COLLEGE of AMERICAN PATHOLOGISTS

Less is More

Real-World of Digital Pathology and AI

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November 7, 2023

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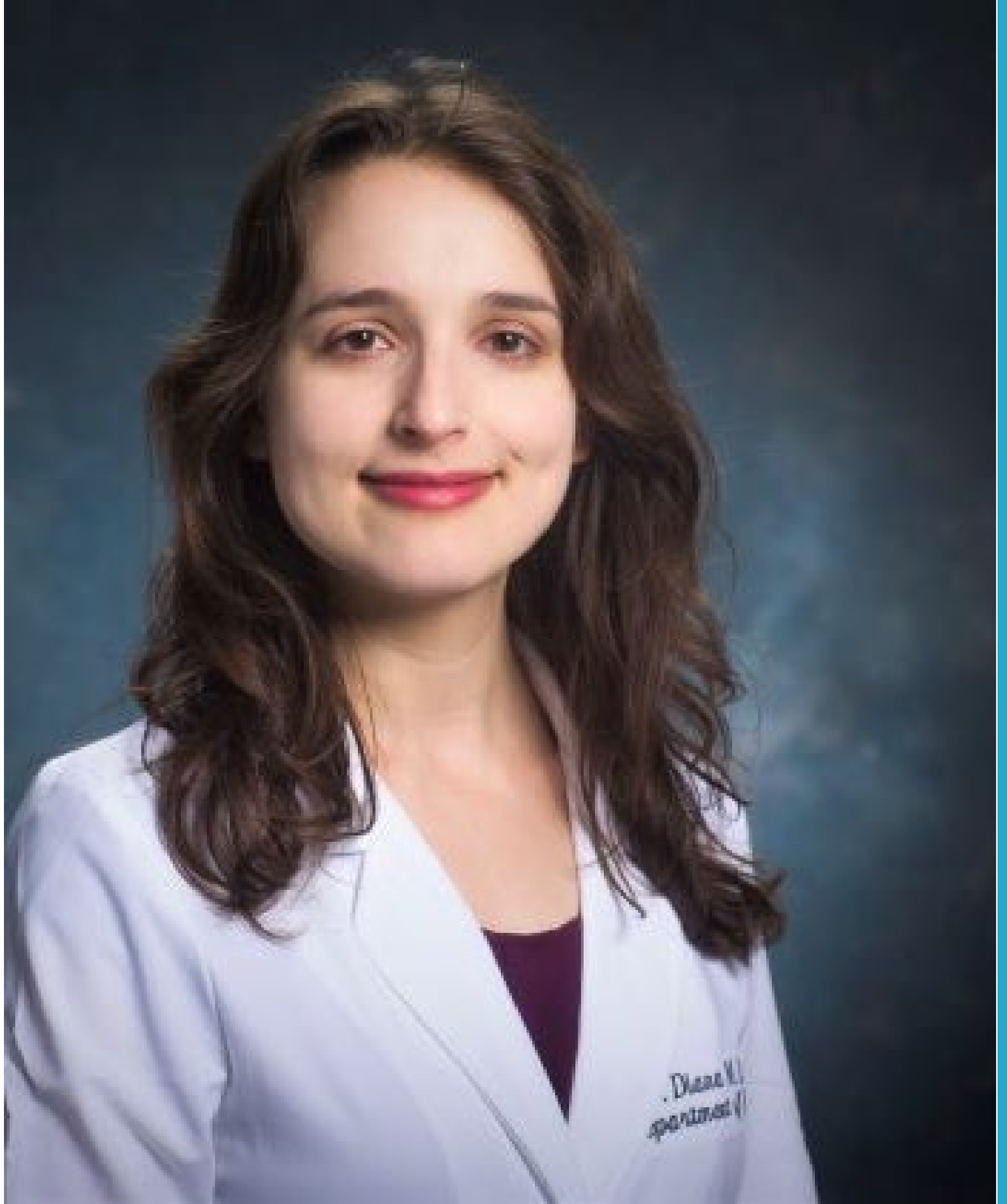
- Member– Practice Management Committee
- PMC Liaison –Digital Content Committee
- Associate Professor of Pathology – University of Alabama at Birmingham
- Medical Director, AP Division, UAB Highlands Hospital
- CAP State Commissioner for Alabama and Division Commissioner for the Florida Panhandle
- Board certified AP/CP and Cytopathology



Eyas M Hattab MD, MBA, FCAP

- Member, Practice Management Committee, House of Delegates
- Professor and Chair of Pathology and Laboratory Medicine at University of Louisville
- AP/CP certified with subspecialty fellowships in neuropathology and oncological surgical pathology
- Internationally recognized neuropathologist

Dibson Dibe Gondim, MD, FACP

- Member of the Artificial Intelligence Committee, CAP
- Director of Pathology Informatics and Assistant Professor of Pathology at the University of Louisville
- Certified by the American Board of Pathology in:
  - Anatomic Pathology
  - Neuropathology
  - Clinical Informatics
- Lead on the large-scale digital pathology and AI Initiative at the University of Louisville

Disclaimer

The information presented today represents the opinions of the panelists and does not represent the opinion or position of the CAP.

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The information in this presentation is provided for educational purposes only and is not legal advice.

Topics for Today's Discussion

- Introduction
- CLIA updates
- Billing
- Real world applications of digital pathology
- Artificial intelligence
- Integrated sign-out dashboard

What is digital pathology?

- Acquiring and interpreting pathology information from a digitized glass slide
  - Diagnosis
  - Consultation
  - Teaching
  - Multi-disciplinary conference presentation
  - And so much more!

Artificial Intelligence (AI)

- Developing algorithms and models using digital analysis and machine learning

Is remote sign-out feasible post COVID?

Yes, you can sign out digital slides without a CLIA certificate for your house or other remote location!

As long as the primary lab meets updated guidelines

Memorandum: "Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-Public Health Emergency (PHE) Guidance" Center for Clinical Standards and Quality/Quality, Safety & Oversight Group. Centers for Medicare & Medicaid Services. May 11, 2023.

Primary site requirements

- **Has CLIA certification and complies with all relevant Federal laws.**
- **Is certified to perform all the of work performed at the remote site and the laboratory director is responsible for all testing.**
- **Retains all documentation, including tests performed remotely and list of staff working remotely.**
- **Indicates remote site location on the reports (coding system ok).**

Memorandum: "Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-Public Health Emergency (PHE) Guidance" Center for Clinical Standards and Quality/Quality, Safety & Oversight Group. Centers for Medicare & Medicaid Services. May 11, 2023.

Yes, you can code!

- Category III digital CPT codes now available
- Must use whole-slide imaging
- No codes for
  - Education/research
  - Tumor boards/clinical conferences
  - Archiving
  - Validation

https://www.cap.org/advocacy/payments-for-pathology-services/digital-pathology-codes

Diagnosis, Special Stains and IHC

Digital Code	In conjunction with
+0751T	88302
+0752T	88304
+0753T	88305
+0754T	88307
+0755T	88309
+0756T	88312
+0757T	88313
+0758T	88314
+0759T	88319
+0760T	88342
+0761T	88341
+0762T	88344
+0763T	88360

Coming soon on Jan. 1- cytology, expanded surgical and hematology codes

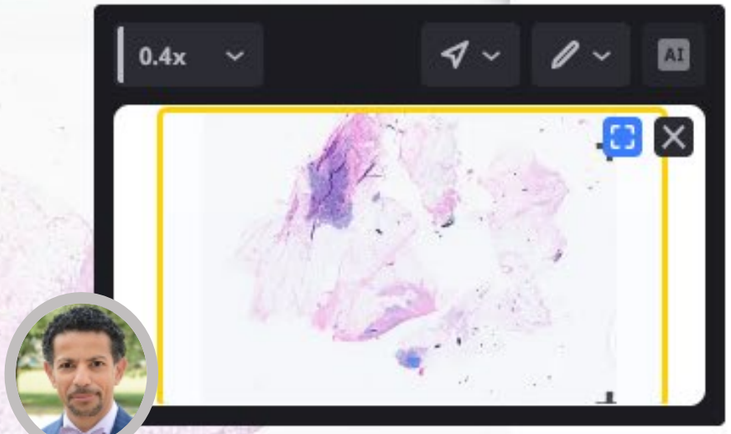
Digital Code	In conjunction with	Digital Code	In conjunction with	Digital Code	In conjunction with
+0827T	88104	**+0838T**	88321	**+0849T**	88364
+0828T	88106	**+0839T**	88323	**+0850T**	88366
+0829T	88108	**+0840T**	88325	**+0851T**	88368
+0830T	88112	**+0841T**	88331	**+0852T**	88369
+0831T	88141	**+0842T**	88332	**+0853T**	88377
+0832T	88160	**+0843T**	88333	**+0854T**	85060
+0833T	88161	**+0844T**	88334	**+0855T**	85097
+0834T	88162	**+0845T**	88346	**+0856T**	88348
+0835T	88172	**+0846T**	88350		
+0836T	88177	**+0847T**	88363		
+0837T	88173	**+0848T**	88365		

Digital Pathology: Real-world applications

- Not one size fits all
- Many different applications
  - Specific operational / logistical function
  - Specific mission (education, research, etc)
  - Improved staffing / access
  - Grow business (referrals, consultations)
- Means to an end! (AI deployment)

Inhouse consultation

I have an interesting case and would appreciate your expert opinion.



Of course!

Thank you. Here is the link:
https://digitalslide/case

I see. Is there something specific that concerns you?

Actually, yes. I can set the concerning area as the start view. Here:
https://digitalslide/case/zoomLevel

Great, I will take a look…

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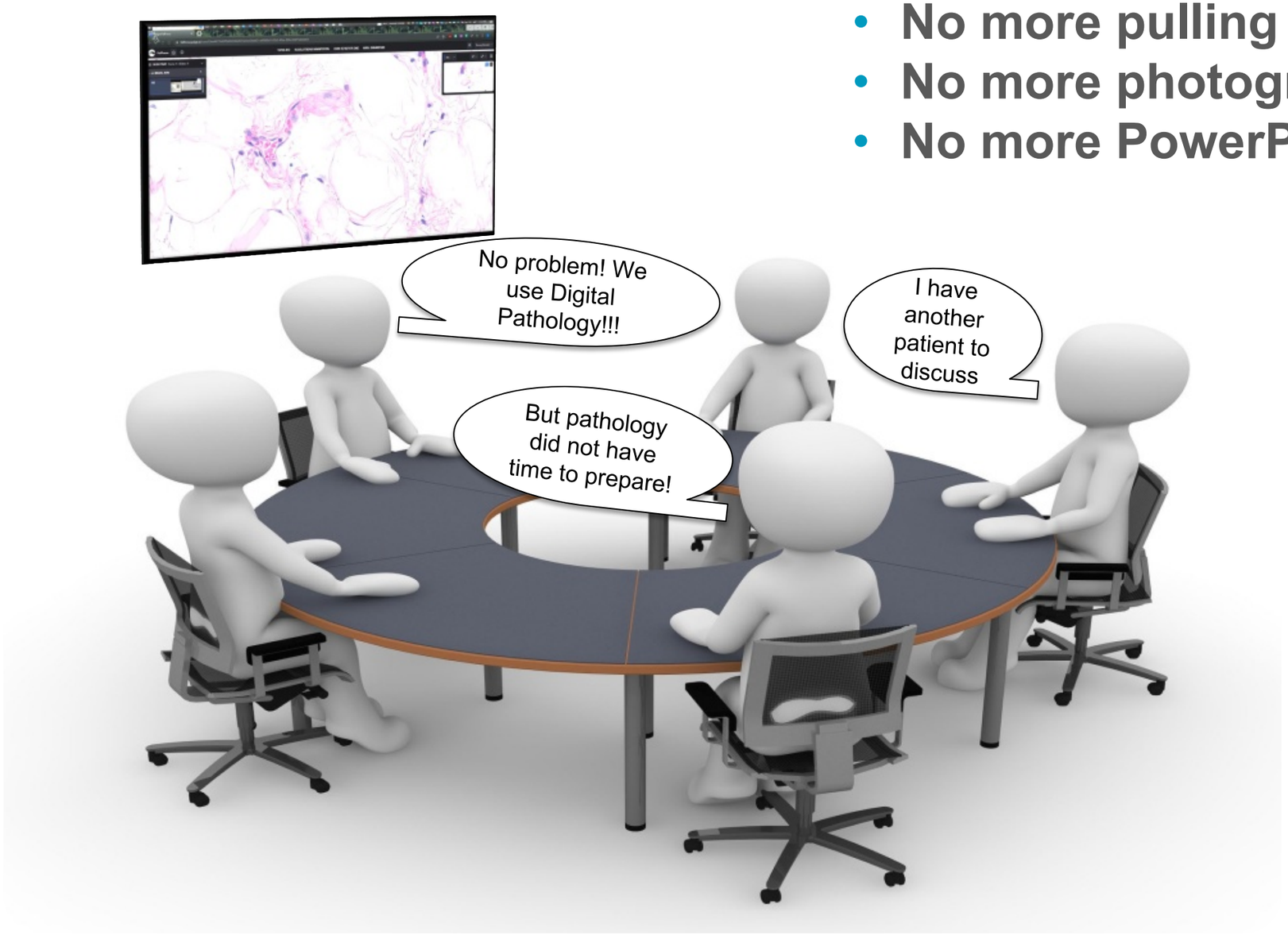
Great, I will take a look...

- **Easily communicate in real time!**
- **No shuffling slides between locations!**
- **Better turnaround time!**

External digital consultation / point of care

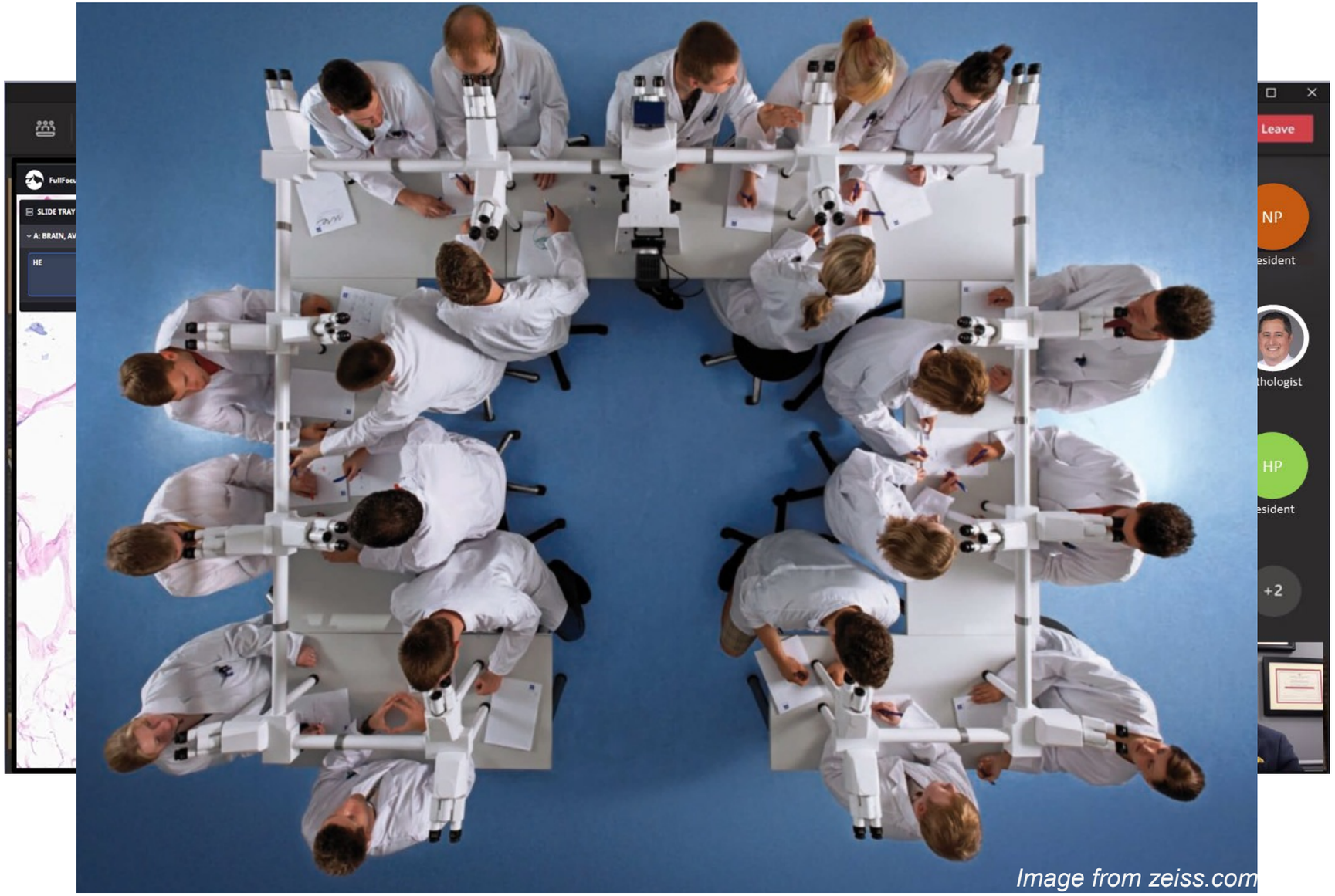
- Using digital pathology for external consultation
  - ~~Cumbersome physical workflow~~
    - ~~Extra paperwork~~
    - ~~Slides packaged / sent~~
  - ~~Shipping costs and labor add up over time~~
  - ~~Suboptimal turnaround time~~
  - ~~Original slides lost, broken, or never returned~~

Conferences and Tumor Board



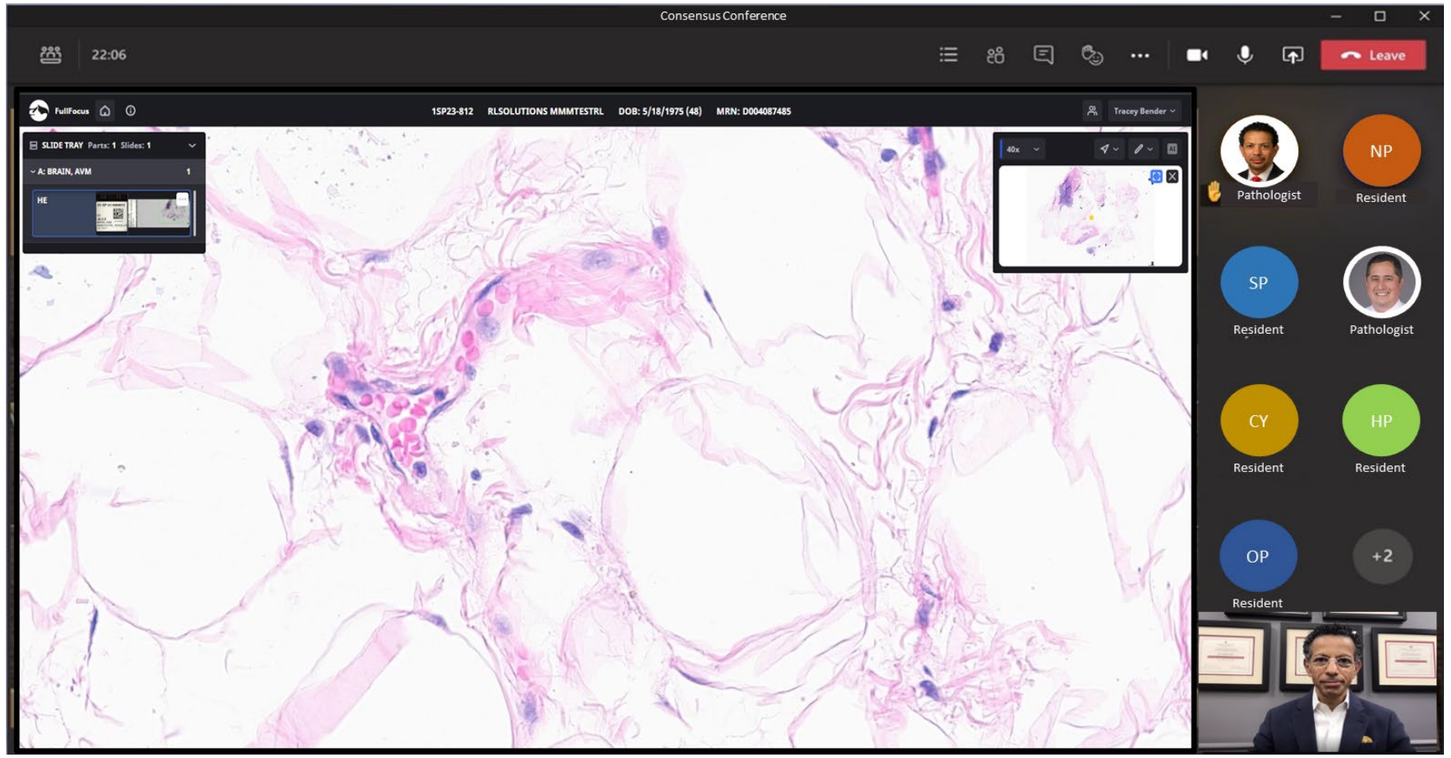
- No more pulling slides!
- No more photographing the slides!
- No more PowerPoint presentations!

Consensus Conference

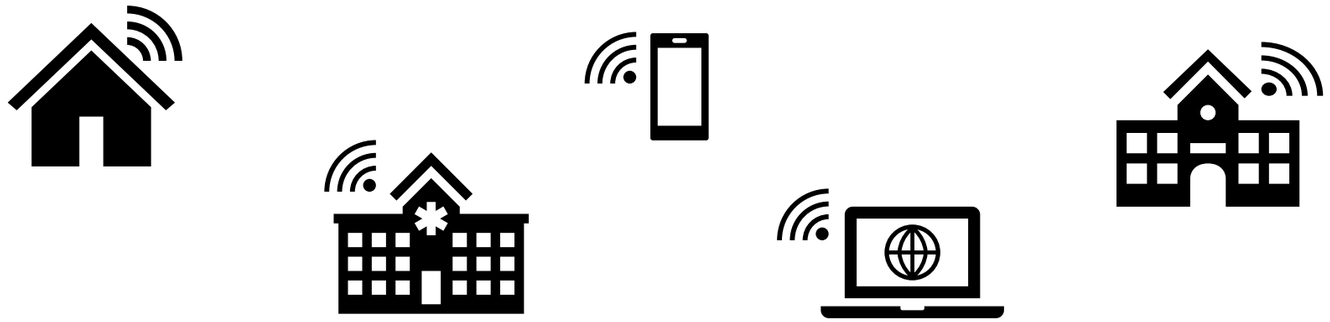


After

Consensus Conference



- Better attendance!
- No more crowding!
- Sign in from anywhere!

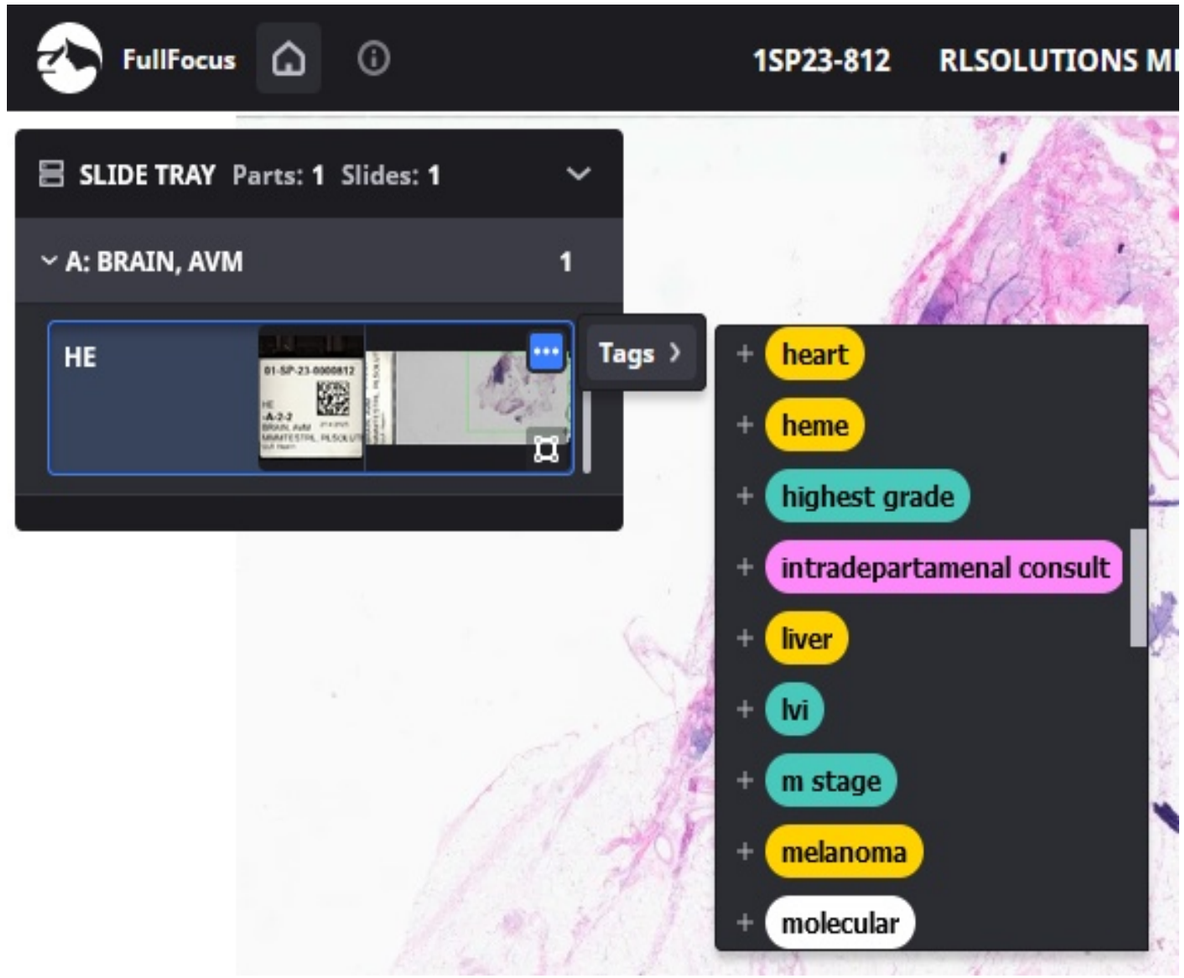


After

“Tagging” cases

- Advanced cataloging / organizing
- Automated workflow processes
- Easy data sharing and collaboration
- A tag can be any label! Customizable

“Tagging” cases



Tagging through the digital slide viewer

“Tagging” cases

Pathology Report Internal Comments

ssss/+40+SP23000XXX001001001/pituitary fossa/pitnet, corticotroph type, sparsely granulated, silent

accession	pathologist	slide_site	slide_comment	slide_url
03-SP-23-XXX	HATTAB, EYAS, MD-PAT	cornea	fungal keratitis	https://DigitalSlideViewer/launchCase
03-SP-23-XXX2	HATTAB, EYAS, MD-PAT	cornea	chronic corneal edema with bullous keratopathy	https://DigitalSlideViewer/launchCase
40-SP-23-XX	HATTAB, EYAS, MD-PAT	clivus	rathke cleft cyst	https://DigitalSlideViewer/launchCase
40-SP-23-XX	HATTAB, EYAS, MD-PAT	sphenoid mass	chordoma	https://DigitalSlideViewer/launchCase
03-SP-23-X3	HATTAB, EYAS, MD-PAT	eyelid	merkel cell carcinoma	https://DigitalSlideViewer/launchCase
40-SP-23-XXX	HATTAB, EYAS, MD-PAT	pituitary fossa	pitnet, corticotroph type, sparsely granulated, silent	https://DigitalSlideViewer/launchCase
40-SP-22-X1	HATTAB, EYAS, MD-PAT	spine	myxopapillary ependymoma	https://DigitalSlideViewer/launchCase

Tagging through the pathology report to send to a common database

“Tagging” cases

to photograph | potential GSU | tumor board | resident lecture | case of interest

UPDATED INTEGRATED DIAGNOSIS

FINAL INTEGRATED DIAGNOSIS:

Solitary fibrous tumor, CNS WHO grade 2

HISTOLOGIC DIAGNOSIS:

Spindle cell tumor

RELEVANT ANCILLARY INFORMATION:

STAT6 (IHC): Positive

Consensus Methylation Profiling Class: Solitary fibrous tumor, CNS WHO grade 2 (see Comment)

CNS WHO GRADE:

WHO grade 2

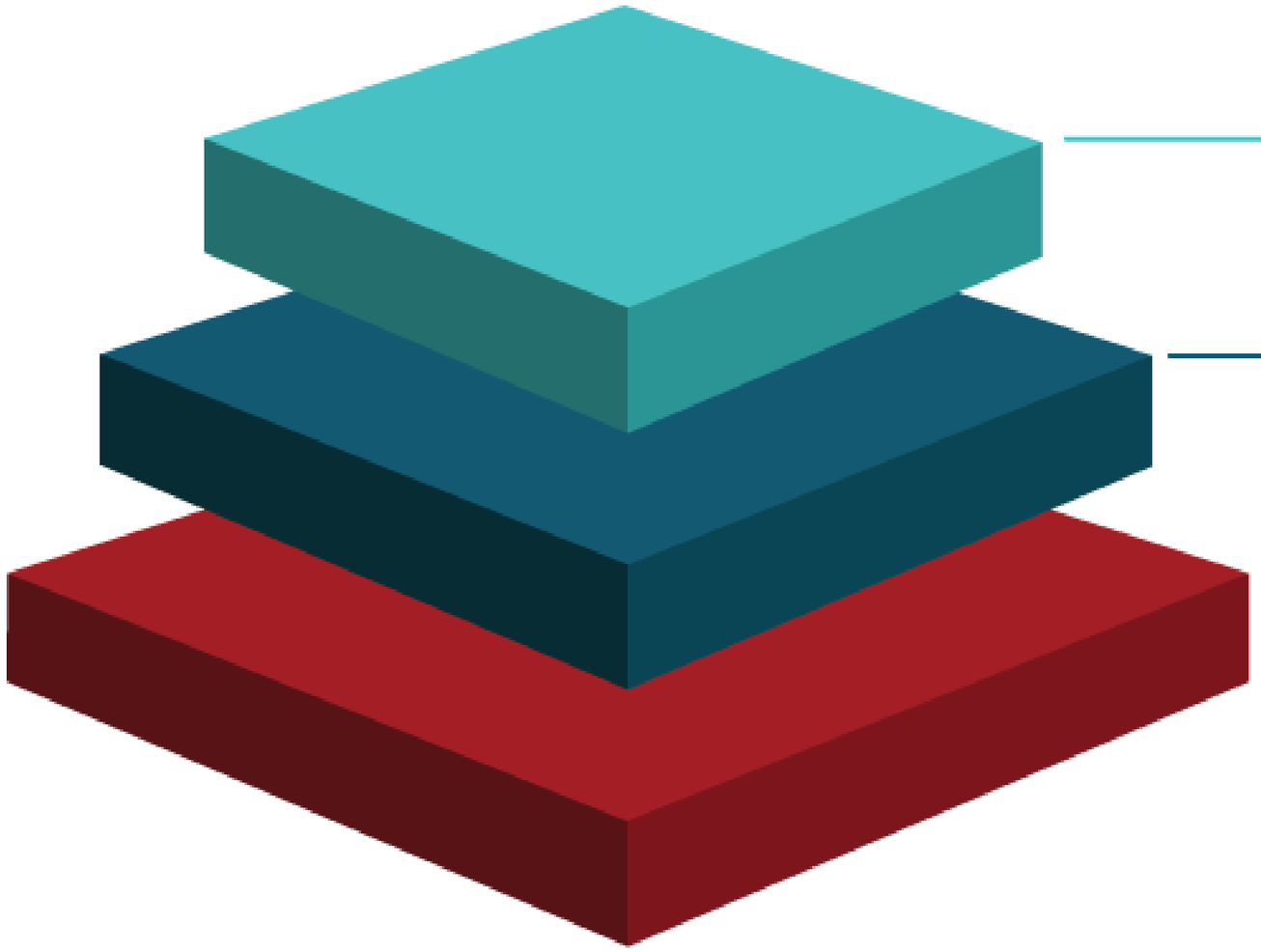
Tagging through other sources

DP Implementation is not without challenges

- Cost/Business case (initial investment and ongoing maintenance)
- Regulatory issues
- Buy in (C-suite, pathologists, clinicians, staff, etc)
- Requires significant workflow adjustments
- Requires IT support, clinical information management, etc
- Vulnerable to interruptions
- Scanning/viewing limitations
  - Cytology, bone marrows, H. pylori, mitoses, polarization, etc
- Requires a QA program
  - Failure rate, re-scanning

Artificial Intelligence

- Basic requirements
- Common AI-based systems for histopathology
- Ensuring trustworthiness in AI pathology
- Maximizing productivity
- AI + DP interoperability



Computational pathology
(AI-based approaches)

Digital pathology

High-quality histology

Pathologists: The pillars of precision medicine

- Masters of doing more with less
- Efficiency masters
  - Unparalleled skill in maximizing precision with fixed resources
- Precision medicine champions
  - Crucial to the seamless integration of advanced diagnostics into patient care
- Escalating duties
  - Steering through intricate molecular diagnostics landscape
  - Absorbing rapid growth in medical knowledge
  - Adapting to a tight web of regulatory requirements
- Sustainability check
  - Evaluating the potential for overload
  - Necessity of innovative tools to support pathologists' expanding roles

Image by Clker-Free-Vector-Images from Pixabay

The role of AI in pathology

- **AI as a tool**
  - Requires careful exploration and mastery
  - Still in early stages—potential unknown risks
  - Our duty to understand and mitigate risks
  - Robust DP Infrastructure is critical
- **Implementation challenges**
  - Substantial effort for AI system deployment
  - Not universally established infrastructure
- **Productivity and AI**
  - AI deployment alone ≠ guaranteed productivity gains
  - True potential lies in AI + knowledge + optimal implementation

Common AI-based systems for histopathology

#1 Classification & detection

#2 Digital biomarker and virtual staining

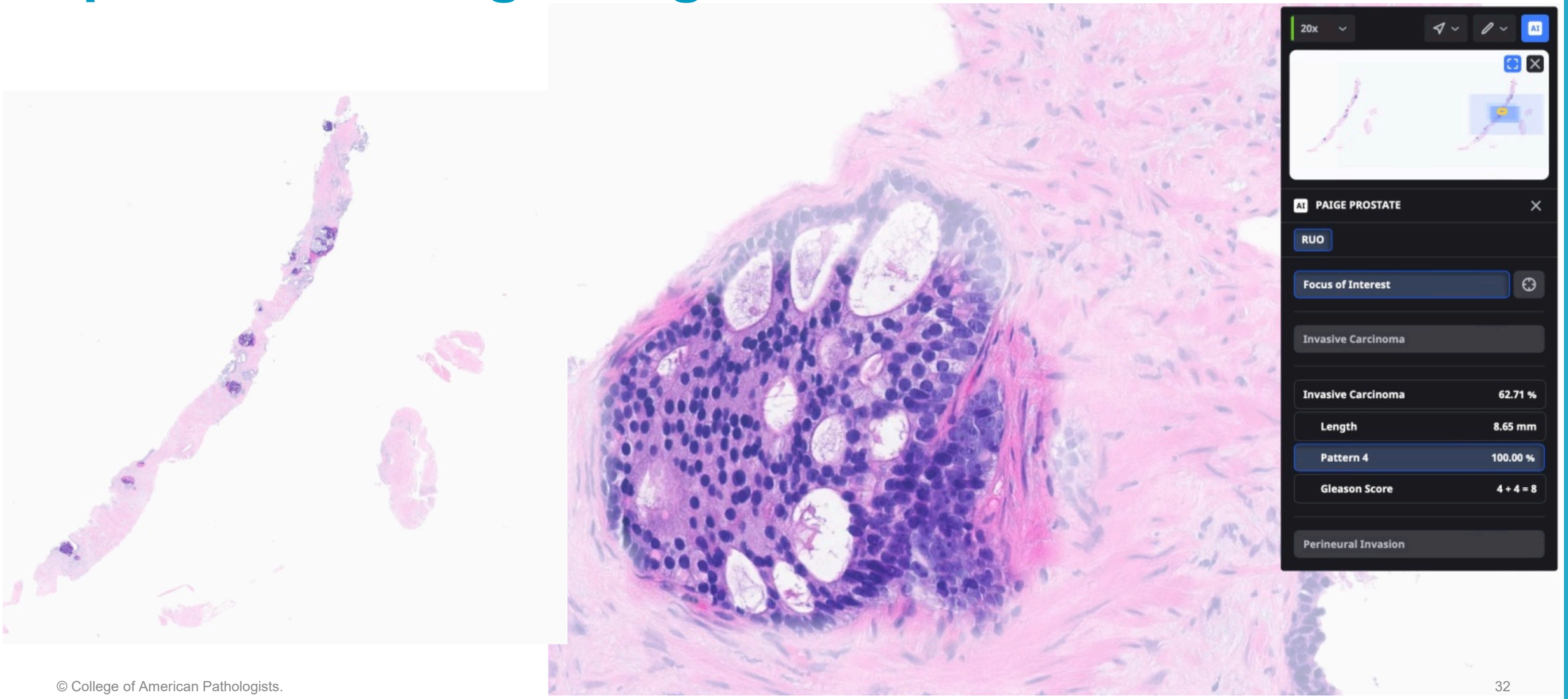
#3 Image-based predictive/prognostic model

(Note: This list is not exhaustive)

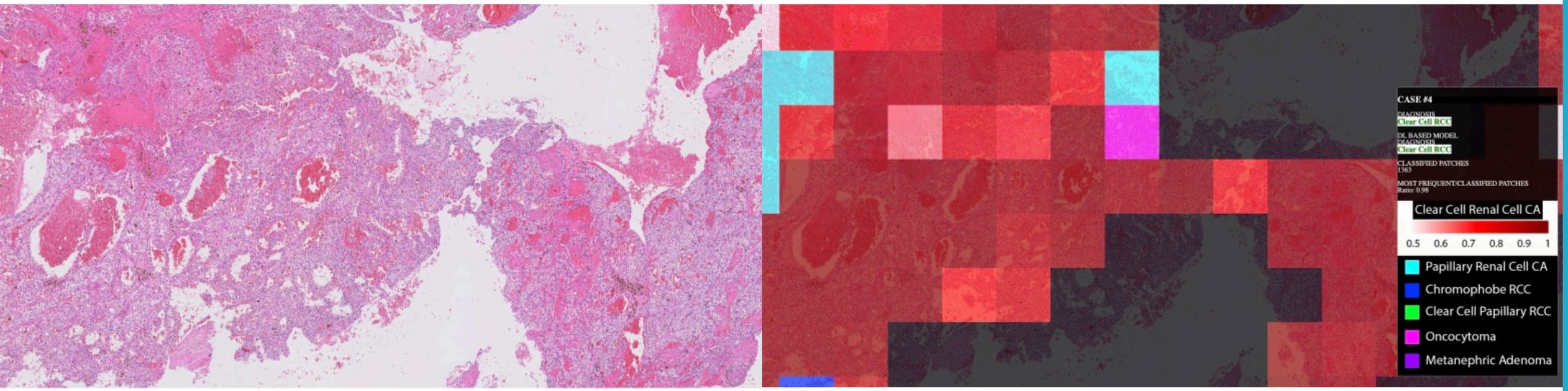
#1 Classification & detection systems

- **Tumor detection, quantification, and grading**
  - Advanced algorithms for tumor analysis
  - Example: solutions for prostate and breast biopsies
- **Metastasis detection**
  - Automated detection of lymph node metastases
- **Mitotic activity assessment**
  - AI-driven counting of mitotic figures
- **Result verification**
  - Tools for pathologists to confirm AI findings
  - Visualization techniques
    - Use of masks and heatmaps for AI-histology correlation

#1 Example: AI for cancer identification, quantification, grading, and PNI detection



#1 Example: AI for kidney tumor classification with heatmaps



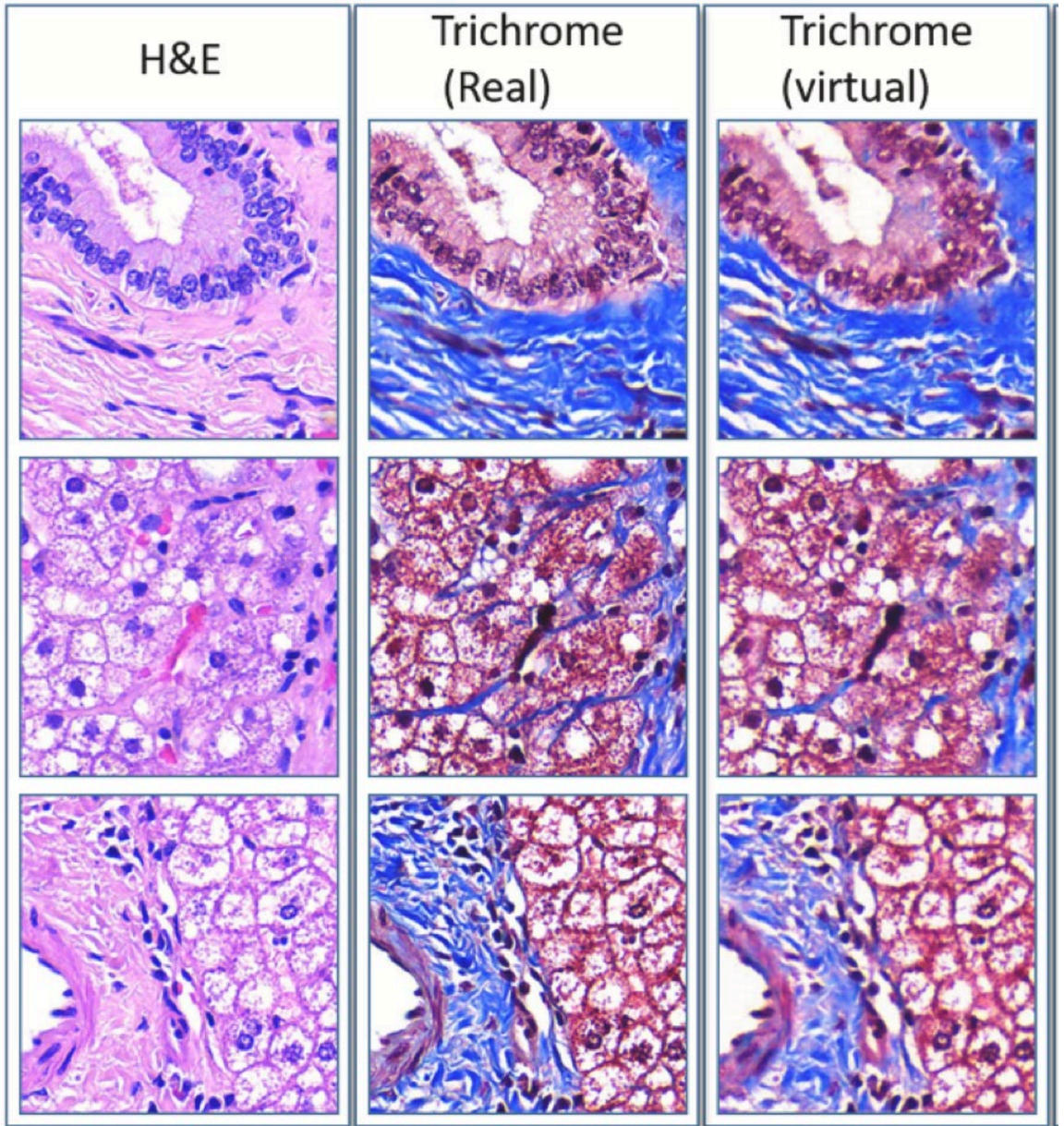
More examples can be found here: http://aistain.com

Gondim DD, Al-Obaidy KI, Idrees MT, Eble JN, Cheng L. Artificial intelligence-based multi-class histopathologic classification of kidney neoplasms. J Pathol Inform. 2023 Feb 16;14:100299. doi: 10.1016/j.jpi.2023.100299. PMID: 36915914; PMCID: PMC10006494.

#2 Digital biomarker and virtual staining

- **Enhanced turnaround time**
  - Accelerate result availability, bypassing the wait for traditional staining or other ancillary studies.
- **Resource efficiency**
  - Decreases dependence on physical instruments, supplies and specialized personnel
- **Consideration of risks**
  - Validation could be performed based on gold standard
  - Challenge prospective monitoring
  - Limited literature about real world deployment

#2 Example: Virtual trichrome for liver



Naglah A, Khalifa F, El-Baz A, Gondim D. Conditional GANs based system for fibrosis detection and quantification in hematoxylin and eosin whole slide images. Medical Image Analysis. 2022 Oct 1;81:102537.

Systems and methods for digital transformation of medical images and fibrosis detection
Provisional patent, US Patent App. 17/845,880
El-Baz, A.S., Gondim, D., Naglah, A., and Khalifa, F.

#3 Image-based predictive/prognostic models

- **Optimal treatment guidance**
  - Utilizing AI to recommend the most effective treatment options tailored to individual patient profiles
- **Prognosis group stratification**
  - AI algorithms assist in categorizing patients into prognosis groups, enabling personalized care plans
- **Case study: ArteraAI prostate test**
  - An example of AI's application in providing prognostic insights for prostate cancer management
- **Verification challenges**
  - The current limitations in secondary methods for independent result confirmation

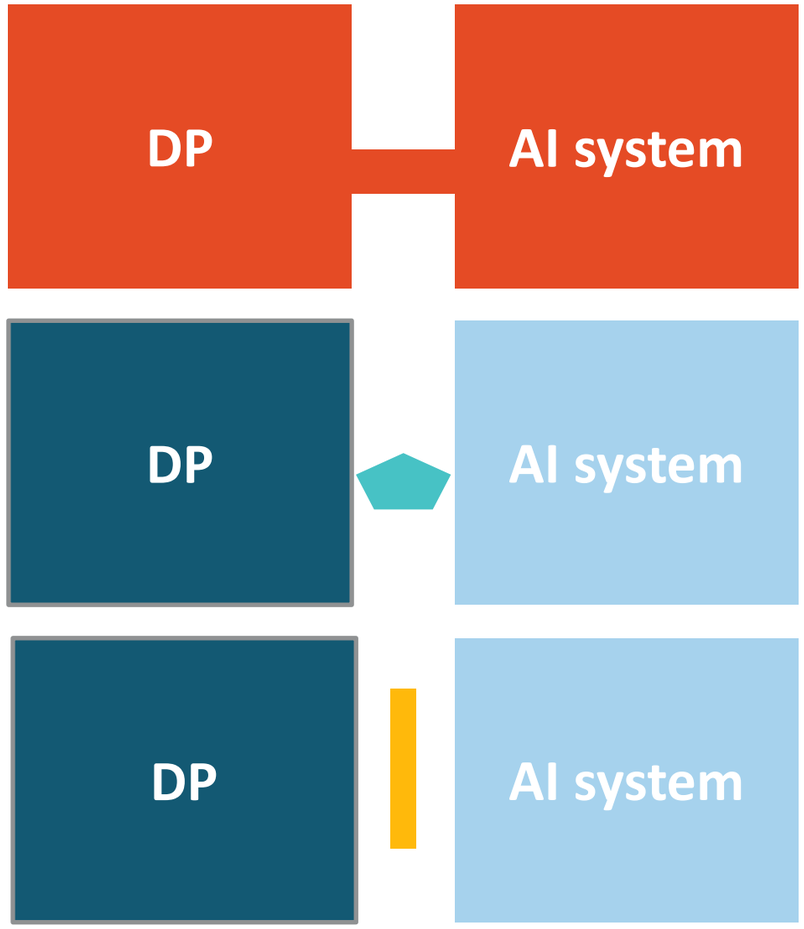
Ensuring trustworthiness in AI pathology

- **Critical role of validation**
  - Validation protocols are paramount to establish the reliability of AI results
- **Pathologist oversight (human-in-the-loop)**
  - Pathologist in the decision-making loop to adjudicate AI findings
  - Pathologist oversight not possible for biomarkers, virtual staining, and predictive/prognostic assessments
- **Adjudication workflow integration**
  - Incorporating a structured workflow for pathologists to review and adjust AI outcomes
- **Risk mitigation**
  - Addressing the potential for false negatives or positives, which could inadvertently increase the pathologist's workload

DP + AI Interoperability

- **Full-spectrum integration (ideal)**
  - EHR + LIS + DP + AI
  - Lab-centric control (LIS + DP + AI)
- **Efficiency in case management**
  - Eliminates the need for manual retrieval across different applications
  - Allows order placement from image management systems (IMS) to laboratory information system (LIS)
  - Easy export of images from digital pathology (DP) to LIS
- **Seamless asset tracking**
  - Simplifies the monitoring of asset status, improving turnaround times and resource allocation

DP + AI Interoperability



Integrated (same vendor)

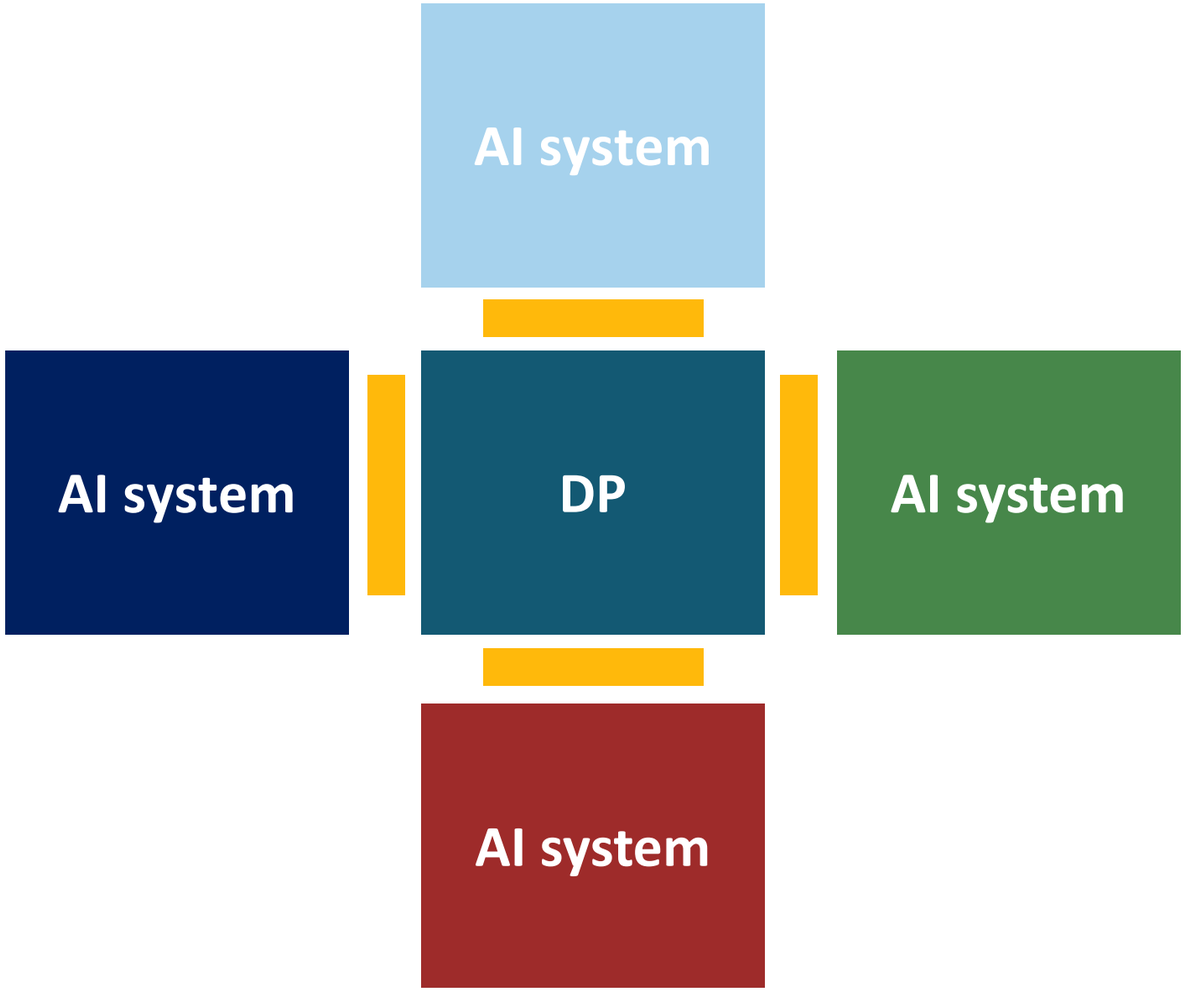
Custom interface

Standard-based interface

Standard-based interfaces

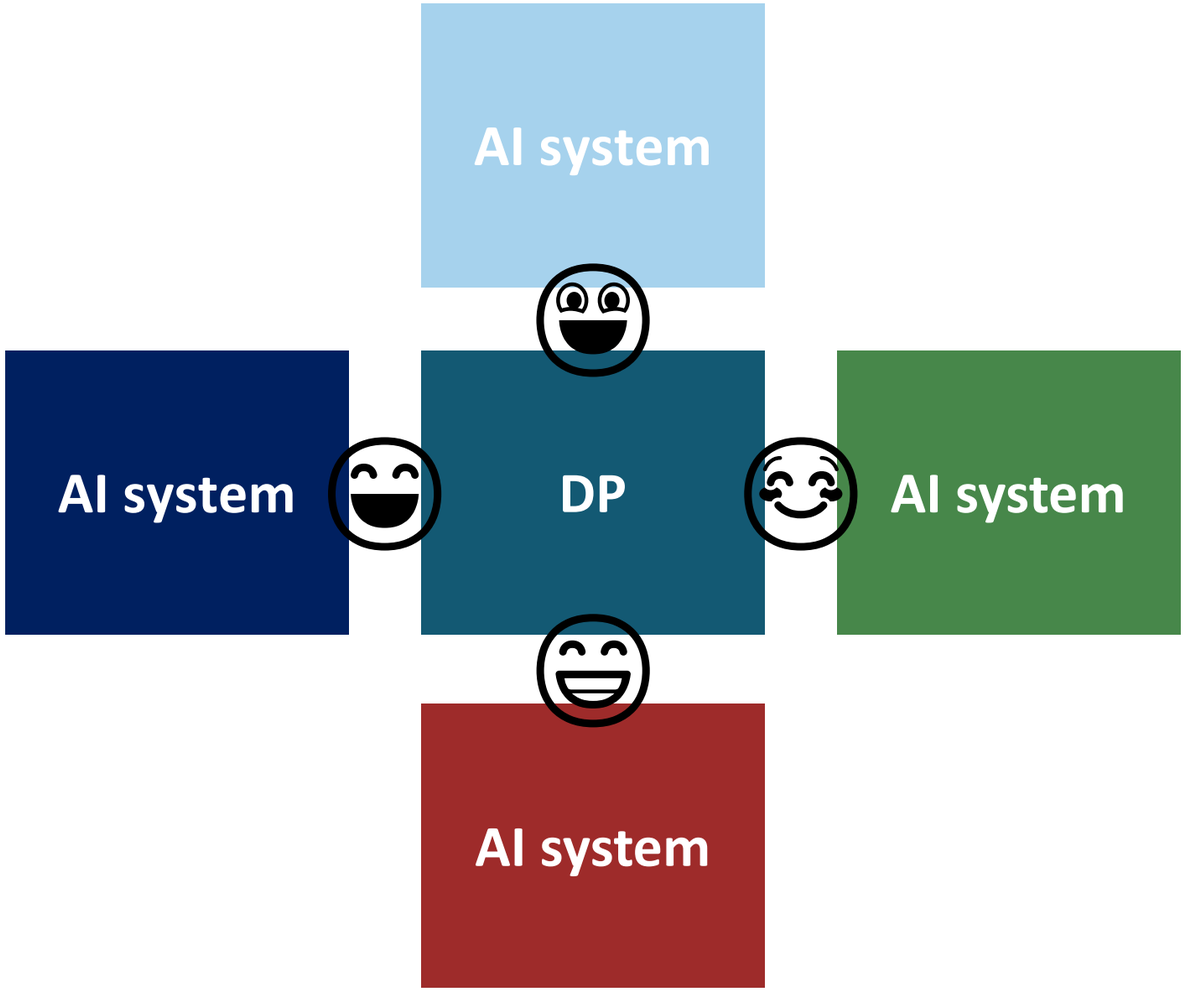
Potential to plug and play

(NOT A REALITY IN THE MARKET)



Custom interfaces

(Not scalable – Not sustainable)



Custom interfaces

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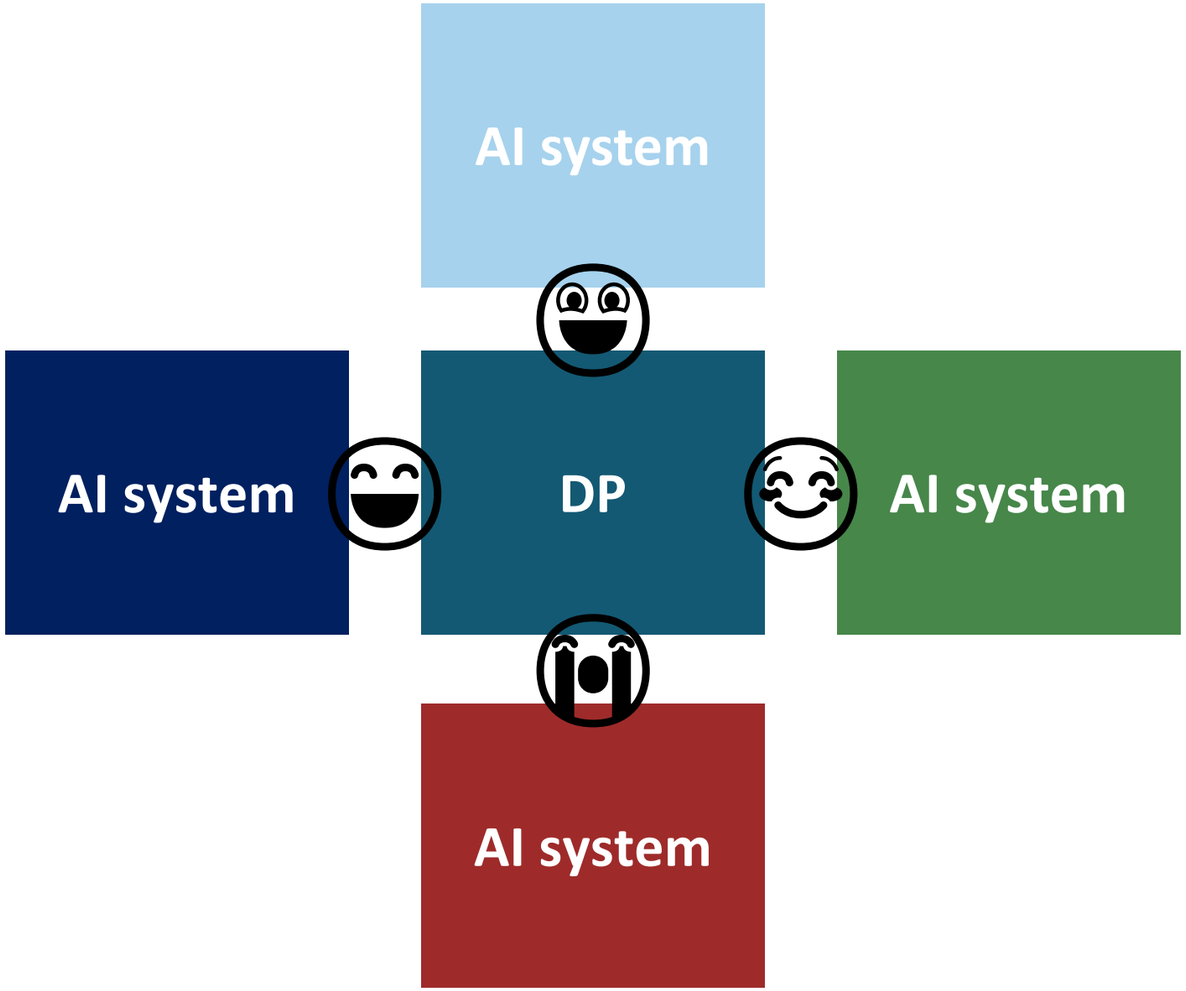

Custom interfaces

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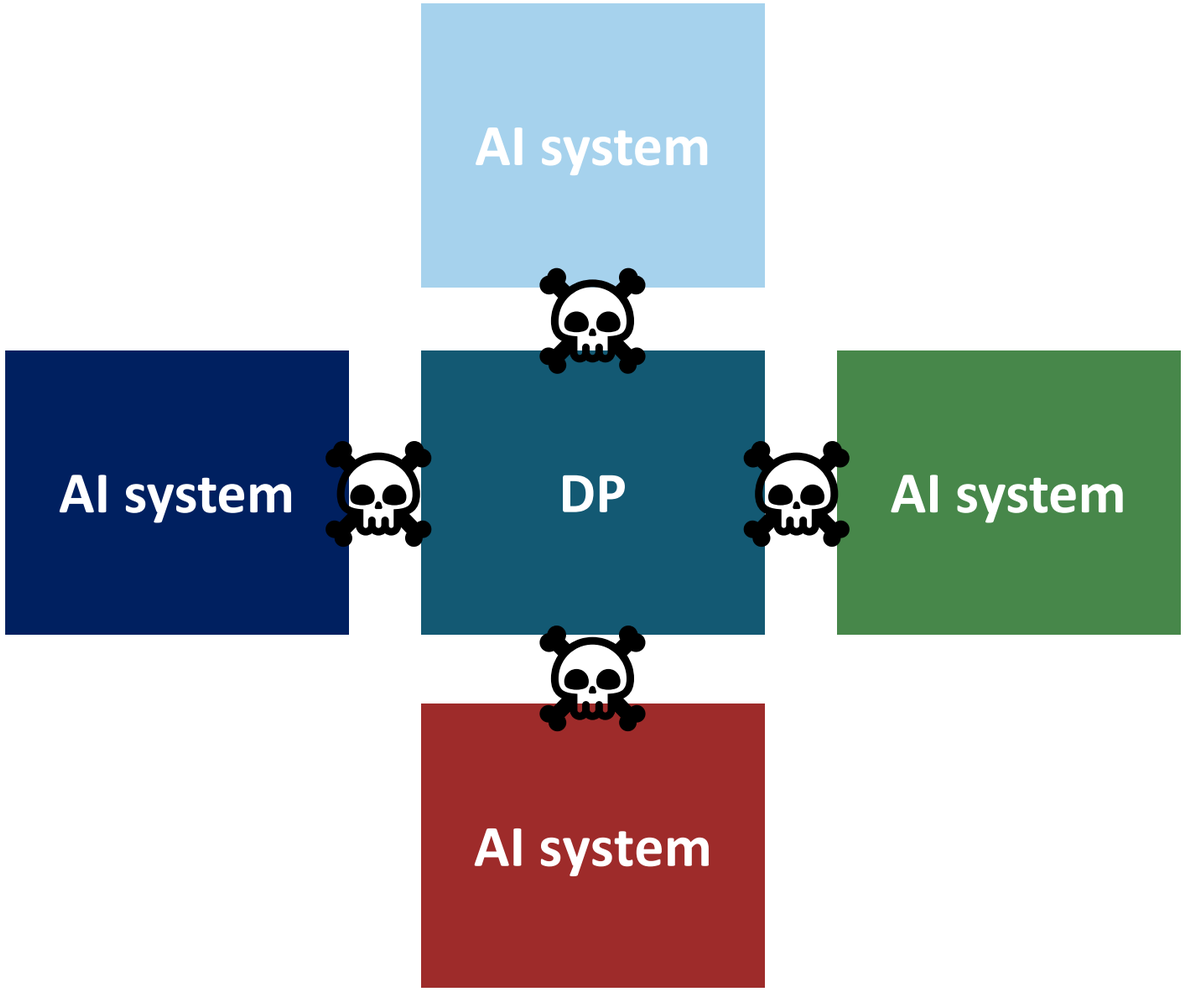

Example: LIS + DP + AI Interoperability

Vantage
Roche

Cerner PathNet

Paige

Custom interface

Current interface architecture at UofL Health

Conclusion & take-home messages

- DP and AI offer the potential for enhanced accuracy and productivity
- High-quality histology and lab operational efficiency are paramount
- Leveraging AI's full potential
  - Expertise, exploration, validation, and interoperability
- Adjudication risk
  - Suboptimal accuracy = workflow complexities and higher workloads
- Interoperability risk
  - Inadequate interoperability = workflow complexities and higher workloads

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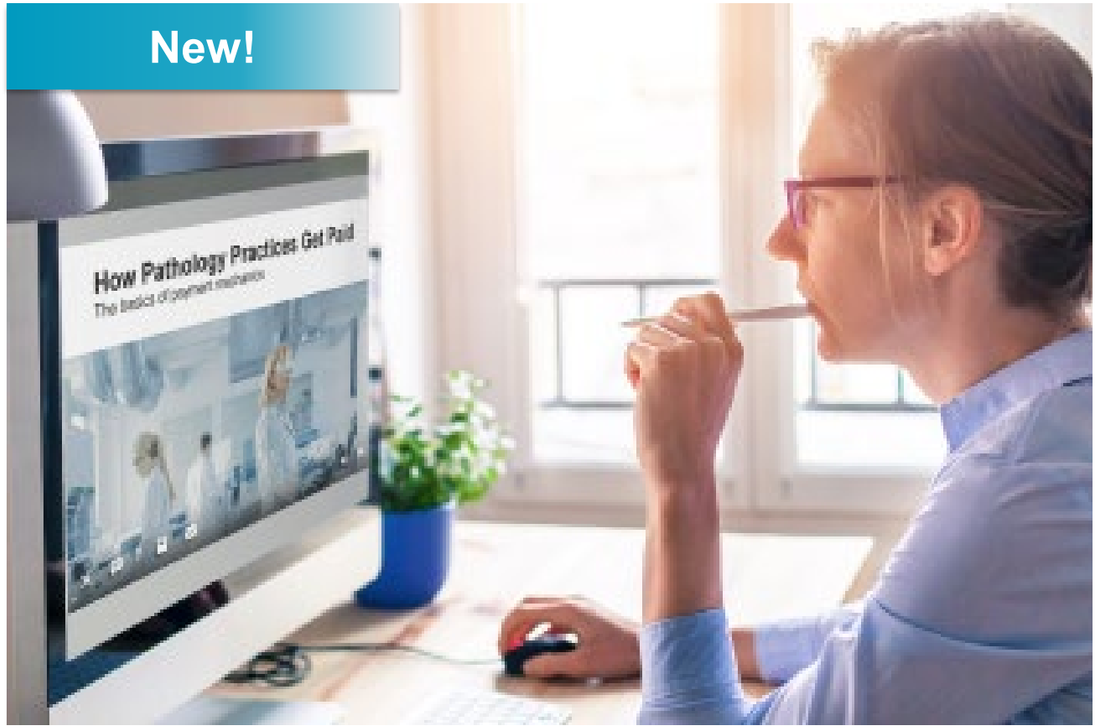
Essential online courses to help grow your management skills to lead your practice



1. Relative Value Units (RVU's)—Understanding the Basics
2. How Pathology Practices Get Paid
3. Revenue Cycle Management
4. Analysis and Interpretation of Billing Reports
5. Basic Practice Cost Analysis
6. Capacity Management and Workflow Analysis
7. Basic Contracting and Fee Analysis
8. Basic Budget Development

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Additional Resources

Practice Management

- https://www.cap.org/member-resources/practice-management

Practice Management Articles

- https://www.cap.org/member-resources/articles/category/practice-management

We value your feedback!

If after attending this discussion and later you applied any of what you learned to your practice, please share your feedback of how it worked for your practice at https://www.cap.org/member-resources/practice-management/practice-management-inquiry-form .

Watch for the session evaluation form. Your feedback is important!