# Moving Down the Digital Path
# The Next Evolution in Clinical Trials Testing

The continued emergence of personalized medicine alongside the need for more consistent and less variable tissue analysis and interpretation has led to an increased reliance on central laboratories to perform anatomic pathology testing and services in support of clinical studies. This demand, coupled with a growing shortage of pathologists worldwide, has also placed considerable pressure on the industry to more seriously consider innovative digital imaging technology, which until recently was only used for consultation and/or consensus opinions and not for primary diagnosis. 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 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 help pave the way for their use in clinical trials sooner than expected.

## Enhanced Collaboration and Consultation

Digital pathology, which encompasses telepathology (viewing an image on a computer display rather than a microscope) and image analytics (extracting data from digital images), has been around for more than 30 years, yet only within the last five years has the image quality improved enough to have a role in diagnostic pathology. Adoption has remained slow in part because the cost advantage is still unclear. 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, thereby making consultation and collaboration more efficient and timely.

WSI is one of the more common imaging modalities used by pathologists worldwide and involves scanning conventional glass slides to produce digital slides.

Computer algorithms can be applied to digitized slides to assist pathologists in the identification of areas of interest or in automatically scoring the positivity of various immunohistochemical stains.

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## The Central Lab's Role in Digital Pathology

Central laboratories are already playing an increasingly vital role in guiding sponsors and CROs in selecting specific patient populations to participate in trials based on pathology results, and digital pathology presents an opportunity for them to support highly targeted therapeutics and precision medicine even further. Because the images produced using these solutions are digital, critical areas of the slides themselves can be documented within the diagnostic report and included as part of the data set to provide important additional information. The ability to incorporate the area of interest right into the electronic dataset allows other pathologists working on the trial to quickly see the correlation between the interpretation that the pathologist rendered and the image being reviewed. Additionally, pathologists in distinct locations can quickly and efficiently collaborate on difficult cases without having to wait to review slides sent by mail.

## Sub-Specialty Access

More targeted approaches in clinical development have also placed a spotlight on the need for access to pathologists in disease subspecialties. When it comes to incorporating computer image analysis into a pathologist's diagnostic tool set, digital pathology offers 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 as many pathologists needed with a certain expertise to participate in a trial.

With demand for pathological services in clinical trials on the rise and anatomic pathologists in increasingly short supply, digital pathology technology may hold the key to sponsors and CROs looking to scale pathology resources for global trials. 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.

Central labs anticipating this shift have 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.

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