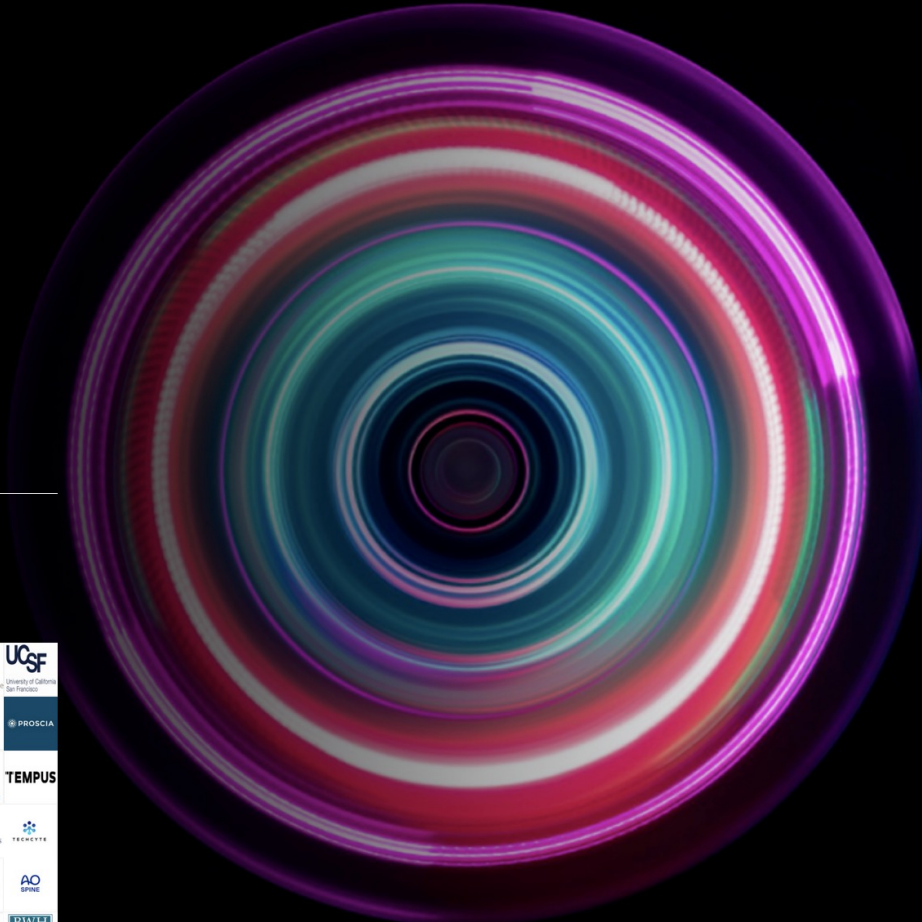


Pathology Innovation Collaborative Community

Plcc

The Alliance for Digital Pathology

A collaborative community with FDA participation



Executive Summary

Pathology Innovation Collaborative Community (PIcc)

The Alliance for Digital
Pathology



Executive Summary 10 Key Points

- Regulatory Science Initiative
- MDIC acts as the formal convener
- Aims to facilitate innovations in pathology
- Advance safety and effectiveness evaluations
- Harmonize approaches to speed up delivery to patients
- FDA participation (CRDH, OSEL)
- Collaboration in the pre-competitive space (anti-trust monitoring applies)
- Open to all stakeholders (public and private)
- Emphasis on benefit to patients
- Membership is free and all materials are available

www.pathologyinnovationcc.org

Plcc Alliance


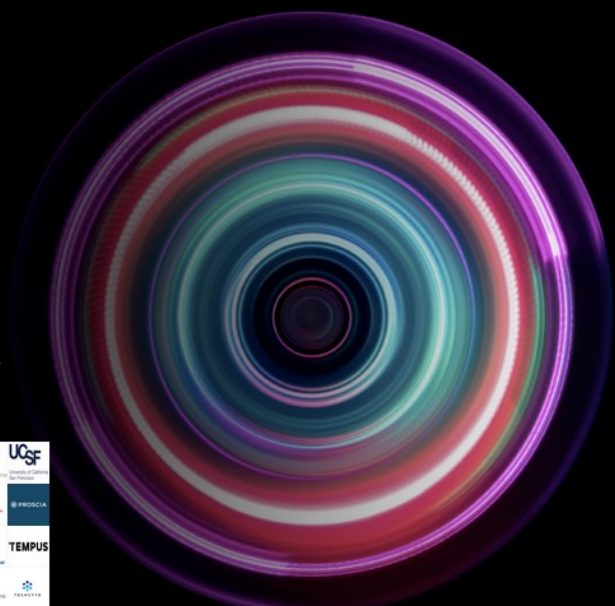
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Pathology Innovation Collaborative Community

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The Alliance for Digital Pathology

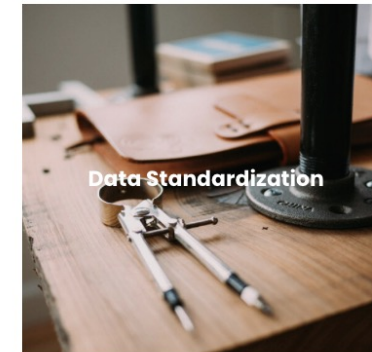
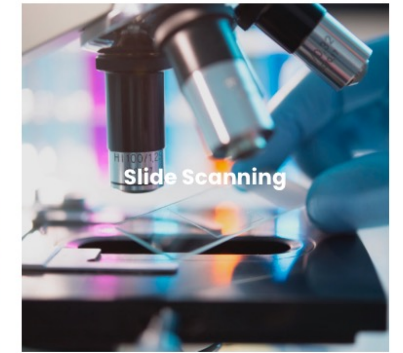
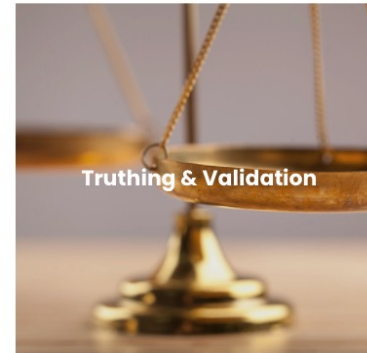
A collaborative community with FDA participation



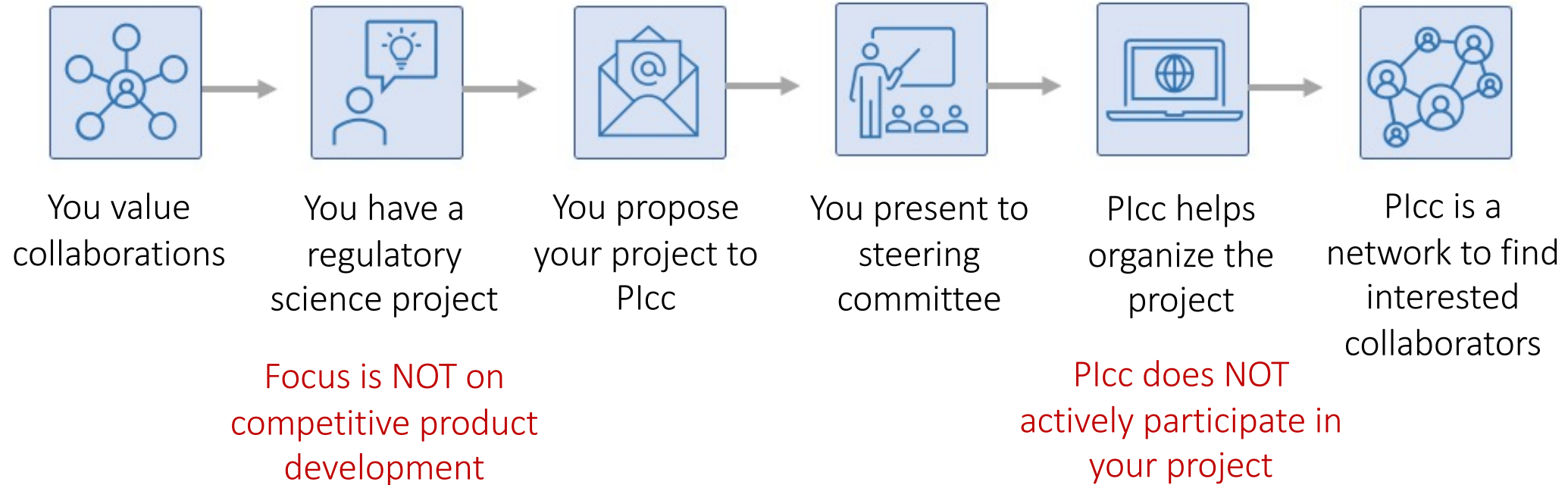
How we operate

- PICC is providing the infrastructure and platform for individual projects
- Currently >20 projects
- Aggregation into 9 workgroups (when applicable)

Working Groups



What does this look like, practically?



“Plcc is a collaborative community that provides the infrastructure to connect stakeholders.”

Accomplishments

Metrics

467 Members

6 full-membership meetings

5 web-based speakers/events

5 steering committee meetings

9 workgroup meetings

3 peer-reviewed publications
(concept, truthing, payor,)

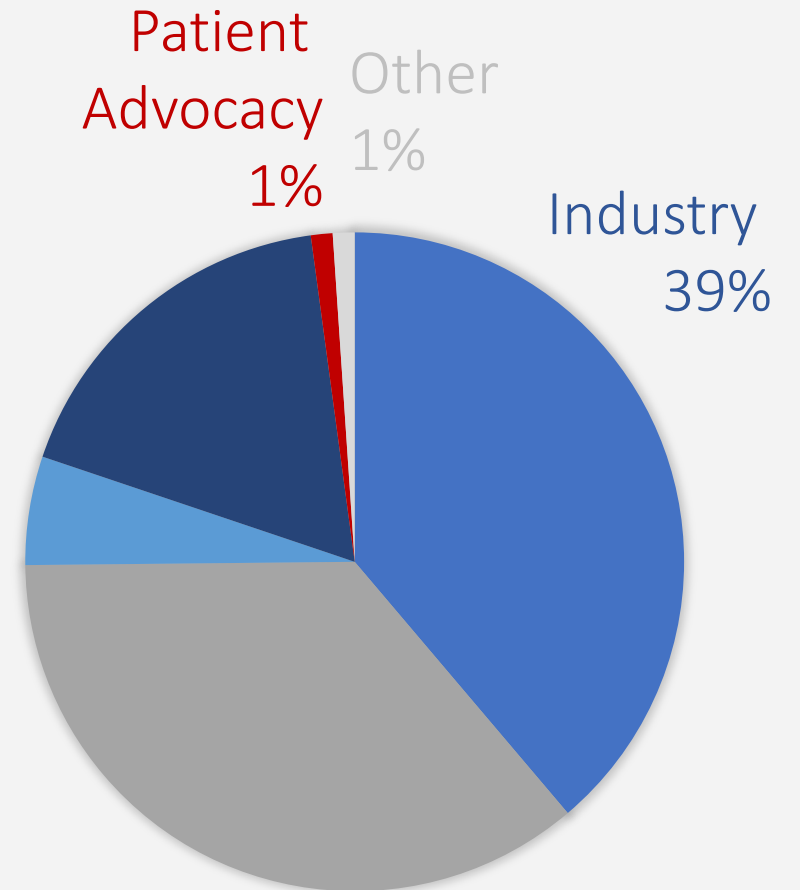
ALL MATERIALS AVAILABLE ONLINE

Membership

Regulators or
Government
18%

Professional
Organizations
5%

Academia
or Clinical
39%



Project overview (5 examples)

- A regulatory science approach for **morphology-based biomarkers** in tissue sections
Looking for FDA input (Kim Blenman)
- MDDT PROPOSAL: TILs Annotated Dataset
project OSEL (Brandon Gallas)
- Standardization of Data for Pathology Research
Looking for FDA input (Kingsley Ebare)
- CMS/CLIA Allowing Temporary Remote Signout During COVID-19 Pandemic
(Regulatory Flexibilities)
Develop resources for time after the pandemic (Joe Sirintrapun, Joe Lennerz)
- Trainees group (educational resources for regulatory science projects)
Looking for FDA input (Julia Thierauf, Sarah Dudgeon)
- <https://www.digitalpathologyalliance.org/projects/project-proposals>

Vision for 2021/2022

- Harmonize approaches to speed up delivery to patients
- MDDT submission
- Increase patient and patient advocacy engagement
- Grow membership and increase awareness
- Emphasize the importance of regulatory science
- Publications
- Provide input into regulatory decision making

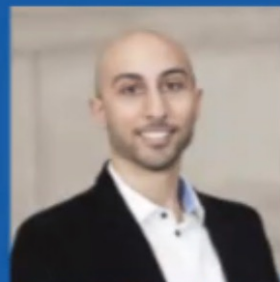
Artificial Intelligence Powered Cancer Diagnostics: How Regulatory Science Can Reshape Digital Diagnostics



Joe Lennerz, MD, Ph.D.
Massachusetts General Hospital



Esther Abels
Visiopharm



Matthew G Hanna, MD
Memorial Sloan Kettering Cancer Center



Edward Margerrison, Ph.D.
FDA | CDRH



Laura Lasiter, Ph.D.
Friends of Cancer Research



Markus Herrmann, MD, Ph.D.
Harvard Medical School

MDIC Annual Forum

Artificial Intelligence Powered Cancer Diagnostics: How
Regulatory Science Can Reshape Digital Diagnostics

The image shows a YouTube video player interface. At the top left, there is a circular logo with the letters "MDIC" and the text "Artificial Intelligence Powered Cancer Diagnostics" next to it. To the right of the title are two icons: a clock for "Watch later" and a share icon for "Share". The main content area displays a grid of six video thumbnails, each showing a different participant in a virtual meeting. The thumbnails are arranged in two rows of three. Below the thumbnails, there is a "MORE VIDEOS" link. At the bottom of the player, there is a progress bar showing the video is at 38:27 out of 49:15. To the right of the progress bar are icons for closed captions, settings, the YouTube logo, a comment icon, and a full-screen icon.

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- NIH staff guidance on coronavirus (NIH Only) »

Bridge to Artificial Intelligence

BRIDGE2AI

Common Fund » Common Fund Programs » Bridge to Artificial Intelligence (Bridge2AI)

Bridge2AI

For Researchers

- Funding Opportunities
- Program FAQs
- Program Resources
- NIH Working Group
- Scientific Meetings

New Funding Opportunity

Integration, Dissemination, and Evaluation (BRIDGE) Center will integrate activities across Bridge2AI Data Generation Projects to develop cross-cutting products and best practices

[Learn More](#)

NEW Funding Opportunity

INTEGRATION, DISSEMINATION, AND EVALUATION (BRIDGE) CENTER (RFA-RM-21-023)

BRIDGE2AI

Follow Bridge2AI



Learn about Bridge2AI

Welcome to the Bridge2AI webpage! Visit our [FAQs](#) and [NIH Working Group](#) pages to learn more about the program. Check back regularly for the latest news and updates.

Hear from NIH leaders about their vision for Bridge2AI! Watch now to learn more about the Bridge2AI

Bridge to Artificial Intelligence (Bridge2AI)

Data Generation Projects for the NIH Bridge to Artificial Intelligence (Bridge2AI) Program (OT2)

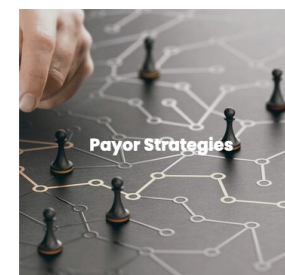
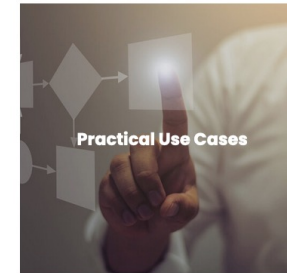
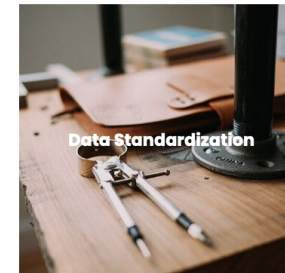
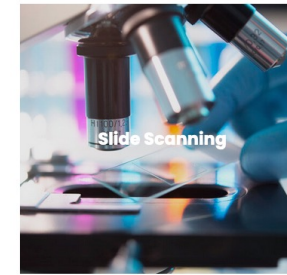
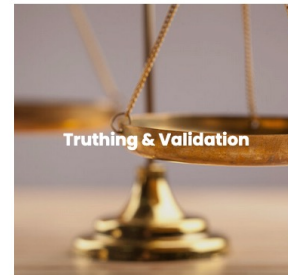
Other Transaction Opportunity Announcement

Overview Information

Participating Organization(s)	National Institutes of Health
Components of Participating Organizations	This Research Opportunity Announcement (ROA) is developed as a Common Fund initiative (https://commonfund.nih.gov/) through the NIH Office of the Director, Office of Strategic Coordination (OD-OSC). All NIH Institutes and Centers participate in Common Fund initiatives. The ROA will be administered by OD-OSC on behalf of the NIH.
Research Opportunity Announcement Title	Data Generation Projects for the NIH Bridge to Artificial Intelligence (Bridge2AI) Program (OT2)
Activity Code	OT Other Transactions (OT2) This Funding Opportunity will use the Other Transactions

Workgroup updates

Working Groups



Tailoring automated data augmentation to H&E-stained histopathology

Khrystyna Faryna¹

Jeroen van der Laak¹

Geert Litjens¹

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GEERT.LITJENS@RADOUDUMC.NL

¹ *Department of Pathology, Radboud University Medical Center, Nijmegen, the Netherlands*

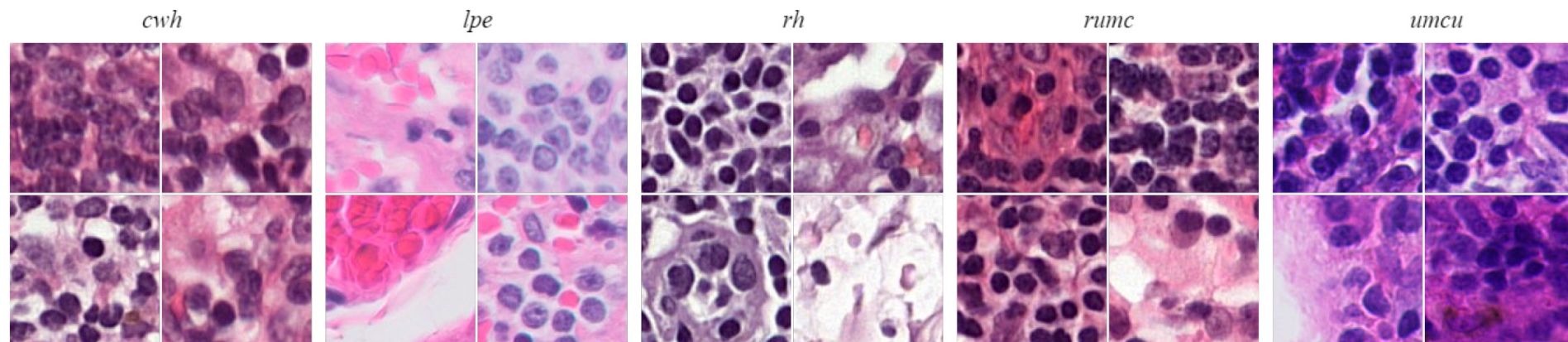


Figure 1: Stain variation among different centers in tumour metastasis detection in breast lymph node tissue resections. Examples of WSI patches originating from different institutions (from left to write): *cwh*, *lpe*, *rh*, *rumc*, *umcu*.



STANDARDIZATION OF DATA FOR PATHOLOGY RESEARCH

Kingsley Ebare, MD, MPH
Esther Abels, MSc

HIPAA and the Leak of “Deidentified” EHR Data

Kenneth D. Mandl, M.D., M.P.H., and Eric D. Perakslis, Ph.D.

The permissible sharing of patient data among health care organizations and their business associates for treatment, payment, and operations purposes has led to a torrent of electronic health record (EHR) data flowing out of health care provider silos. The Health Insurance Portability and Accountability Act (HIPAA) also permits business associates to deidentify data on behalf of a

health care provider, insurance plan, or clearinghouse (so-called covered entities); once data are deidentified, the business associate may use them freely, unless it is contractually prohibited from doing so. Organizations that don't qualify as business associates under HIPAA may also gain access to and use deidentified data sets. Such policies have enabled the rise of a multibillion-dollar industry

comprising dozens of health-data aggregation companies and hundreds more companies producing tools and technologies that aggregate, link, and monetize EHR data.

This phenomenon has been amplified by the explosion of data production since the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 began promoting widespread adoption of EHRs to en-

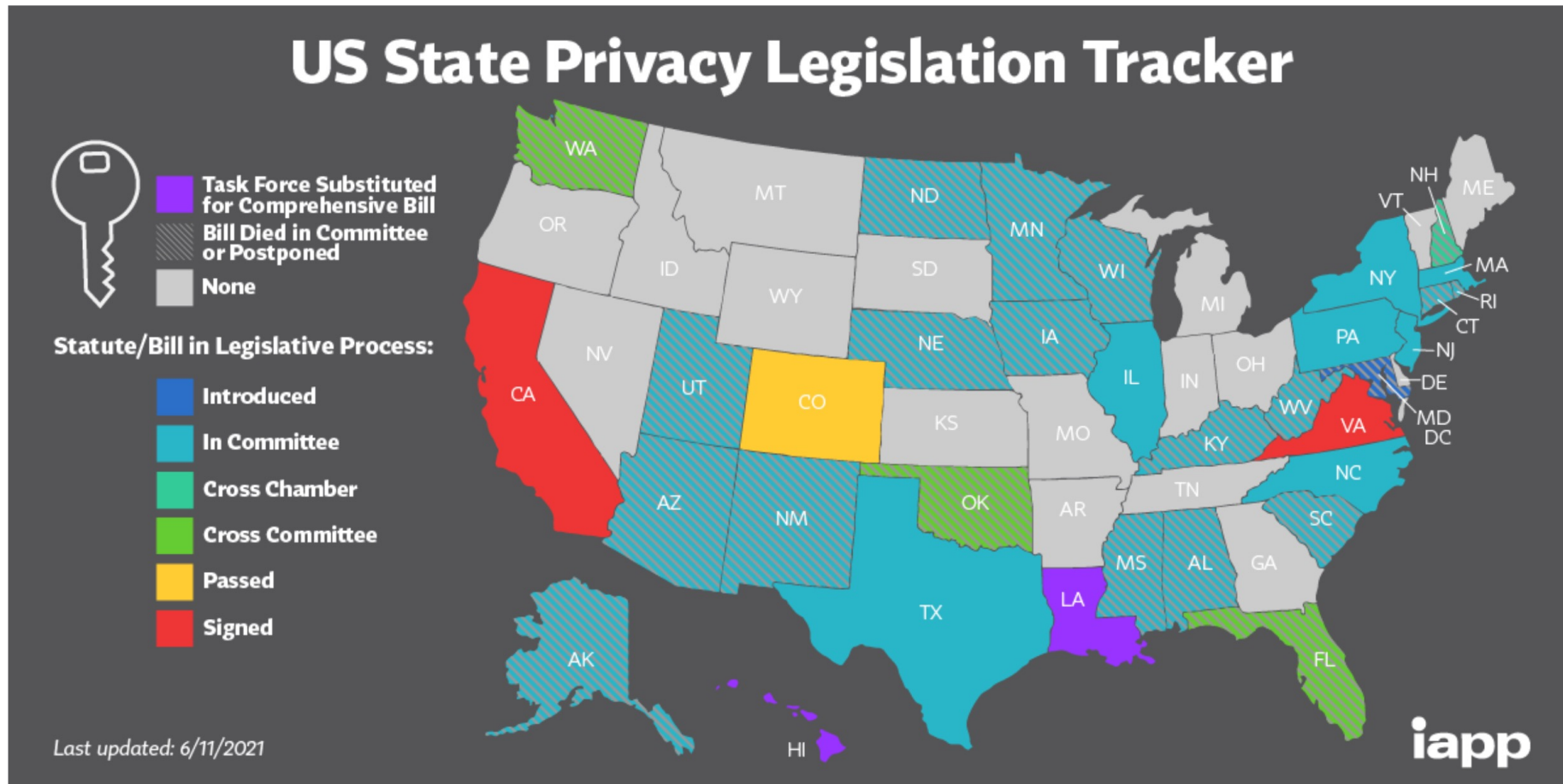
The New England Journal of Medicine

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<https://iapp.org/resources/article/us-state-privacy-legislation-tracker/>

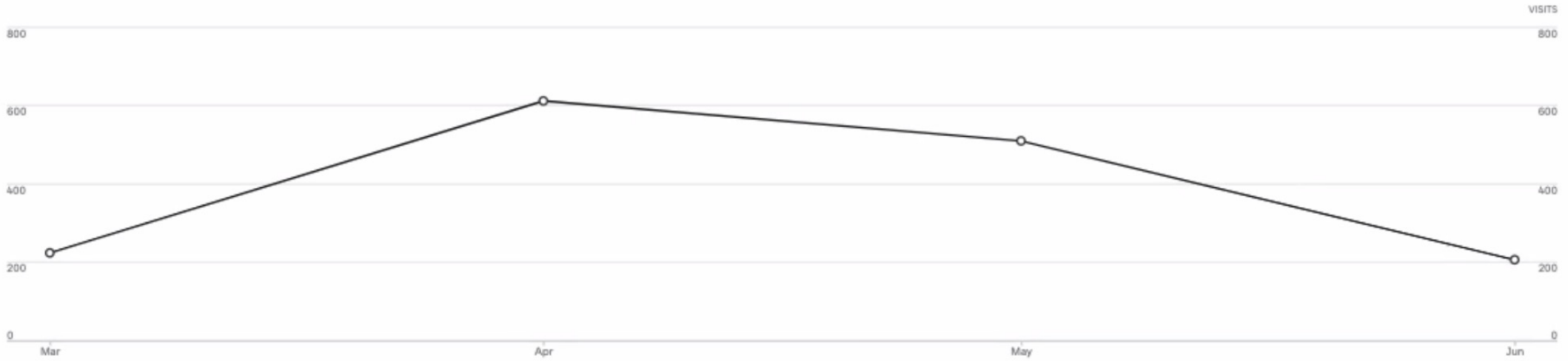


VISITS 1.5K +100% yr/yr	BOUNCE RATE 61.3% +100% yr/yr	UNIQUE VISITORS 1K +100% yr/yr	PAGEVIEWS 4.4K +100% yr/yr
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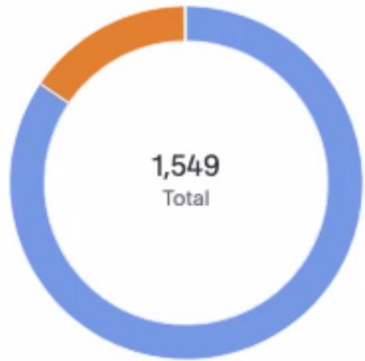
Visits

Mar 1–Jun 22, 2021 • 1,549 Total +100% yr/yr

Monthly ▾

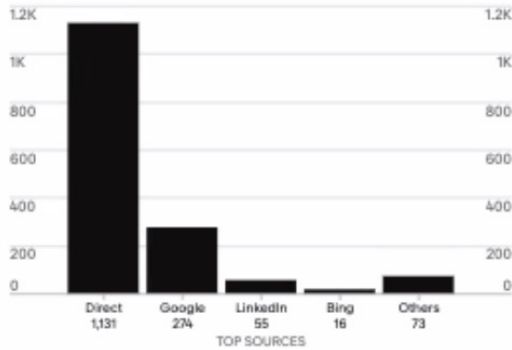


Top Devices by Visits

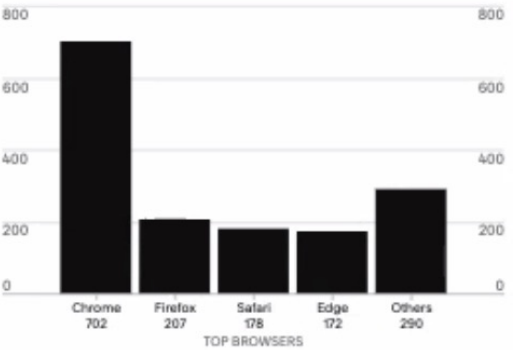


- Desktop
- Mobile
- Tablet

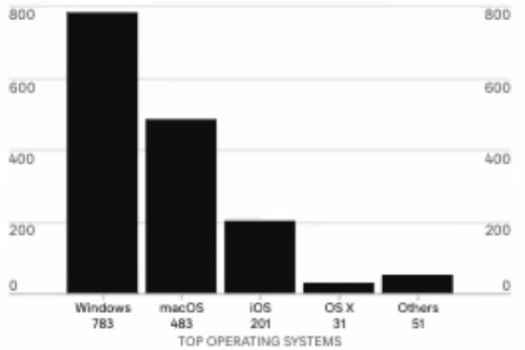
Top Sources by Visits



Top Browsers by Visits



Top Operating Systems by Visits





Pathology and
Laboratory Quality
Center

Recommendations for Validating Whole Slide Imaging Systems for Diagnostic Purposes in Pathology

Anil V Parwani, MD, PhD
On behalf of the CAP
WSI Validation Expert
Panel



www.cap.org v. 1



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Member Resources Advocacy Laboratory Improvement Learning Protocols and Guidelines Publications

Home > Protocols and Guidelines > Current CAP Guidelines > Validating Whole Slide Imaging for Diagnostic Purposes in Pathology

Validating Whole Slide Imaging for Diagnostic Purposes in Pathology



Background

The US Food and Drug Administration has approved select digital whole slide imaging (WSI) systems for primary diagnoses in surgical pathology, ushering in new applications for digital pathology. The "Validating Whole Slide Imaging for Diagnostic Purposes in Pathology: Guideline Update" helps pathologists and laboratories confirm diagnostic accuracy and equivalence with light microscopy of whole slide imaging (WSI) systems before they are actually used for diagnostic purposes.

We convened an expert panel of pathologists, histotechnologists, and a methodologist to develop the 2021 guideline update. Adhering to the National Academy of Medicine guideline standards and now using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, the update offers three strong recommendations and nine good practice statements, which largely reaffirm the original guideline recommendations.

Validation of WSI is crucial to ensure the quality and consistency of diagnostic performance based on digitized slides. For patients, this could mean receiving their pathologic diagnosis more quickly with the same quality test results and thereby possibly receiving treatment sooner. The guideline update is available as an early online release in Archives of Pathology & Laboratory Medicine.


Have a Question or Comment?
Send us an email.
Email the Center

CAP.org

- WSI Validation


MAY 18 2021



Validating Whole Slide Imaging Systems for Diagnostic Purposes in Pathology: Guideline Update From the College of American Pathologists in Collaboration With the American Society for Clinical Pathology and the Association for Pathology Informatics

Andrew J. Evans, MD, PhD ; Richard W. Brown, MD; Marilyn M. Bui, MD, PhD; Elizabeth A. Chlipala, BS, HTL(ASCP)QIHC; Christina Lacchetti, MHSc; Danny A. Milner, Jr, MD, MSc(Epi), MBA; Liron Pantanowitz, MD; Anil V. Parwani, MD, PhD; Kearin Reid, MLIS, MT(ASCP); Michael W. Riben, MD; Victor E. Reuter, MD; Lisa Stephens, MBA, HTLA(ASCP) CM; Rachel L. Stewart, DO, PhD; Nicole E. Thomas, MPH, CT(ASCP) CM

Arch Pathol Lab Med (2021)

<https://doi.org/10.5858/arpa.2020-0723-CP> [Article history](#) 

 Split-Screen

 Views 

 PDF

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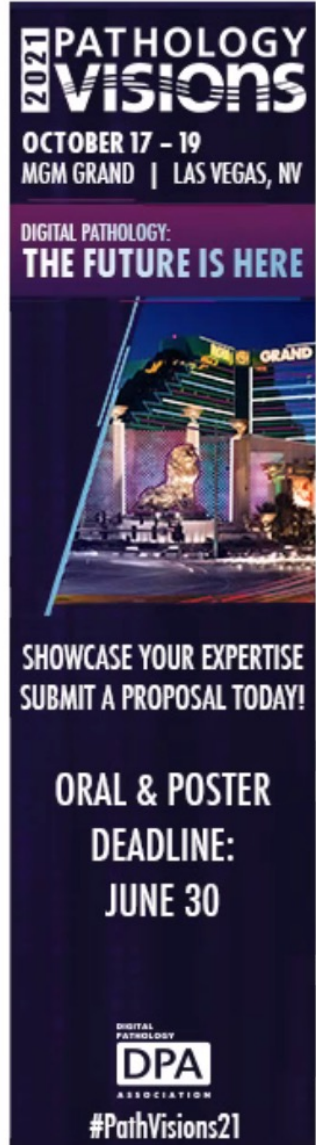
 Tools 

Context.—

The original guideline, “Validating Whole Slide Imaging for Diagnostic Purposes in Pathology,” was published in 2013 and included 12 guideline statements. The College of American Pathologists convened an expert panel to update the guideline following standards established by the National Academies of Medicine for developing trustworthy clinical practice guidelines.


Objective.—

To assess evidence published since the release of the original guideline and provide updated recommendations for validating whole slide imaging (WSI) systems used for diagnostic purposes.



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NEJM Catalyst Innovations in Care Delivery

Theme Issue: Artificial Intelligence

NEJM Catalyst Innovations in Care Delivery invites manuscripts to be considered for inclusion in an upcoming theme issue on artificial intelligence. In keeping with our emphasis on practical innovations in care delivery, we seek accounts of AI and machine learning applied to important aspects of care delivery, such as clinician burnout, safety and efficiency, social determinants of health, and primary care. Submissions will receive expedited review.

Issue date: December 2020

- Timing of submissions: April–August

Components:

- In Depth articles, case studies, and expert articles – see our [Author Center](#) for guidelines
- A report drawing on a survey from the [NEJM Catalyst Insights Council](#)
- A possible virtual event held in conjunction with the issue
- We are seeking sponsorship for this theme issue

Sample articles:

- [“Interpretable Machine Learning Models for Clinical Decision-Making in a High-Need, Value-Based Primary Care Setting”](#) by Surabhi Bhatt, MS, Adam Cohon, PhD, Jenna Rose, MHS, Natalia Majerczyk, Brian Cozzi, MS, Drew Crenshaw & Griffin Myers, MD, MBA – Vol. 2 No. 4 | April 2021
- [“AI-Enabled Clinical Decision Support Software: A “Trust and Value Checklist” for Clinicians”](#) by Christina Silcox, PhD, Susan Dentzer & David W. Bates, MD, MSc – Vol. 1 No. 6 | Nov-Dec 2020
- [“Machine Learning and the Pursuit of High-Value Health Care”](#) by Ishani Ganguli, MD, MPH, William J. Gordon, MD, MBI, Claire Lupo, Megan Sands-Lincoln, PhD, MPH, Judy George, PhD, Gretchen Jackson, MD, PhD, Kyu Rhee, MD, MPP & David W. Bates, MD, MS – Vol. 1 No. 6 | Nov-Dec 2020

In-person meeting

