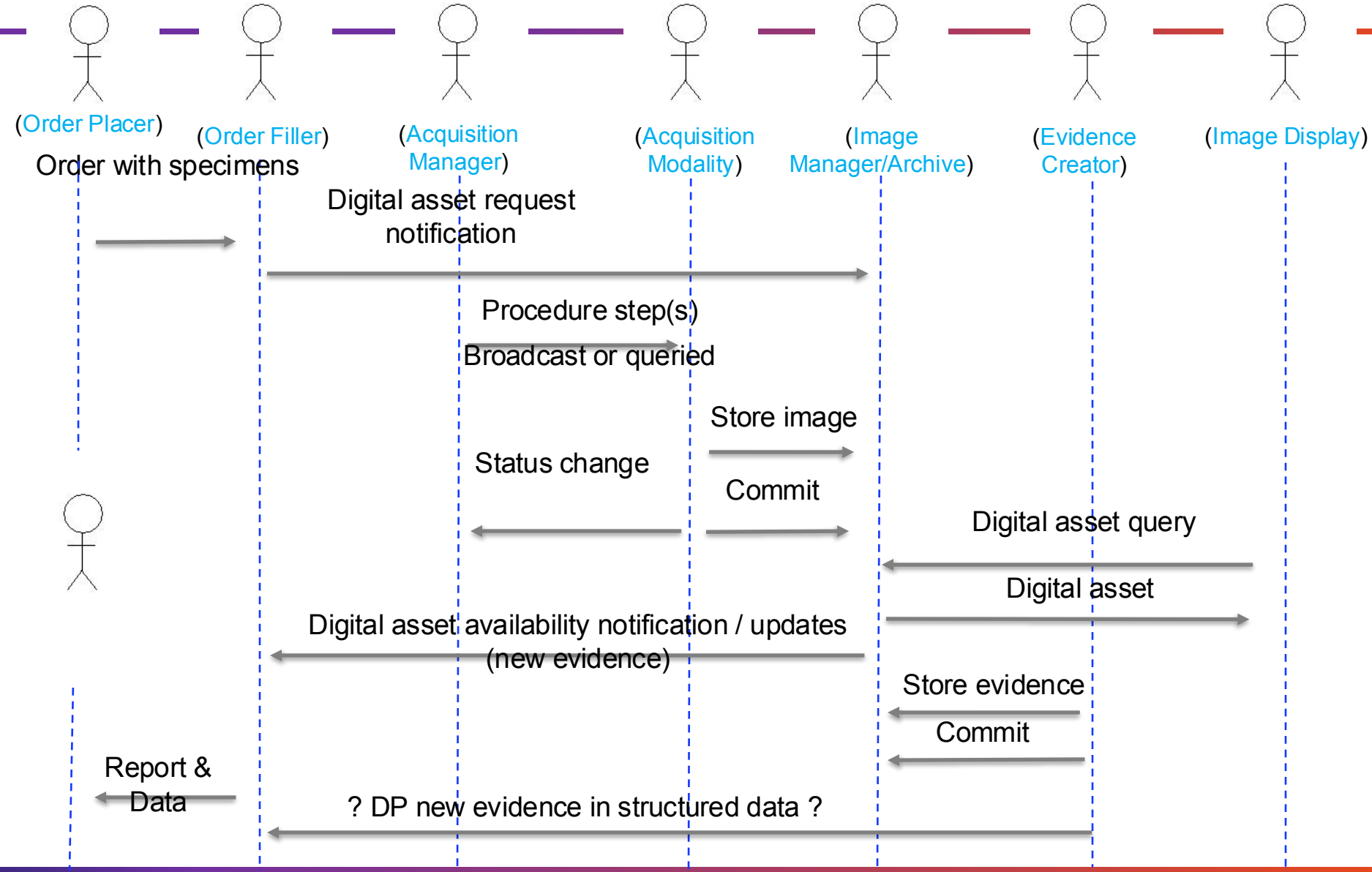
Collaboration with DICOM WG26

- Ensure support for data needed in DICOM Supplement 222
- Identify boundary of usage to DICOM Structured Report and DICOM Segmentation Images
- Create mapping of data elements between HL7 and DICOM Supplements
- Identify standards that need to be augmented to support digital pathology workflows and interoperability of WSI (e.g. SNOMED CT lacks robust support for immunohistochemistry)

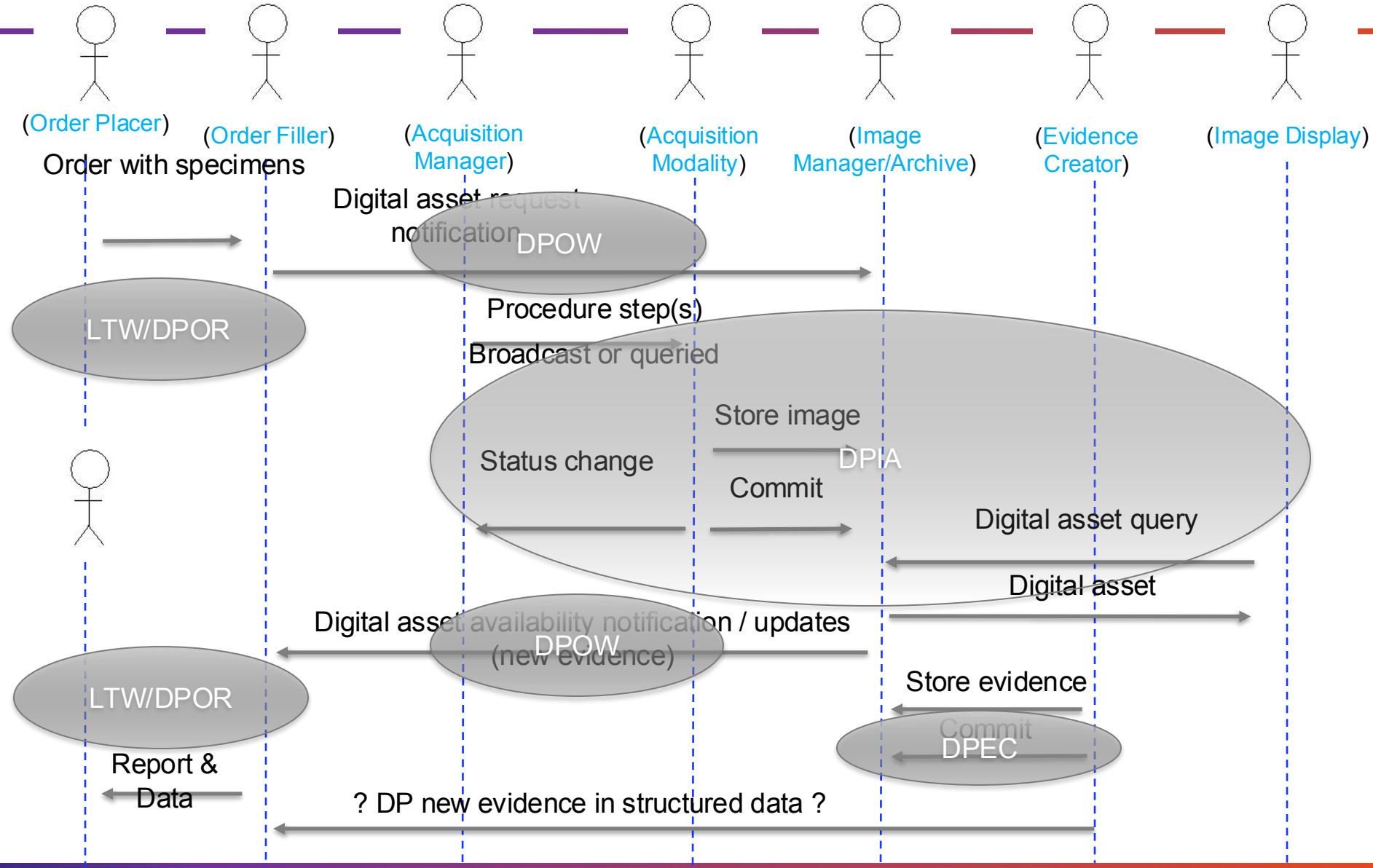
How can YOU (PACS/Imaging Analytics/Scanner/LIS/EHR-s Vendors) help?

- Evaluate use cases in Integrating the Health-care Enterprise Pathology and Laboratory Medicine Guideline for Digital Pathology Interoperability
- Contribute to current profile development:
  - DPOW – profile for digital imaging request and digital image availability notification between image manager/archive (PACS) and order filler (LIS).
  - DPEC – profile for evidence creation by an image analyzer resulting in a new digital asset or quantitative data (AI/ML vendors needed!)
  - Use existing LTW for routine orders to the lab and for image manager/archive transmitting results to order filler.
- Consider having your product in a Connectathon with other leading digital pathology vendors!
- Effort required: monthly 1-2 hour teleconference, document review, Connectathon participation

Digital Pathology Transactions



Digital Pathology Transactions - Profiles



Scope of DP Profiles

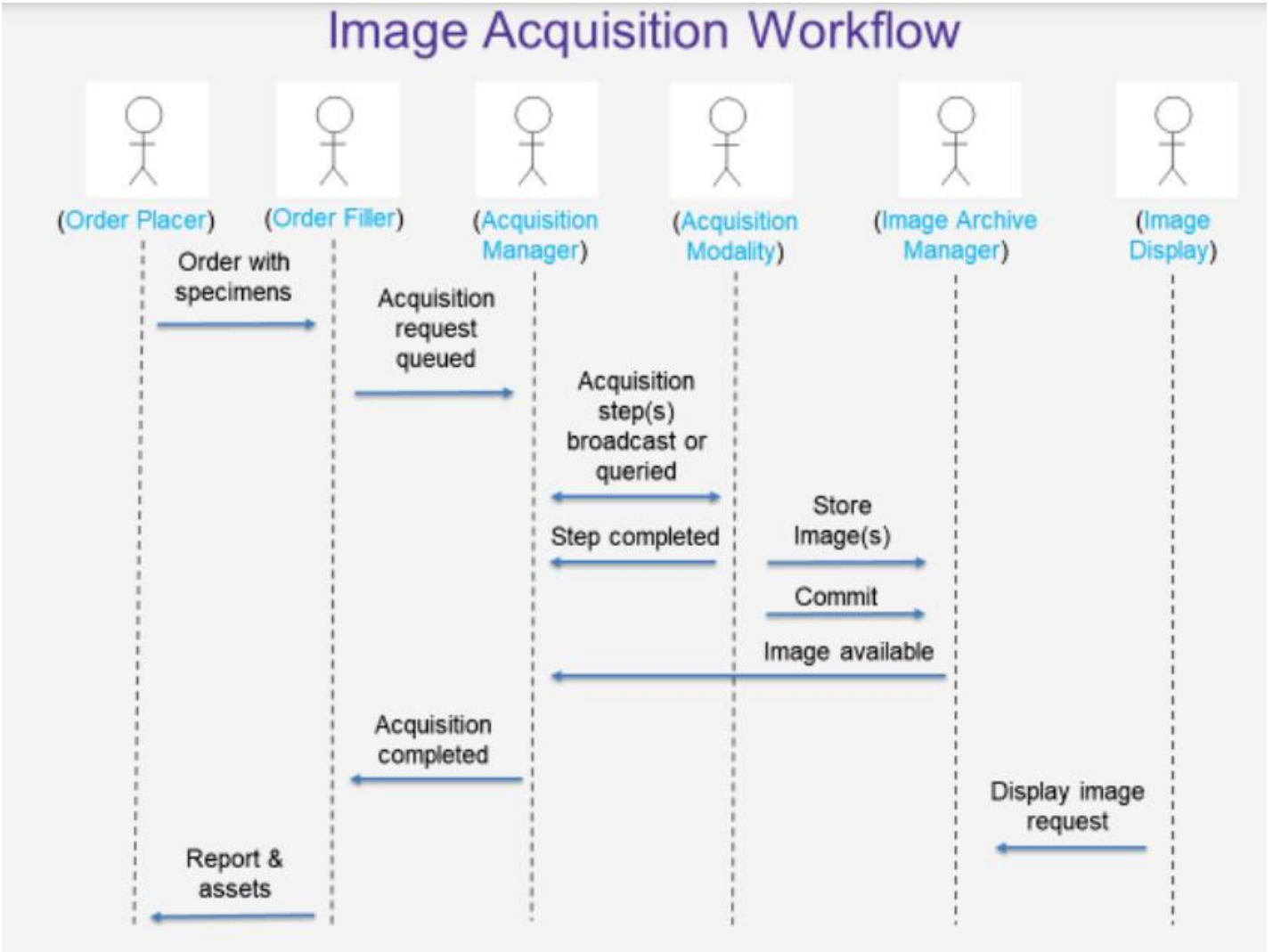
- DPIA – constrained to creation, storage and display of a DICOM file
- DPOW – focused on workflow meeting the communication needs of the image manager/archive (PACS), order filler (LIS), and acquisition manager when new WSIs created
- DPEC – evidence creation focused on analysis of a WSI
- DPOR – orders/result paradigm between the order placer (EHR) and order filler (LIS) already exists in IHE technical framework as LTW and need not be reinvented unless the digital pathology workflow adds requirements

Digital Pathology Image Acquisition (DPIA)

Digital Pathology Image Acquisition (DPIA)

Use Cases

- Whole Slide Image Acquisition
  - Parallel to IHE LAW in Clinical Lab
  - Support for additional meta data
    - For DICOM data model
    - For work processes (instructions on magnification, information on stains / processing of slide material)



Digital Pathology Image Acquisition (DPIA)

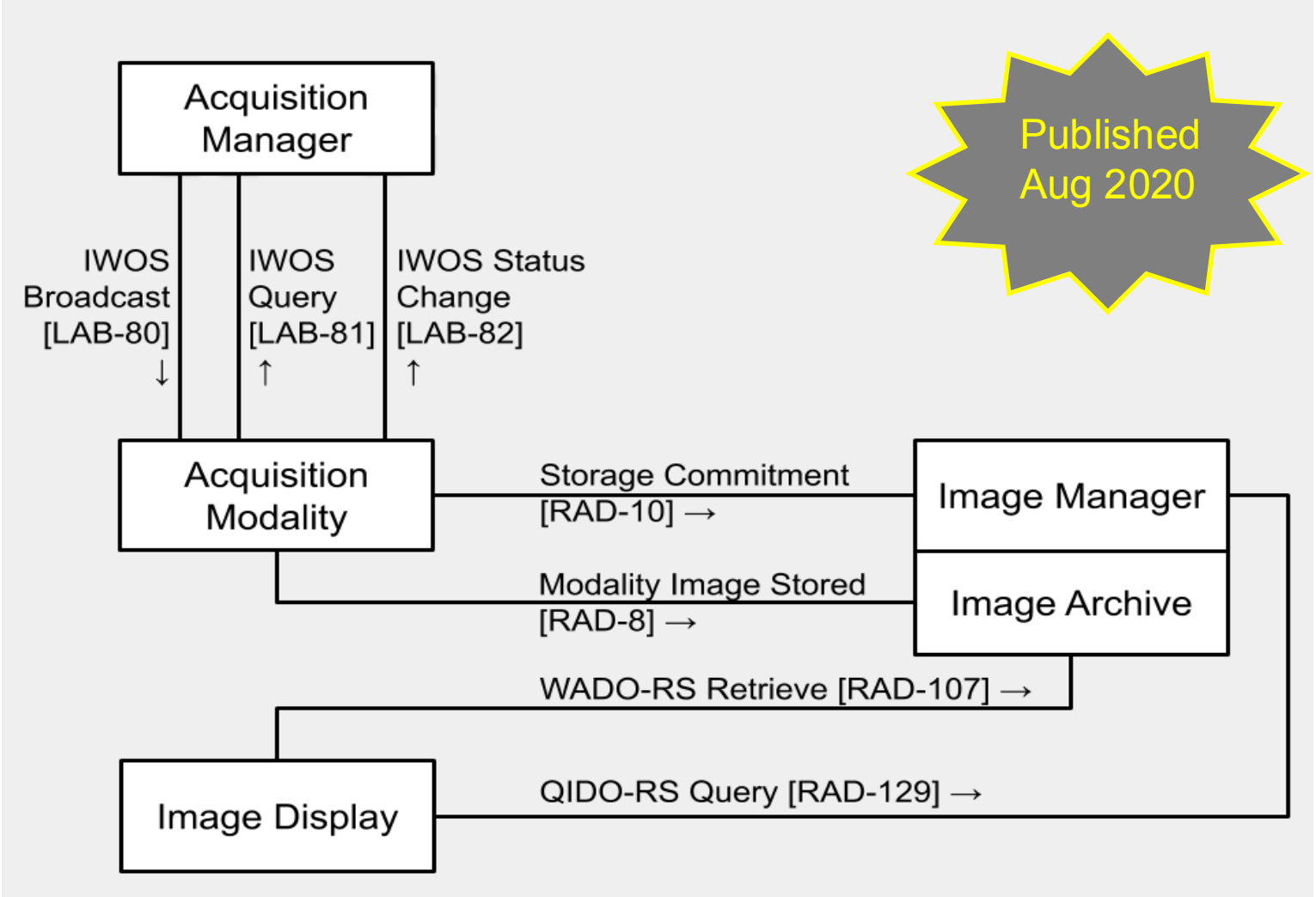
LAW's cousin for Pathology, built in close collaboration with DICOM WG26: profile for acquisition of a digital image from a physical asset, usually a glass slide, but possibly also a gross specimen.

IWOS: Imaging Work Order Step

a service request that defines the detail for image acquisition.

Acquisition Modality

a device (e.g., digital camera or whole slide imaging scanner) that acquires digital images of a physical specimen, to fulfill an IWOS.



DPIA - Use Cases

- Originally focused on simplest approach for WSI acquisition
  - Acquisition Modality (scanner) scans a new WSI, notifies the Acquisition Manager (scanner software), who sends the WSI to the Image Manager/Archive (PACS)
  - Acquisition Manager (scanner software) broadcasts metadata to one or more Acquisition Modalities (scanners) of incoming WSIs that need to be scanned
- The latest update (v1.3) addresses how to accept critical metadata needed to populate the DICOM WSI file
  - Example: how to tell ER vs PR stain looking at WSI (other than a human reading the label today)

DPIA - Use Cases

- New Change Proposal In Draft
  - Acquisition Manager needs to be able to communicate with Order Filler (LIS) to populate key metadata elements
    - On LAB-80, use SPM-2 for slide ID, SPM-3 for block ID (null for cytology),repeatable SPM-6 segment for stain, SAC-3 for container ID, add IPC for DICOM metadata
  - Pre-adopt IPC segment.
  - Use SNOMED CT as controlled vocabulary as needed for specimen segment fields

SPM-6	Specimen Additive (this CWE field repeats and could convey multiple values including additives, routine stains, special stains and IHC)
SPM-27	Specimen Container Type (like CID 8103)
SPM-4	Specimen Type
SPM-7	Specimen Collection (like CID 8109)
SPM-8	Specimen Source (like CID 8104)

Digital Pathology Order Workflow (DPOW)

DPOW - Use Cases

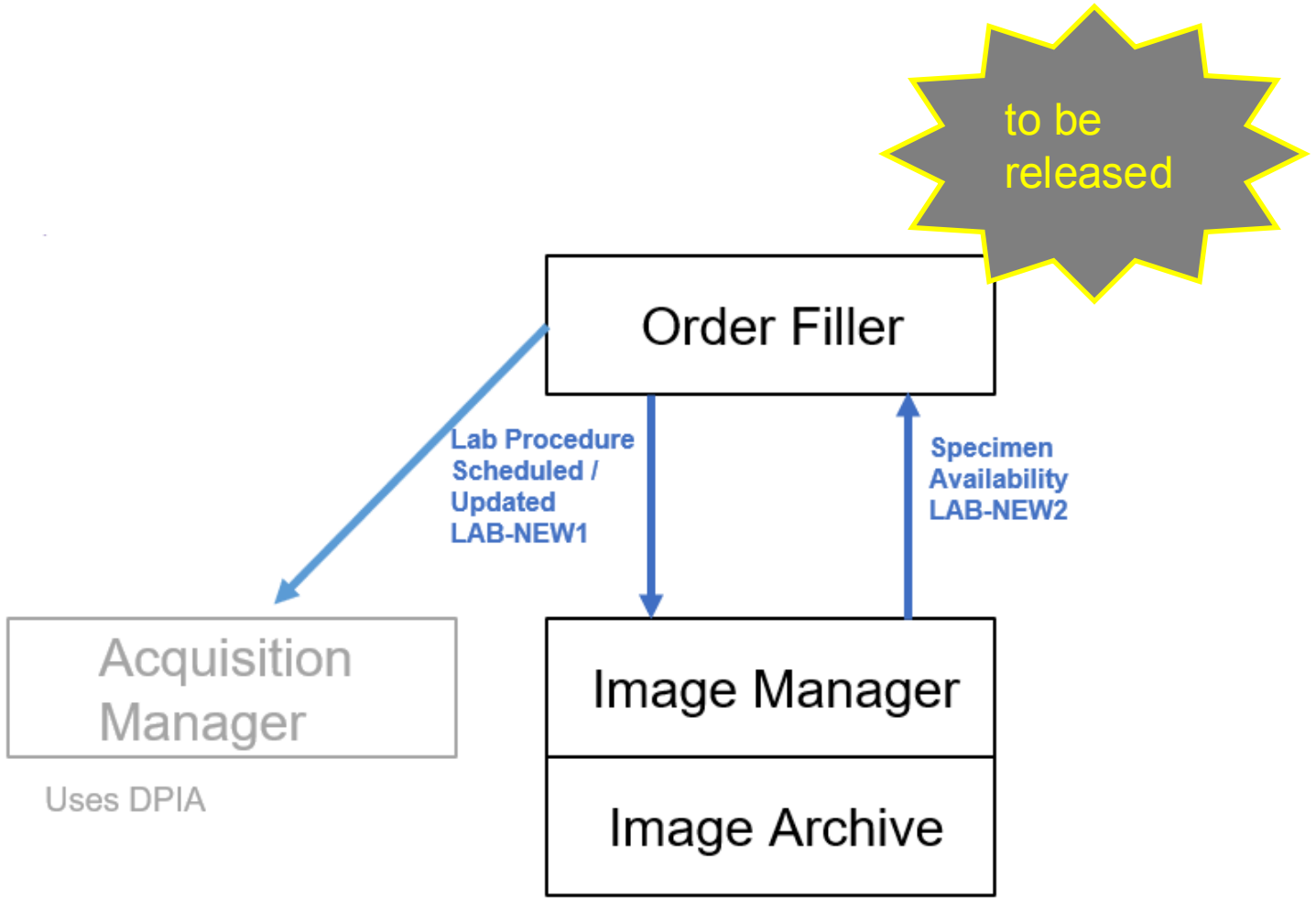
- Digital asset request notification
  - Order filler (LIS) announces to acquisition manager (IMS) and image manager/archive (PACS) that a request for a digital asset exists
  - This will not reflect physical asset inventory necessarily (which is the sole purview of the order filler)
- Digital asset availability notification
  - Notification from the image manager/archive (PACS) back to the order filler (LIS) on the availability of digital assets for viewing
  - This will allow the order filler (LIS) to communicate to the user whether digitization has been completed
- Communication of WSI related metadata between Image Manager/Archive (PACS) and Order Filler (LIS)
  - For example, right click on an image of a slide and request a recut or IHC stain

Digital Pathology Order Workflow (DPOW)

Built in close collaboration with DICOM WG26
This profile supports request and notifications of digital asset availability by the filler

IWOS: Imaging Work Order Step
- a service request that defines the detail for image acquisition.

Acquisition Modality
- a device (e.g., digital camera or whole slide imaging scanner) that acquires digital images of a physical specimen, to fulfill an IWOS.



Digital Pathology Evidence Creation (DPEC)

DPEC - Use Cases

- Rare Event Detection (evidence may be new annotations or coordinates)
  - Microorganism detection, e.g. acid-fast bacilli
  - Tumor features, e.g. lymphovascular invasion, margin involvement, lymph node metastasis detection, mitotic figure labeling
- Quantitative Analysis (evidence is numeric data)
  - Biomarker staining, e.g. Ki-67, ER, PR, HER2
  - Mitotic rate count per unit area
- Qualitative Analysis (evidence is Boolean or ordinal data)
  - Tumor identification and/or classification, e.g. tumor of unknown primary, most abnormal cells on a pap smear
  - Prioritization of slide review based on presence or absence of lesional features, e.g. tumor detection
  - Case distribution based on algorithm derived metadata (e.g. complexity of case or presence of tumor etc)
- Events (e.g. Heat Map, evidence may be complex data objects)
  - Record which digital tiles in which digital scans have been viewed by a user
- More Complex Image Manipulation (evidence may be a new WSI)

Connectathon Test Cases (DPIA)

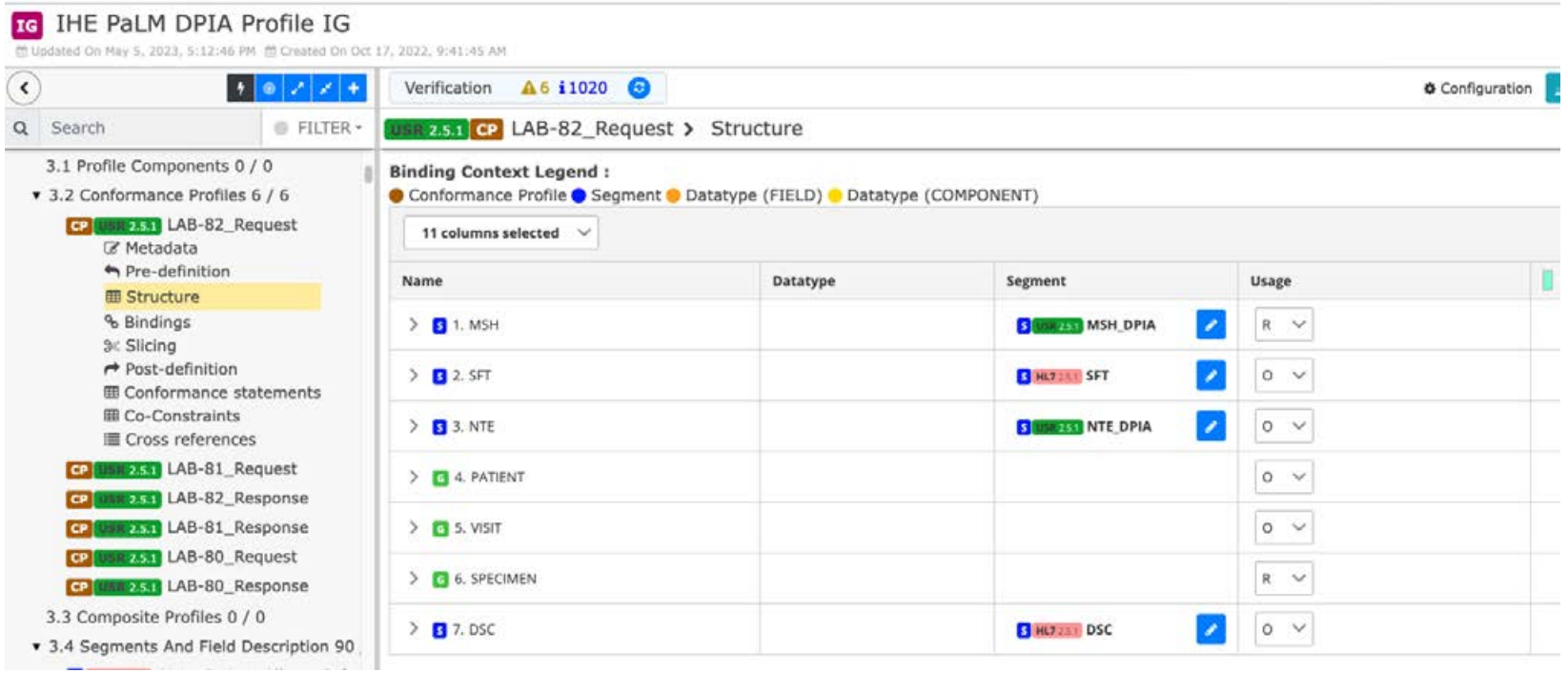
Connectathon Test Cases

Test case name	Actors under test	Transaction(s)
DPIA Image Work Order Step Broadcast	ACQUISITION_MANAGER, ACQUISITION_MODALITY	LAB-80, LAB-82
DPIA Query for IWOS	ACQUISITION_MANAGER, ACQUISITION_MODALITY	LAB-80, LAB-81, LAB-82
DPIA full Workflow	ACQUISITION_MANAGER,ACQUISITION_MODALITY, IMAGE_MANAGER/IMAGE_ARCHIVER	LAB-80, LAB-81, LAB-82, RAD-8, RAD-10
DPIA Image Retrieve and Display	IMAGE_DISPLAY, IMAGE_MANAGER/IMAGE ARCHIVER	RAD-129, RAD-107

The first two test instances address the two modalities of IWOS transmission: broadcast and query

The third and fourth include also the Radiology transactions, for images archive, retrieve and display

DPIA (HL7 v2) in IGAMT



Developed all DPIA HL7v2 message profiles through the usage of IGAMT tool, for every transactions

Starting point to include HL7v2 messages validators for DPIA into Gazelle's HL7v2 Validator

DPIA: HL7v2 -> DICOM mappings

A1:E1 | Table 1. List of mandatory fields in DPIA transactions having a mapping with DICOM. Segments: SPM, OBX, ORC and SAC

	A	B	C	
1	**Table 1. List of mandatory fields in DPIA transactions having a mapping with DICOM. Segments: SPM, OBX, ORC and SAC**			
2	**HL7 v2 Mandatory Field**	**Usage (OPT)**	**DICOM element**	**"Comm**
3	SPM-4 (Specimen type)	R	DICOM Specimen Description Sequence (0040,0560) Item 1 Specimen Type Code Sequence (0040,059A).	This field d Any physica this attribut (e.g., an os
4	SPM-30 (Accession Number)	R	Map Component 1 ID Number to DICOM: • Accession Number (0008,0050) • Referenced Request Sequence (0040,A370) Item 1 Accession Number (0008,0050) If present, map Component 4 Assigning Authority to DICOM • Issuer of Accession Number Sequence (0008,0051) • Referenced Request Sequence (0040,A370) Item 1 Issuer of Accession Number Sequence (0008,0051) E.g., DPIA "SP19-000425". Shall be the same as SAC-2.	This field c involved in identifiers.
5	OBX-3 (Observation Identifier)	R	Shall be DCM: 110180 "Study Instance UID"	This field c
6	OBX-5 (Observation Value)	R	Shall be of EI data type and contain a DICOM UID (OID) in Component 1 Entity Identifier. Map to DICOM Study Instance UID (0020,000D).	This field c
7				
8				
9				
10	**Table 2. List of "Required" or Optional fields having a mapping with DICOM, for NOT MANDATORY segments of DPIA messages: PID, OBR, SAC**			
11	**HL7 v2 Field**	**Usage (OPT) in segment**	**DICOM element**	
12	PID-3 (Patient Identifier)	R	Map to DICOM Patient's ID (0010,0020).	This field c a patient (e etc.).
			Map to DICOM Patient's Name (0010,0010).	

Specimen Event Tracking (SET)

Specimen Event Tracking (SET)

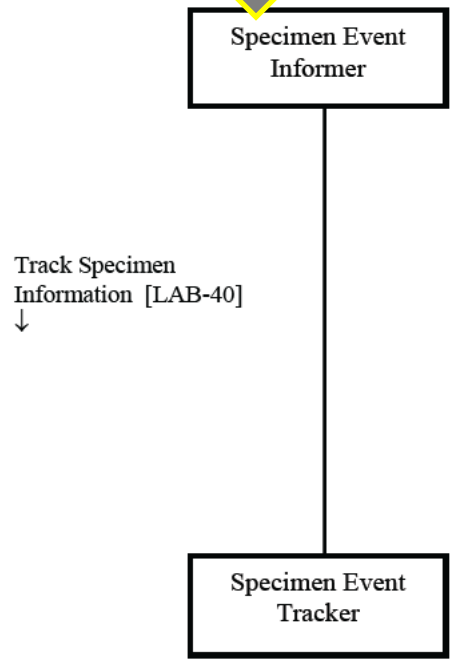
This profile enables tracking of all meaningful events concerning biological specimens in-vitro produced for diagnostic testing, from collection to archival or disposal.

Published Nov 2021

Use Cases:

1. Container Delivery and Specimen Collection Tracking
2. Specimen Inter and Intra organization transfer
3. Specimen tracking within the Laboratory
4. Biobank Specimen Tracking

Events tracked
Containers prepared for specimen collection
Specimen collection succeeded
Specimen collection failed
Specimen departed
Specimen arrived
Specimen accepted
Specimen rejected
Specimen identifier changed
Specimen archived
Specimen retrieved from archive
Specimen procedure step successfully produced a derived specimen
Specimen procedure step succeeded (with no derived specimen)
Specimen procedure step failed
Specimen disposed of



Connectathon Test Cases

Atomic test cases defined in Gazelle, each one testing a specific SET tracking event

IGAMT profiles developed for HL7v2 message validation

- SET_containers_prepared
- SET_spec_acc
- SET_spec_archived
- SET_spec_arrived
- SET_spec_coll_failed
- SET_spec_coll_success
- SET_spec_departed
- SET_spec_disp_of
- SET_spec_proc_derived
- SET_spec_proc_no_derivation
- SET_spec_proc_unsuccess
- SET_spec_reid
- SET_spec_reject
- SET_spec_retr_from_archive

Laboratory Testing Workflow (LTW)

Laboratory Testing Workflow (LTW)

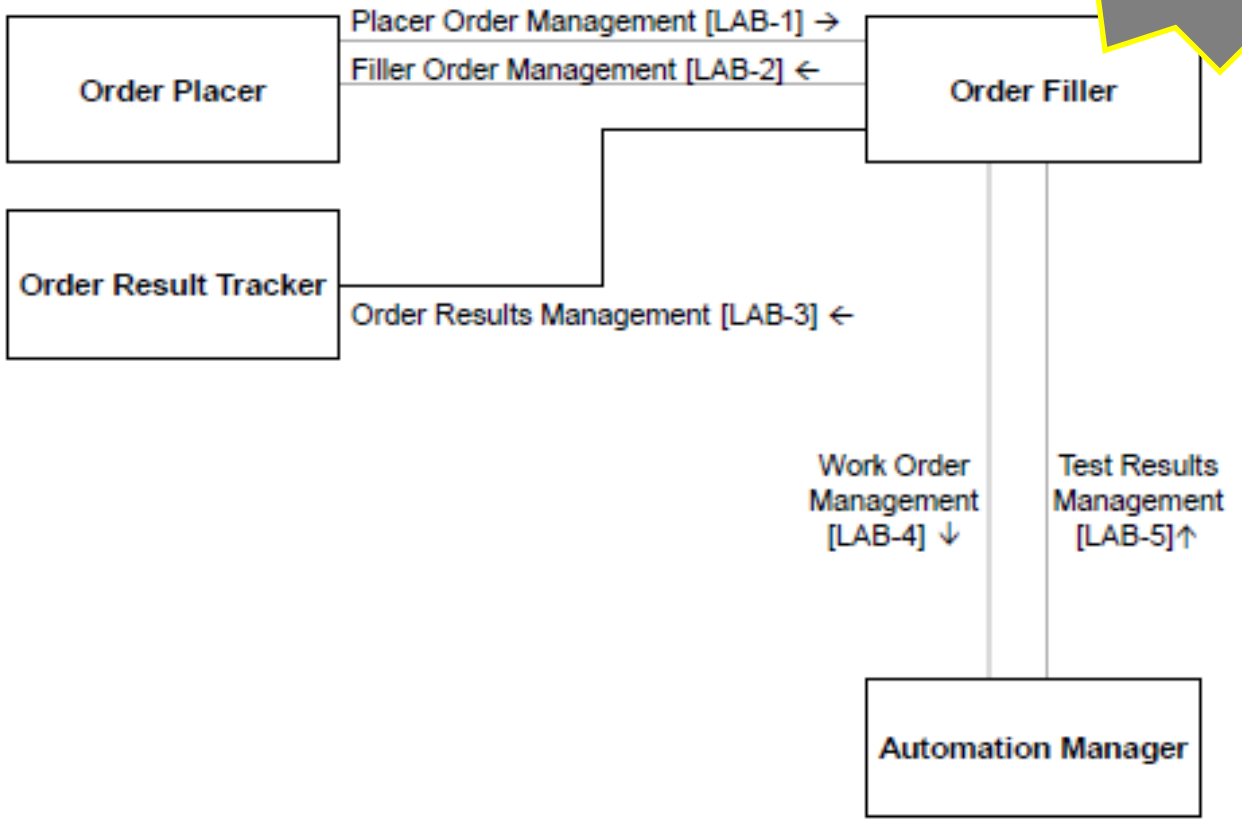
Ordering, scheduling, processing, and result reporting associated with IVD tests performed by clinical labs in healthcare institutions

3 major use cases:

- Specimen collected by orderer
- Specimen collected by lab staff
- Specimen collected by 3rd party

- Systems involved: HIS/EMR, LIS, LAS/middleware
- Enhances quality of care (reduces man copy, redundant orders, orphan or lost specimens, transcription errors).
- Improves throughput (saves phone call and paper reports, streamlines tests scheduling, processing, reporting).

Last Published 2019 in TF



Connectathon Test Cases

Test case name	Actors under test	Transaction(s)
LAB_FILLER_ORDER_MANAGEMENT	ORDER_PLACER, ORDER_FILLER	LAB-2
Laboratory Test Results Management	ORDER_FILLER, AUTOMATION_MANAGER	LAB-5
Laboratory Work Order Management	ORDER_FILLER, AUTOMATION_MANAGER	LAB-4
LTW_OF_ORT	ORDER_FILLER, ORDER_RESULT_TRACKER	LAB-3
LTW_ORDER	ORDER_PLACER, ORDER_FILLER	LAB-1
LTW workflow	ALL	ALL BUT LAB-2

Laboratory Analytical Workflow (LAW)

Laboratory Analytical Workflow (LAW)

Data exchange for patient samples and QC test orders & their results between IVD testing systems and health informatics systems (LIS, middleware)

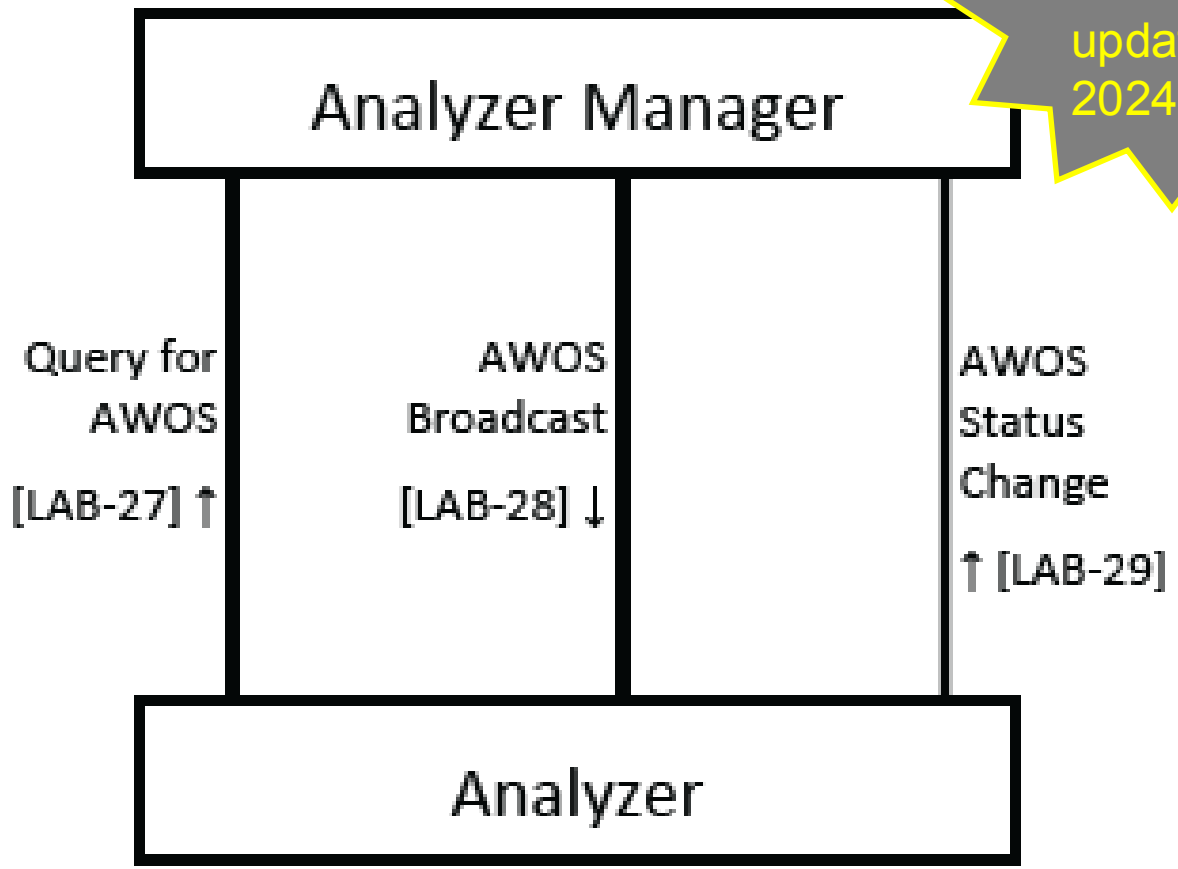
AWOS: Analytical Work Order Step:

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

Supports several profile options

- Supplemental results (e.g.; graphs, images, raw values)
- Handling of multiple runs
- Microbiology AWOS and results / representation of an isolate
- Parent results & child orders
- AWOS update

Published in TF in 2019 – updates in 2024



Connectathon Test Cases

Test case name	Actors under test	Transaction(s)
LAW AWOS Received Prior To Specimen Arrival	ANALYZER, ANALYZER_MANAGER	LAB-28, LAB-29
LAW AWOS Update Prior To Specimen Arrival	ANALYZER, ANALYZER_MANAGER	LAB-28, LAB-29
LAW Manual Urgent AWOS	ANALYZER, ANALYZER_MANAGER	LAB-27, LAB-28, LAB-29
LAW Normal Process With AWOS Manual Entry	ANALYZER, ANALYZER_MANAGER	LAB-29
LAW Normal Process When Analyzers Query	ANALYZER, ANALYZER_MANAGER	LAB-27, LAB-28, LAB-29
LAW Query Prior to Specimen Arrival at AM	ANALYZER, ANALYZER_MANAGER	LAB-27, LAB-28, LAB-29
LAW Reflex Decided On The Analyzer Immediately After First Run	ANALYZER, ANALYZER_MANAGER	LAB-27, LAB-28, LAB-29
LAW Rerun Decided On The Analyzer Immediately After first Run	ANALYZER, ANALYZER_MANAGER	LAB-27, LAB-28, LAB-29

LAW Updates – 2024

Add the possibility to send Additional Result Identifiers like LOINC Codes

Query by Sample ID and Carrier/Position

Fix ambiguities about OBX-2 usage in message

IMPORTANT: All these updates have been also acknowledged by CLSI AUTO16, that will be also updated accordingly

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 600+ Organizational Members:
- Join IHE Laboratory Planning & Technical Committees
  - Mailing list: https://groups.google.com/a/ihe.net/forum/#!forum/palm
  - If any issues please contact the CAP staff lead Kevin Schapp serving as the administrative secretariat (kschap@cap.org)
- Non-members have limited participation:
  - Review & comment during Supplement Public Comment period
  - Implement IHE Profiles and test them at connectathons

Alphabet soup

Acronym	Description
APSR	Anatomic Pathology Structured Report (CDA R2 report template)
ARPH	Anatomic Reporting to Public Health
ATNA	Audit Trail and Node Authentication
AWOS	Analytical Work Order Step
CAP	College of American Pathologist
CDA R2	Clinical Document Architecture Revision 2
CLSI	Clinical and Laboratory Standards Institute
CT	Consistent Time
DICOM	Digital Imaging and COmmunications in Medicine
DPIA	Digital Pathology Image Acquisition
EHR	Electronic Health Record
EMR	Electronic Medical Record
HIE	Health Information Exchange
HL7	Health Level Seven
IICC	In-Vitro Diagnostics Industry Connectivity Consortium
ILW	Inter-Laboratory Workflow
ISO	International Organization for Standardization
IT	Information Technology
IVD	In-Vitro Diagnostic
IWOS	Imaging Work Order Step
JAHIS	Japanese Association of Healthcare Information Systems Industry
LAW	Laboratory Analytical Workflow
LCC	Laboratory Clinical Communication
LCSD	Laboratory Code Set Distribution

Acronym	Description
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
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
SET	Specimen Event Tracking profile
SNOMED CT	Systematized Nomenclature of MEDicine Clinical Terms
TMA	Transfusion Medicine - Administration
UCUM	Unified Codes for Units of Measure
XD-LAB	Clinical Laboratory report CDA R2 template
XDM	Cross-Enterprise Document Media Exchange
XDR	Cross-Enterprise Document Reliable Exchange
XDS	Cross-Enterprise Document Sharing

VIENNA 2025 JUNE 23/27

IHE EUROPE CONNECTATHON®

Thank you for your attention

IHE CATALYST

IHE EUROPE Integrating the Healthcare Enterprise