2015 Science Writers Symposium

Lab Tour: Digital Pathology

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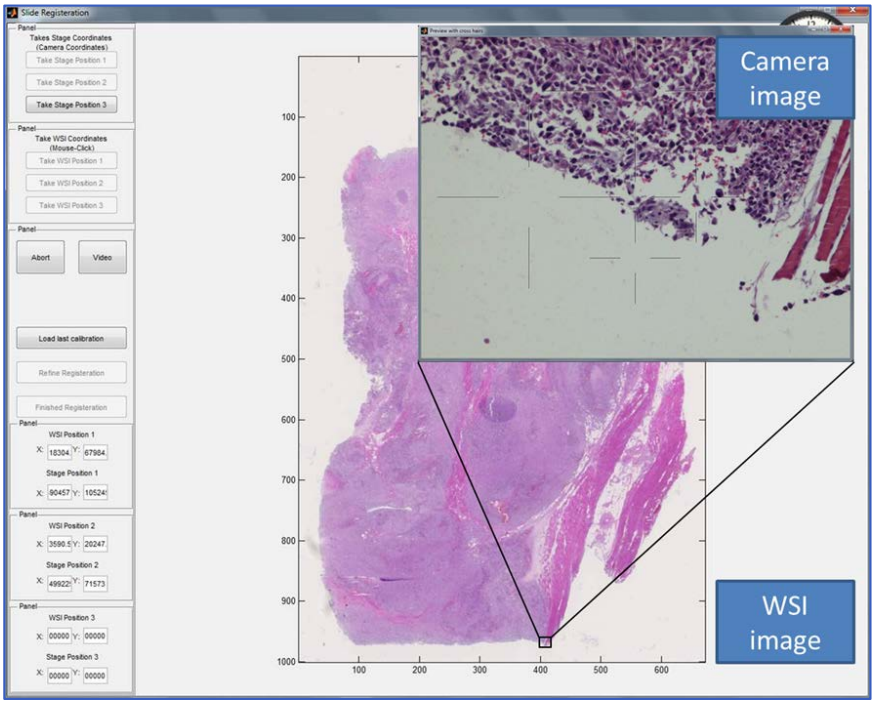

A real-time camera image of the microscope view is matched to the digital whole slide image (WSI), an image scanned at another time and place. This matching is referred to as registration. Registration permits the pathologist to evaluate the exact same locations and features of a slide on a microscope and on a computer monitor. Consequently, we can reduce or eliminate a large source of variability in the studies with pathologists; namely, we reduce the variability in what the pathologists are looking at.

Pathology is lagging behind other parts of medicine in its use of digital technology. This is because a core technology, the scanner that digitizes the glass slide, has not been approved for general use. Primarily, the methods to evaluate technical and pathologist performance have not been adequately developed.

The FDA is exploring, developing, and demonstrating methods to evaluate the technical performance of the scanner, also known as a whole slide imaging device (WSI). The FDA is also designing, executing, and analyzing studies that determine how well pathologists perform when using one of these systems. This research will yield templates and protocols that industry can follow to generate evidence that their systems are safe and effective to use. This research will also provide information on which technical characteristics are important and how they impact pathologist performance.

Adequately understanding technical characteristics and their impact on pathologist performance can potentially reduce the size, cost, and duration of clinical studies. This can lead to clinical trial strategies that balance the enormous scope of microscope uses against feasibility and rigor.

Finally, we develop and share software tools for collecting and analyzing data, and we are leading a working group in this area to engage the community, access expertise, and build consensus.
https://nciphub.org/groups/wsi_working_group

Questions? Contact FDA's Office of Media Affairs at 301-796-4540 or fdaoma@fda.hhs.gov