

# CLINICAL INSIGHT

OUR SERIES OF TECHNICAL REPORTS WRITTEN BY OUR TEAM OF GLOBAL CENTRAL LAB EXPERTS ON ISSUES AFFECTING CLINICAL TESTING TODAY



## DIGITAL PATHOLOGY'S ROLE IN REVOLUTIONIZING GLOBAL TRIALS

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With only 20,000 pathologists in the United States<sup>1</sup>, a number that represents 80 percent of all pathologists worldwide, the medical and research fields are confronting a critical shortage of these skilled doctors despite the growing number of new cancer cases being diagnosed every year. This shortage is projected to increase exponentially in the coming years as the demand for pathology services in clinical trials grows and as more pathologists look to retirement.

These realities have placed mounting pressure on the industry to seriously consider innovative digital imaging technology, which until recently was only used for consultation and/or consensus opinions and not for primary diagnosis in the United States.

Now, the FDA has granted regulatory clearance of the first whole slide imaging (WSI) system for digital pathology for primary diagnostic use in the United States, allowing for the review and interpretation of digital surgical pathology slides prepared from biopsied tissue.

This clearance suggests noteworthy progress in the industry's wider acceptance of digital pathology systems and may be key to scaling pathology resources for global trials.

### EMBRACING INNOVATIVE IMAGING TECHNOLOGY

Encompassing telepathology (viewing an image on a computer display rather than a microscope) and image analytics (extracting data from digital images), digital pathology has been in use for more than 30 years. Adoption has remained slow in part because of unclear cost advantages, but within the last five years, the technology has improved enough to play a larger role in diagnostic pathology.

Unlike digital radiology in which digital technology replaces the film, digital pathology still requires a glass slide. Yet once the glass slide has been digitized, it can quickly and efficiently be viewed by multiple pathologists simultaneously.

With digital images, critical areas of the slides themselves can also be documented within the diagnostic report and included as part of a data set to provide important additional information. The ability to easily incorporate this data alone and streamline laboratory processes, makes consultation and collaboration more efficient and timely.

In addition, regulatory support for digital pathology systems continues to gain traction and may signal a shift in the industry's readiness to consider uses beyond just consultation.

## CLINICAL TRIALS SEE A FUTURE IN DIGITIZED PATHOLOGY

Digital pathology presents an opportunity for central laboratories to support highly targeted therapeutics and precision medicine even further, offering many advantages to both diagnostic and clinical trials testing, including the ability to access a broader network of skilled pathologists with sub-specialty expertise. Having access to enough pathologists or to one with expertise in a particular disease state is one of the major barriers facing clinical trials – particularly those that require an anatomical or surgical pathologist.

Because digital pathology systems enable images to be sent and reviewed remotely, central labs are no longer restricted by geographical location and can recruit pathologists needed with a certain expertise to participate in a trial. Additionally, pathologists in distinct locations can quickly and efficiently collaborate on difficult cases without having to wait to review slides sent by mail.

Central labs anticipating this shift have already started the validation process to begin offering digital pathology as part of their repertoire of clinical trial testing services and offer the best chance of meeting trial demands in a more cost-effective and timely manner.

ACM Global Laboratories has recently added digital pathology tools to bolster its anatomic pathology clinical trial services with the use of Leica Biosystems' Aperio AT2, a high volume, digital whole slide scanner. The Aperio AT2 is setting new standards in digital pathology in its ability to consistently deliver precise electronic slides that are available for remote viewing in less than a minute.

Using a whole slide scanner not only expands upon the anatomic pathology testing performed at ACM, but also increases its ability to scale pathology resources for sponsors and CROs conducting global trials.

For more information on our digital pathology capabilities, visit our website at [www.acmgloballab.com](http://www.acmgloballab.com), call +1-866-405-0400 or email [rcarlson@acmlab.com](mailto:rcarlson@acmlab.com).

## REFERENCES

1. The U.S. Anatomic Pathology Market, Forecast & Trends 2016 publication

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## BENEFITS

### OF DIGITIZED PATHOLOGY

- Access to network of skilled pathologists
- Opportunity to directly incorporate the critical image into the study dataset
- Increases in the availability and access to important diagnostic skill sets
- Enhanced collaboration and consultation on difficult cases
- High throughput for anatomic pathology
- External sharing and collaboration (institution to institution)
- Internal sharing (Hub & Spoke Network) and collaboration
- Integrated with hospital and laboratory information systems
- Fast file review and transfer
- Computer algorithms can be applied to assist in areas of interest
- Simplifies laboratory workflows