



Considerations in the Implementation of Digital Pathology and Pathology Assist Applications

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Agenda

Evaluate Practice Scope and Business Needs

Assemble the Right Team of Stakeholders

Develop a Business Case

Disseminate information—communicate

Evaluate Practice Scope and Business Needs

Community and/or Hospital Based Practice? Academic?
Reference? Hybrid?



Clinical Use (primary/retrospective/consult diagnosis, frozen
section, rapid onsite evaluation, remote consultation)



Education, Research, Innovation



Information System (LIS, EMR) – Current and Future



Current Department/Institutional Revenue, Case Volumes
and Anticipated Growth

MUST HAVES AND EXPECTATIONS

Assemble the Right Team of Stakeholders



MUST HAVE

Team of Stakeholders

Medical Leadership

- Identify use case(s)
- End user, customer
- Decision-maker
- Road map contributor

IT Leadership

- Clinical systems, LIS/EMR
- Interface development
- Road map contributor

Operational Leadership

- Contribute to use case(s) identification
- Identify resource limitations
- Road map contributor
- Hardware decision-maker

C Suite Executives

- Contingency planning
 - » Stakeholder attrition
 - » Roadmap scope
 - » Resource constraints
 - » Project/program manager (direct report)
 - Facilitator: road map development, deliverables

Team of Stakeholders



Develop a shared understanding of roles and responsibilities

RACI: Responsible, Accountable, Consulted, Informed



Remove historical barriers

Identified during Define phase, SWOT analysis, etc.



Identify your institutions' high-level use case(s)

At our institution, for example: Clinical, Education, Research and Innovation informs requirements/RFP



Evaluate risk

Based on information gathered



Make decisions

SWOT Analysis

STRENGTHS

- Executive and AP Division Chief support
- Existing client interest and use cases (stain and return/consultations)
- Collaboration between ARUP divisions and MDs
- Enthusiastic attending pathologists
- Engaged resident/fellow group
- Some institutional experience w/ DP vendors
- Collaborative local and national contacts

WEAKNESSES

- Upfront investment cost
- Complexity of implementation
- Lack of clarity on future efficiency gains/cost savings
- Skepticism from some pathologists
- National downward trends in pathologists, while healthcare facilities continue to grow* (reflected in local market)

* [*Trends in the US and Canadian Pathologist Workforces from 2007 to 2017*](#)

OPPORTUNITIES

- Alignment with business strategy and academic mission
- **Potential** scalability of surgical and cytopathology
- Improved training and **Education** pipeline
- Capacity for data usage: data bank creation
- Research and Innovation
- Increase client retention through consultation
- Improve quality and reduce waste
- Recruitment/retention
- Space savings (*pathologist office footprint)
- Bridging between AP and CP
- Flexible support of future institutional growth Potential for storage cost reduction

THREATS

- Prioritization of high-margin projects
- Lack of capital
- Pathologist retention and recruitment
- Lack of clarity on data governance and ownership
- Changing regulatory environment
- **FDA Oversight and Regulation of Laboratory Testing**
- Risk of non-implementation: [*Why Kodak Missed the Digital Revolution After Starting it*](#)

Hardware & Software Evaluation and Selection

Define internal current state

- Process map
 - Detailed understanding of pre-analytic laboratory logistics including test ordering, barcoding, tracking, histology, signout
- Understand current rate limiting factors

Make decisions in the context of internal use case

- LIS interoperability
 - IT Stakeholders must be engaged in assessment RFP
- IT must ensure that vendor talk can be actualized
- SurgPath v. HemePath v. Cytology
- Pathology assisted devices (AI)
 - Evaluate for efficiency/quality improvement
 - Evaluate cost

Hardware & Software Decision Making

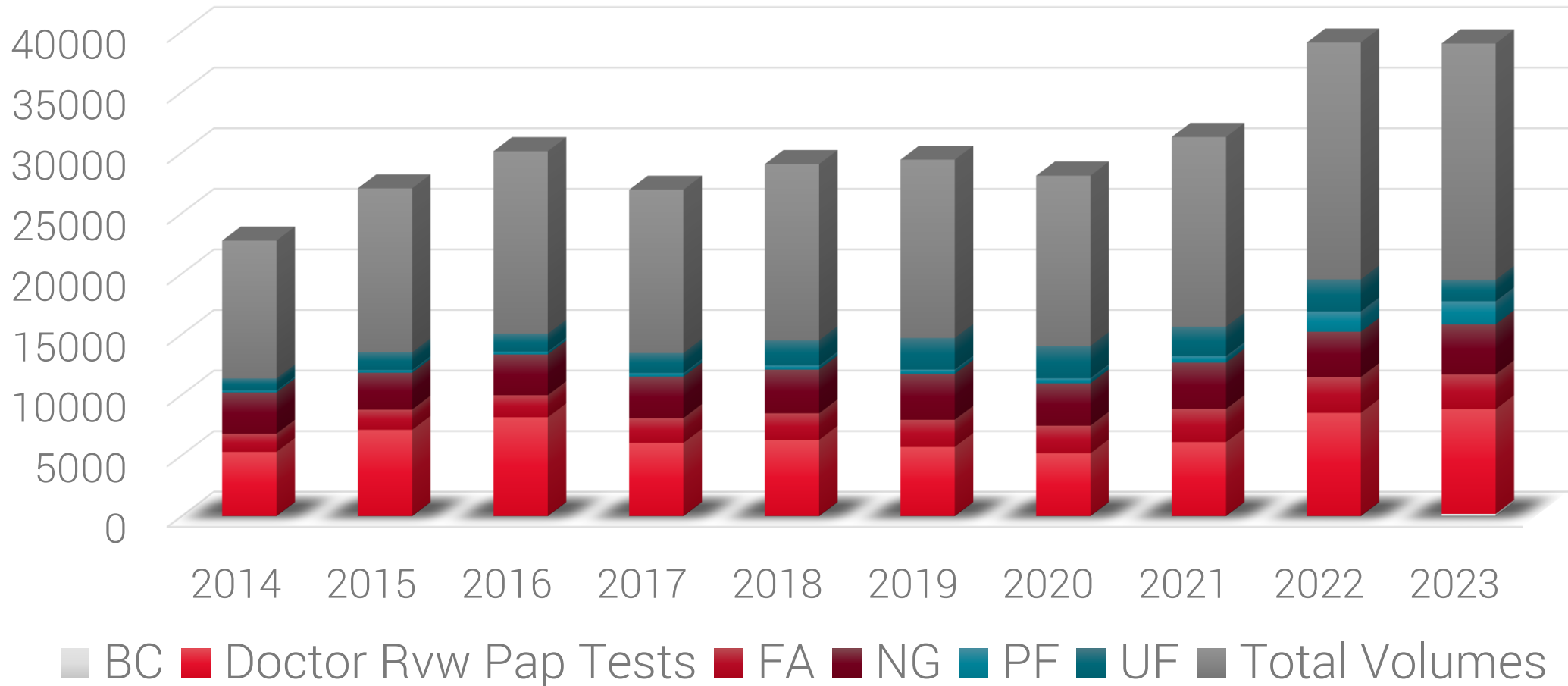
- Hands on demonstration with Vendors
 - » Develop in-house subject matter expertise
 - Engage interested internal parties (listen)
- Vet with professional peers with similar use cases

Key stakeholders will ensure appropriate personnel

e.g. IT LIS/EMR expertise, scanning workforce, data scientist, quality.

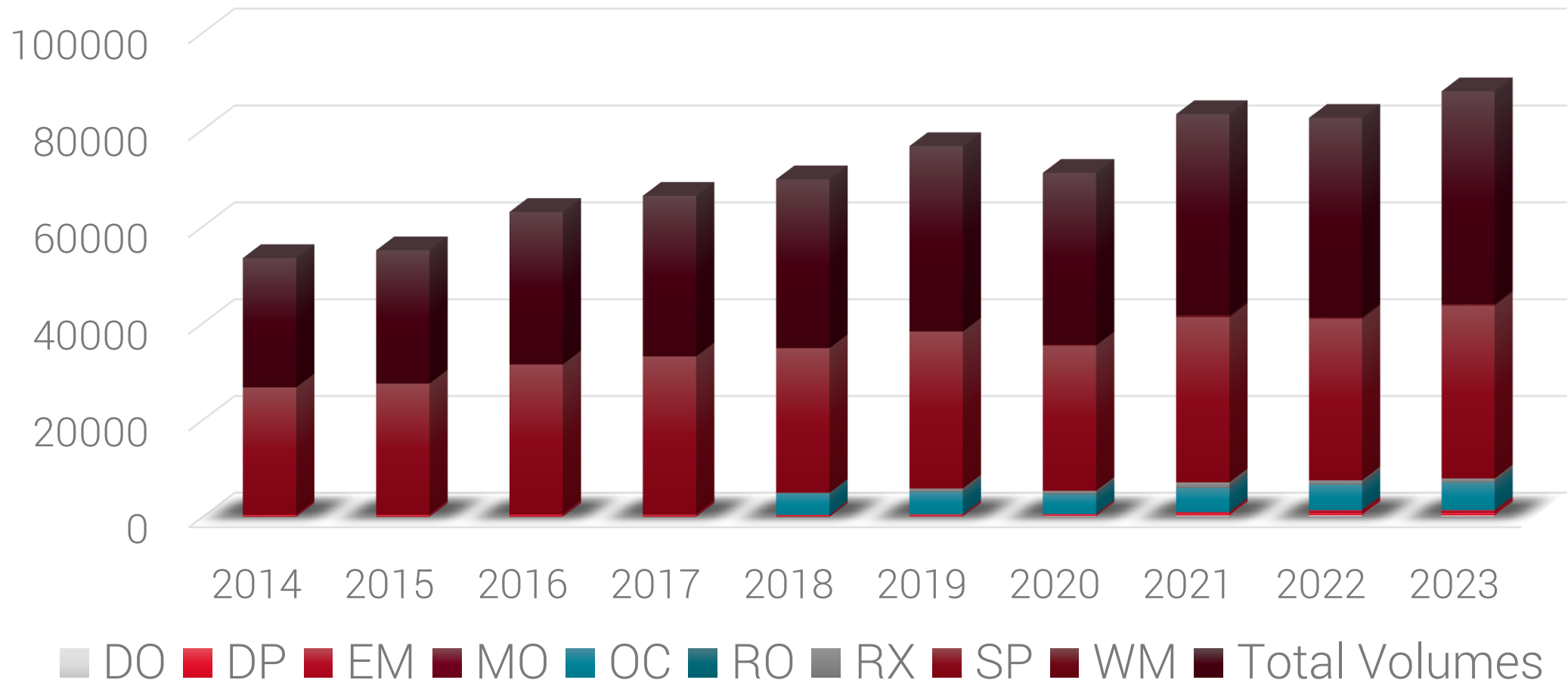
Analyze: Past and Current Slide Volume

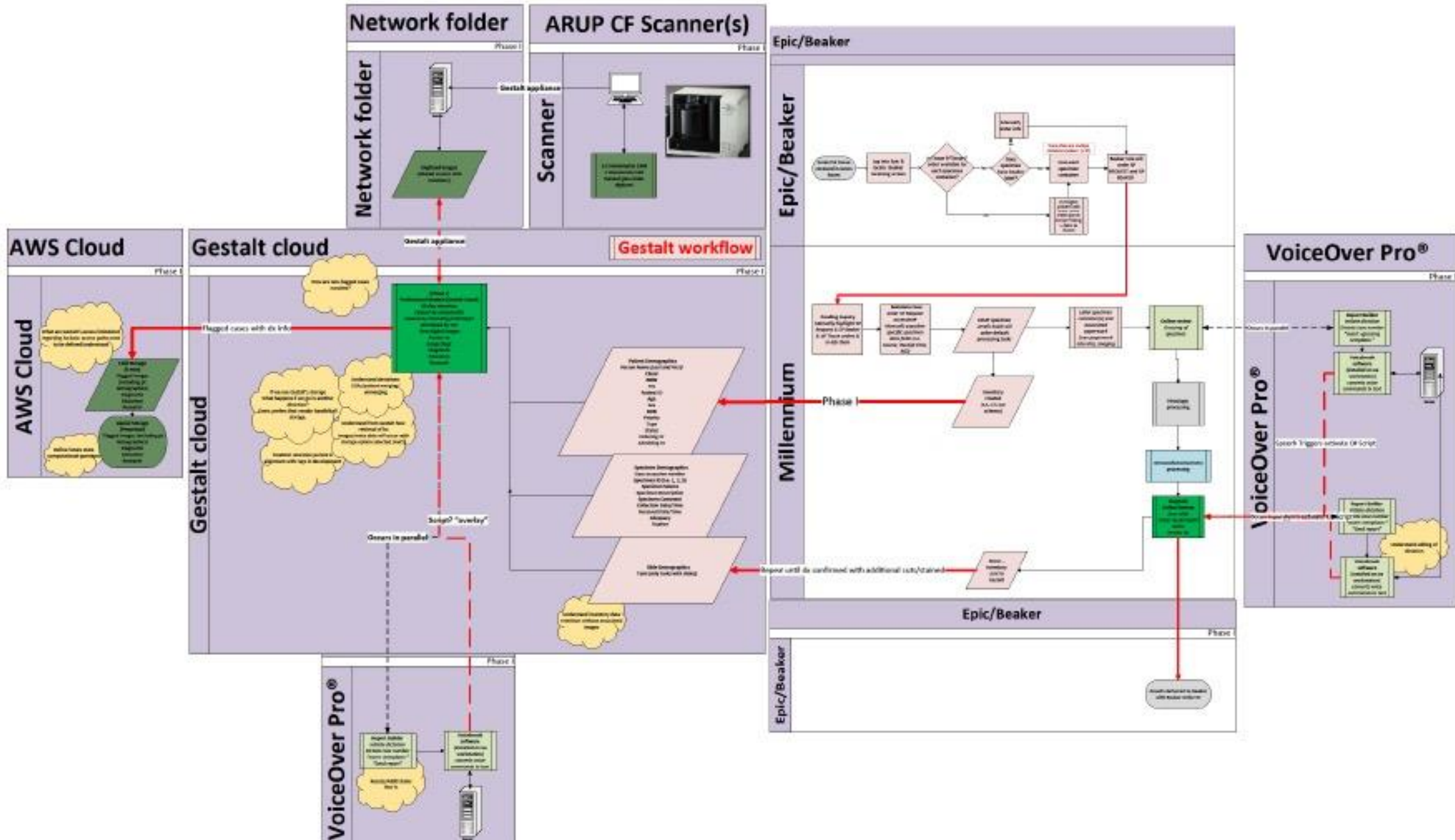
Cytology



Analyze: Past and Current Slide Volume

Surgical Pathology





Improve: Evaluating Risk

Implementation vs Non-implementation

- » Implementation
 - Inferior image quality
 - Lack of end user buy-in
 - End user availability (for validation)
 - Insufficient training
- » Non-implementation
 - eg [Why Kodak missed the digital revolution after starting it](#)

Resource limitations

- » IT Storage Capacity
- » Software/hardware technical support (ARUP)
- » Hardware: supply chain
- » Workforce availability
- » Space: scanning footprint
- » Commercial product viability

Improve: Evaluating Risk

Cybersecurity

- Data governance/rules
 - » How processed/handled
 - Client attrition plan
- Resource access (Breach)
 - » Scan/return process exposes network to risk
 - How secure are our Clients' network?
 - › e.g. incorrect URLs used
 - How is the industry addressing this?

Cybersecurity

- Data travel risk
 - » Dependent on workflow
- Data accessibility/longevity
- Data availability
 - » Cloud connection lost

Objectives and Outcomes



Scan Slides

Objective: Upgrade existing scanners to current technology

Outcome: Improved image quality, higher throughput, increased lab efficiency. Reduce waste, rework.



Access Images and Data

Objective: Interface SMS with LIS, automate management of work queues, enhance security

Outcome: Increased efficiency and accuracy at pathologist sign-out, improved client experience



Analyze Images

Objective: Assisted analyses, improve communication with lab, enable virtual collaboration

Outcome: Increased pathologist efficiency/capacity, improved TAT and patient care



Render Diagnosis

Objective: Integrate with voice recognition software, bidirectional interfacing results to LIS, capture data

Outcome: Increased pathologist efficiency/capacity, enhance data/metric tracking



Provide Training/Education

Objective: Build training sets and exams for trainees, track performance and productivity

Outcome: Support academic mission, enhanced resident and fellow training program, improved recruitment/retention



Enable Research

Objective: Access historical images and data bank

Outcome: Support academic/research mission, track patient outcomes



■ “...and Now, a Warning”

Lessons Learned



**NOW, A WARNING. NOW, A
WARNING?**

LESSONS LEARNED

“...and Now a Warning”

**Plan beyond
initial
deployment
1, 2-3, 5, 10
years**

**Develop a
contingency
plan for
attrition in
stakeholder
roles**

**Don't
underestimate
the IT lift**

**If you think
you have
enough IT,
you don't**

**Attend the
Digital
Pathology
Association's
annual
conference**

**Review of
publications
that align with
your
institution's
use cases**



**Culture shift
is necessary.**

Notable Resources and Publications

- Hanna MG et al. Integrating digital pathology into clinical practice. *Mod Pathol*. 2022 Feb;35(2):152-164. doi: 10.1038/s41379-021-00929-0. Epub 2021 Oct 1. Erratum in: *Mod Pathol*. 2021 Oct 13;: Erratum in: *Mod Pathol*. 2021 Nov 9;: PMID: 34599281.
- Dash RC et al. *J Pathol Inform*. 2021 Mar 24;12:16. doi: 10.4103/jpi.jpi_98_20. PMID: 34221632; PMCID: PMC8240547.
- Lujan G et al. Dissecting the Business Case for Adoption and Implementation of Digital Pathology: A White Paper from the Digital Pathology Association. *J Pathol Inform*. 2021 Apr 7;12:17. doi: 10.4103/jpi.jpi_67_20. PMID: 34221633; PMCID: PMC8240548.
- Ardon O et al. Quality Management System in Clinical Digital Pathology Operations at a Tertiary Cancer Center. *Lab Invest*. 2023 Nov;103(11):100246. doi: 10.1016/j.labinv.2023.100246. Epub 2023 Sep 1. PMID: 37659445.
- <https://digitalpathologyassociation.org>

THANKS | TEAM RECOGNITION

Executive Stakeholder	Julio Delgado, MD
IT Leadership	Gloria Pitt, Pam Alexander, Bryce Limb
AP Section Chief Operational Director Group Manager	Kajsa Affolter, MD Amy Sandoval, MLS(ASCP) ^{CM} Lindsey Fairbourn, HTL(ASCP)
Cytology Section Chief Group Manager	Ben Witt, MD Jeff Hadley, MBA, BS, CT(ASCP)
HemePath Section Chief Group Manager	Madhu Menon, MD, PhD/Anton Rets, MD Jeff Chumley, MS, MLS(ASCP) ^{CM}
ST MolOnc Chief/Cytogenetics Chief Operational Director Group Manager(s)	Anna Matynia, MD/Erica Andersen, MD, PhD Mike Graczyk, MBA, MLS(ASCP) ^{CM} MB Chantry Clark, C(ASCP) ^{CM}
Digital Pathology Project Manager	Sumie S. Edwards, MLS(ASCP) ^{CM}
IT Support	Amy Stradley, Marvin Lopez, Smitha Singh
AP Support (SMEs)	All current scanning groups







A nonprofit enterprise of the University of Utah and its Department of Pathology