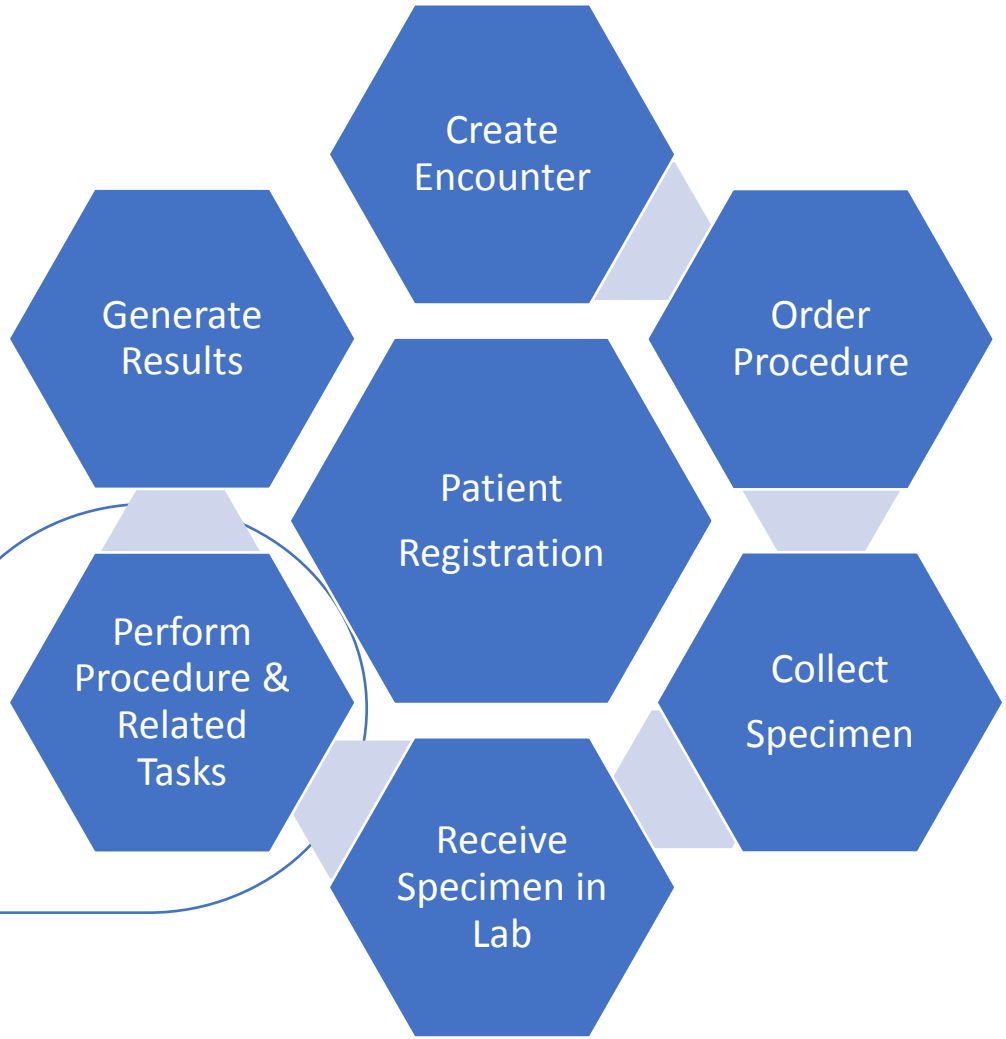
IHE Anatomic Pathology Redesign

Sardinia, Italy
Nov. 13-15, 2017

Specimen Workflow in a Nutshell (variations likely depending on context, e.g. collection location)



APW?

Digital APW Use Case #1

- Create digital copies of glass slides to preclude exhausting tissue block for outside slide reviews
  - Request for case review from outside facility or patient
  - All glass slides reviewed by pathologist and key slides identified
  - Selected “key” slides digitally imaged
  - Original key slides sent out for review
    - In future, digital version can be submitted for review
  - If additional review request comes in, can reference digital versions and/or wait for original slides
    - Usually blocks not sent out by policy

Digital APW Use Case #2

- Creating digital copies of immunohistochemistry positive control slides to preclude the need for creating multiple positive control slides for distribution to pathologists
  - Request for IHC stain processed as usual
  - Only one IHC positive control run per batch
  - IHC positive control slides imaged and saved to network folder
  - Positive controls NOT distributed ($$$ savings)
  - Glass IHC slides reviewed by pathologist but same positive control reviewed digitally by all pathologists for a given IHC (i.e. only a single cytokeratin positive control slide even if requested across 10 different patient samples)

Digital APW Use Case #3

- Creating digital copies of all glass slides for primary diagnosis
  - Specimen collected and transported
  - Specimen gross exam with possible digital imaging and annotation
  - Specimen processing
    - Glass slides produced as usual
    - All glass slides fed into high volume automated digital scanner
      - Scanner tags images requiring manual intervention
  - Digital images deposited in network share, VNA, or PACS
  - Interface message to LIS sent as each barcode read off slide
    - Acknowledgment from LIS indicates case is valid and ready for association with digital slide assets
    - Additional message sent when slide digitization completed
  - Interface message sent every time slide viewed or annotated

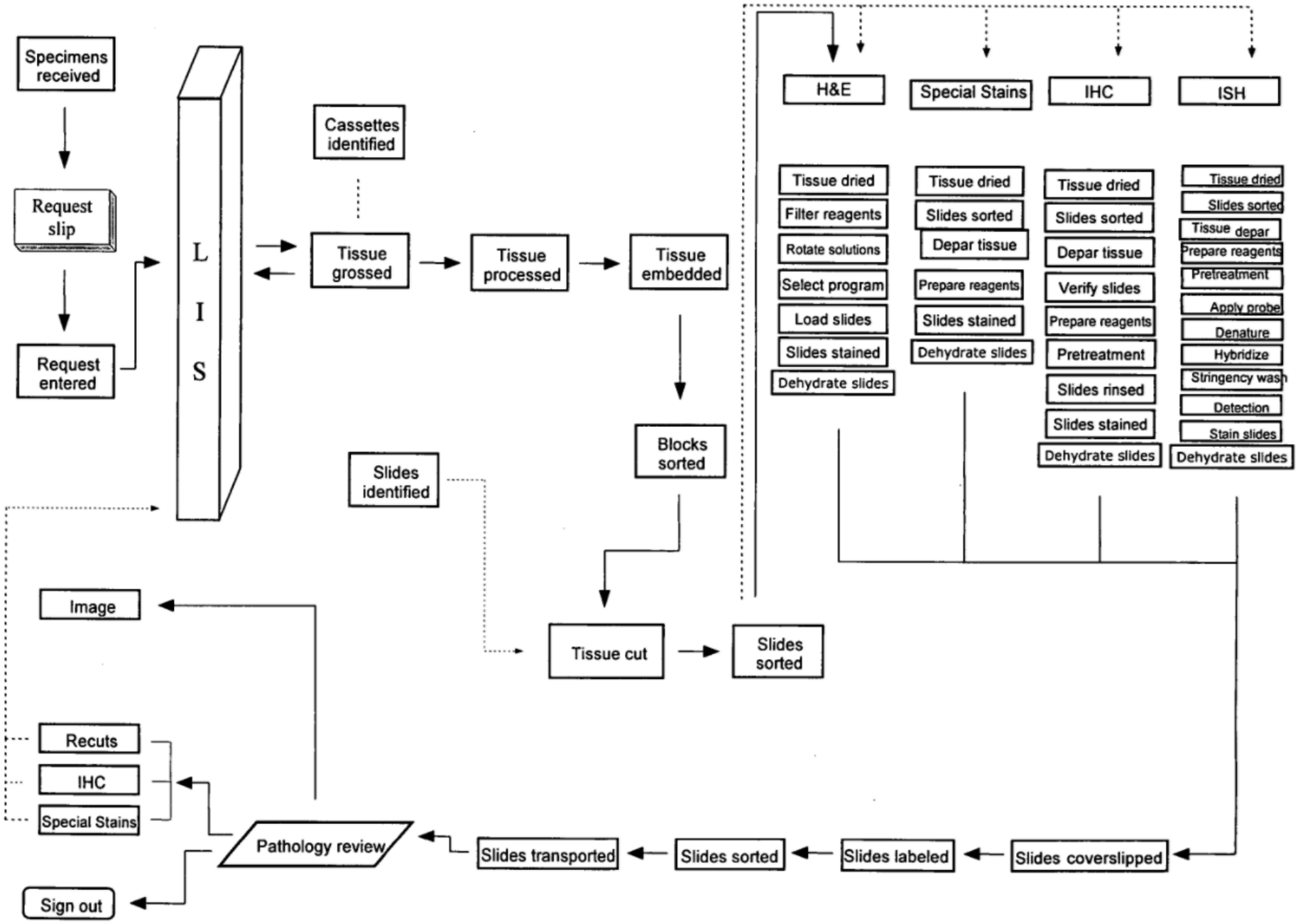
Digital APW Use Case #4

- Conversion from a legacy information system
- Transfer of existing electronic data to include text and images (WSI also) on specimens that have already been evaluated and “resulted”
- Legacy accession # needs to be considered against go-forward accessioning schema

APW Scope

- Start with a tissue specimen received in laboratory?
  - Proposal: common profile for order management and result management for all of PALM (check Berlin F2F notes)
    - More likely to change ordered procedure, need to specify site (laterality is important)
    - Another input as consult from another laboratory ILW (Lab-35, Lab-36)
    - Result: ORU vs APSRv2 document (messaging profile, can have both)
    - Can leverage LCC (Lab-6, Lab-7)
  - Lab-1, Lab-2, Lab-3 exist today and can be leveraged
- In scope: creation of glass slides that have been digitized and manage those digital assets for presentation and interpretation
  - Actors: viewer, acquisition device, storage device, order filler, analyzer manager, analyzer
  - Separate profiles for: creation, interpretation, (and possibly viewing as a separate profile)
- Out of scope: FNA ultrasound images (as this is covered by existing radiology profile),
- Uncertain: specimen radiograph, in vivo microscopy
- Clinical tissue specimen workflow only?
  - Research, teaching, tumor board out of scope
  - Our scope is to provide infrastructure to support a future profile that to manage use cases
- Every digital asset has a parent?
  - root is patient?
- Should or should not cover tissue microarrays (many patients on one slide)?

Histology Process Map



Automated lean methods in anatomical pathology

US 20070141711 A1

Publication number	US20070141711 A1
Publication type	Application
Application number	US 11/639,586
Publication date	Jun 21, 2007
Filing date	Dec 15, 2006
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Also published as	CA2628317A1, CA2628317C, CN101341387A, CN101341387B, EP1969338A1, EP1969338B1, US20170030810, WO2007078842A1, Less «
Inventors	Randy Stephens, Brian Kram
Original Assignee	Randy Stephens, Kram Brian H
Export Citation	BiBTeX, EndNote, RefMan

Patent Citations (26), Referenced by (37), Classifications (13), Legal Events (1)

External Links: USPTO, USPTO Assignment, Espacenet

ABSTRACT

An embodiment of the method of the invention is a method of automating information flow in a laboratory performing tissue staining comprising positioning a networked label printer adjacent to a cutting station, the printer configured to access patient data directly or indirectly from the hospital LIS, the printer being configured with a data element scanner in electronic communication with said printer; inputting data from a tissue cassette-associated data element at said printer, whereby inputting data comprises reading the data from the cassette-associated data element and uploading the cassette data to the LIS; identifying the corresponding test protocol identifier and then downloading the test protocol data to the printer; printing information on labels corresponding to each test specified in the LIS for the patient; attaching a single label to each slide; and cutting a tissue section for each labeled slide and mounting the section on the slide.

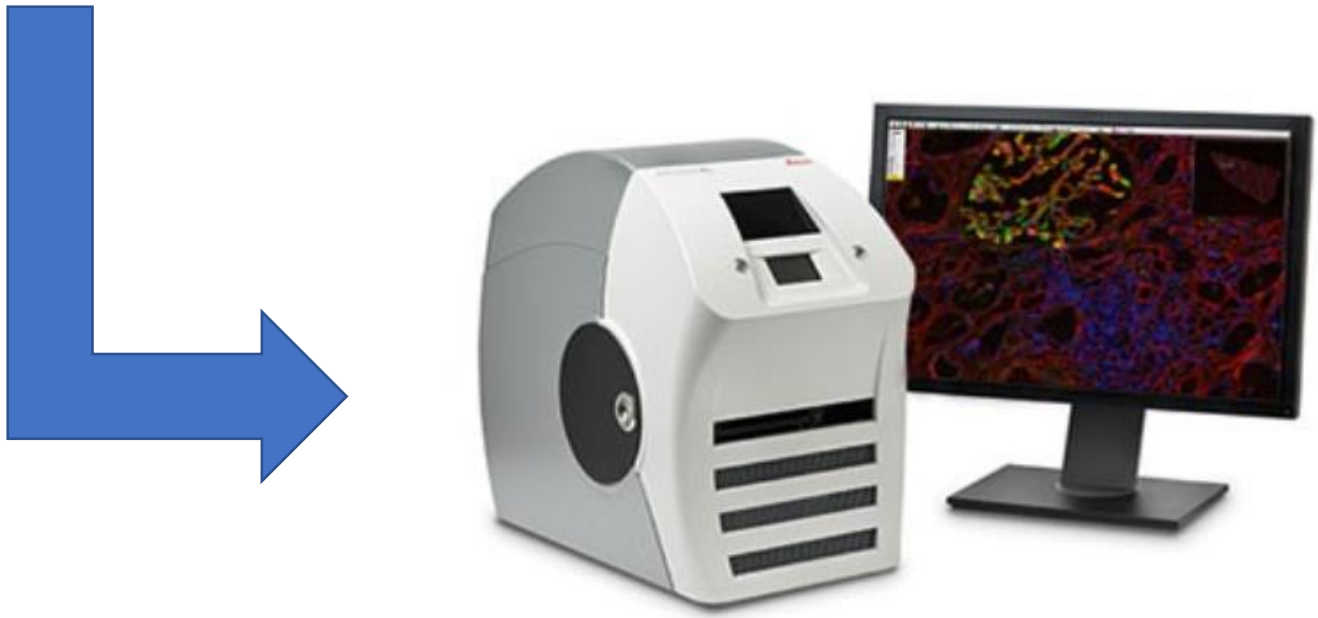
cassette & slide printers

continuous rapid tissue processors

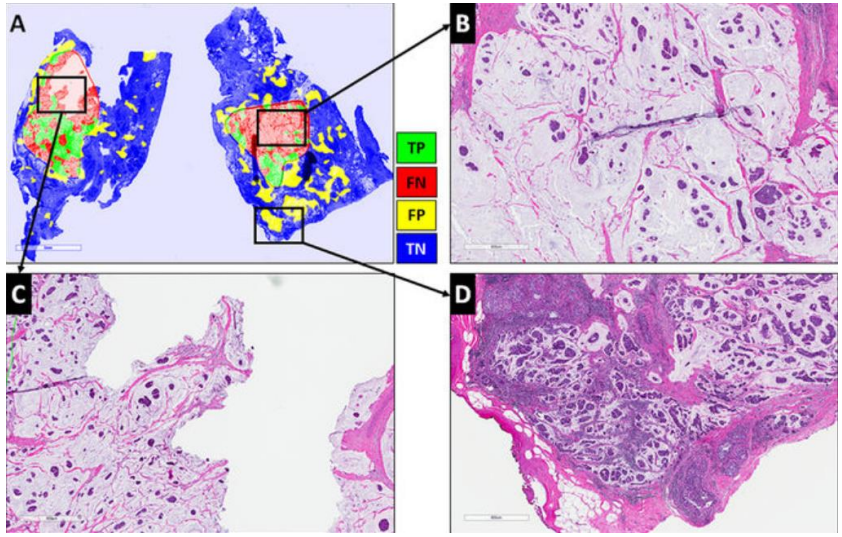
automated embedder
& sectionable cassette system

automated microtome

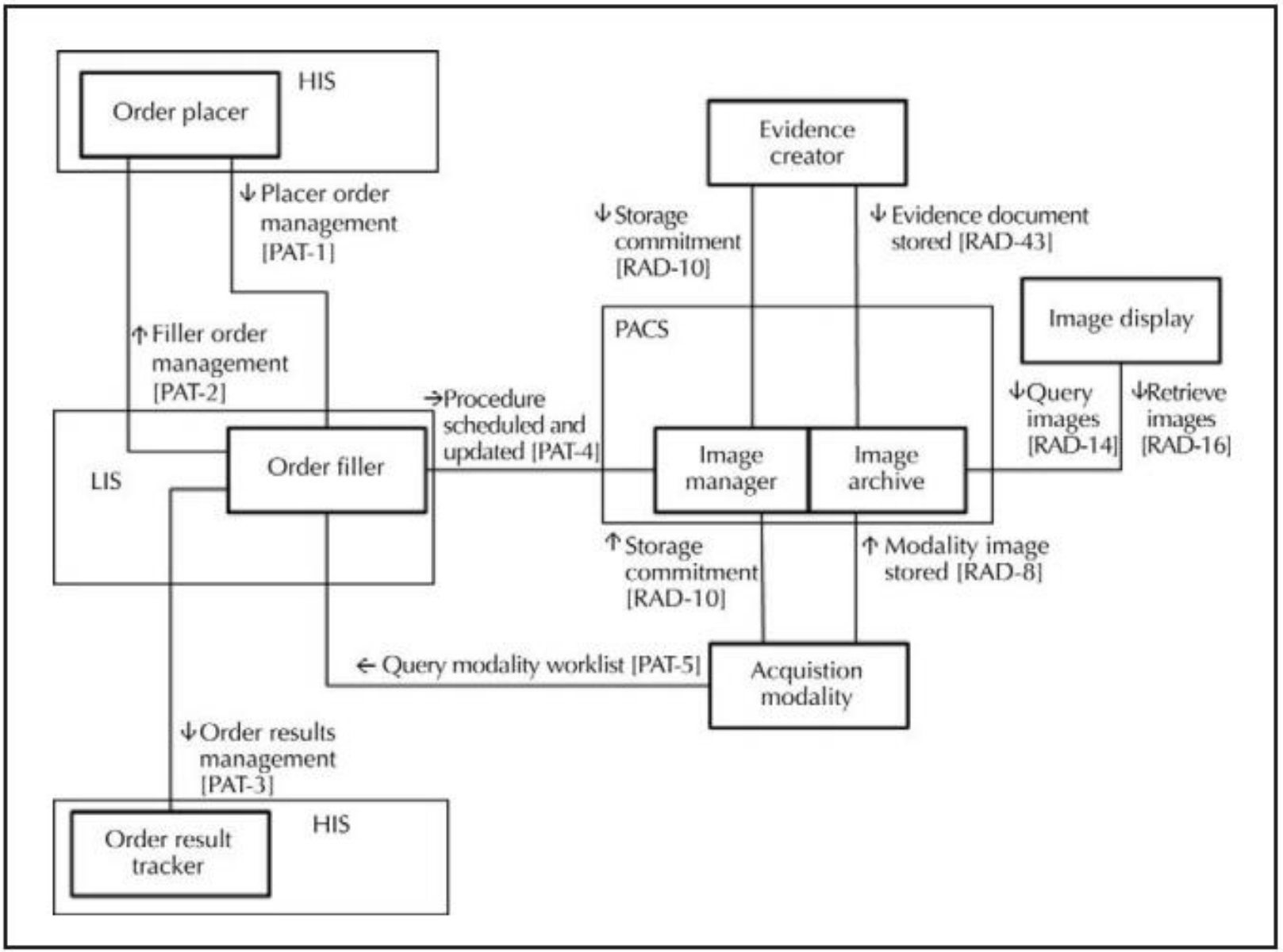
high quality staining & slide tracking



The Promise of Machine Learning / AI

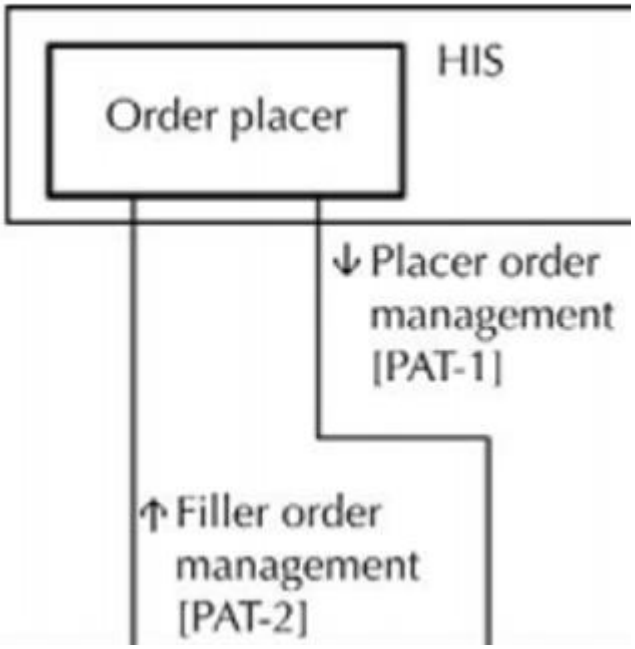


Current APW Diagram



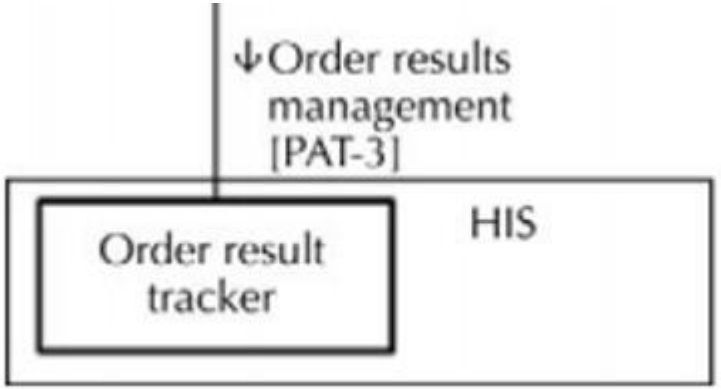
Daniel et al., Arch Pathol Lab Med—Vol 133, November 2009

One step at a time…



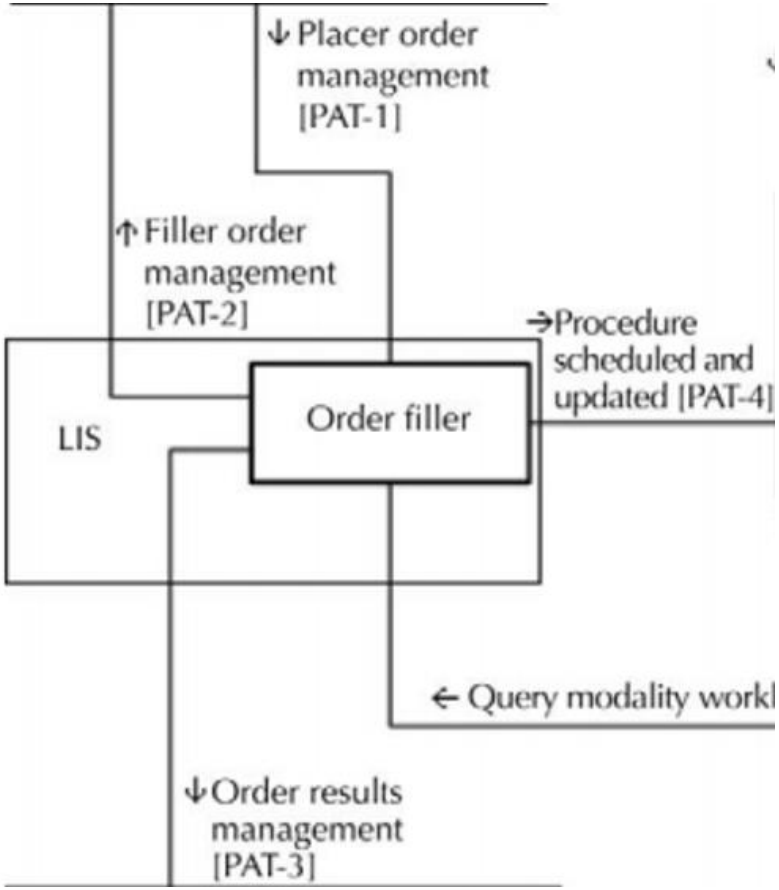
- Most EHR systems will have a single order for submitting a tissue specimen to an LIS
- Order questions may include:
  - Source (e.g. skin), procedure (e.g. shave biopsy), site (e.g. rt cheek)
- Other data elements include:
  - Patient name, MRN
  - Collector ID, date/time stamp
- Barcoding
  - 1D for clinical lab automation
  - 2D for small containers

One step at a time…



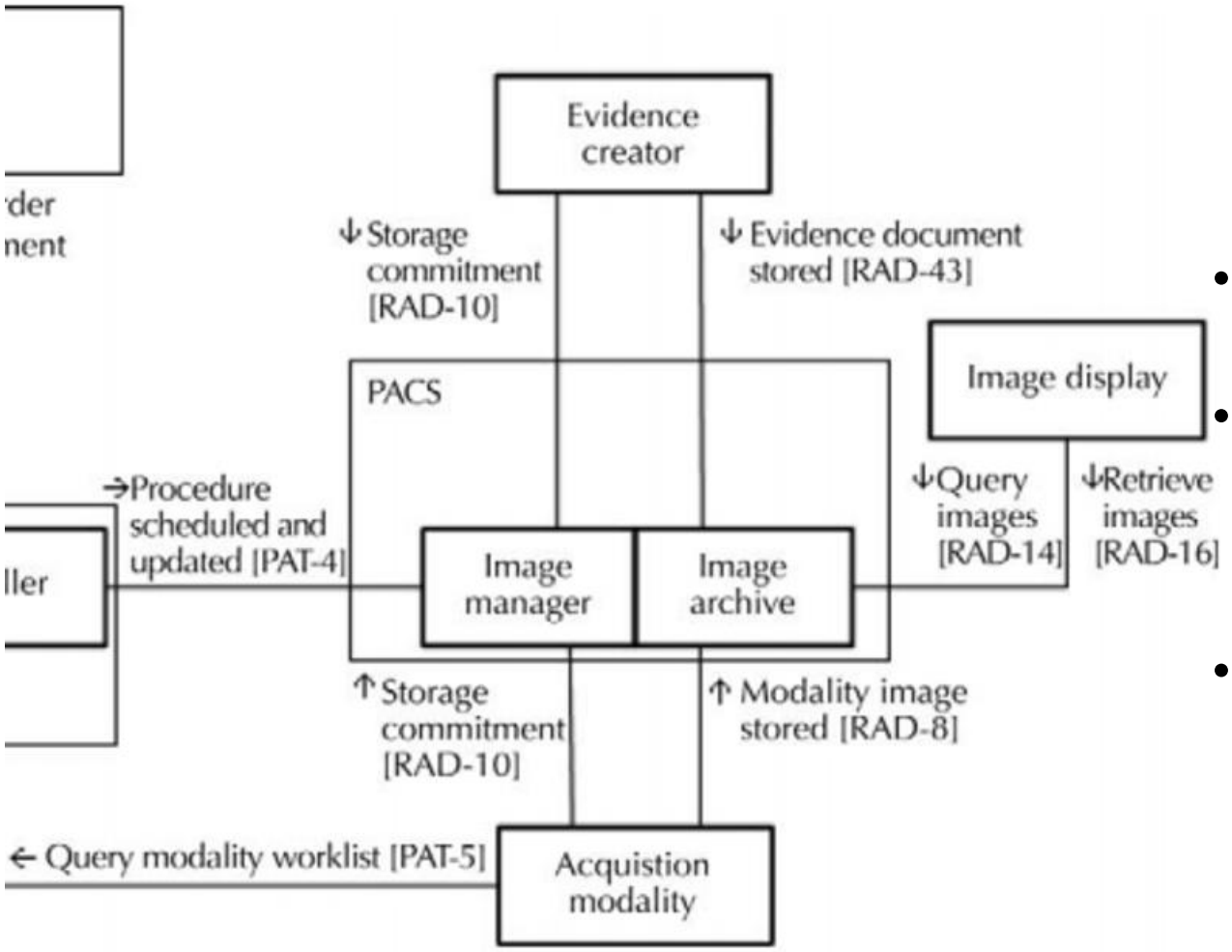
- The “result” can be the final pathology report OR a set of digital assets (we should decide)

One step at a time…



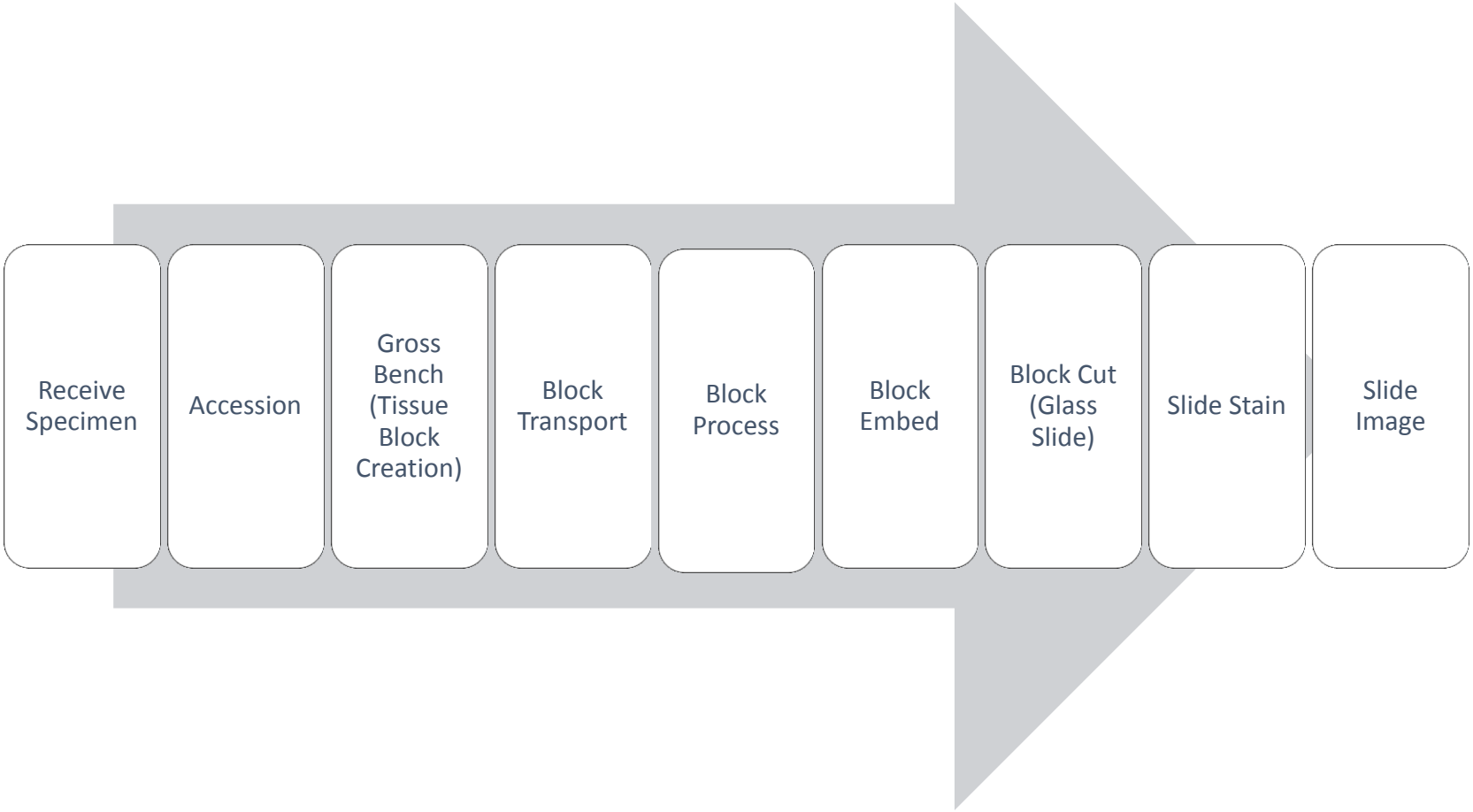
- The LIS needs to manage the "manufacturing process" of the digital image(s) and if in scope, the text report, including structured and possibly unstructured data
- The LIS could create work orders similar for the clinical laboratory
- Histologic "events" tracked by an LIS are largely manual or barcode driven today but we should expect greater use and granularity in the future

One step at a time…



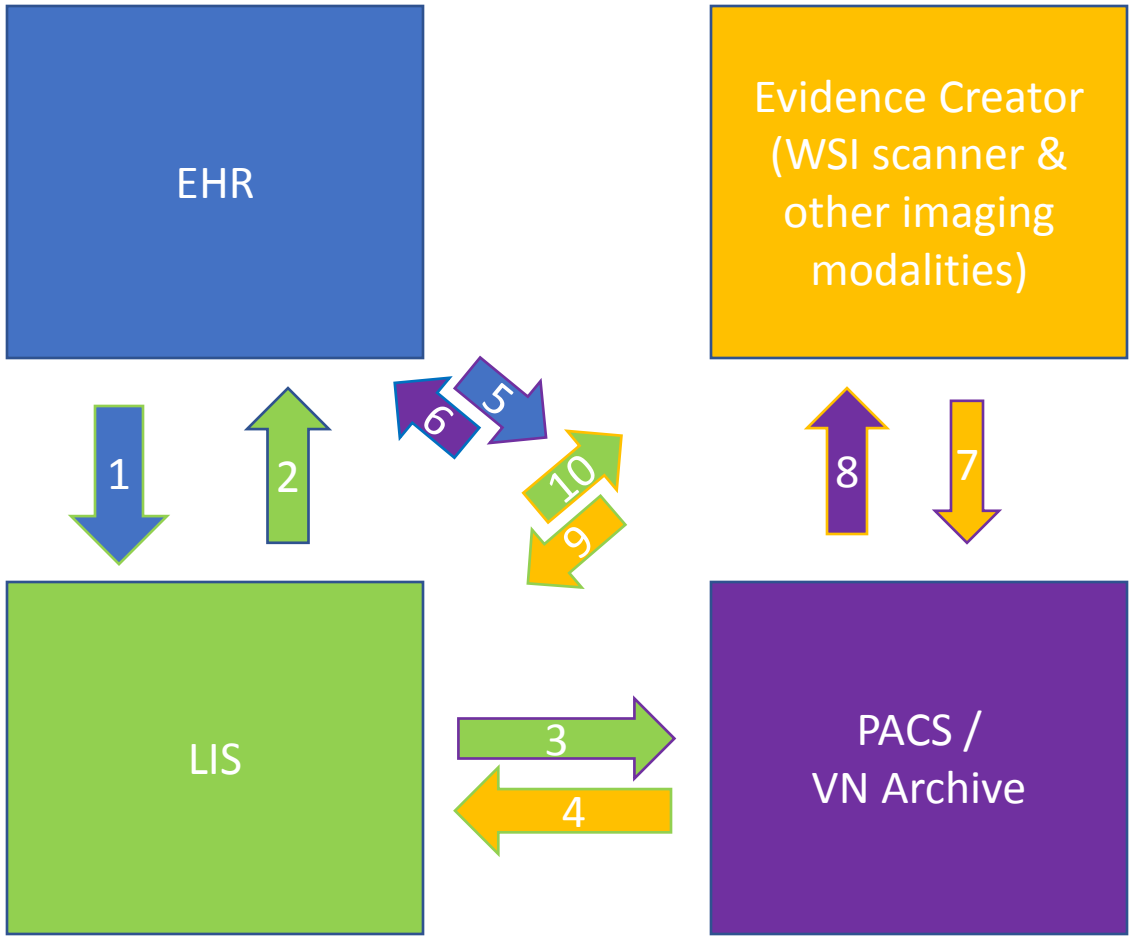
- Once a digital slide has been created we can explore the other half of the original APW
- An LIS may not use a PACS
- An image manager need not be linked to an image archive
- Image display is best driven by the LIS

Tissue Processing Workflow



Workflow steps (transactions) for APW v2

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



Actors

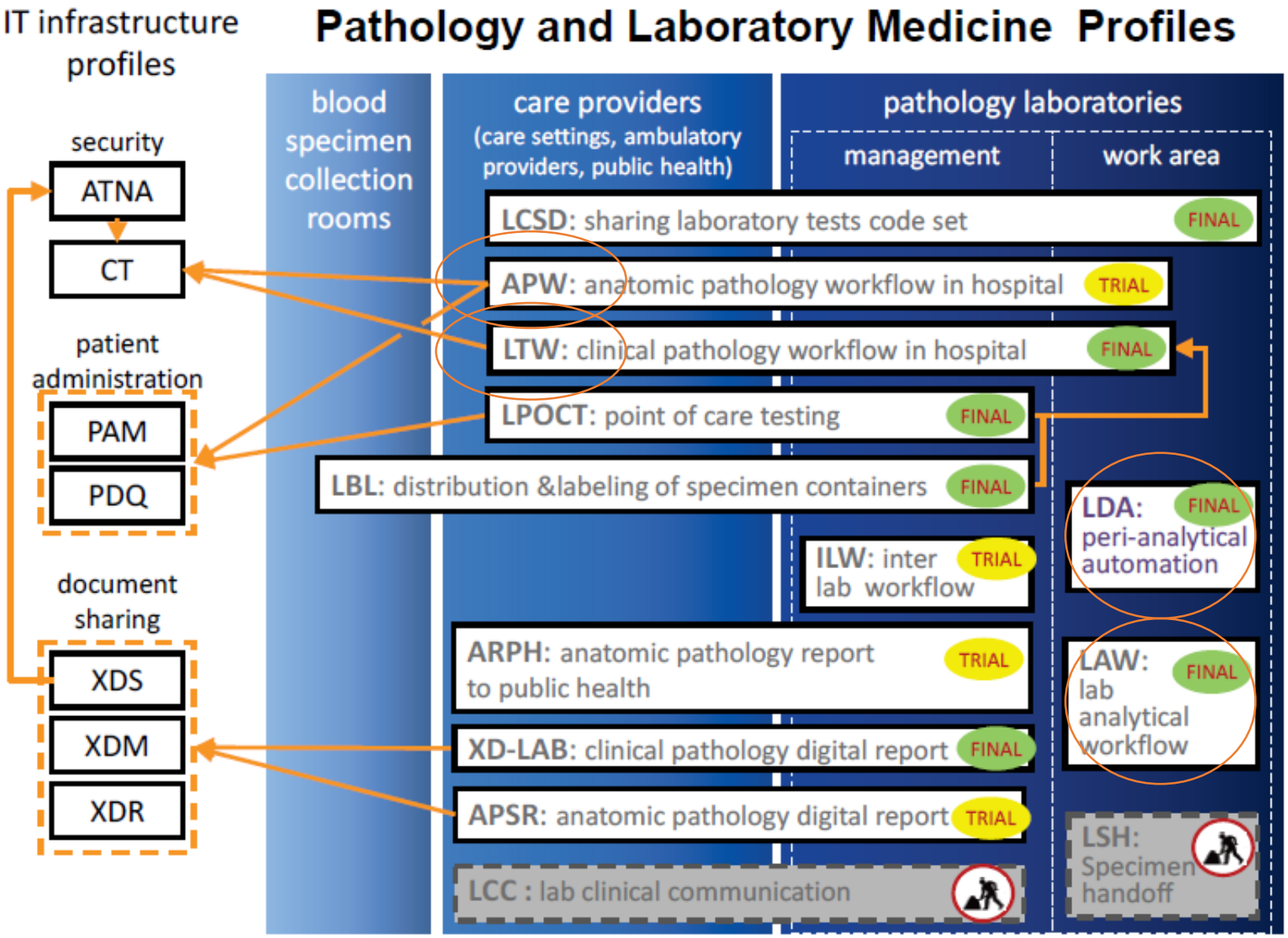


Figure 2-1: IHE Pathology and Laboratory Medicine Profiles

LTW Overview

The LTW Profile carries three kinds of work units related to one another as shown on Figure 3.4.1-1, each of these units being performed on one or more specimens collected from the subject.

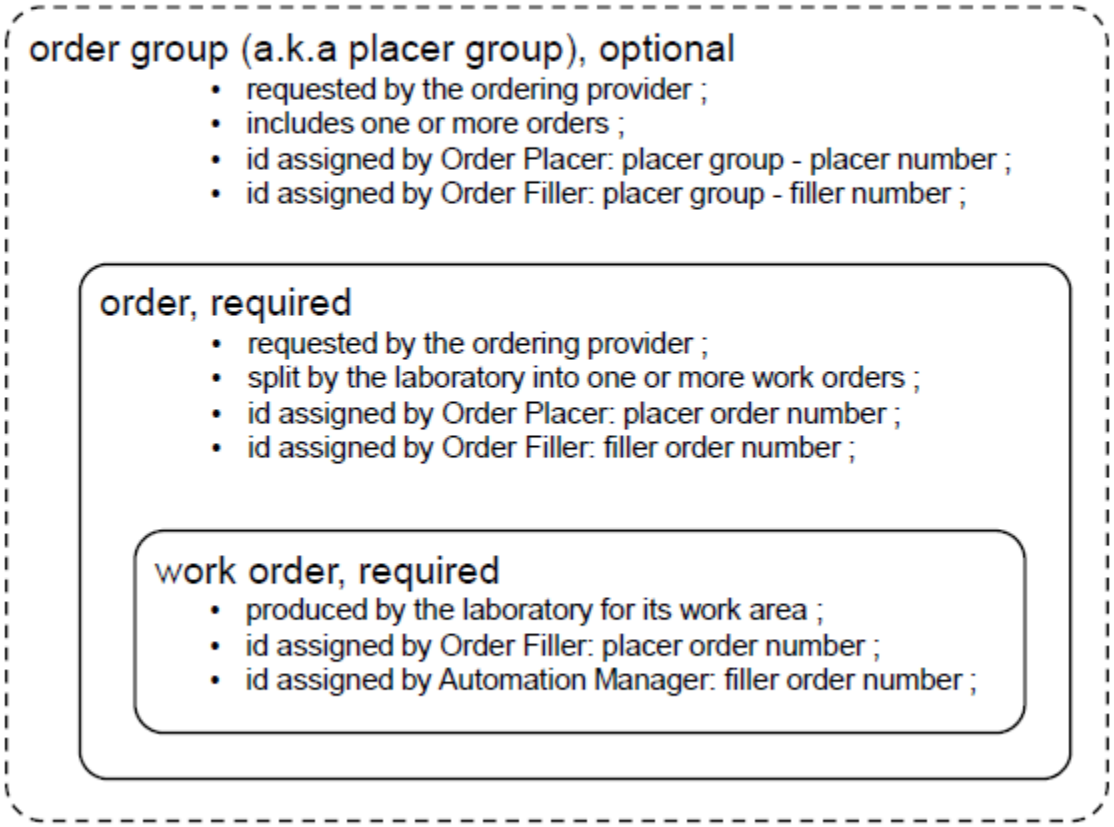


Figure 3.4.1-1: Hierarchy of work units in LTW Profile

LTW

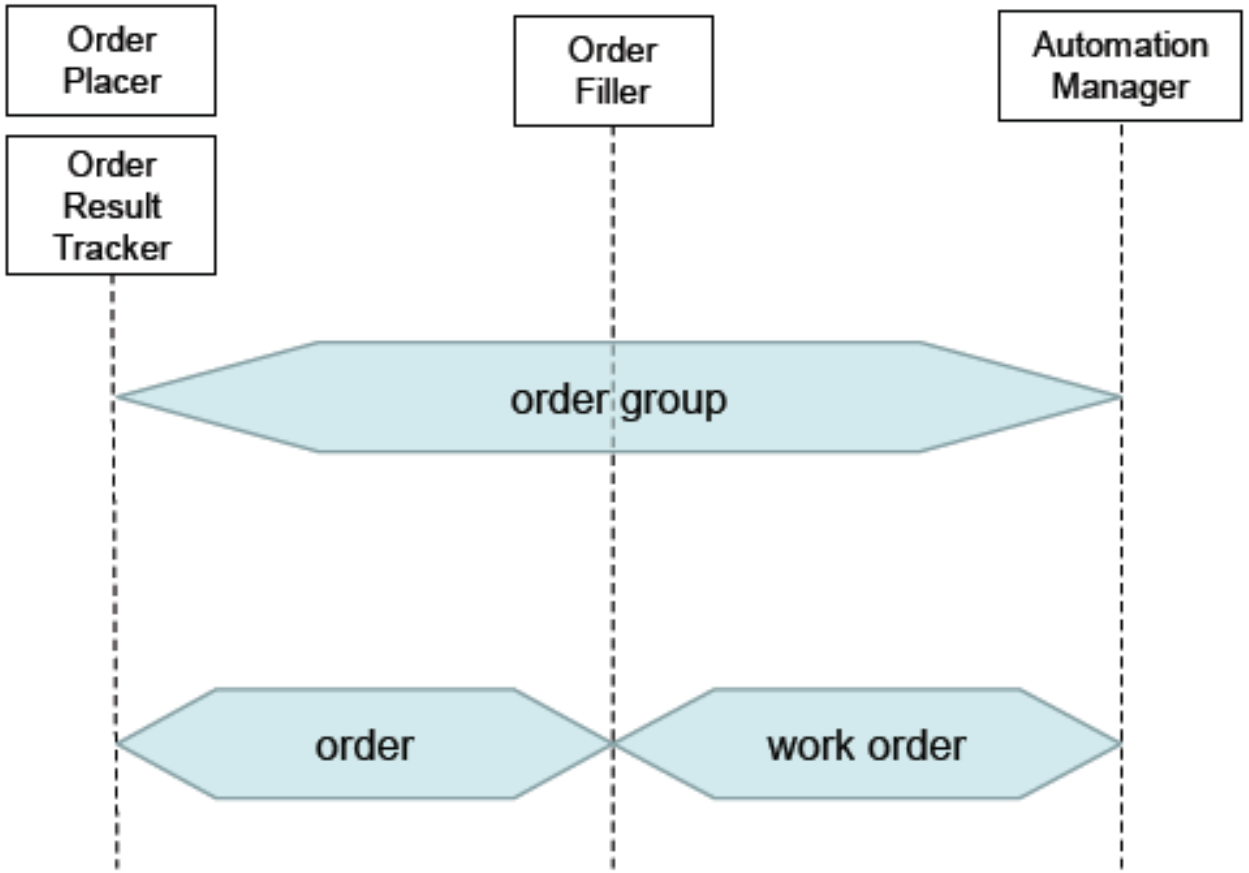


Figure 3.4.1-2: Scope of work units in LTW Profile

LTW

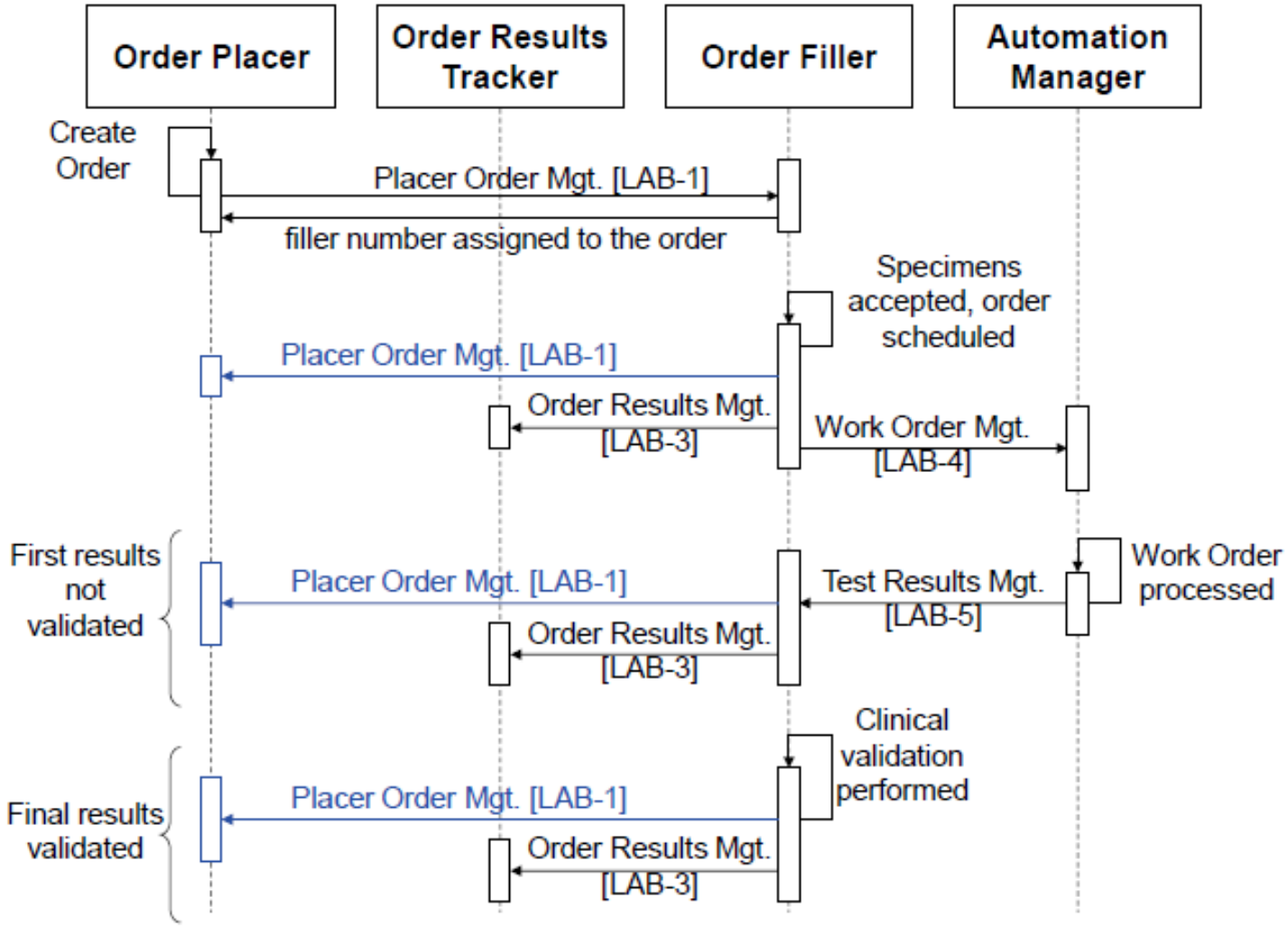


Figure 3.4.2.1-1: Placer Order Process Flow in LTW Profile

LDA Overview

The LDA carries Specimen Work Order Steps (SWOS). A SWOS is an atomic operation on a specimen assigned to one Pre/Post-processor. When a system is implementing Automation Manager in both LTW and LDA, one of its tasks is to split a Work Order received in LTW into as many SWOS as needed in LDA, as represented on Figure 4.4.1-1.

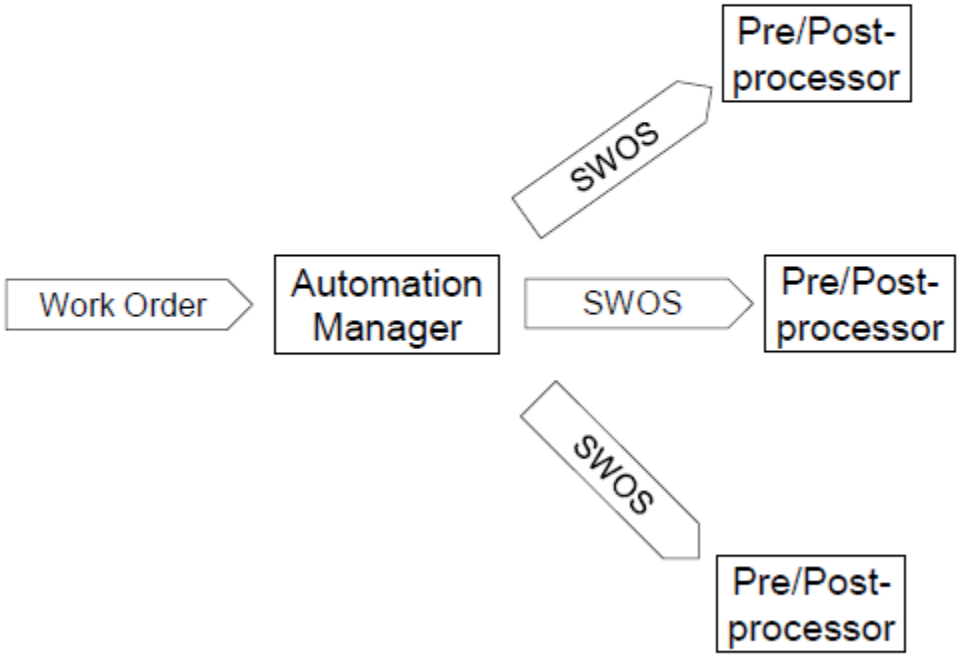


Figure 4.4.1-1: Scope of work units in LDA Profile

LAW Overview

An AWOS is assigned a unique identifier (AWOS ID) by the Analyzer Manager. This AWOS ID is memorized by the Analyzer and included in all messages exchanged back and forth related to that AWOS. The AWOS sent by the Analyzer Manager also keeps track of the Work Order that spawned it, carrying its Work Order ID, as shown in Figure 5.4.1-1.

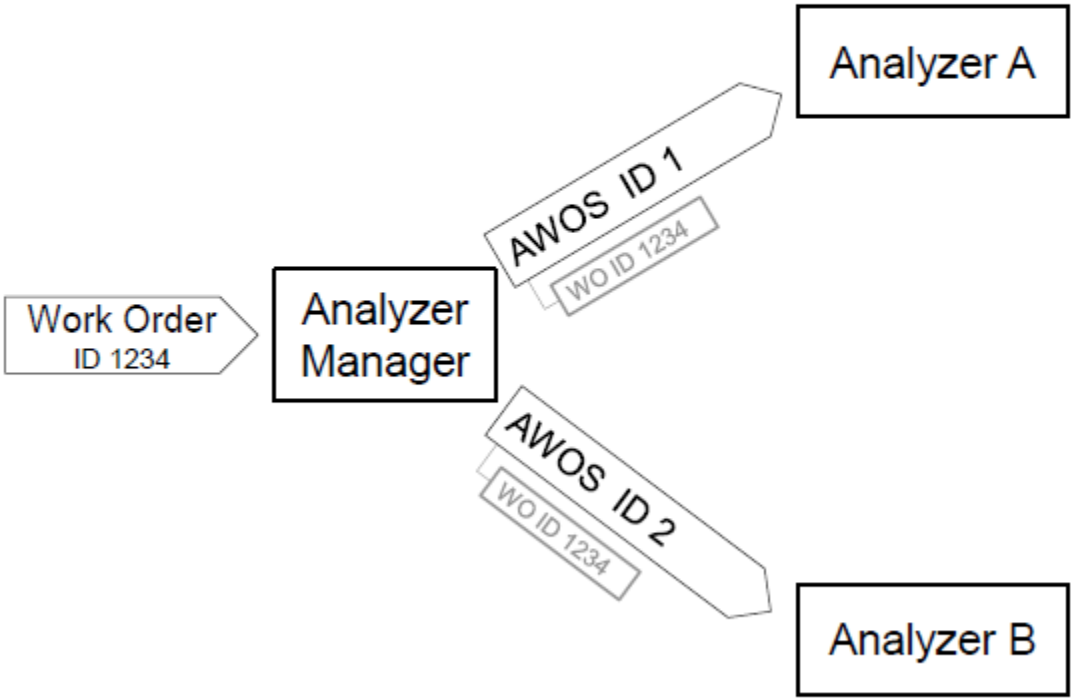


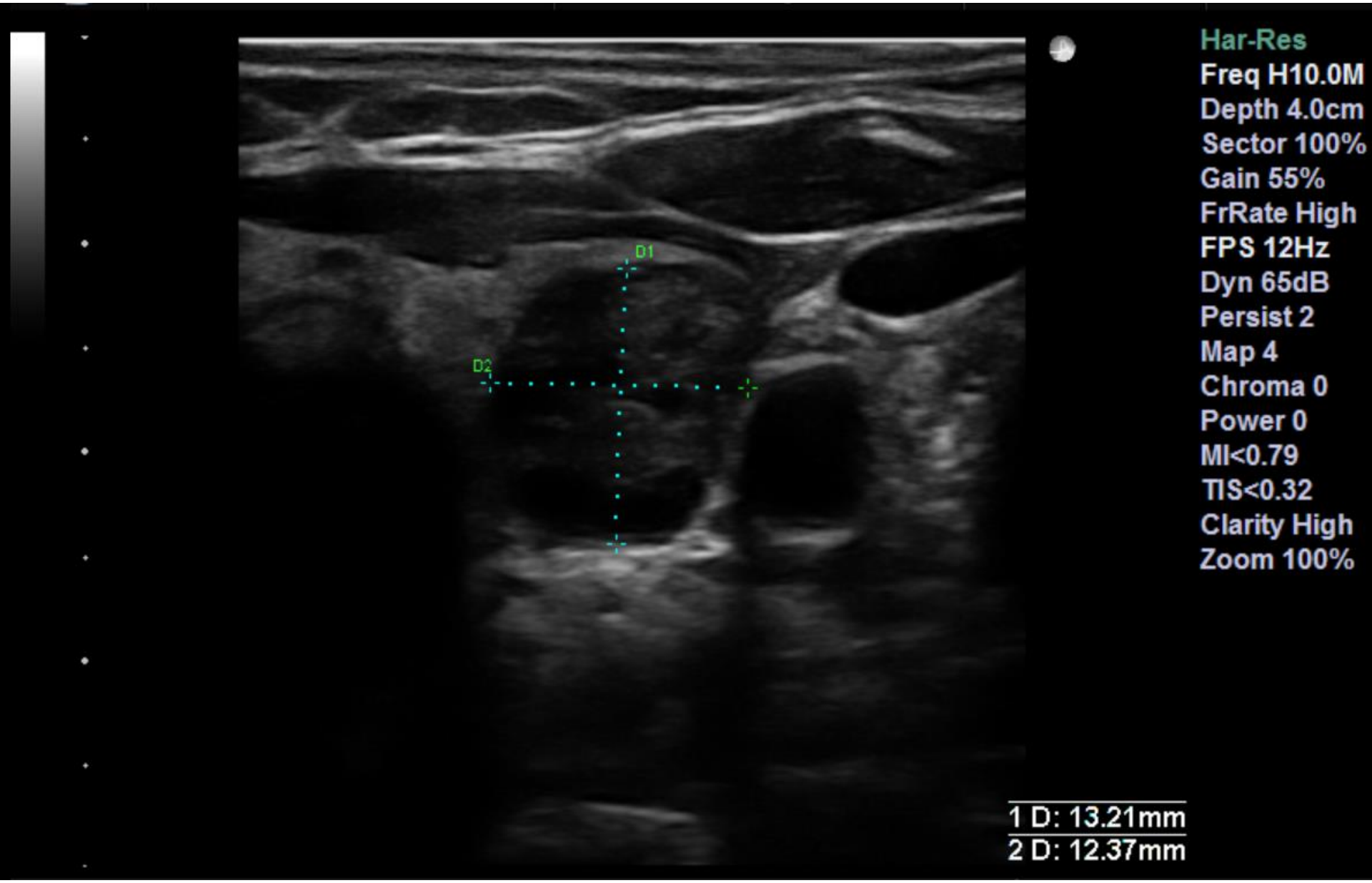
Figure 5.4.1-1: Splitting of a Work Order into a number of AWOSs

The EHR and LIS Connection

- The EHR focuses on the integrated care of a single patient
- The AP LIS focuses on the production, storage and conveyance of the diagnostic interpretation of stained tissue
- AP LIS modules are becoming part of larger EHR systems
- There is more to imaging than WSI
- We need to consider analyzers that work synchronously or asynchronously using machine learning for feature / pattern recognition and image analysis, likely managed by future LIS

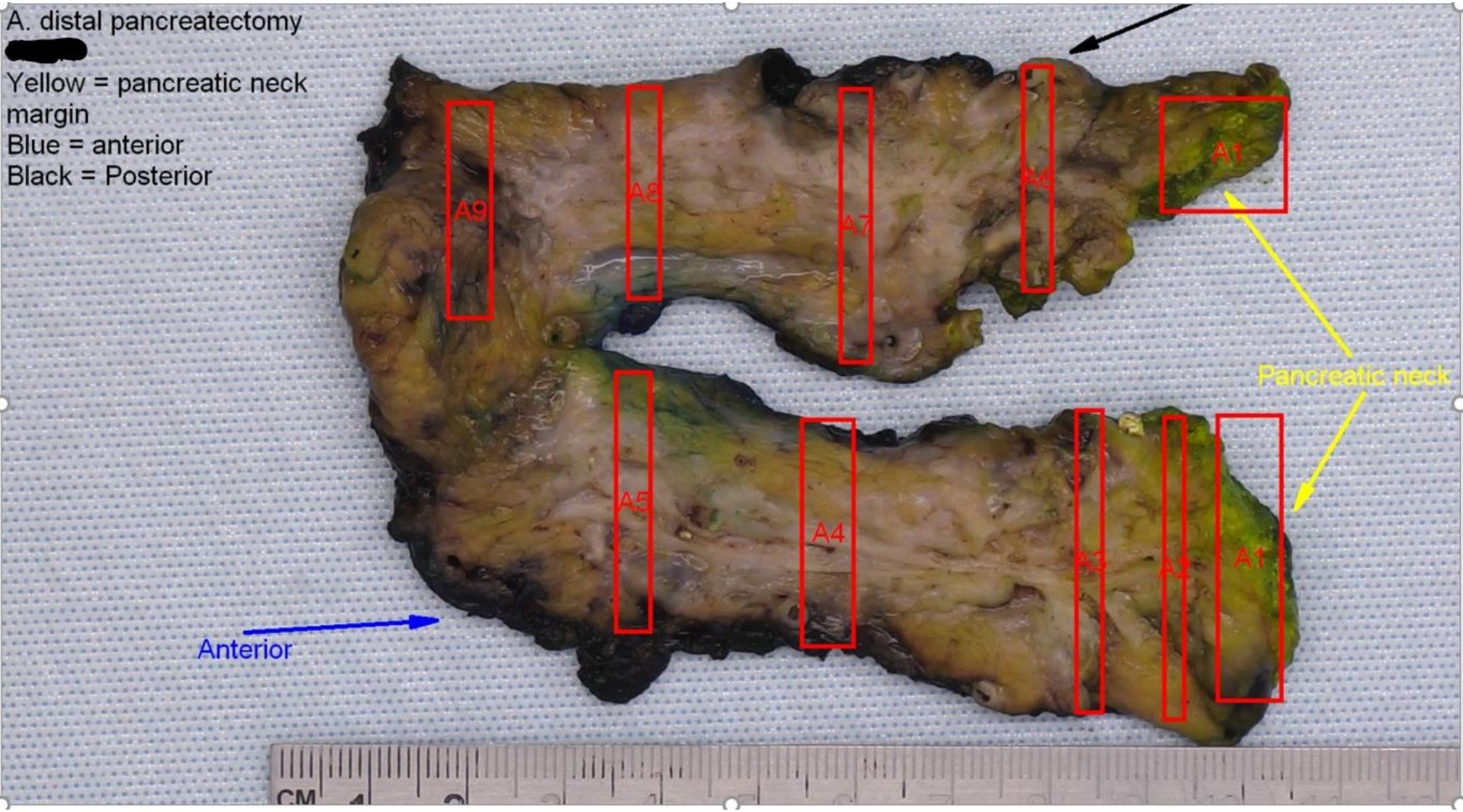
Anatomic Pathology: Typical Digital Assets

- In Vivo Imaging (non-diagnostic)
  - FNA ultrasound for needle placement
- Ex vivo Imaging
  - Gross specimen radiograph (non-diagnostic)
  - Glass slide (diagnostic)
    - H&E
    - Papanicolaou, Wright stain
    - IHC
    - FISH
  - Instrument output (e.g. HPV DNA result)
- Digital assets include whole slide images but also other assets


Har-Res
Freq H10.0M
Depth 4.0cm
Sector 100%
Gain 55%
FrRate High
FPS 12Hz
Dyn 65dB
Persist 2
Map 4
Chroma 0
Power 0
MI<0.79
TIS<0.32
Clarity High
Zoom 100%
D1
D2
1 D: 13.21mm
2 D: 12.37mm

Gross Specimen Imaging

- Prior to case accessioning
  - ID with MRN, patient name, date/time stamp
- Annotations
  - Block designations, clip designation, biopsy site, calcifications


A. distal pancreatectomy
[redacted]
Yellow = pancreatic neck margin
Blue = anterior
Black = Posterior
A9
A8
A7
A6
A1
Pancreatic neck
A5
A4
A3
A2
A1
Anterior
CM

The Glass Slide

- Label
  - Identifiers
  - Barcode, 2D vs 3D
- Control tissue
- Diagnostic tissue
  - Multiple fragments
  - Coded fragments (e.g. 2 LNs, 1 bisected and inked)
- Tissue microarrays

Metadata – Data about data
(Classify as Localized to Instrument, APLIS, or EHR)

- Slide scanning order(s)
  - Magnification, Z-stacking, digital filters
- Slide received in machine
- Slide scanning started
- Slide scanning completed
- Slide scanning errors / warnings
- Slide manually retouched
  - Operator ID, date/time stamps begin/end, audit trail of functions applied

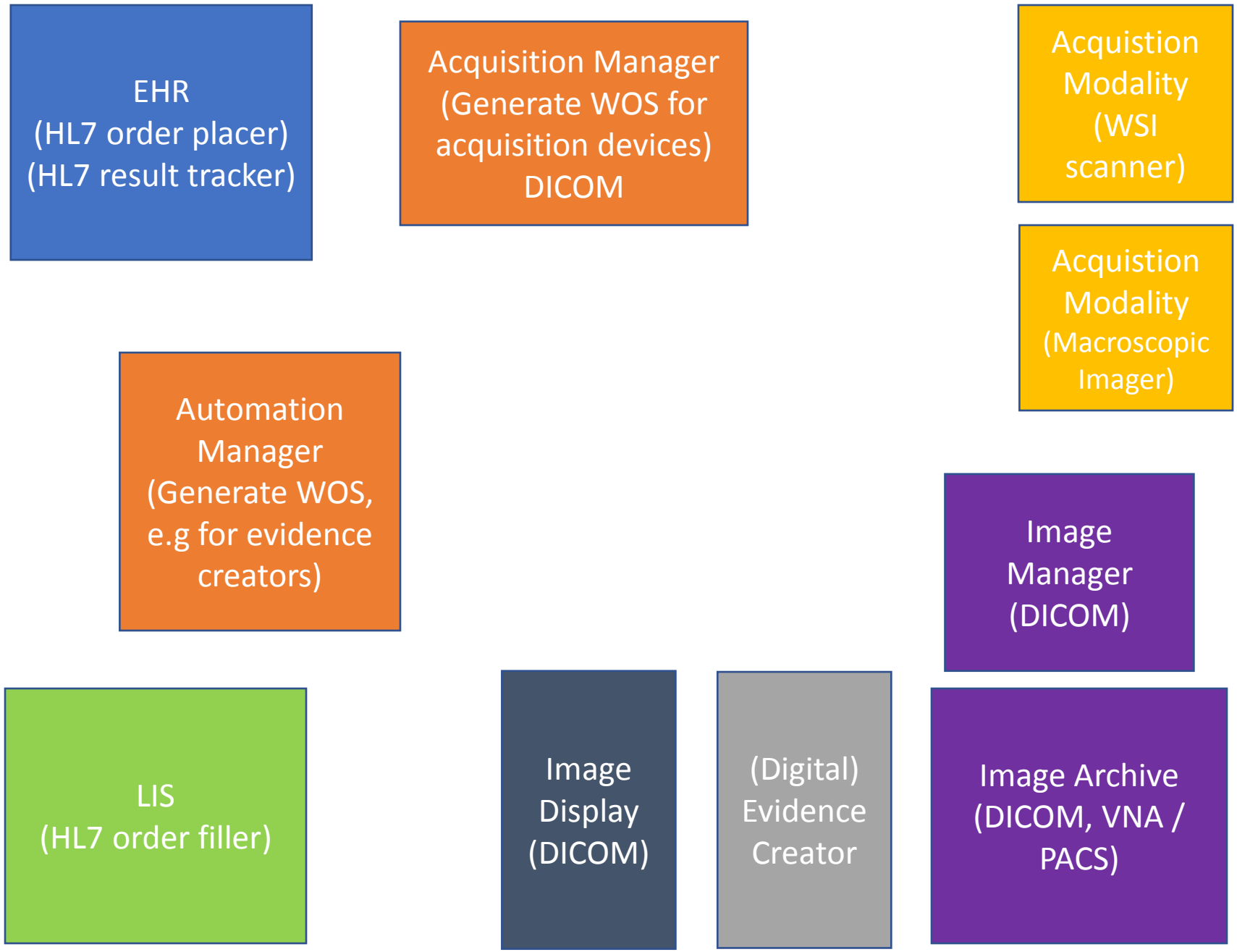
Metadata – Data about data
(Classify as Localized to Instrument, APLIS, or EHR)

- Slide received/available in AP LIS / PACS
- Slide viewing started
  - Viewer ID
  - Start time, End time
  - Audit trail of X-Y-Z at Mag M
  - Audit trail of digital filters applied at timepoint
  - Tissue Annotations
    - Margin (designate), distance to margin, benign neoplasia, dysplasia, in situ malignancy, invasive malignancy, infectious finding, inflammatory finding (acute, chronic, specified, unspecified), cell classification, structure classification, uncertain finding (ROI not otherwise classified), tumor size (with axis designations), tissue floater, mitotic figure, mitotic hot spot ROI, capsule invasion, lymph node metastasis (size, extranodal)
    - Mark up coordinates relative to slide origin or ROI origin
  - Slide Annotations
    - Stain issues (too pink), cutting issues (too thick, fragmented), visibility issues (frozen section artifact, air dry artifact)

Metadata – Data about data
(Classify as Localized to Instrument, APLIS, or EHR)

- Slide viewing completed
- Slide viewing inquiry
  - Viewer ID (years in practice, area of specialty)
  - Start time, End time
  - Slide ID to include stain (H&E vs IHC etc)
  - Case type (breast, GI, lung, b9 vs neoplastic dz etc)
  - Percent of tissue not viewed
  - Percent of tissue not viewed twice
  - Percent of tissue not viewed at higher than 10x mag
  - Size of tissue on slide (area of polygon)

Next Steps


EHR
(HL7 order placer)
(HL7 result tracker)
Acquisition Manager
(Generate WOS for acquisition devices)
DICOM
Acquistion Modality
(WSI scanner)
Acquistion Modality
(Macroscopic Imager)
Automation Manager
(Generate WOS, e.g for evidence creators)
Image Manager
(DICOM)
LIS
(HL7 order filler)
Image Display
(DICOM)
(Digital) Evidence Creator
Image Archive
(DICOM, VNA / PACS)

INCLUDED FOR REFERENCE ONLY

Digital Pathology Standards Integration Committee

IHE PaLM Change Proposal & DICOM considerations

Berlin, May 25th 2016

Digital Pathology Standards Integration Committee

- Initiated by Visiopharm (2015)
- Identifying and resolving **practical issues** around ***use*** **of standards** for DP
- International group of vendors and users involved

Activities

- Meetings
  - Kick-off October 2015
  - DICOM and IHE training 2016
  - F2F meeting April 2016
  - Berlin meeting May 25th
- Change proposal submitted to IHE for APW profile
- IHE proposal approved
- DICOM suppl. 145 suggestions

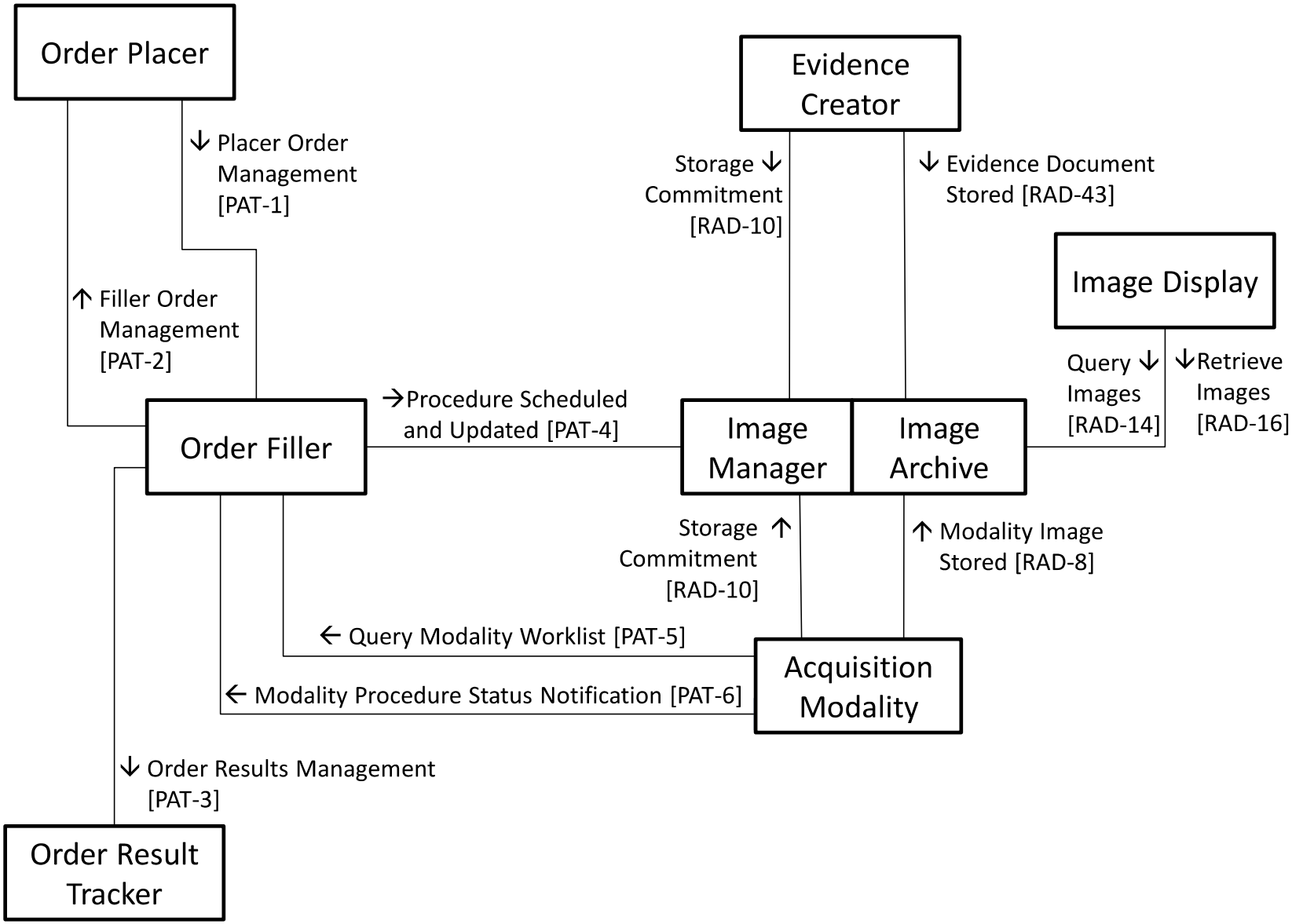
Proposal

- Improve and expand profile with more recent experience from using DP for
  - Tight workflow integration (primary diagnostics!)
  - Image processing
  - Practical implementations

Proposal

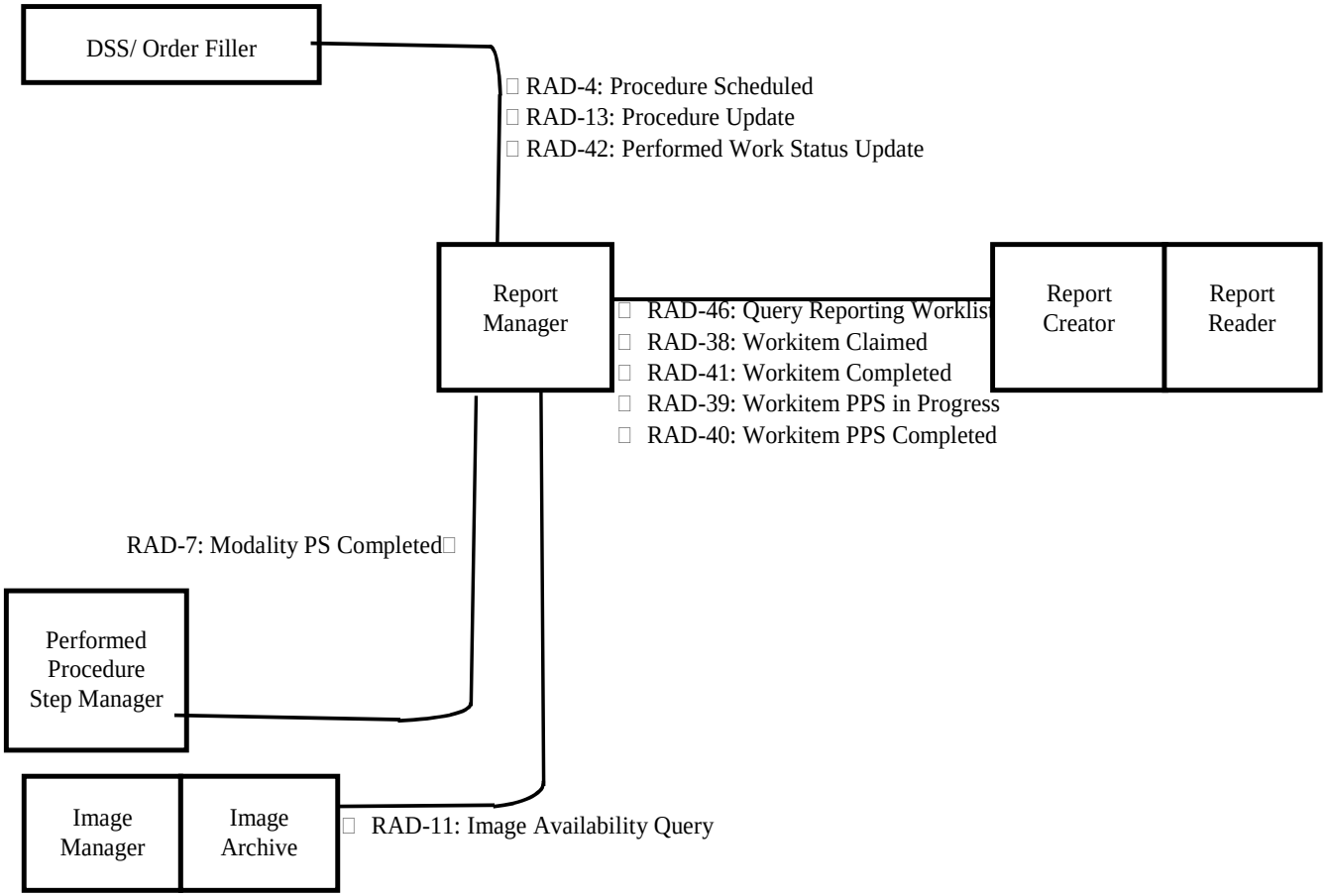
- Review APW profile (w/focus on DP)
  - Make APW actor-transaction diagram consistent with SWF
- Extend APW with following use cases:
  - Pathology reporting (comparable to RAD reporting)
  - Quality control around using WSI
- Adjust “Pathology General Workflow with post processing“

Current actors/transactions APW

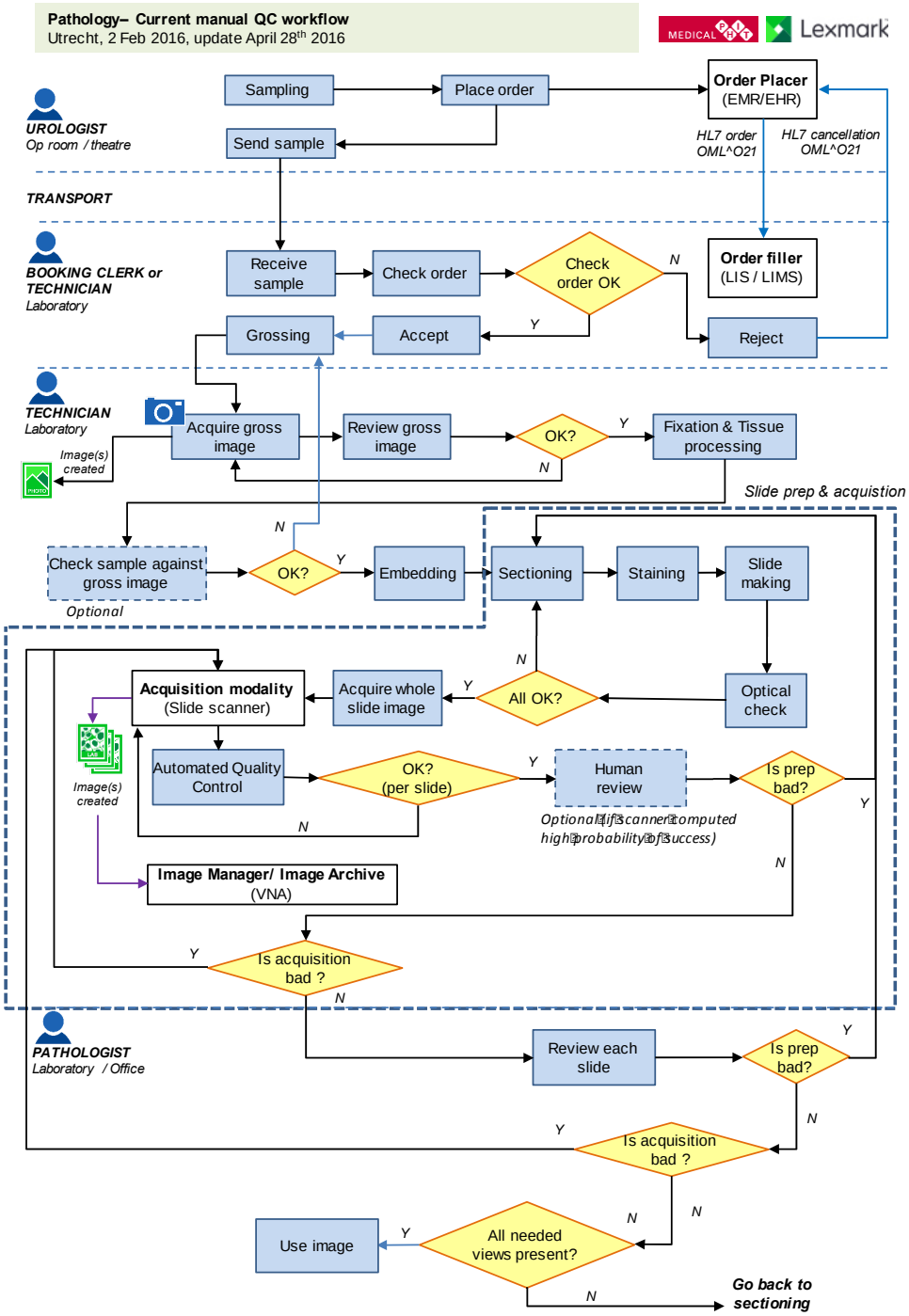


Use case: Pathology reporting

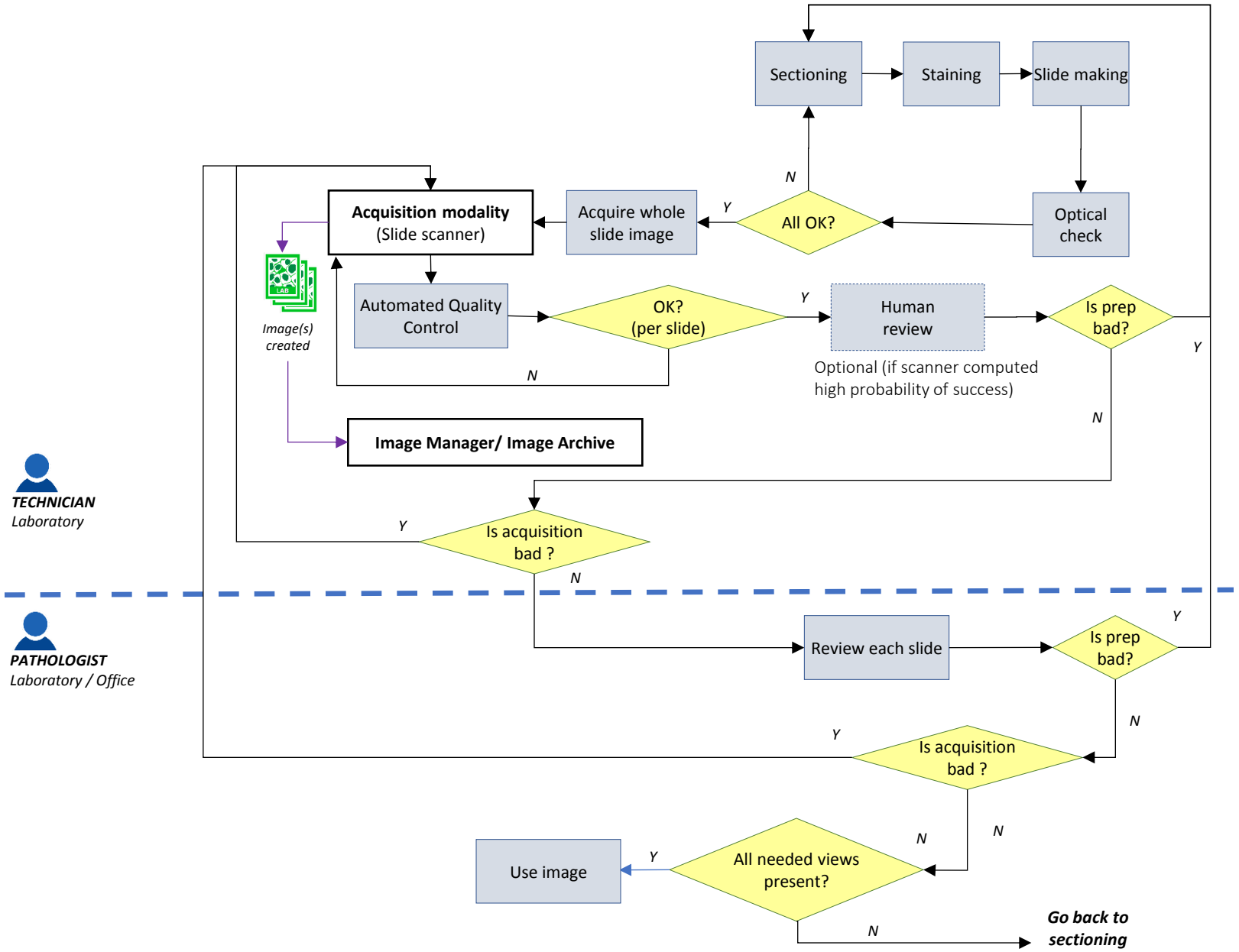
- See RAD vol. 1, chapter 13



Use case: quality control using WSI

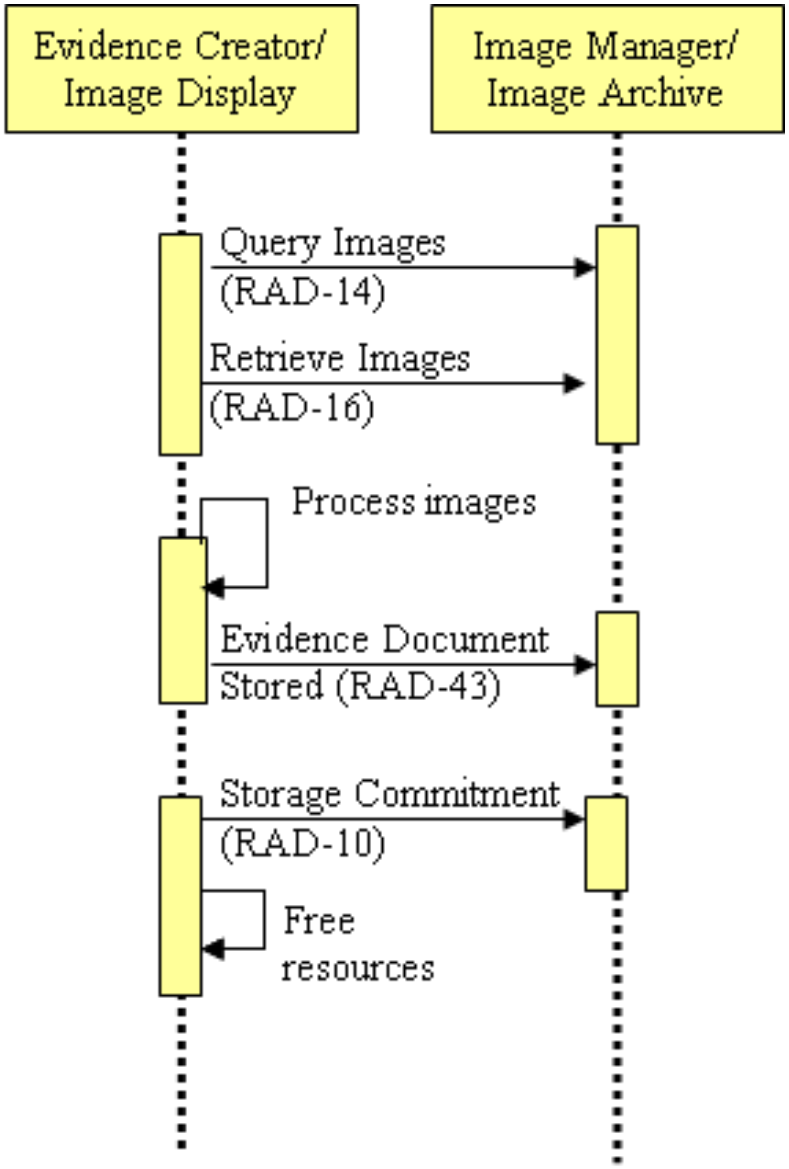


Use case: quality control using WSI



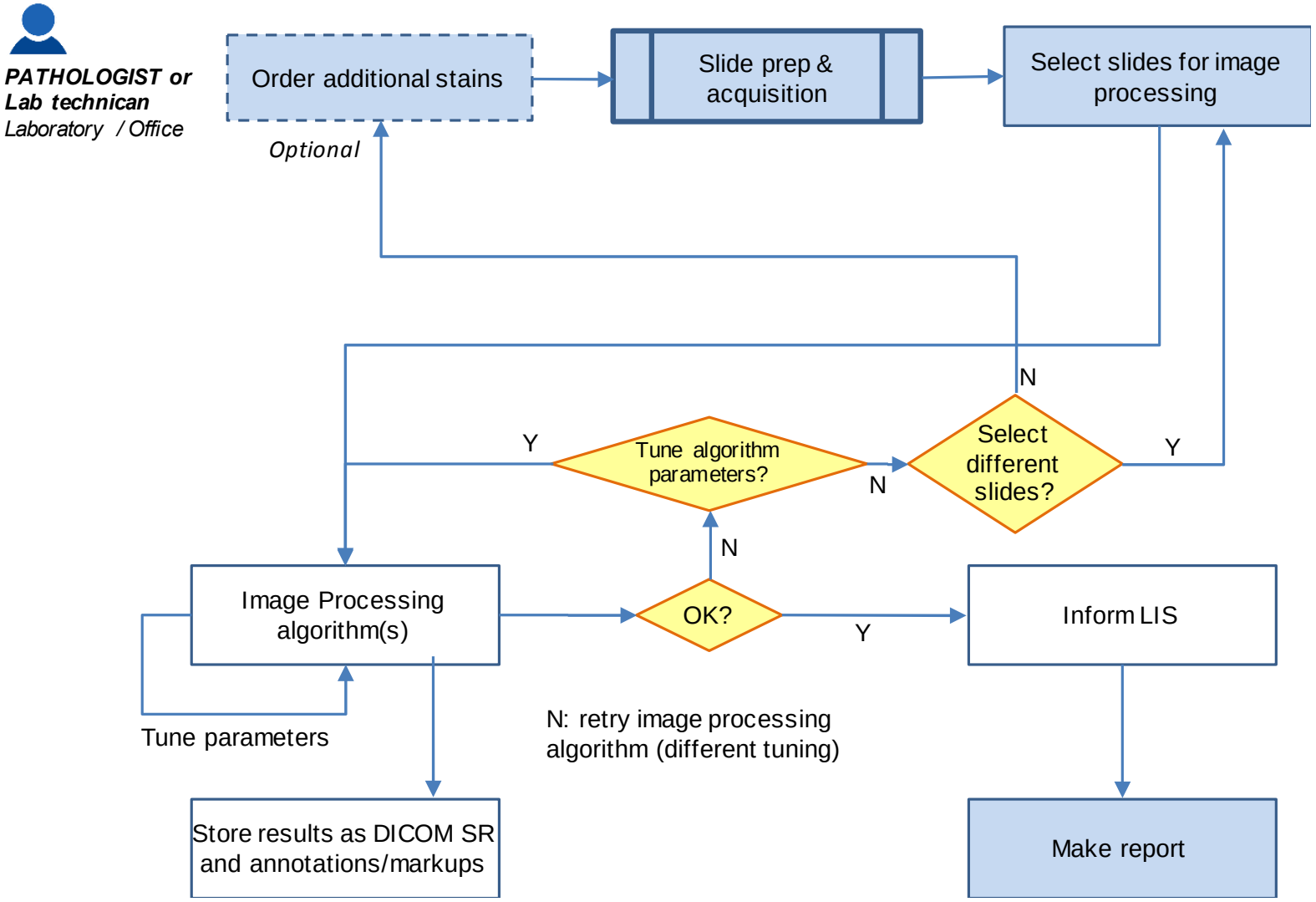
Pathology General Workflow with post processing

- Current use case:



Pathology General Workflow with post processing

- Extended use case:



Other IHE APW proposed changes

- Replace RAD-43 with RAD-10
- RAD-16 (retrieve image)
  - Fetching selected number of frames
  - PaLM-16: DICOM 2011 PS3.4, Annex Y instead of Annex C
  - Webservice version (QIDO/WADO)
- Specimen preparation information not always available at scanner, how to add later to image?
- Relation to LTW, LAW and/or LDA

DICOM issues

- Annotations / markups
  - Store using real-world coordinates?
  - Potentially 1000s polygons in one level / Z plane / colour plane, multiplied by planes stored within instance
  - For computational purposes and zooming not feasible to store as overlay
  - How to retrieve for tiles displayed on screen?
- Overlay object
  - Per frame ?
  - Per depth of field level / colour plane ?
  - Per instance ?
  - Per study ?

DICOM issues

- Virtual double-staining (applied by CAD software)
  - How to register and store?
  - How to standardise?
  - Blending – like PET-CT ?

DICOM recommendations

- Optical path per image instead of frame
- Same tile size for all images (for all layers)
- Handling of empty tiles (fixing background colour?)
- Lens power shouldn’t be Type 3 but Type 1
- Tag needed for number of pyramid levels (at study level)
- Z-plane can have 1 → n tiles in it, large file size, multiple bit depths
  - Mix of bit depth could be a problem, especially with move to multi-spectral (50-60 channels)
  - Consider dictating maximums, or when to create a new separate object
- Limit amount of transfer syntaxes