Digital Pathology
Clinical Implementation in Neuropathology

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Disclosures

- Nothing to disclose

Learning Objectives

1. Outline the steps necessary to successfully implement digital pathology

2. Name key stakeholders to be involved in operationalizing digital pathology at your institution

3. Identify advantages and disadvantages of digital pathology in clinical practice

Digitization





What is Successful Digitization?

- Is an institution-wide clinical transformation program.
- It requires clinical governance and accountability, rigorous validation, and a sustainable information architecture.
- It must demonstrate improve diagnostic service, resilience, collaboration, and data use while maintaining or improving quality, turnaround time, and patient safety.

Practical institutional roadmap

I. Define scope and value proposition
II. Map and redesign workflow
III. Build the platform
IV. Validate and train
V. Pilot and scale
VI. Optimize and innovate

I. Define scope and value proposition

A. Select initial use cases and define clinical outcomes: Prioritize use cases using clinical impact, feasibility, volume, operational pain points, and measurable benefit.

Phase	High Value use case	Clinical Value	Caveats
Early	Multidisciplinary conference and tumor board review	Improves shared visualization and reduces slide transport	Often an excellent early "proof of value," but is distinct from primary diagnosis
Early	Consultation and expert second opinion	Faster image sharing and fewer risks of physical-slide loss	Requires consent/privacy and cross-institutional sharing policies if multi-institutional
Early	Remote primary diagnosis for routine surgical pathology	Enables flexible staffing, subspecialty coverage, and continuity during	Requires full end-to-end validation and reliable fallback
Intermediate	Frozen-section workflows	Faster access to remote expertise, especially after-hours	Requires separate validation owing to section quality, artifacts, and time constraints
Advanced	Computational pathology and AI-assisted workflows	Quantitation, triage, quality control, biomarker support, research reuse	Needs independent clinical validation, monitoring, and human oversight

I. Define scope and value proposition

B. Establish governance, and document baseline workflows and metrics
Create a group of stakeholders to determine the why and implement procedures and standards

Who needs to be at the table?

- Pathology medical director and subspecialty physician champions.
- Anatomic pathology operations leadership.
- Histology and laboratory supervisors.
- Pathology informatics and enterprise IT.
- LIS, EHR, cybersecurity, privacy, procurement, and finance representatives.
- Quality/accreditation personnel.
- Clinical service-line partners, especially surgery, oncology, radiology, and tumor-board leadership.
- Research, biobanking, and AI/data-science representatives where applicable.

Define the Why?






- Multiple locations: limited number of experts
- Improve patient care (e.g. decrease loss assets, decrease errors)
- Connect teams and improve collaboration: consults, tumor boards, multidisciplinary care, tumor banks, etc.
- Improving workflow, and turn around time
- Streamline processes
- Improving quality control
- Storage of assets that do not degrade over time
- Education, training, enduring quality material easily accessible
- Research (Organized accessible datasets)

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Implement Procedures and Standards

- Technical standards
- Budget
- Validation
- Risk acceptance
- Service-level expectations
- Prioritization
- Performance review



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Understanding the financial aspects of digital pathology: A dynamic customizable return on investment calculator for informed decision-making

Orly Ardon [a,*], Sylvia L. Asa [b], Mark C. Lloyd [c], Giovanni Lujan [d], Anil Parwani [d], Juan C. Santa-Rosario [e], Bryan Van Meter [f], Jennifer Samboy [g], Danielle Pirain [h], Scott Blakely [i], Matthew G. Hanna [a]

DPA

ROI CALCULATOR

ACCESS NOW

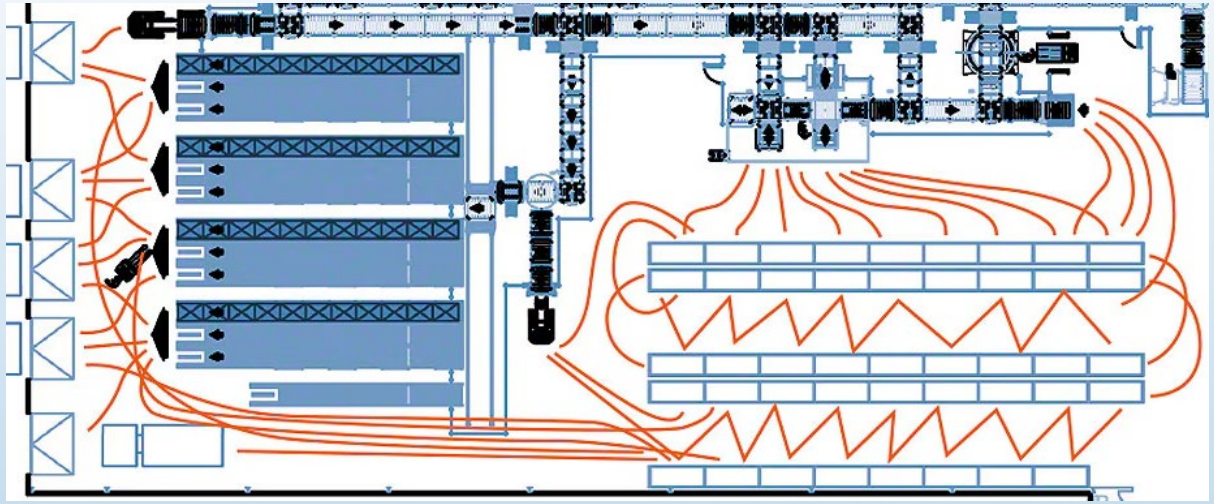
https://digitalpathologyassociation.org/roi-calculator

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II. Map current workflow

Map the entire current specimen journey

- Identify pain point areas to improve flow and decrease potential bottlenecks
- What is the current slide identification process?
- How are cases assigned?
- How are slides distributed?
- How and when are slides stored or retrieved?



Accessioning

Grossing

Processing

Embedding

Specials

IPOX

Sectioning

Staining/ coverslipping

Muscle

IF

EM

- Pathologist Assignment
- Slide Distribution

Scanning

Pathologists' offices

Trainees

Shelves

Admins

S/O Rooms

Storage/Retrieval/Disposition of assets

II. Redesign workflow

Digital pathology should remove handoffs and waiting, rather than digitize inefficient analog practices.

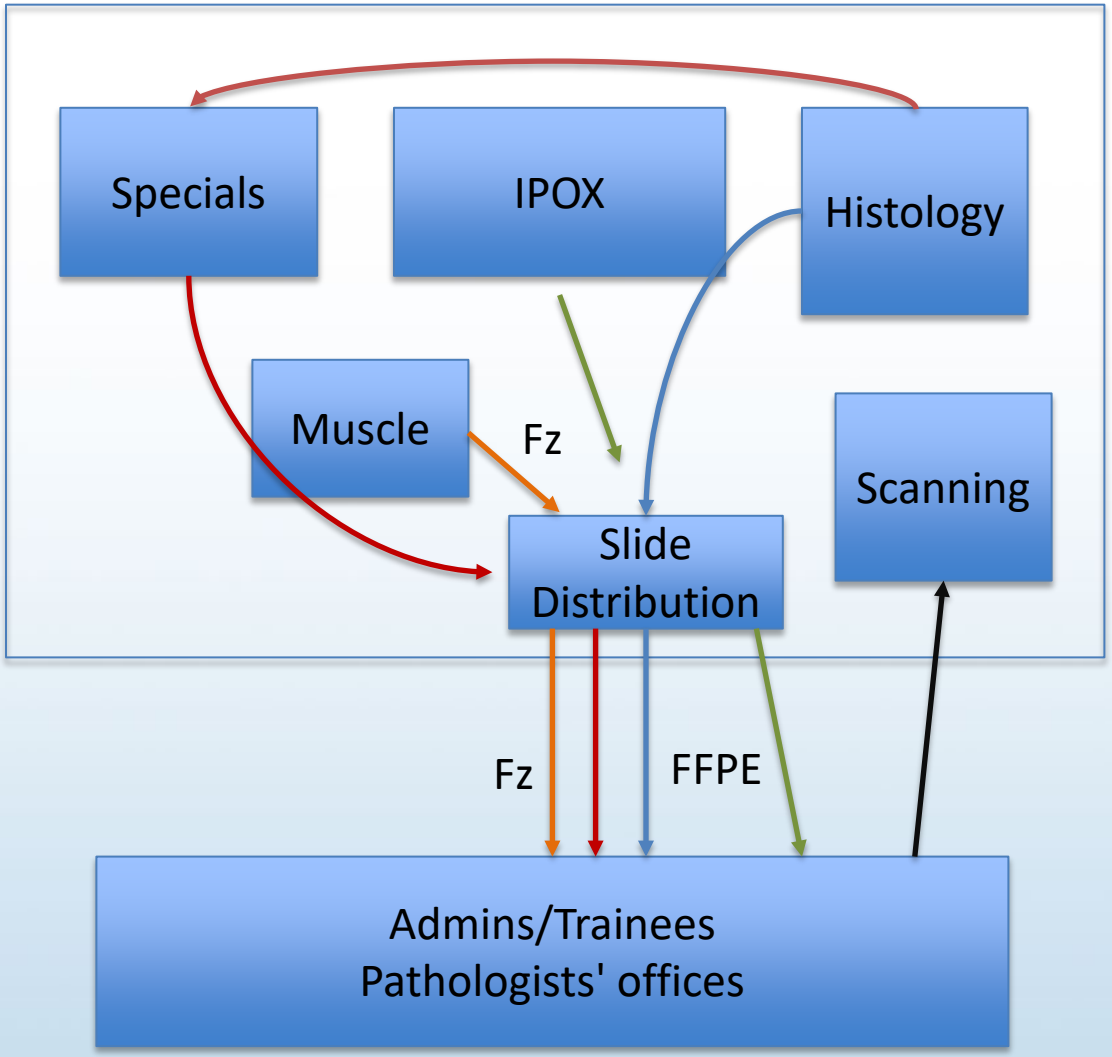
Build reliable pre-analytic processes

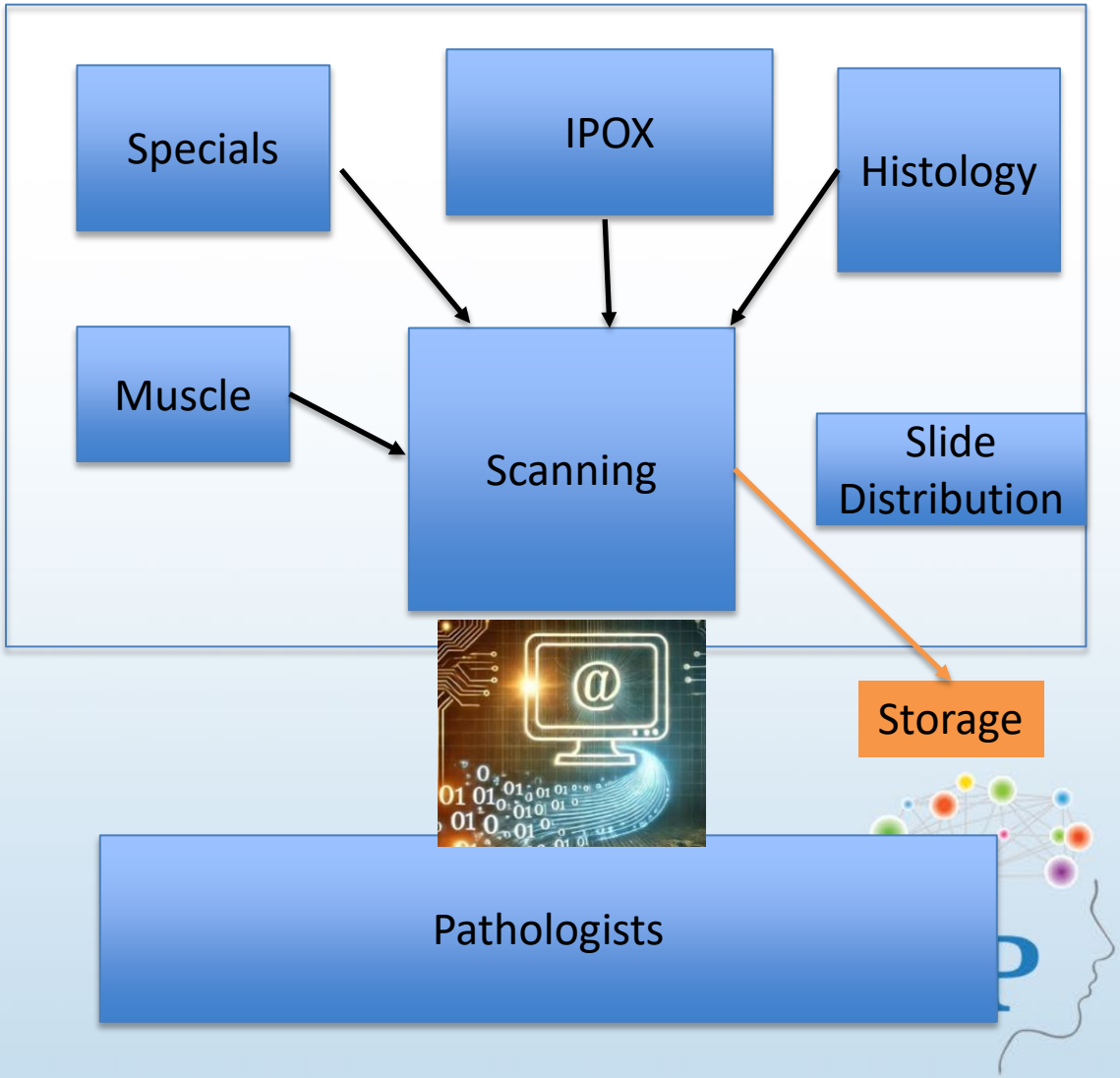
- Standardized tissue processing, microtomy, staining, coverslipping, and slide labeling.
- High-quality barcode workflows linking patient, case, block, slide, stain, and scanner/image identifiers.
- Clear rules for which slides require scanning and at what priority.
- Slide preparation standards that reduce scanning failure: clean coverslips, minimal mounting-medium artifacts, appropriate tissue placement, limited air bubbles, and avoidance of label/tissue obstruction.
- Defined handling for difficult material: fatty tissue, fragmented biopsies, decalcified tissue, thick sections, hemorrhagic or pigmented specimens, cytology, smears, frozen sections, and outside material.
- A formal “scan-ready” checkpoint, ideally embedded in the laboratory workflow.

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II. Redesign workflow
(Muscle Biopsy)







Four services, five image types, one patient context



THE FOUR SERVICES

1 Neuropathology (NF)

Surgical biopsies and resections, from intraoperative consultation through final sign-out.

2 Muscle & Nerve (IB, MM)

Biopsy service combining brightfield, enzyme histochemistry, IHC, special stains, and ultrastructure.

3 Hospital brain cutting

Autopsy brain examination, with gross photography captured at the cutting bench.

4 ADRC brain cutting

Research and brain-bank cutting sessions on the same capture and review workflow.

WHAT WE DIGITIZED FOR THEM

Whole slide images — DICOM SM

H&E, special and enzyme stains, IHC

Electron microscopy — attached to case

Ultrastructure for muscle and nerve

Gross photography — DICOM XC

Brain cutting and autopsy bench images

Priors and reports — PACS-driven

Historic cases and the LIS report in view

The point: Digitization was never only glass to whole slide images. For neuropathology we moved every image the service depends on — brightfield, electron microscopy and gross — into one patient context on the enterprise platform.

Retain an intentional glass-slide fallback

Digital-first does not mean glass-unavailable.

Define:

- When a pathologist should retrieve glass.
- Where glass slides are stored and how rapidly they can be accessed.
- Who responds to scanner failures, image-quality concerns, viewer unavailability, or network downtime.
- How case completion is documented when the review modality changes.
- How the laboratory will continue operation during planned and unplanned downtime.

Glass should remain an appropriate escalation for technical limitations, unusual preparations, problematic scanning, or any case in which the pathologist judges it necessary for safe interpretation.

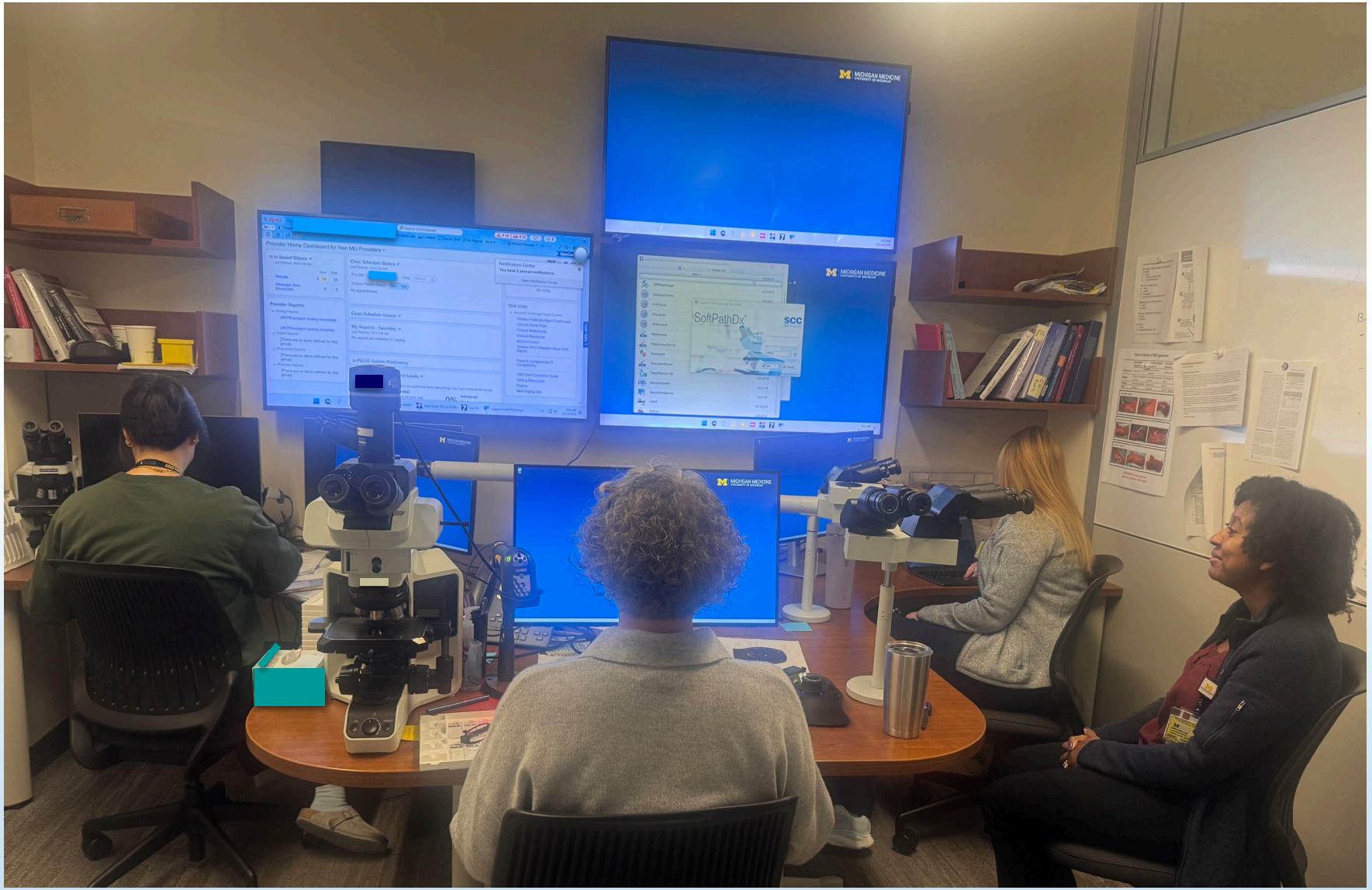
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II. Redesign workflow not just the microscope

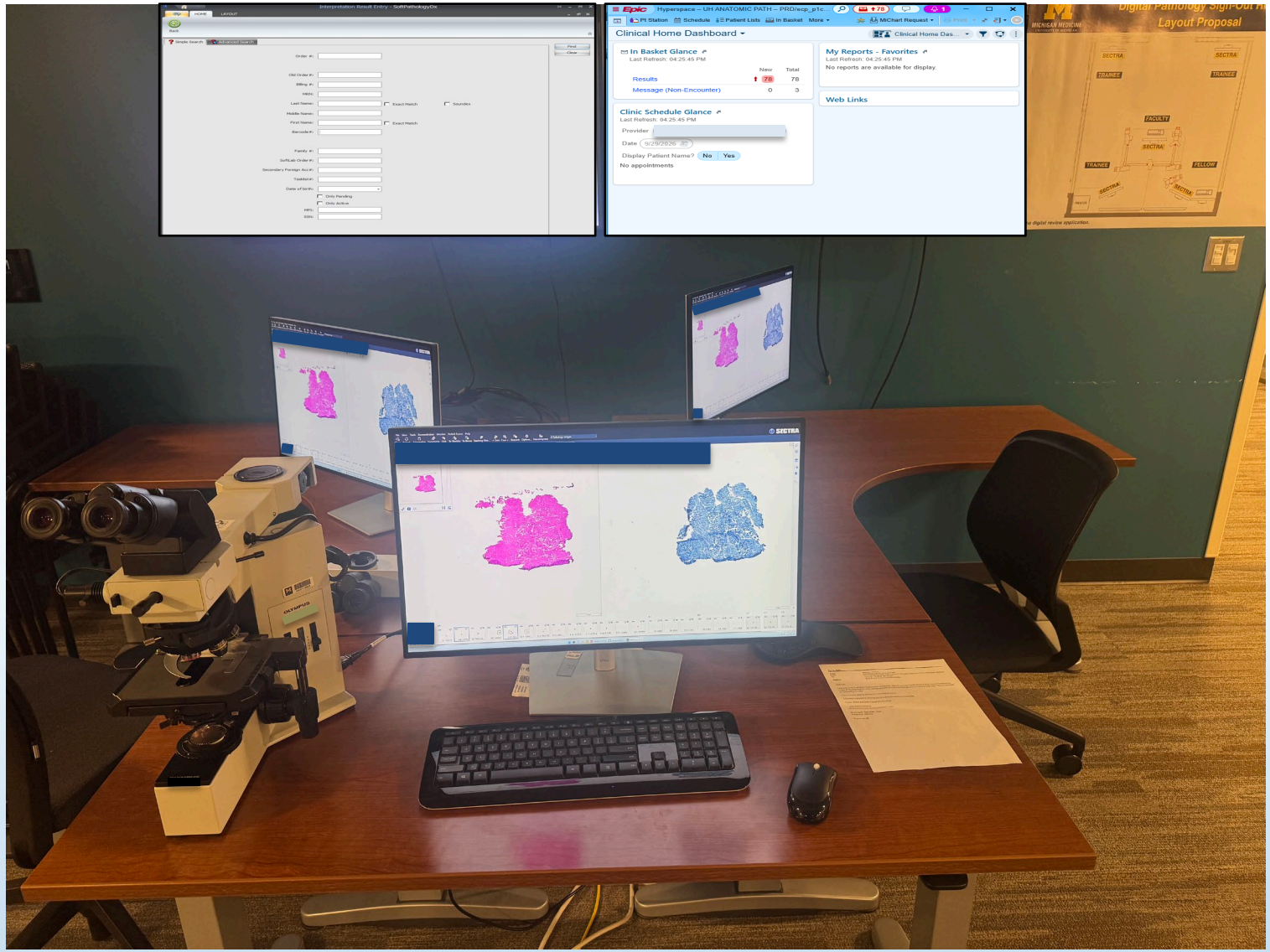




II. Redesign workflow not just the microscope



II. Redesign workflow not just the microscope





II. Redesign workflow not just the microscope



(Re)-Design the Digital Worklist

The pathologist should begin the day in a case-centered digital worklist rather than search across separate applications.

Essential functionality:

- LIS-driven case assignment and status.
- Direct launch from the LIS to the correct case and slide.
- Visibility of all scanned slides, including H&E, levels, special stains, IHC, and outside slides.
- Access to requisition data, gross description, prior pathology, relevant radiology, molecular testing, and clinical history.
- Digital annotation, measurement, screenshot/export controls, and consultation tools.
- Clear indicators for missing, failed, pending, rescanned, or glass-only slides.
- Case-level support for sign-out, amendment, and audit trail.

The image management system should be a clinically integrated component of the pathology workflow, not a separate image repository that pathologists must repeatedly search.

(Re)-Design the Digital Worklist

Worklist

Neuro (NF) 9 patients, 9 examinations

4 Distributed 5 Pending 5 Trainee Reviewed 2 Supplemental needed OR set status to Fina

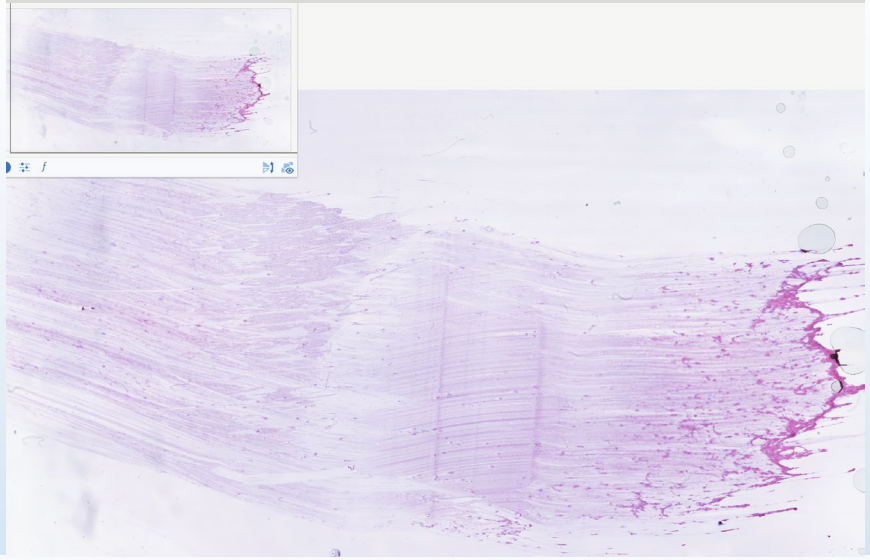
Date and time	Accession number	Name, sex and age	Molecular Order Status (Local WISE Server)
10/6/2026, 3:31 PM	SU-26-123	John Smith	
10/6/2026, 11:13 AM	SU-26-124	Jane Smith	
10/6/2026, 10:28 AM	SU-26-125	Joan Smith	
10/5/2026, 1:27 PM	SU-26-126	John Doe	
9/30/2026, 6:47 PM	SU-26-127	Jane Doe	
10/1/2026, 4:04 PM	SU-26-128	Joane Doe	
10/2/2026, 9:35 AM	SU-26-129	John Dow	
9/15/2026, 10:09 AM	SU-26-130	Jane Daw	Molecular Report Generated

Prior Lab and Rad

Accession number	Date and time	Description	Status	Institution	AP Svc (Local WI...	Referring unit	Se...	Items
MMED41559142	9/29/202...	XR WRIST R 3...	Final	Univ ...			3.	3
MMED41594949	10/7/202...	XR WRIST R 3...	Final	Univ ...			4.	4
MMED42228459	3/12/202...	BI MAMMOG...	Final	Univ ...			1.	2...
MMED42935399	8/21/202...	MR ORBITS ...	Final	Univ ...			2.	2...
MMED43005385	9/8/2026...	CT HEAD W ...	Final	Univ ...			1.	9...
MMED43005420	9/16/202...	NM PET LIMI...	Final	Univ ...			1.	7...
MMED43130376	9/30/202...	CT HEAD WO...	Final	Univ ...			1.	1...
SU-25-456	12/10/20...	Surgical Path...	Final	Pathol...	GA	EAA ...	1.	
SU-26-127	9/30/2...		Distri...	Path...	NF	PA...	4	

Medical Record Number
0123456
Accession Number
SU-26-127
Case History
XX-year-old female with headaches and double vision
Referred by
Mark Twain, MD, UH3 Neurosurgery

SU-26-127 S1 H&E AA 1X





III. Build the platform

Procure scanners, image management, LIS/EHR interfaces, storage, network capacity, monitoring, identity management, and disaster recovery



McClintock, D.S., Abel, J.T., Cornish, T.C. (2022).
In: Parwani, A.V. (eds) Whole Slide Imaging. Springer, Cham.

High-throughput scanners

- Higher slide capacities
- Fast scan times (<1 min/slide)
- One-button operation
- Continuous loading capabilities

Low-throughput scanners

- Lower slide capacities
- Versatility in operation and magnification
- Smaller physical footprint
- Lower cost

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III. Build the platform

Cost HTP : $200K-300K/scanner

Table 1
Summary of digital pathology scanners

Scanner system	Slide volume	Magnification	File format *	Scanning speed per slides	FDA approval
Philips Ultra Fast[12]	300 Regular slides	×20/×40	RAW or iSyntax Compression	60s at ×40 equivalent (15 × 15 mm scan area)	Yes
Huron TissueScope LE120[13]	120 Regular slides (60 whole-mount slides)	×20/×40	24-bit RGB pyramidal bigTIFF uncompressed, JPEG 2000 compressed, flat TIFF and LZW, compressed TIFF	60 s per slide, 15 × 15 mm at ×20	NA
Hamamatsu NZ S360 [14]	360 Regular slides	×20/×40	JPEG compressed image + slide information	Approximately 30 s	Yes
Leica Aperio AT2 [15]	400 Regular slides	×20/×40	SVS	<60 s	Yes
Sakura VisionTek live microscope[16]	4 Regular slides	×2.5/×10/×20 /×40	JPEG, TIFF, BMP, and PNG	3.0 min for 15 × 15 mm (at 0.275 μm/pixel)	NA
Leica Aperio LV1 live microscope[17]	4 Regular slides	×1.25/×5/×20	NA	15 s or less	No
Mikroscan live microscope [18]	2 or 4 Regular slides	×2/×4/×10/×20/×40	NA	9 s	NA
GRUNDIUM OCUS microscope scanner [19]	1 Regular slides	×40 (NA 0.75)	JPEG, SVS, and TIFF	180 s	NA
Roche Ventana DP 600 [20]	240 Regular slides (40 trays of 6 single slides)	×20/×40	BIF, TIF, and DICOM	×20: approximately 36 s ×40: approximately 73 s	No YES

FDA, U.S. Food and Drug Administration; NA, not available.

Leica Aperio GT 450 DX

Zhang DY, et al., Lab Investigation, 2024

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III. Build enterprise-grade technology

A mature digital pathology environment contains:

- **Slide scanners** sized for actual volume, peak demand, priority workflows, redundancy, and service coverage.
- **Image management system/viewer** with appropriate clinical functionality, audit trails, worklists, annotations, and enterprise access controls.
- **LIS integration** for accessioning, slide identity, case status, workflow triggers, and sign-out context.
- **EHR integration** so appropriate users can access pathology images or links in the patient record under governance.
- **Storage tiering** for high-performance current work, nearline retention, archive, backup, and disaster recovery.
- **Network capacity** appropriate for local and remote WSI use, including peak concurrent viewing and image ingestion.
- **Identity/access management** with single sign-on, multifactor authentication when indicated, role-based permissions, and access logging.
- **Monitoring and support tools** for scanner state, image-transfer failures, interface failures, storage capacity, latency, and service uptime.
- **Standards-based interoperability** to mitigate migration risk and facilitate cross-enterprise sharing.

Open formats support more durable interoperability and reduce dependence on proprietary image silos.
Storage: Minimum 1-2 GB /case at 20X. Model storage needs for 5 years, not only one
Network bandwidth: You need sufficient bandwidth between scanner, storage and viewer stations. Inadequate network infrastructure is a common cause of poor adoption.

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Data is an institutional asset

Build a multi-year storage model before go-live, including original images, rescans, derivative images, backups, retention requirements, and projected annual growth.

A sustainable design distinguishes:

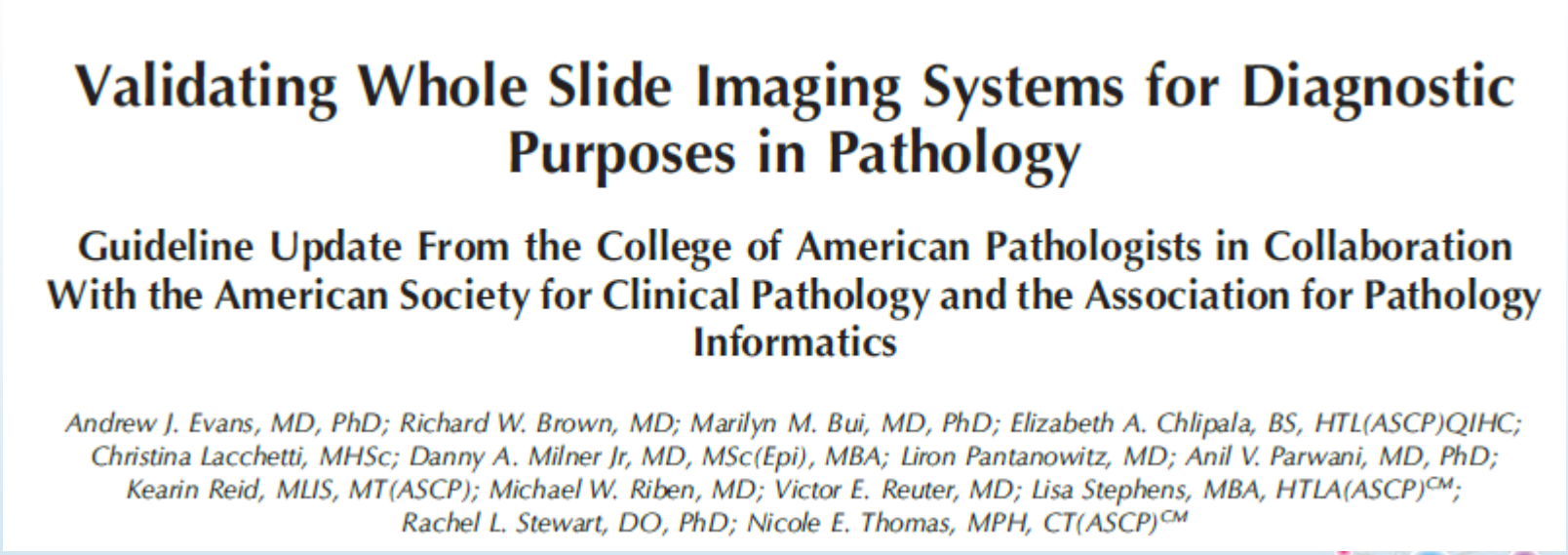
- **Hot storage:** actively signed-out or recently completed cases requiring rapid access.
- **Warm storage:** readily retrievable clinical archive.
- **Cold archive:** long-term retention material with slower retrieval expectations.
- **Protected backup/disaster recovery:** immutable or otherwise resilient copies governed by institutional recovery objectives.

IV. Validate and train

Even for FDA cleared systems, laboratories still need to perform their own validation studies before clinical use. Including validation, training, quality control, competency assessment.

- CAP- Guidelines (2013, updated in 2022).

  Validation for
  - Intended use
  - Specimen type
  - Stain
  - Scanner(s)
  - Monitor(s)
  - Viewer
  - Network
  - Daily diagnostic environment



Validating Whole Slide Imaging Systems for Diagnostic Purposes in Pathology

Guideline Update From the College of American Pathologists in Collaboration With the American Society for Clinical Pathology and the Association for Pathology Informatics

Andrew J. Evans, MD, PhD; Richard W. Brown, MD; Marilyn M. Bui, MD, PhD; Elizabeth A. Chlipala, BS, HTL(ASCP)QIHC; Christina Lacchetti, MHSc; Danny A. Milner Jr, MD, MSc(Epi), MBA; Liron Pantanowitz, MD; Anil V. Parwani, MD, PhD; Kearin Reid, MLIS, MT(ASCP); Michael W. Riben, MD; Victor E. Reuter, MD; Lisa Stephens, MBA, HTLA(ASCP)CM; Rachel L. Stewart, DO, PhD; Nicole E. Thomas, MPH, CT(ASCP)CM

Arch Pathol Lab Med. 2022;146:440–450; doi: 10.5858/arpa.2020-0723-CP)

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CAP- Guidelines

- Use at least 60 cases per each application/use case (e.g. H&E from FFPE, H&E from frozen IOC, Pap-stained slides for cytology, etc.), that reflect the spectrum and complexity of specimen types and diagnosis encountered in routine practice.
- Validation should include another 20 cases for additional applications for the intended specimen type and application use (e.g. IHC or special strains) that were not included in the original 60 cases mentioned above.
- Compare intraobserver concordance between glass and digital slides.
- Minimum of 2-week washout period.
- If WSI/Glass concordance is <95%, laboratories should investigate and attempt to remedy the cause.
- Reconcile discordances

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CAP- Guidelines

Table 5. Summary of Good Practice Statements (GPSs)

GPS 1. All pathology laboratories implementing WSI technology for clinical diagnostic purposes should carry out their own validation studies

GPS 2. Validation should be appropriate for and applicable to the intended clinical use and clinical setting of the application in which WSI will be used. Validation of WSI systems should involve specimen preparation types relevant to intended use (eg, formalin-fixed, paraffin-embedded tissue; frozen tissue; immunohistochemical stains). If a new application for WSI is contemplated, and it differs materially from the previously validated use, a separate validation for the new application should be performed

GPS 3. The validation study should closely emulate the real-world clinical environment in which the technology will be used

GPS 4. The validation study should encompass the entire WSI system. It is not necessary to separately validate each individual component (eg, computer hardware, monitor, network, scanner) of the system or the individual steps of the digital imaging process

GPS 5. Laboratories should have procedures in place to address changes to the WSI system that could impact clinical results. This statement was revised from the 2013 guideline

GPS 6. Pathologists adequately trained to use the WSI system must be involved in the validation process

GPS 7. The validation process should confirm that all of the material present on a glass slide to be scanned is included in the digital image

GPS 8. Documentation should be maintained recording the method, measurements, and final approval of validation for the WSI system to be used in the anatomic pathology laboratory

GPS 9. Pathologists should review cases/slides in a validation set in random order. This applies to both the review modality (ie, glass slides or digital) and the order in which slides/cases are reviewed within each modality. This statement was revised from the 2013 guideline

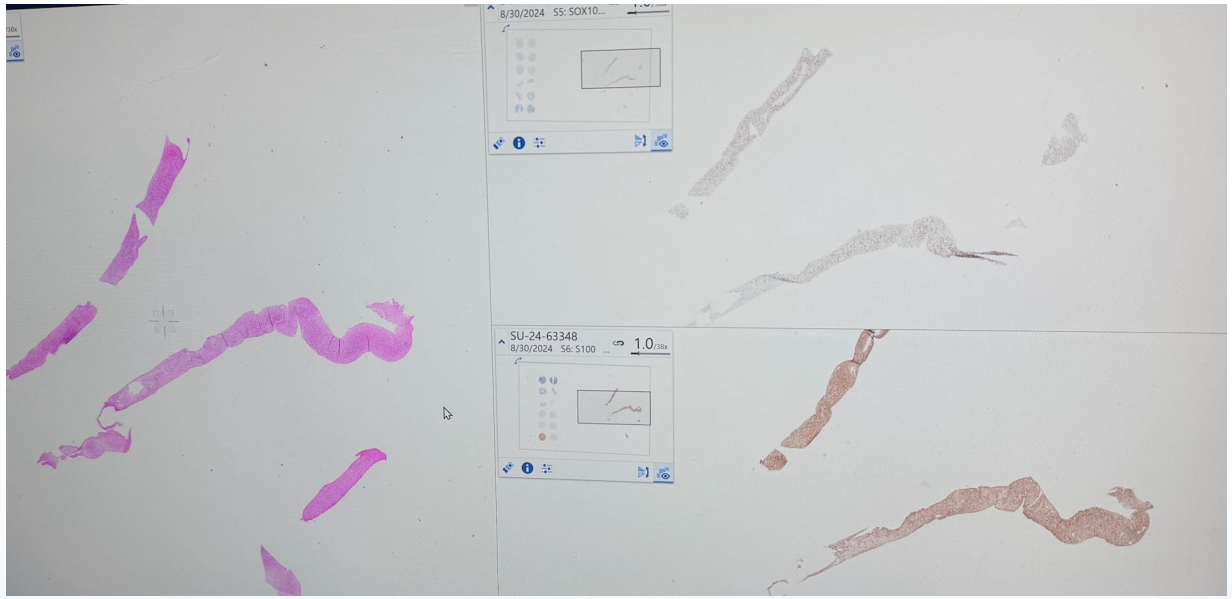
Abbreviation: WSI, whole slide imaging.

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IV. Validate and train

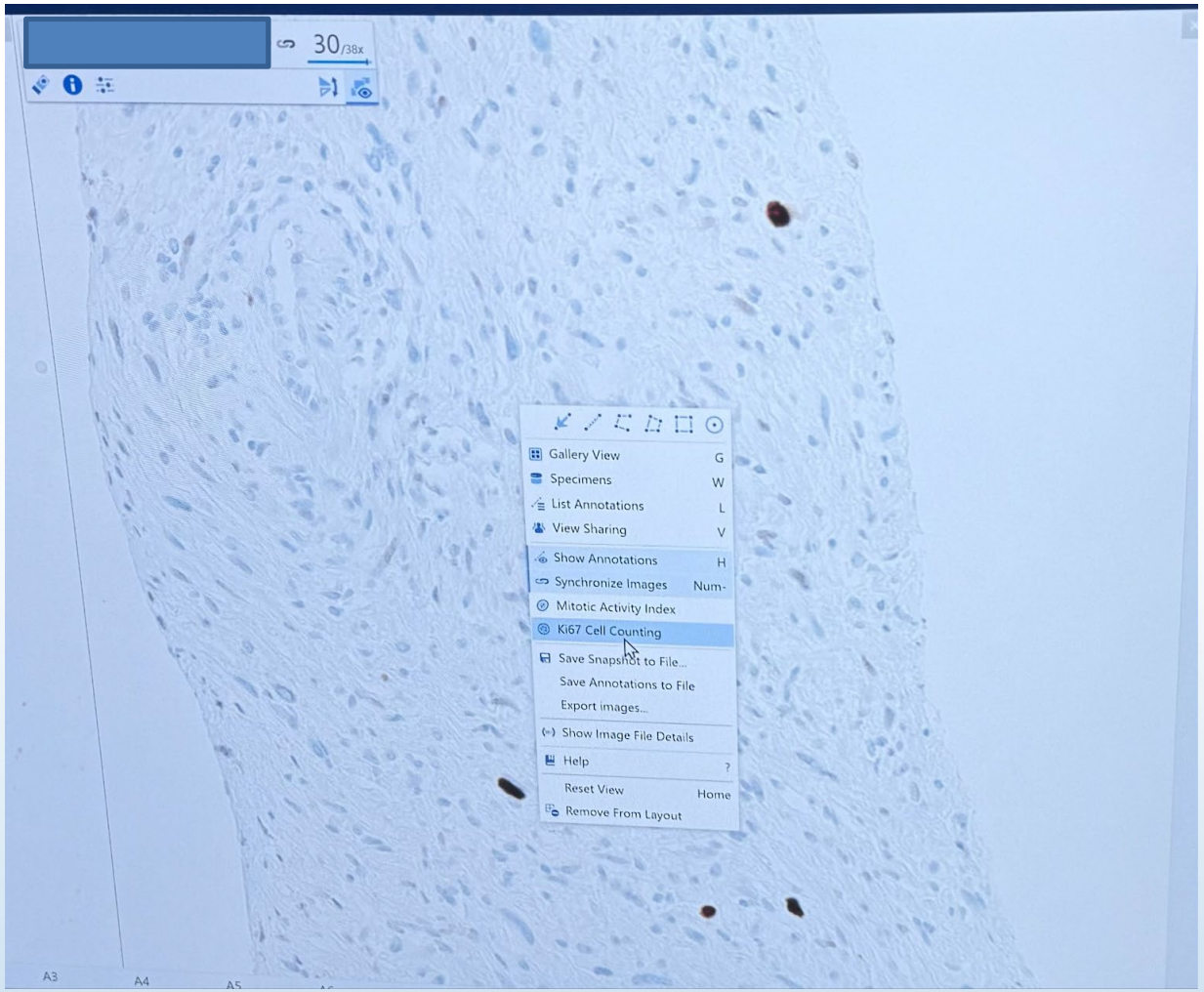








IV. Validate and train





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End to End Clinical Workflow Validation

Technical-Performance Recommendations

- Scanner & Display performance
- Workflow safety
- Training

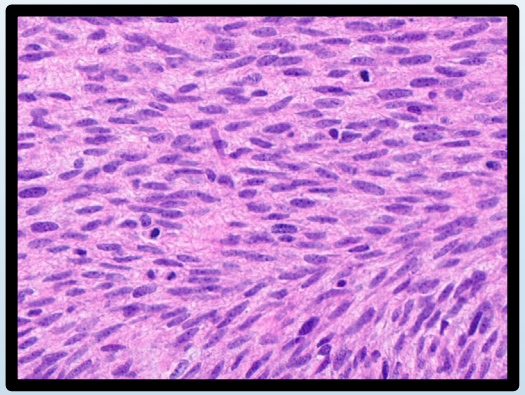
- Develop SOPs
- Quality management
- Downtime plans
- Ongoing monitoring after “go-live”

Pre-analytical





Analytical



Post-analytical

DX

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IV. Validate and train

Train for digital diagnostic practice

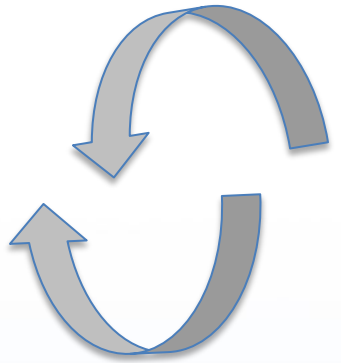
- Navigation at low and high power and recognition of viewer artifacts.
- Appropriate use of overview versus high magnification.
- Recognition of tissue-detection, focus, compression, color, and stitching failures.
- Digital measurement and annotation tools.
- Criteria for requesting a rescan or retrieving glass.
- Ergonomics.
- Downtime procedures and escalation pathways.
- Specialty-specific scenarios

Training must include laboratory staff as well as pathologists.

Histotechnologists, accessioning personnel, slide-file teams, and IT support should understand how their work affects image quality, case completeness, and TAT.

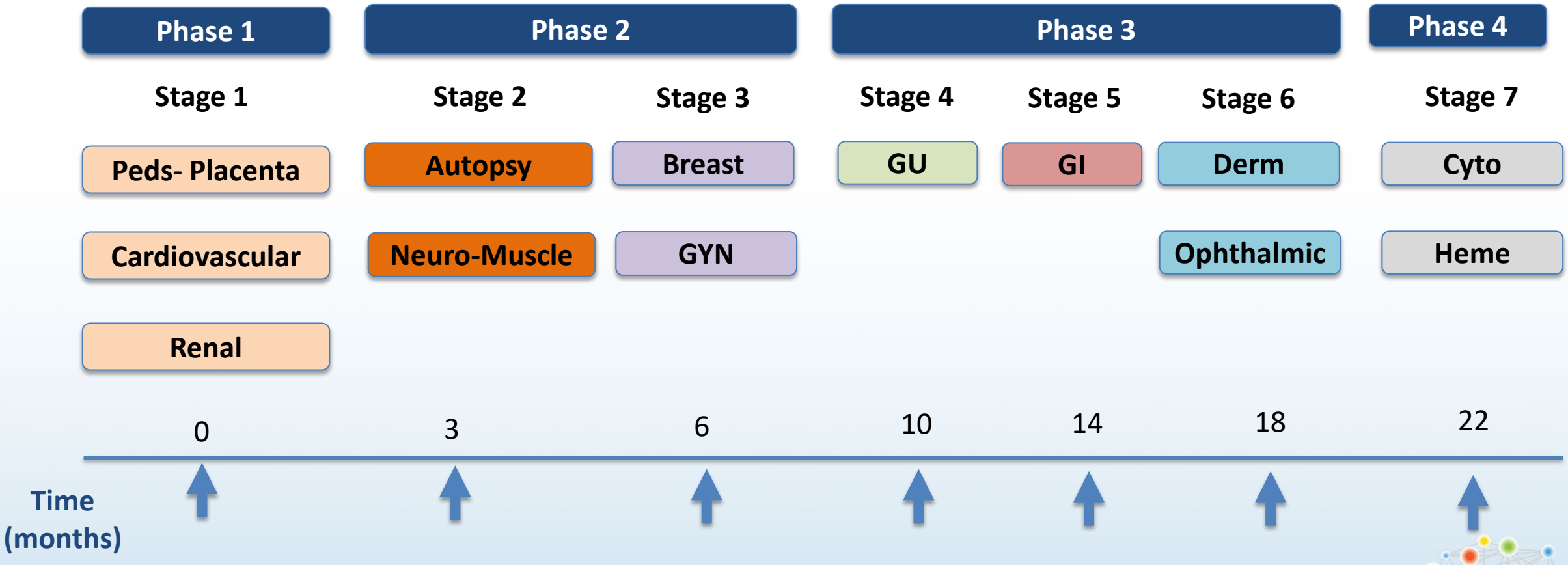
V. Pilot and Scale

- Launch in a bounded service
- Measure performance
- Fix bottlenecks

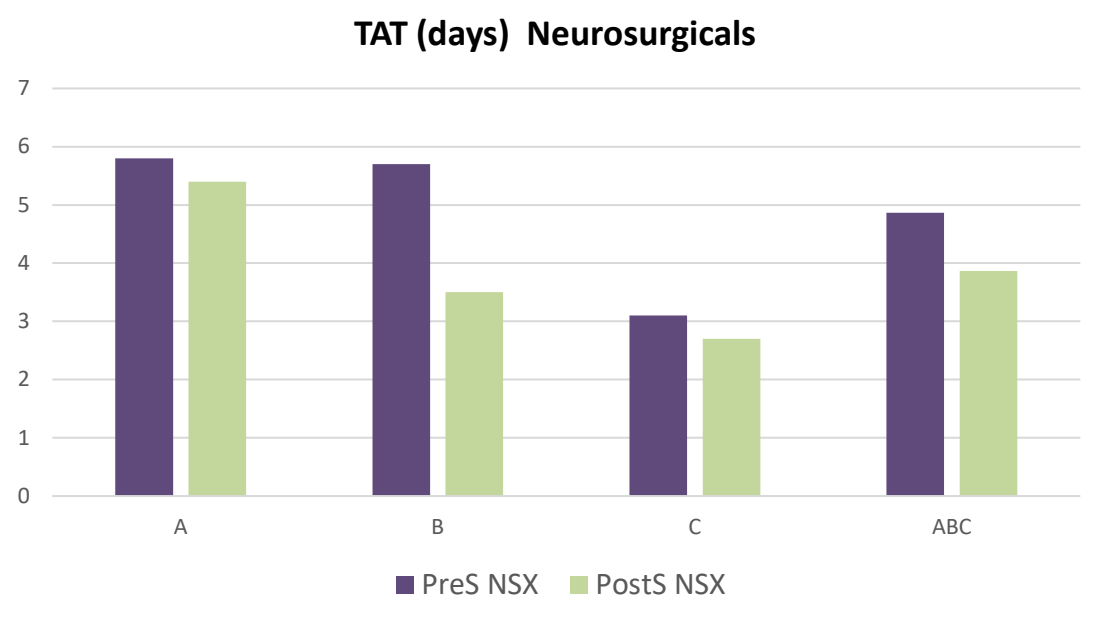


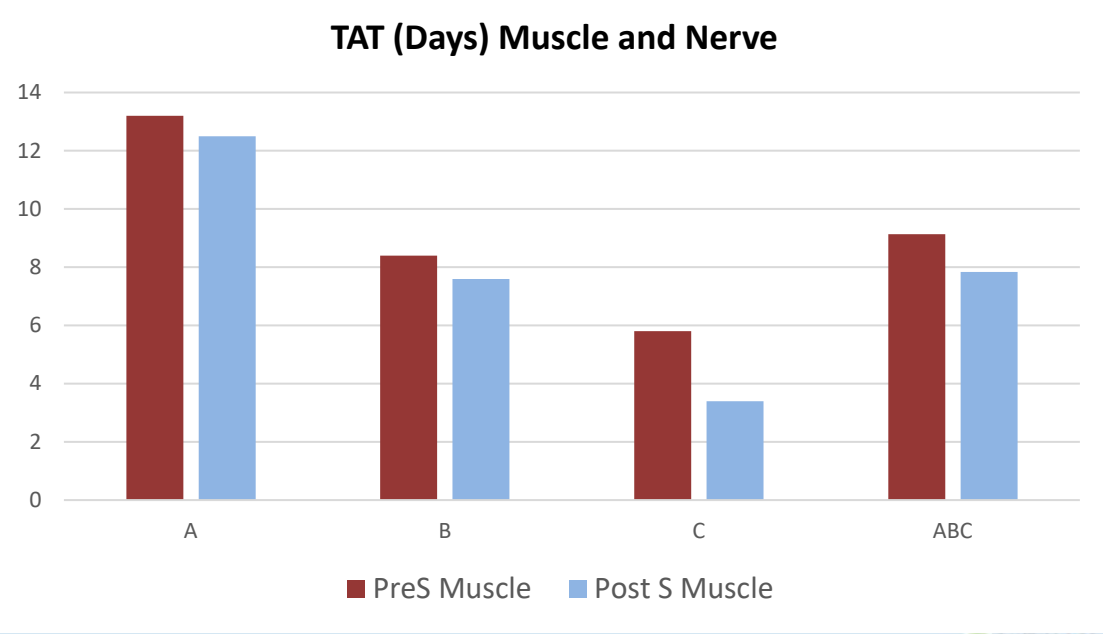
Add additional sites, specimen types, and clinical uses

Digital Pathology Go-Live Roll Out Phases (UMich)



Neuropathology Service Data TAT
Pre-scanning, Post scanning (Hybrid)





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ROLL-OUT

The eight-step go-live playbook, applied to neuropathology



1

Meet the service chief

Map how the service actually works before recommending anything: biopsies, cutting sessions, EM turnaround.

2

Update the offices

Hardware lands before training, not after. Faculty offices and sign-out rooms scheduled first.

3

Build the worklists

Service-specific routing in Sectra: NF, muscle and nerve, hospital and ADRC brain cutting each get their own view.

4

Publish the training schedule

Early and visible. Faculty, residents, fellows, admins and scan techs all see the dates up front.

5

Start image QC early

Scanning and quality checks begin before go-live so stain, focus and coverage defects surface before sign-out.

6

Interactive training

Faculty and admins together on real neuropathology cases, led by Sectra with the service super users.

7

Validate digital sign-out

Service-specific dry runs so the edge cases surface before they are live edge cases.

8

Go-live with elbow support

One-on-one floor coverage for every faculty member through their first cases, then hybrid, then fully digital.

Why it went faster: Neuropathology went live in Stage 2 of the AP roll-out. The playbook was already written — we reused the questions, the training cadence and the QC checks from Stage 1 and spent our time on what is specific to this service.

VI. Optimize and innovate

Measure outcomes that matter

Create a dashboard with baseline, implementation, and steady-state metrics:

Domain	Examples
Patient care	- Turnaround time - Delayed cases - Error/near-miss trends
Diagnostic quality	- Glass–digital discrepancy rate - Rescan rate - Image-quality failures - Frequency and reasons for glass fallback
Operations	- Scan-to-availability time - Slide transport reduction - Lost-slide events - Backlog - Scanner utilization - Downtime
User experience	- Pathologist adoption - Technologist workload - Ergonomics/visual-fatigue - Perceived diagnostic confidence - Clinician/tumor-board satisfaction
Financial stewardship	- Cost per scanned slide - Storage cost trajectory - Personnel utilization - Avoided courier/transport costs - Reduced duplicate slide preparation
Research and innovation	- Cases available for annotated cohorts - AI-ready data quality - Number of validated algorithms or image-analysis workflows

VI. Optimize and innovate

Assign permanent ownership for the clinical platform, including:

- Medical director for digital pathology
- An operational manager,
- Pathology informatician
- IT/application support
- Designated laboratory super-users.

VI. Optimize and innovate

Create a durable operating model with long-term sustainability and recurring funding for:

- Scanner maintenance and eventual replacement.
- Software licenses, interfaces, and upgrades.
- Storage growth, backup, disaster recovery, and data migration.
- Cybersecurity monitoring and patch management.
- Informatics and application-support staff.
- Validation and change-control work.
- Education, competency assessment, and onboarding.
- Ongoing quality management and performance reporting.

VI. Optimize and innovate

- Plan for computational pathology responsibly
- The best time to plan for AI is during the initial architecture design
- Preserve structured metadata, robust slide-to-case linkage, controlled annotation workflows, versioned datasets, access governance, and an approach for model monitoring.

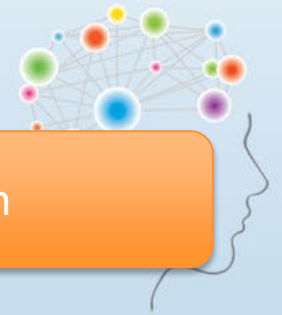
AI should enter clinical care only through a separate governance process that defines:

- The precise clinical claim and intended population.
- Local validation and external generalizability assessment.
- Human review and override responsibility.
- Algorithm version control.
- Drift monitoring and periodic revalidation.
- Bias, equity, privacy, cybersecurity, and medico-legal oversight.
- Integration into the pathologist's worklist rather than an isolated dashboard.

Decision support

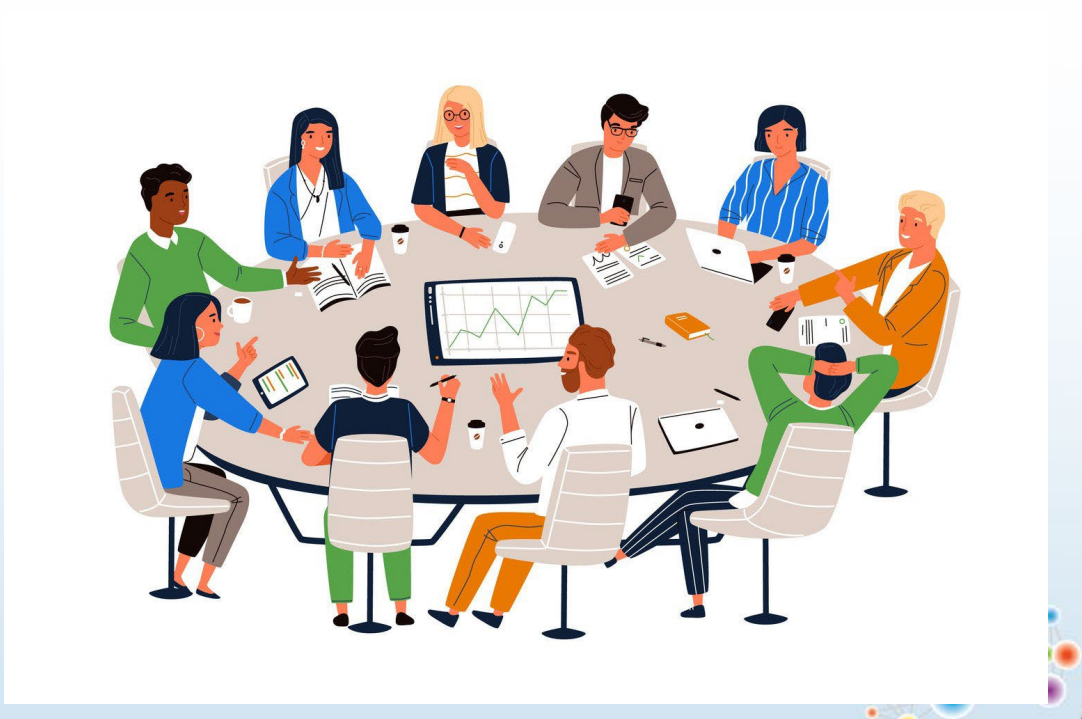
Prediction

Research



Practical institutional roadmap for Clinical Implementation of Digital Pathology

I. Define scope and value proposition
II. Map and redesign workflow
III. Build the platform
IV. Validate and train
V. Pilot and scale
VI. Optimize and innovate



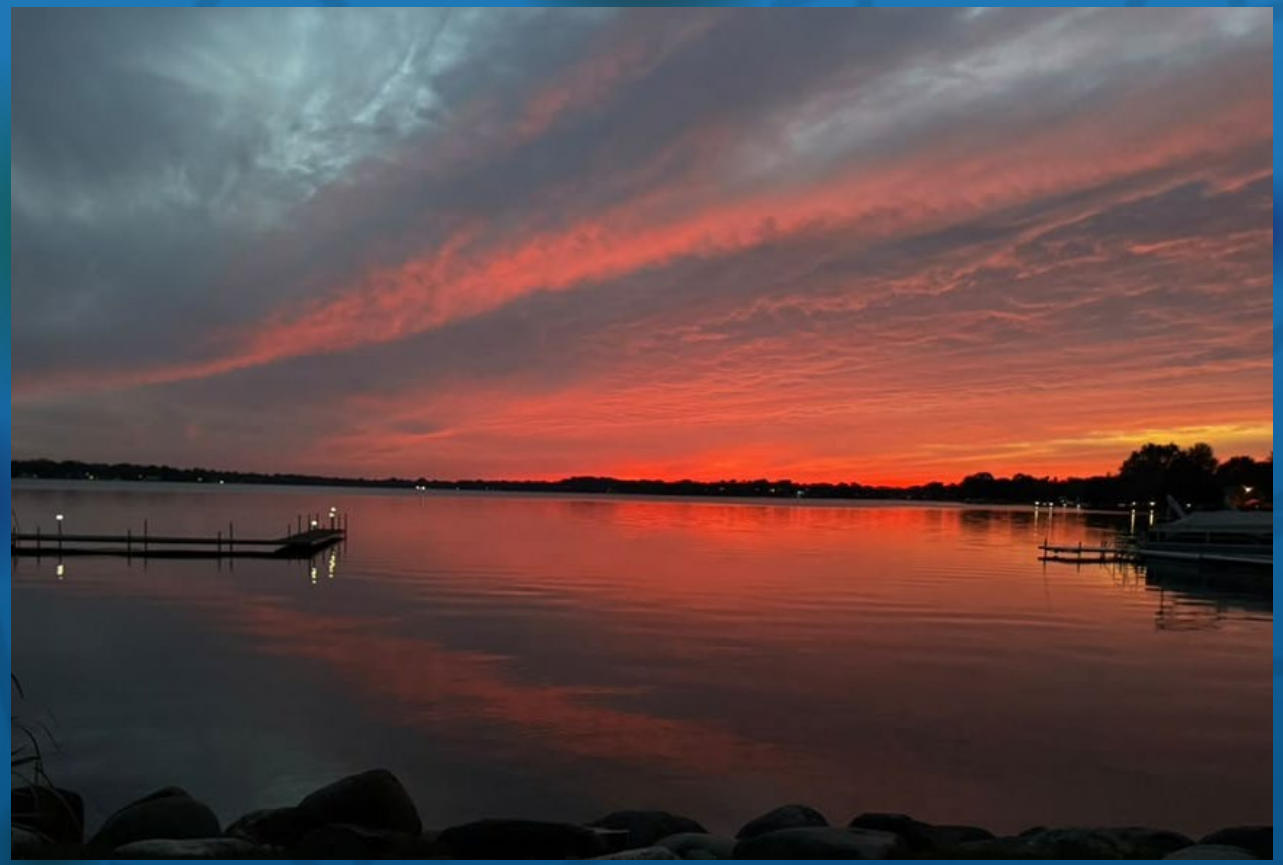
What is Successful Digitization?

- Is an institution-wide clinical transformation program.
- It requires clinical governance and accountability, rigorous validation, and a sustainable information architecture.
- It must demonstrate improve diagnostic service, resilience, collaboration, and data use while maintaining or improving quality, turnaround time, and patient safety.

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Digital Pathology
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Questions?

Comments!

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