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Insight Brief

Digital Pathology Implementation

Introduction

Digital pathology has been around for decades with various levels of adoption globally. There are several benefits to digitizing pathology glass slides. First, pathologists are able to review the slides remotely or consult with a remote pathologist without the potential of losing the glass slide.[1,2] Second, a digital image opens the gateway to machine learning to increase accuracy and efficiency in the pathology workflow from organizing cases with the prioritizing the most pressing cases, assisting with identification of cancer.[2]

Within the last few years, especially since COVID, there has been a rapid adoption of digital pathology workflow. However, there still remains some barriers to wide spread adoption. Within one local system, it is easy to set-up a workflow that includes a scanner, Image Management System (IMS), a pathologist workstation, and storage. When you try to set-up multi-site systems, especially in different countries, regulations as to what is approved for clinical use will vary. Another barrier is the rigid approved workflows. If an algorithm is approved for use with only one type of scanner with one IMS, this limits the ability of local pathology labs' implementation since they will not be able afford buying multiple digital pathology workflows for specific use case scenarios. This leads into the last barrier, the lack of interoperability. Each scanner has their own proprietary file format. Even if they all use DICOM, they each have their own methods for the image compression aspect (JPEG-XL, JPEG2000, so forth). So no two DICOM files are actually the same. The IMS can be on-prem or in the Cloud. The IMS could have ICC enabled or not enabled. The IMS could be research based or clinical based, but not both even if built on the same initial programming architecture. The lack of color calibration standards that leads to scanners creating different color renditions to their digital images. Not to mention the pathologist workstations having a wide range of monitors for viewing from a standard desktop monitor to a medical grade monitor that effect the final colors visualized by the pathologists. These are some of the barriers that have slowed down the adoption of digital pathology globally.[2]

With the above in mind, let's discuss further what we faced implementing a digital pathology workflow on a global scale and how we tried to overcome these challenges.

Our network consists of five anatomic pathology laboratories located in four countries: two sites in the United States — Valencia, California, and Research Triangle Park, North Carolina — as well as sites in Edinburgh, Scotland; Singapore; and China. Establishing a harmonized global workflow required acknowledging differences in local regulations, technical maturity, staffing models, and infrastructural capabilities. The strategic challenge was not only to create unified standards but also to ensure that each laboratory could achieve equivalent performance regardless of regional constraints. Harmonization extended beyond hardware; it required establishing shared operating procedures, synchronized scanner configurations, uniform validation strategies, and consistent QC measures.[2]

Global operations must also consider cross border data flows; for example, China mandates that patient data remain local, influencing where images can be stored or processed such as with algorithm development. Achieving alignment required constant coordination among clinical, IT, and regulatory stakeholders, along with the establishment of feedback loops so that issues arising in one region could be addressed in all regions. The strategic advantage of a global digital pathology workflow includes increased resilience — allowing a global pool of pathologists to support workload balancing — improved turnaround times, and enhanced ability to run multi regional clinical trials efficiently.

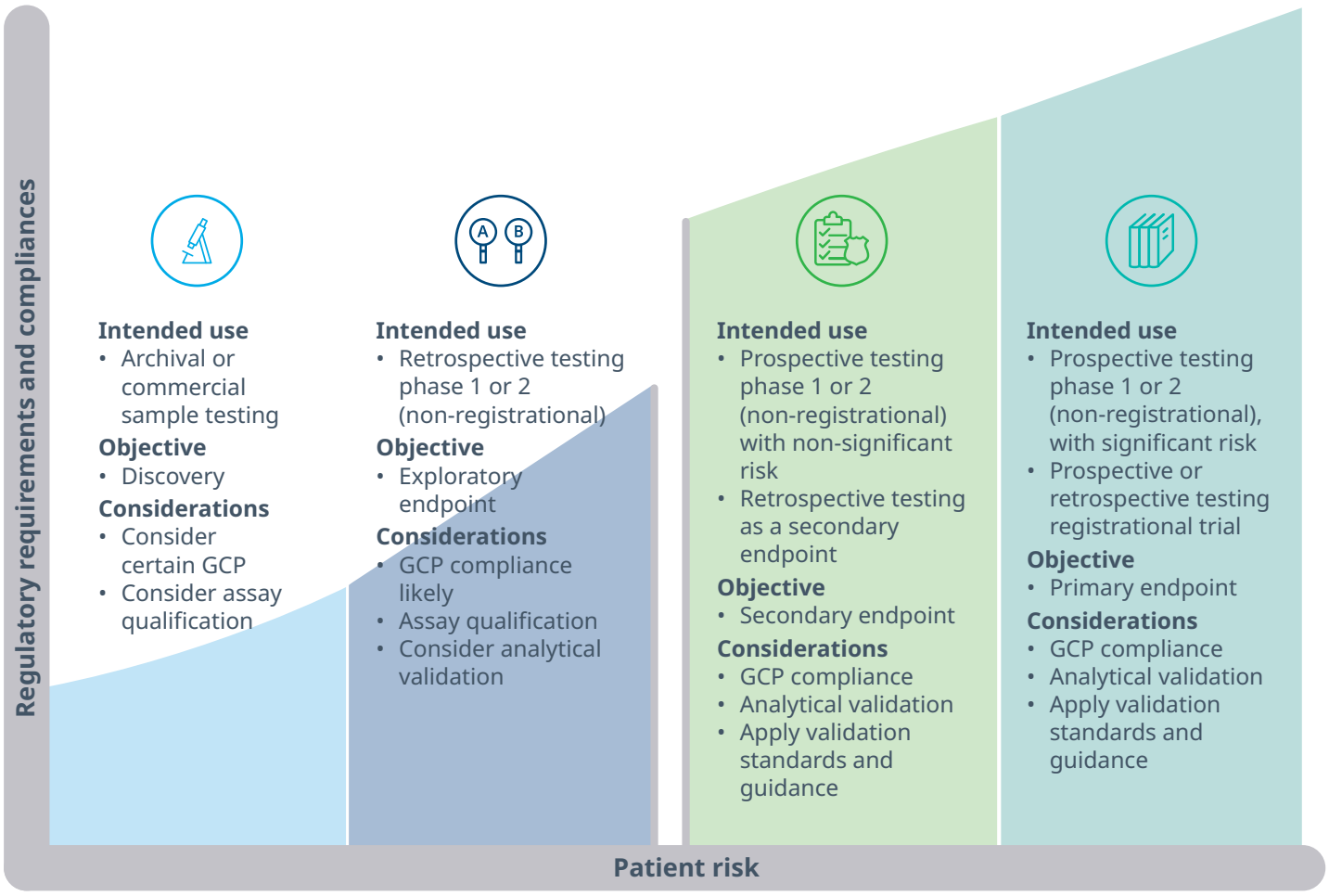
For this successful transition to a global digital pathology workflow, we first identified a global team. Identifying a global team ensures the initiative is grounded in shared expertise and leadership. Early in the process, the organization prioritized bringing together scientific leaders, operational specialists, validation experts, and cross functional support staff, ensuring that each aspect of the workflow — from slide preparation to AI integration — had a dedicated champion.

Second, the global team needed a deep understanding of regulatory requirements governing each component of the diagnostic process. This required evaluating the compliance requirements for each instrument and workflow step, including FDA/IVDR considerations, restrictions on digital review for certain tests, and data privacy rules affecting storage and transfer.

The level of validation, compliance oversight, and regulatory requirements varies according to the intended use of digital pathology within a clinical trial and the associated level of patient risk (Figure 1). As patient risk and clinical impact increase, so do the regulatory and validation requirements for digital pathology.[2]

Figure 1: A clinical trial study design determines this risk to the patient who participates in the study

The greater the risk to the patient, the greater the requirements that must be met, regardless of the phase of the clinical trial. The intended use of a digital application or tool in a clinical trial is the largest factor that drives the regulatory requirements. Prospective testing, in which a lab test result supports eligibility for enrollment in the clinical trial, carries greater risk than retrospective testing, in which the result does not have an impact on patient management. The use of the result to meet a study objective (i.e., endpoint) also impacts the level of compliance, which can be a separate but not mutually exclusive consideration. However, the permutations of a clinical study design can be endless, and each clinical study must be considered independently.



In some regions, certain tests cannot be reviewed digitally and mandate glass slide evaluation, requiring workflow accommodations to maintain compliance. Data residency laws, especially with the use of ML/AI for data outputs, required the team to implement an IT cloud infrastructure that could process and store this information within the defined regulatory borders. Storage expectations vary across institutions; while private practices may retain images briefly as they have the glass slides archived, a clinical research environment may require retention of digital images for 10 to 20 years. This long term storage obligation affects capital budgeting, infrastructure planning, and compliance oversight. Finally, return on investments assessments must consider not only purchasing costs but operational gains such as reduced shipping, improved QC, faster turnaround, and enhanced diagnostic consistency. This underscores the importance for a global team to include regulatory and IT personnel to be included in the planning before any workflow is implemented.[2]

Now let's discuss the implementation of a digital pathology workflow. The implementation focused on systematically deploying scanners, viewers, IMS platforms, and integrated reporting systems across all five laboratories. A dependable IT team was essential for integrating scanners, IMS platforms, reporting tools, and QC processes across all laboratories. Validation procedures were performed according to CAP guidelines to ensure that each instrument and workflow step met diagnostic grade standards. These validations included pathologist concordance studies, image quality assessments, and performance checks across different tissue types. During and after implementation, regular review of potential software updates (ie scanners, IMSs, etc) for validation and deployment occur on a biannual basis to ensure consistent performance. All Standard Operating Procedures (SOPs) were revised to reflect new workflows, including slide scanning, data upload, image QC, and reporting protocols.

Once a system is implemented, the focus needs to be set on training and change management to ensure the workforce could adopt the new tools confidently. This transition affects not only laboratory staff but also pathologists, sales teams, clients, and auditors, making comprehensive planning essential. This required an effective communication strategy for stakeholder education. Laboratory staff require training on new equipment, including scanner operation, QC procedures, and troubleshooting. Pathologists need training to ensure comfort and competence with digital review, often involving concordance studies and supervised reporting sessions. Business directors and sales teams also need education on how to communicate new capabilities to clients and sponsors, ensuring accurate representation of workflow improvements and service offerings. This includes updating customer-facing materials — including brochures, websites, and sales collateral. Change management includes updating clients about workflow transitions, communicating implementation timelines, and managing expectations about turnaround time or data availability during the transition period.[2]

Lastly, as a global team, we are responsible for the continued success of the digital pathology workflow. This requires continuous monitoring of the current systems to ensure structured feedback loops between staff, IT teams and leadership to implement any changes required. In addition, the global team reviews new technologies and changes to regulations to identify potential and/or required changes to the digital pathology workflow. The truly successful global digital pathology places an emphasis on building organizational readiness so that digital pathology becomes not a one time project but a permanent, evolving operational capability, which we have successful instituted at our global anatomic pathology laboratories.[2]

References

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CONTACT US

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08.2026.RDS. 26-CRS-2848-08AUG