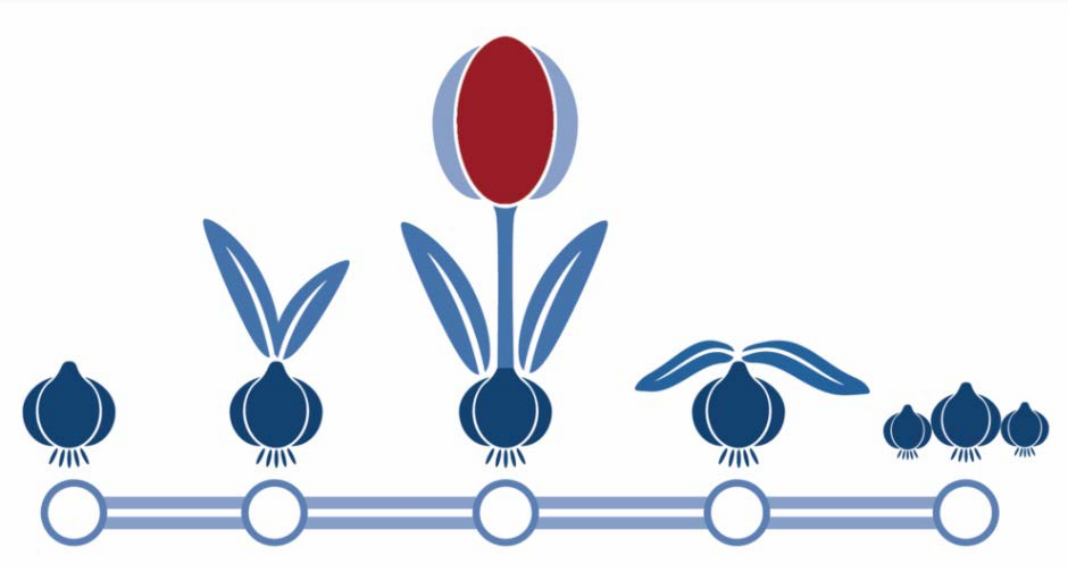
From: Alliance for Digital Pathology
To: Gallas, Brandon D.
Subject: Real-world data for remote sign-out beyond emergency use
Date: Wednesday, May 13, 2020 5:11:19 PM



The Alliance for Digital Pathology

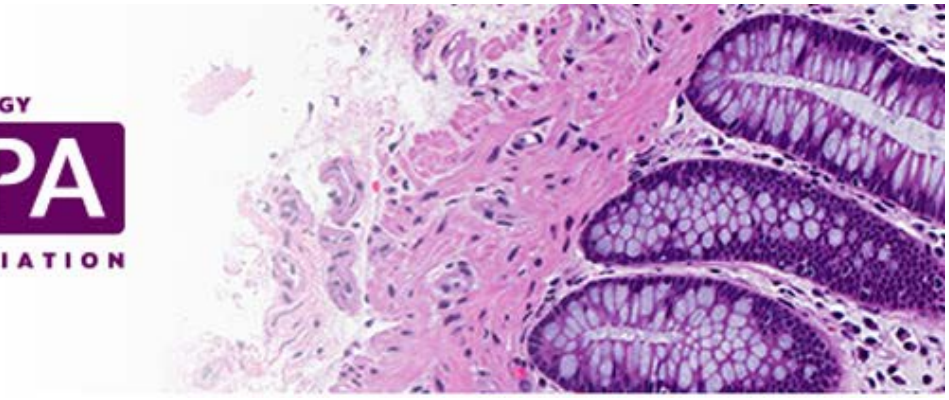
The Alliance is pleased to announce our support in a new project from the DPA:

Real-world data for remote sign-out

The Digital Pathology Association (DPA) is currently conducting a survey on how digital pathology is being used in remote sign-out. Both the CMS and the FDA have relaxed regulations in order to enable pathologists to work remotely with digital pathology in order to maintain high quality patient care during the COVID-19 pandemic.

Take the Survey

The full message from the DPA is copied below:



*"Never let a good **crisis** go to waste" — Winston Churchill*
"Do what you can, where you are, with what you have." — Teddy Roosevelt

Dear pathologists, trainees and lab professionals,

The Digital Pathology Association (DPA)* has been advocating the remote sign-out emergency use and needs your help to assess the safety and validity of remote sign-out of pathology cases. If you are doing remote sign-out or plan to do it, please participate in this short (5-10 minutes) confidential survey. Your experience will help understand and evaluate the use of this technology beyond the current pandemic. We request that you complete this survey no later than **Monday, June 1, 2020.**

Until recently, in several countries, remote sign out was not allowed. Due to the national public health crisis and the need to avoid exposure risks to health care providers, patients, and the community, authorities from different countries have temporarily allowed pathologists to review pathology slides remotely**. In addition, in some countries specific guidance has been released regarding the remote use of digital pathology systems and in US this includes systems that have not been cleared***.

In the United States, these actions mean that primary diagnoses can be rendered

from a non-CLIA-licensed site as long as certain criteria are met. The remote setup may utilize a non-FDA approved consumer grade monitor under condition the system is properly validated.

At the time of this crisis and months beyond, the DPA is committed to partnering with other entities such as the College of American Pathologists (CAP) and the Alliance for Digital Pathology to help make a positive impact in this difficult situation. One of the key initiatives that the DPA is working on is to gather real world data collection regarding remote sign-out for primary diagnosis and monitor/display. This data collection will help the DPA and regulators better understand how remote sign out is being conducted. Specifically, the goal will be to:

1. Collect data from pathologists using remote sign-out with whole slide images regarding scanners, operating systems, displays, etc.
2. Evaluate if patient's pathology specimens can be safely diagnosed remotely, utilizing different displays
3. Collect data to analyze if remote primary diagnosis can be safely performed and what work will be needed to drive safe adoption
4. Use such data to provide guidance and/or Quality Assurance metrics to users on how to best validate and support safe remote sign-out
5. Show vendors what is needed, such as limitations in their technology to adequately support remote sign-out

In order to help us better prepare for this data collection project, we are seeking your much-needed help in completing this brief survey:

https://www.surveymonkey.com/r/DPAremotesignout

We appreciate your consideration and look forward to the productive engagement of all pathologists as well as laboratory and IT professional staff to provide critical real-world data. This effort will help the DPA work with regulatory agencies such as the FDA to continue discussions how to develop favorable and flexible guidance which could extend the remote use of innovative technologies such as digital pathology and artificial intelligence tools to help us weather this pandemic and better prepare for future disasters.

The DPA and its members greatly appreciate your participation in this survey and intend to publish the results.

*The DPA is a nonprofit organization comprised of Pathologists, scientists, technologists, and industry representatives dedicated to advancing the field of digital pathology
**accessed April 24, 2020
http://www.clpmag.com/2020/03/digital-pathology-association-commends-cms-waiving-restrictions-remote-pathology-diagnoses/
https://www.usa.philips.com/healthcare/resources/landing/philips-intellisite-pathology-solution
https://www.leicabiosystems.com/news-events/news-details/article/leica-biosystems-receives-fdas-enforcement-discretion-for-use-of-aperio-imagescope-dx-viewing-softw/News/detail/

https://digitalpathologyalliance.org