COLLEGE of AMERICAN PATHOLOGISTS

Coming Reimbursement Opportunities for Digital Pathology

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Anil Parwani, MD, PhD, MBA, FCAP
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Conflicts of Interest

None of the speakers have any Conflicts of Interest

Marilyn Bui, MD, PhD, FCAP

Dr. Bui is the chair of the Digital and Computational Pathology Committee, Vice Speaker of the House of Delegates, and the ex-officio member of the Board of the Governors. She is a Senior Member in the Department of Pathology at Moffitt Cancer Center in Tampa, FL. She serves as the Scientific Director of Analytic Microscopy Core and the Section Head of Bone and Soft Tissue Pathology. She is also a Professor and Director of the Cytopathology Fellowship at the University of South Florida (USF) Morsani College of Medicine.

The CAP Committees hosting this webinar

Digital and Computational Pathology Committee

- The charge of the Digital and Computational Pathology Committee (DCPC) is to advance the adoption of digital pathology within the CAP and to serve as a respected resource for information and education for pathologists, patients and the public on the practice and science of digital pathology.

Committee Leadership

- Marilyn Bui, MD, PhD, FCAP Chair
- Savitri Krishnamurthy, MD, FCAP Vice Chair

Workgroups of the DCPC

- Digital Pathology Implementation and LAP Checklist, Digital Pathology Resource Guide, DCPC Website, HistoQIP-WSI, Education, and IVM/EVM Awareness and Education Subcommittee (AWE)

The CAP Committees hosting this webinar

Economic Affairs Committee

- The charge of the Economic Affairs Committee (EAC) is to assist pathologists as they exercise their medical expertise and judgment in the best interest of the patient by promoting and developing payment policies that allow the provision of high quality pathology services; and to facilitate pathologists' understanding of the payment policies and requirements of the government and other payers.

Committee Leadership

- Stephen Black-Schaffer, MD, FCAP Chair
- Ronald W McLawhon, MD, PhD, FCAP Vice Chair and Chair, CPT RUC Subcommittee
- Theresa S Emory, MD, FCAP, Chair, Payment Policy Subcommittee

Objectives of this webinar

1. Understanding the background of the new digital pathology CPT codes and its impact on our daily practice.
2. Sharing the best practices of adopting these codes in various practice settings.
3. Seeking feedback from our member community how can DCPC help to facilitate digital transformation in your practice.

Savitri Krishnamurthy, MD, FCAP

Dr. Krishnamurthy is the vice chair of the Digital and Computational Pathology Committee and is Professor of Pathology at The University of Texas MD Anderson Cancer Center in Houston, TX. She completed her Pathology residency training in New England Medical Center, Tuft's University in Boston followed by fellowship training in Oncologic Pathology at Memorial Sloan Kettering Cancer Center in New York and Cytopathology at the University of Texas MD Anderson Cancer Center.

Our Speakers and Panelist

Stephen Black-Schaffer, MD, FCAP

Dr. Black-Schaffer is the chair of the CAP's Economic Affairs Committee. Dr. Black-Schaffer is an Associate Professor of Pathology at Harvard Medical School and Associate Chief of Pathology at Massachusetts General Hospital, where he is the Pathology Residency Training Program Director, and a practicing surgical and cytopathologist.

Anil V Parwani MD, PhD, MBA, FCAP

Dr. Parwani is a Professor of Pathology at The Ohio State University. He serves as the Vice Chair and Director of Anatomical Pathology. Dr. Parwani is also the Director of Pathology Informatics and Director of the Digital Pathology Shared Resource at The James Cancer Hospital. His research is focused on diagnostic and prognostic markers in bladder and prostate cancer, and molecular classification of renal cell carcinoma.

Juan C. Santa-Rosario MD, FCAP

Dr. Santa-Rosario is the Medical Director for CorePlus, a pathology laboratory in Puerto Rico. Graduated from the University of Puerto Rico School of Medicine. He is board-certified in Clinical and Anatomic Pathology and has been in practice for 14 years. Dr. Santa has gained expertise in the developing field of Digital Pathology with the application of artificial intelligence solutions by the successful deployment of this technology in routine practice at their laboratory.

S. Joseph "Joe" Sirintrapun, MD, FCAP

Dr. Sirintrapun is an Associate Attending, Director of Pathology Informatics, and a member lead of the Warren Alpert Center for Computational Pathology at Memorial Sloan Kettering Cancer Center (MSKCC). He is also the past 2021 president of the Association for Pathology Informatics (API).

Webinar agenda

1. **Presentations by CAP Members 35-40 minutes**
   - Dr. Black-Schaffer
     - Will share the background of digital pathology CPT codes and their impact on our daily practice
   - Dr. Parwani
     - Will share their institutional experience with digital pathology.
   - Dr. Santa-Rosario
     - Will share their institutional experience with digital pathology.
2. **A moderated discussion of audience questions 20-25 minutes**
   - The discussion will be moderated by Dr. Krishnamurthy
   - Dr. Sirintrapun will be included in this discussion.

The background of digital pathology CPT codes and their impact on our daily practice

Stephen Black-Schaffer, MD, FCAP

CAP Win: Digital Pathology Digitization Procedures in CPT 2023

AMA CPT 2023
Digital Pathology Digitization Procedures Category III Codes, Guidelines and Instruction

Digital Pathology Category III Codes

- The CAP successfully advocated for the addition of new CPT digital pathology codes for 2023
- The CAP worked with the American Medical Association (AMA) CPT Editorial Panel to implement 13 new digital pathology add-on codes
- These new codes will be used to report additional clinical staff work and service requirements associated with digitizing glass microscope slides for primary diagnosis
- The new codes will help pathologists, pathology practices, and laboratories providing digital pathology digitization procedures appropriately report these services

Digital Pathology Digitization Procedures

►*Digital pathology is a dynamic, image-based environment that enables the acquisition, management, and interpretation of pathology information generated from digitized glass microscope slides.*

Glass microscope slides are scanned by clinical staff, and captured images (either in real-time or stored in a computer server or cloud-based digital image archival and communication system) are used for digital examination for pathologic diagnosis distinct from direct visualization through a microscope.

Digitization of glass microscope slides enables remote examination by the pathologist and/or in conjunction with the use of artificial intelligence (AI) algorithms.

Digital Pathology Digitization Procedures

CPT Code	Long Descriptor
+0751T	Digitization of glass microscope slides for level II, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure) ►(Use 0751T in conjunction with 88302)◄
+0752T	Digitization of glass microscope slides for level III, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure) ►(Use 0752T in conjunction with 88304)◄
+0753T	Digitization of glass microscope slides for level IV, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure) ►(Use 0753T in conjunction with 88305)◄
+0754T	Digitization of glass microscope slides for level V, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure) ►(Use 0754T in conjunction with 88307)◄
+0755T	Digitization of glass microscope slides for level VI, surgical pathology, gross and microscopic examination (List separately in addition to code for primary procedure) ►(Use 0755T in conjunction with 88309)◄
+0756T	Digitization of glass microscope slides for special stain, including interpretation and report, group I, for microorganisms (eg, acid fast, methenamine silver) (List separately in addition to code for primary procedure) ►(Use 0756T in conjunction with 88312)◄
+0757T	Digitization of glass microscope slides for special stain, including interpretation and report, group II, all other (eg, iron, trichrome), except stain for microorganisms, stains for enzyme constituents, or immunocytochemistry and immunohistochemistry (List separately in addition to code for primary procedure) ►(Use 0757T in conjunction with 88313)◄

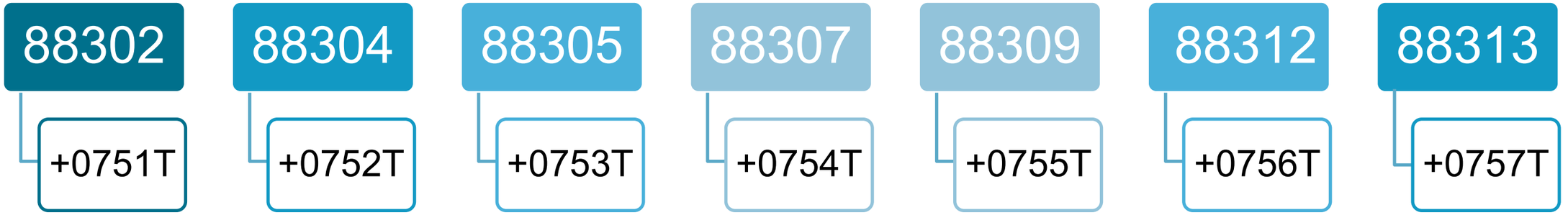
Digital Pathology Digitization Procedures

CPT Code	Long Descriptor
+0758T	Digitization of glass microscope slides for special stain, including interpretation and report, histochemical stain on frozen tissue block (List separately in addition to code for primary procedure) ▶(Use 0758T in conjunction with 88314)◀
+0759T	Digitization of glass microscope slides for special stain, including interpretation and report, group III, for enzyme constituents (List separately in addition to code for primary procedure) ▶(Use 0759T in conjunction with 88319)◀
+0760T	Digitization of glass microscope slides for immunohistochemistry or immunocytochemistry, per specimen, initial single antibody stain procedure (List separately in addition to code for primary procedure) ▶(Use 0760T in conjunction with 88342)◀
+0761T	Digitization of glass microscope slides for immunohistochemistry or immunocytochemistry, per specimen, each additional single antibody stain procedure (List separately in addition to code for primary procedure) ▶(Use 0761T in conjunction with 88341)◀
+0762T	Digitization of glass microscope slides for immunohistochemistry or immunocytochemistry, per specimen, each multiplex antibody stain procedure (List separately in addition to code for primary procedure) ▶(Use 0762T in conjunction with 88344)◀
+0763T	Digitization of glass microscope slides for morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semiquantitative, per specimen, each single antibody stain procedure, manual (List separately in addition to code for primary procedure) ▶(Use 0763T in conjunction with 88360)◀

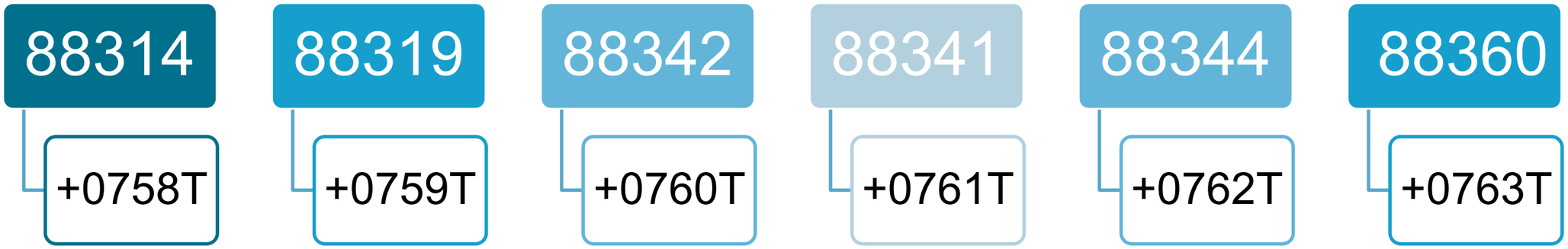
Digital Pathology Digitization Procedures

Category III add-on codes 0751T-0763T may be reported in addition to the appropriate Category I service code when the digitization procedure of glass microscope slides is performed and reported in conjunction with the Category I code for the primary service.

Digital Pathology CPT Codes



Digital Pathology CPT Codes



Digital Pathology Digitization Procedures

Do not report the Category III codes in this subsection solely for archival purposes (eg, after the Category I service has already been performed and reported), solely for educational purposes (eg, when services are not used for individual patient reporting), solely for developing a database for training or validation of AI algorithms, or solely for clinical conference presentations (eg, tumor board interdisciplinary conferences).◄

Digital Pathology Digitization Procedures

Do NOT report the new Category III codes:

- SOLELY for archival purposes (eg, after the Category I service has already been performed and reported)
- SOLELY for educational purposes (eg, when services are not used for individual patient reporting)
- SOLELY for developing a database for training or validation of AI algorithms
- SOLELY for clinical conference presentations (eg, tumor board interdisciplinary conferences)

Digital Pathology Digitization Procedures

- **July 1, 2022: Released to the AMA website**
- **January 1, 2023: Effective Date**
  - **July 2022 - December 2022: Implementation Period**

Next Steps

- **Category III CPT codes are temporary codes for emerging technology**
  - They allow for data collection associated with the service
  - They have no assigned relative value unit (RVUs) or established payment
- **Steps to move to Category I CPT code status**
  - Category I CPT codes are restricted to clinically recognized and generally accepted services, and are not for emerging technologies, services, or procedures
  - It requires that clinical efficacy be well established and documented in the US peer reviewed literature
  - These services must be performed by many physicians in clinical practice in multiple locations
    - Category III code usage is intended to document the need for category I codification

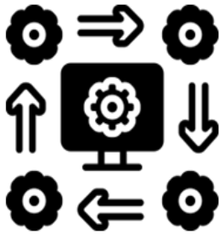
What are pathology departments or labs are doing to adopt the digital pathology codes?

The Ohio State University Medical Center Experince

Anil Parwani MD, PhD, MBA, FCAP

Timeline of Digital Pathology at OSU; Where are we today

2016



The James and DOP develop a comprehensive digital pathology solution, including hardware, software, and clinical workflow
The aspiration of the initiative was to build a world leading digital pathology service organization

2017

Full scale digital pathology scanning services launched enabling the digital pathology team to convert their traditional glass slides into high-resolution digital images for faster and easier viewing

2019

EPIC Beaker goes live. This allows for easy access to a list of scanned slides, as well as the ability to sort slides by Part ID, Block ID, Slide ID, and Image Creation Time

2022

OSU reaches 3M slides scanned and digitized. This represents one of the largest digital pathology assets in the world.

BY THE

3 Million
slide scanned and digitized

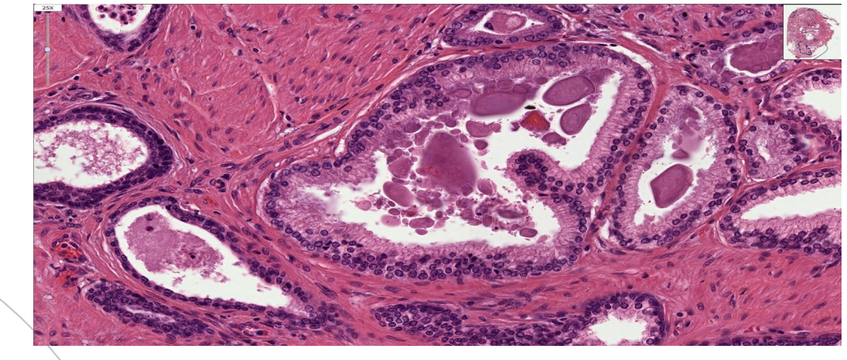
7 Sites
partnering with OSU on digital pathology initiatives

6 Grants
related to digital pathology since 2017 valued at ~$4.9 M

4 Clinical Trials
related to digital pathology since 2017 valued at ~$1.7 M

Digital Pathology: Value Drivers

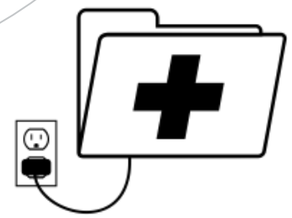
Why is reimbursement and CPT codes critical for us?



Digital workflow enables transmission of images to pathologists increasing the quality of reviews and speed of diagnosis

Expansive pool of pathologists covering a range of specialties

Interoperability across EMRs, IT solutions, and enhanced continuity of care



Robust data warehouse enabling machine learning and AI tools

Data solution used for developing, validating, and testing algorithms for research and clinical development

SUSTAINABILITY OF THE ENTIRE DIGITAL PATHOLOGY PROGRAM IS DEPENDENT ON REVENUE GENERATION SO WE CAN CONTINUE TO GROW THE PROGRAM

REVENUE OPPORTUNITIES USING DIGITAL WORKFLOW

- **Enhanced Diagnostics**
- **Rapid Access to Subspecialists**
- **Information/Imaging Management and Applications**
- **Research Applications**
- **Clinical and Research Revenue Stream Development**

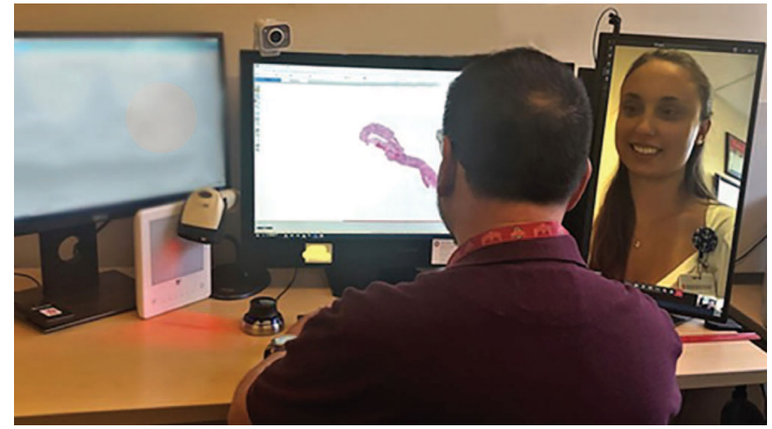
WHAT ARE THE BARRIERS TO ACHIEVE THESE?

- Equipment Operating Cost (software, consult portal build, equipment depreciation, space rental, etc.)
- Staffing Cost
- Operating Cost (utilities, supplies, marketing materials, etc.)
- Capital Investment (scanners, storage, renovation cost for space, etc.)

Major Market Drivers and Constraints

Drivers

- Increased awareness of digital pathology
- Initiatives taken by major players
- Increase in application of digital pathology, particularly in large health systems and in AI/ML



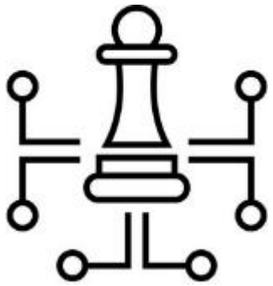
Barriers

- Expense of digital pathology systems, maintenance, and implementation/start up
- Need for specialized staff trained in the technology
- Lack of billable CPT codes for digitization of slides for routine workflows

OSU: Digital Pathology Priorities

Review of current state

- What is working?
- What are the challenges?
- Hardware and software “refresh”



Strategic planning for next phase of growth

- Increased focus on data commercialization and AI

New CPT codes – Why are we not ready yet?

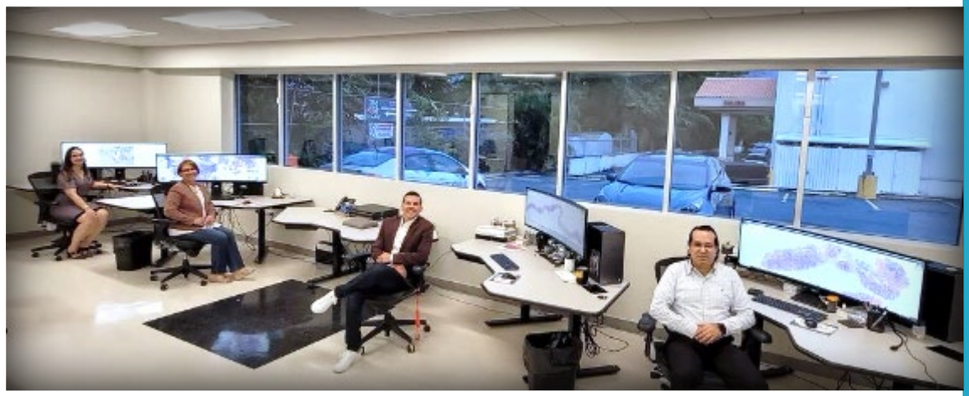
- Need a “complete” digital workflow
- Areas not being scanned 100% include renal pathology, hematopathology, cytopathology
- Special types of slides – Whole mounts etc.
- Need to make modifications in the LIS to add new CPT codes
- Need to document the CPT code usage

The CorePlus Experience

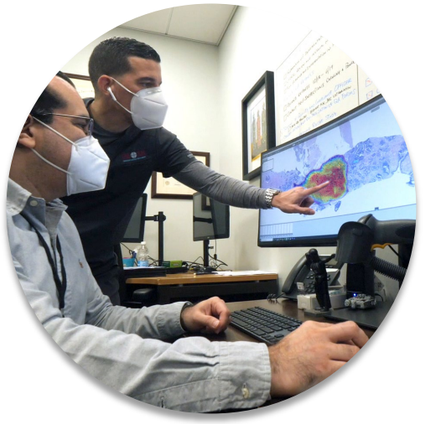
Juan C. Santa-Rosario, MD, FCAP

Practice Overview

- **6 Pathologists**
  - **1 Cytopathologist**
  - **1 Molecular Genetic Pathologist**
- **1 PhD**
- **5 Cytotechnologists**
- **6 Histotechnologists**
- **10 Medical Technologists**
- **…and many more!!!**
- **>150,000** accessions/yr
- **Multispecialty**
- AP/CP
- Referral base
  - Outpatient
  - ASC
- **Island wide coverage**



Our Journey to Full Digitization



IDEA
Why go digital?

2018

RESEARCH
Evaluate scanners and AI technologies for a successful combination

2019

ASSESSMENT
Hardware requirements and laboratory workflow re-design

CONFIGURATION
Scanning profiles configuration, evaluation and selection

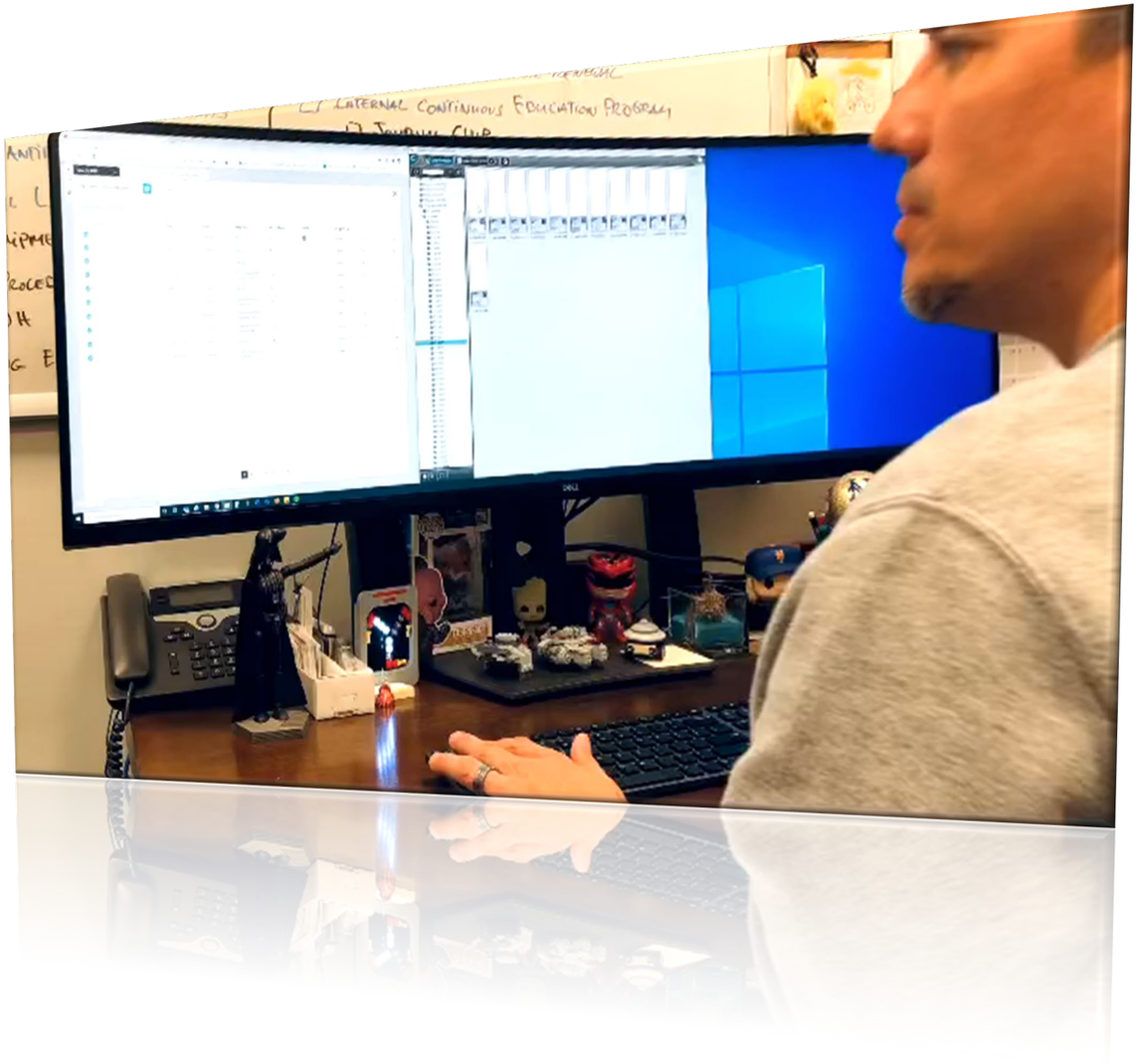
WORKFLOW
Implementation and Workflow refinements

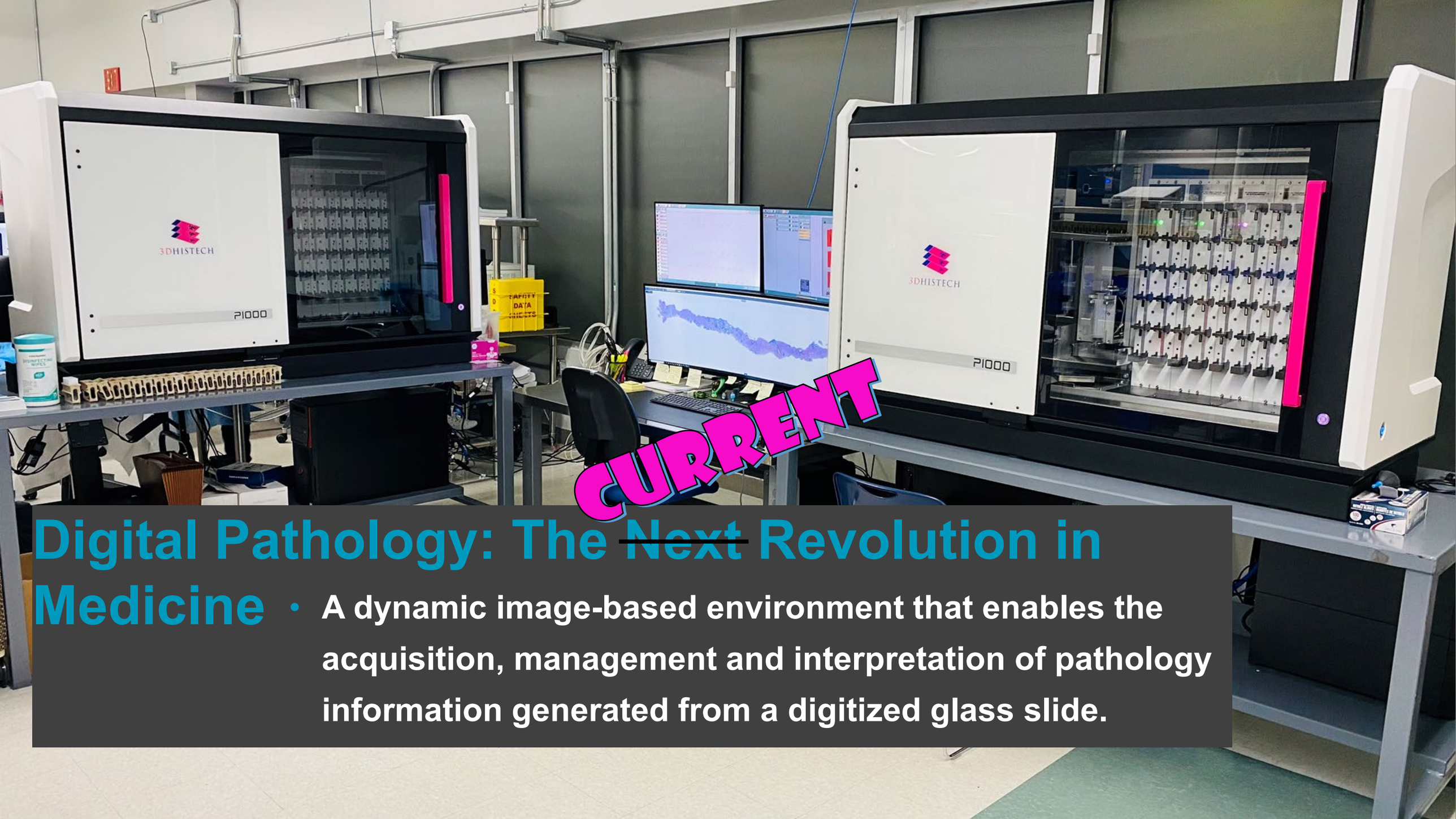
LDT
Deployment of Galen Prostate AI solution

CORE PLUS

Key Considerations for Digital Pathology & AI

- **Improve Patient Care**
- **Innovate** in Artificial Intelligence Assisted Diagnostics
- Introduce **Transformative & Disruptive Technologies**
- **Enable growth** & handle case load increases
- **Connect remote Pathologists**
- **Empower pathologists** at CorePlus to be **industry leaders**





Digital Pathology: The ~~Next~~ Revolution in Medicine

- **A dynamic image-based environment that enables the acquisition, management and interpretation of pathology information generated from a digitized glass slide.**

CAP
Validation Guidelines

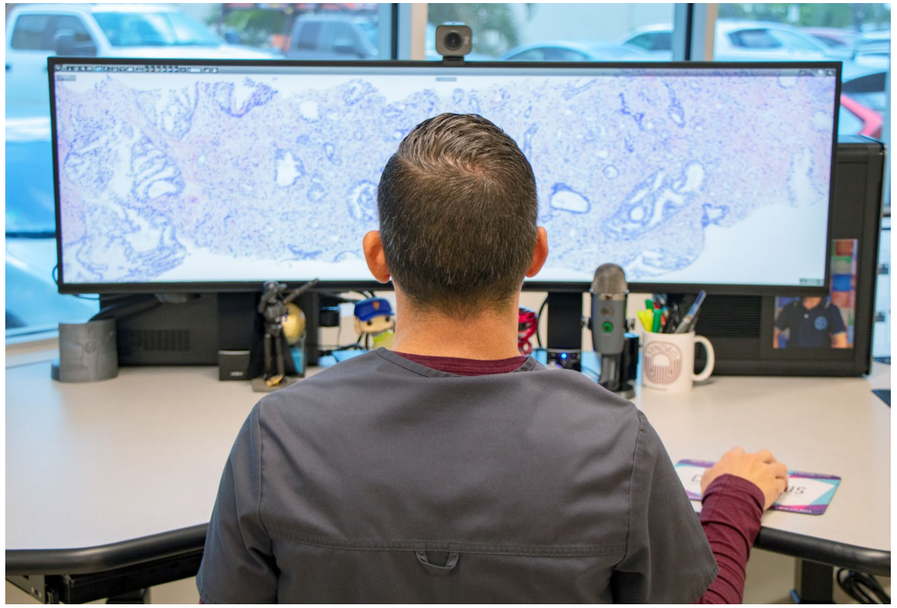
Validating Whole Slide Imaging for Diagnostic Purposes in Pathology

Guideline from the College of American Pathologists Pathology and Laboratory Quality Center

Liron Pantanowitz, MD; John H. Sinard, MD, PhD; Walter H. Henricks, MD; Lisa A. Fatheree, BS, SCT(ASCP); Alexis B. Carter, MD; Lydia Contis, MD; Bruce A. Beckwith, MD; Andrew J. Evans, MD, PhD; Christopher N. Otis, MD; Avtar Lal, MD, PhD; Anil V. Parwani, MD, PhD

Table 1. Guidelines for Validating Whole Slide Imaging (WSI) Systems for Diagnostic Purposes in Pathology

Guideline Statement	Grade of Evidence
1. All pathology laboratories implementing WSI technology for clinical diagnostic purposes should carry out their own validation studies.	Expert consensus opinion
2. Validation should be appropriate for and applicable to the intended clinical use and clinical setting of the application in which WSI will be employed. Validation of WSI systems should involve specimen preparation types relevant to the intended use (eg, formalin-fixed paraffin-embedded tissue, frozen tissue, immunohistochemical stains, cytology slides, hematology blood smears). *Note: If a new intended use for WSI is contemplated, and this new use differs materially from the previously validated use, a separate validation for the new use should be performed.*	Recommendation Grade A
3. The validation study should closely emulate the real-world clinical environment in which the technology will be used.	Recommendation Grade A
4. The validation study should encompass the entire WSI system. *Note: It is not necessary to validate separately each individual component (eg, computer hardware, monitor, network, scanner) of the system nor the individual steps of the digital imaging process.*	Recommendation Grade B
5. Revalidation is required whenever a significant change is made to any component of the WSI system.	Expert consensus opinion
6. A pathologist(s) adequately trained to use the WSI system must be involved in the validation process.	Recommendation Grade B
7. The validation process should include a sample set of at least 60 cases for one application (eg, H&E-stained sections of fixed tissue, frozen sections, cytology, hematology) that reflects the spectrum and complexity of specimen types and diagnoses likely to be encountered during routine practice. *Note: The validation process should include another 20 cases for each additional application (eg, immunohistochemistry, special stains).*	Recommendation Grade A
8. The validation study should establish diagnostic concordance between digital and glass slides for the same observer (ie, intraobserver variability).	Suggestion Grade A
9. Digital and glass slides can be evaluated in random or nonrandom order (as to which is examined first and second) during the validation process.	Recommendation Grade A
10. A washout period of at least 2 weeks should occur between viewing digital and glass slides.	Recommendation Grade B
11. The validation process should confirm that all of the material present on a glass slide to be scanned is included in the digital image.	Expert consensus opinion
12. Documentation should be maintained recording the method, measurements, and final approval of validation for the WSI system to be used in the clinical laboratory.	Expert consensus opinion



diagnostics

MDPI

Guidelines

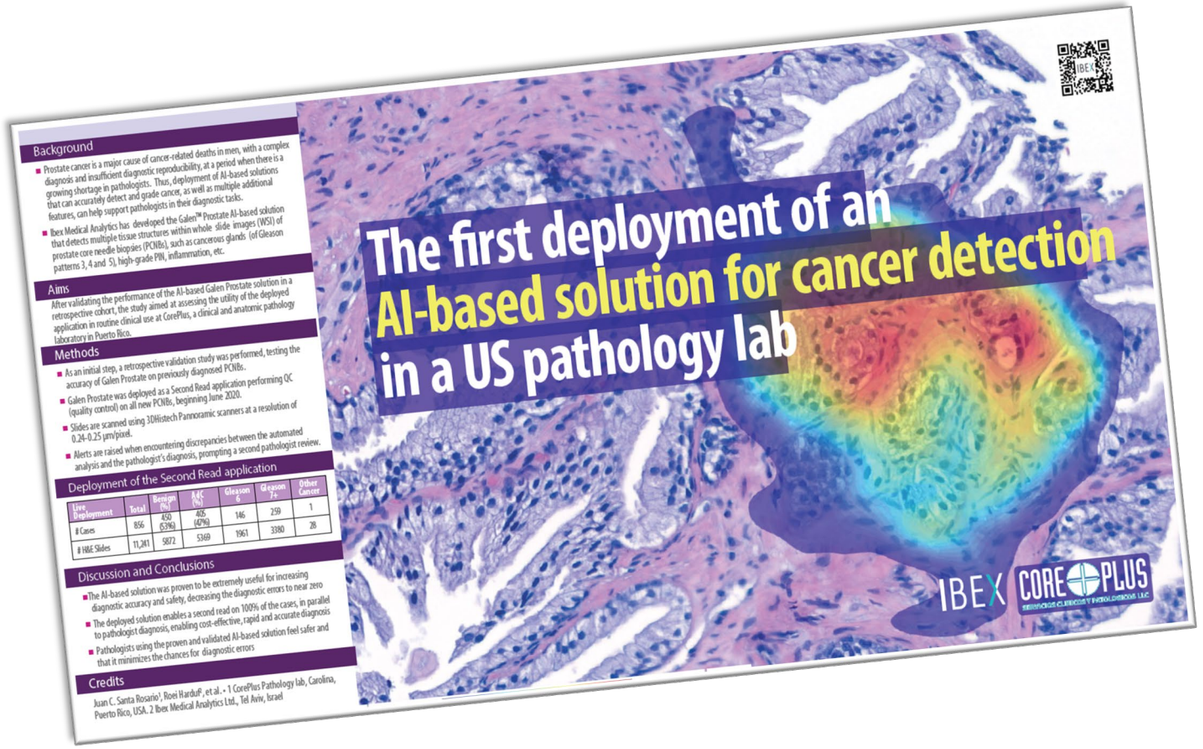
Best Practice Recommendations for the Implementation of a Digital Pathology Workflow in the Anatomic Pathology Laboratory by the European Society of Digital and Integrative Pathology (ESDIP)

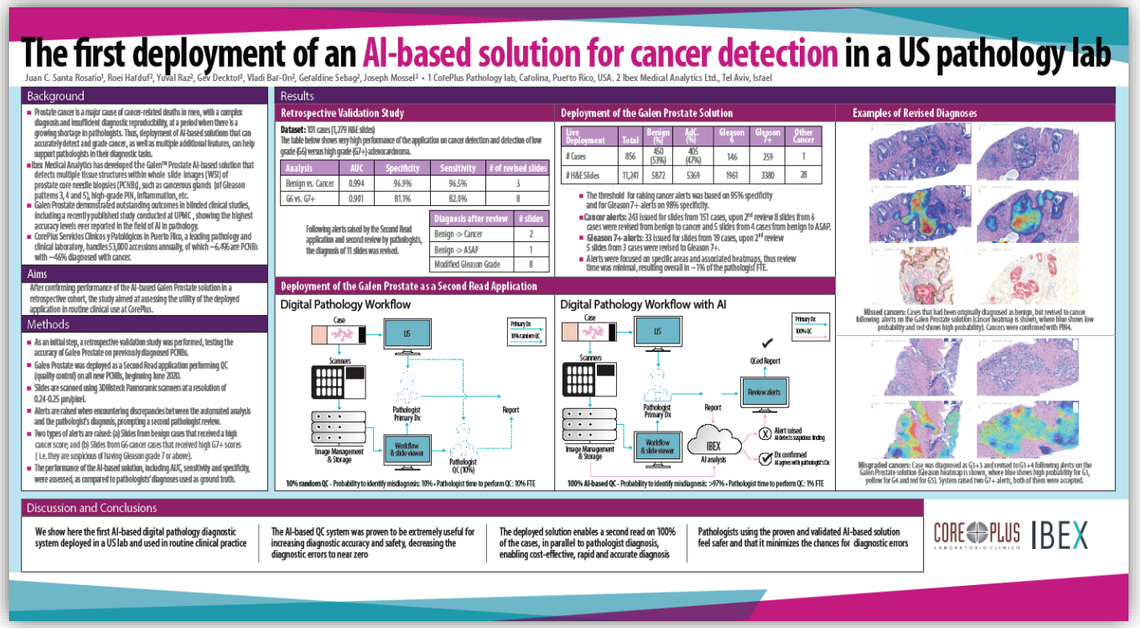
Filippo Fraggetta [1,2], Vincenzo L'Imperio [1,3], David Ameisen [1,4], Rita Carvalho [1,5], Sabine Leh [1,6,7], Tim-Rasmus Kiehl [1,5], Mircea Serbanescu [1,8], Daniel Racoceanu [1,9], Vincenzo Della Mea [1,10], Antonio Polonia [1,11,12], Norman Zerbe [1,5] and Catarina Eloy [1,11,12,*]

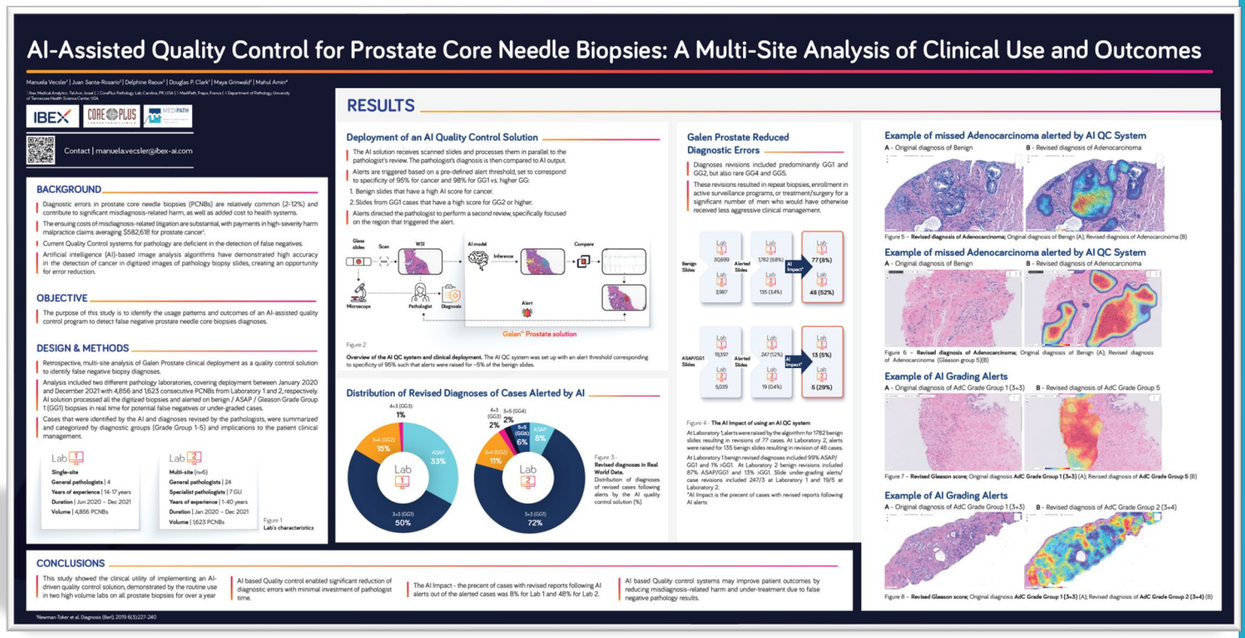

Remote Sign-out
Work-life balance

Disrupting with Artificial Intelligence

Poster Presentations







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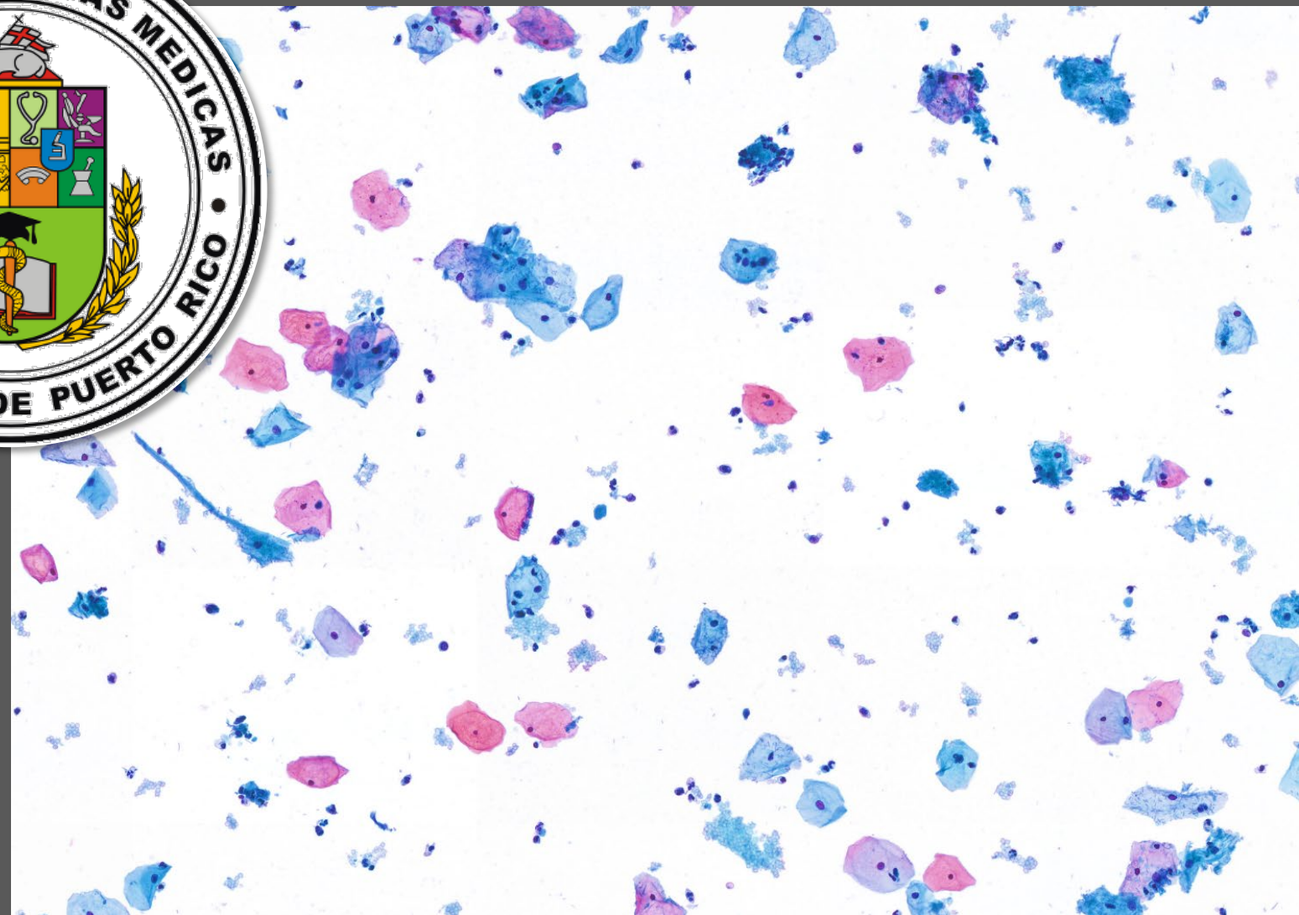
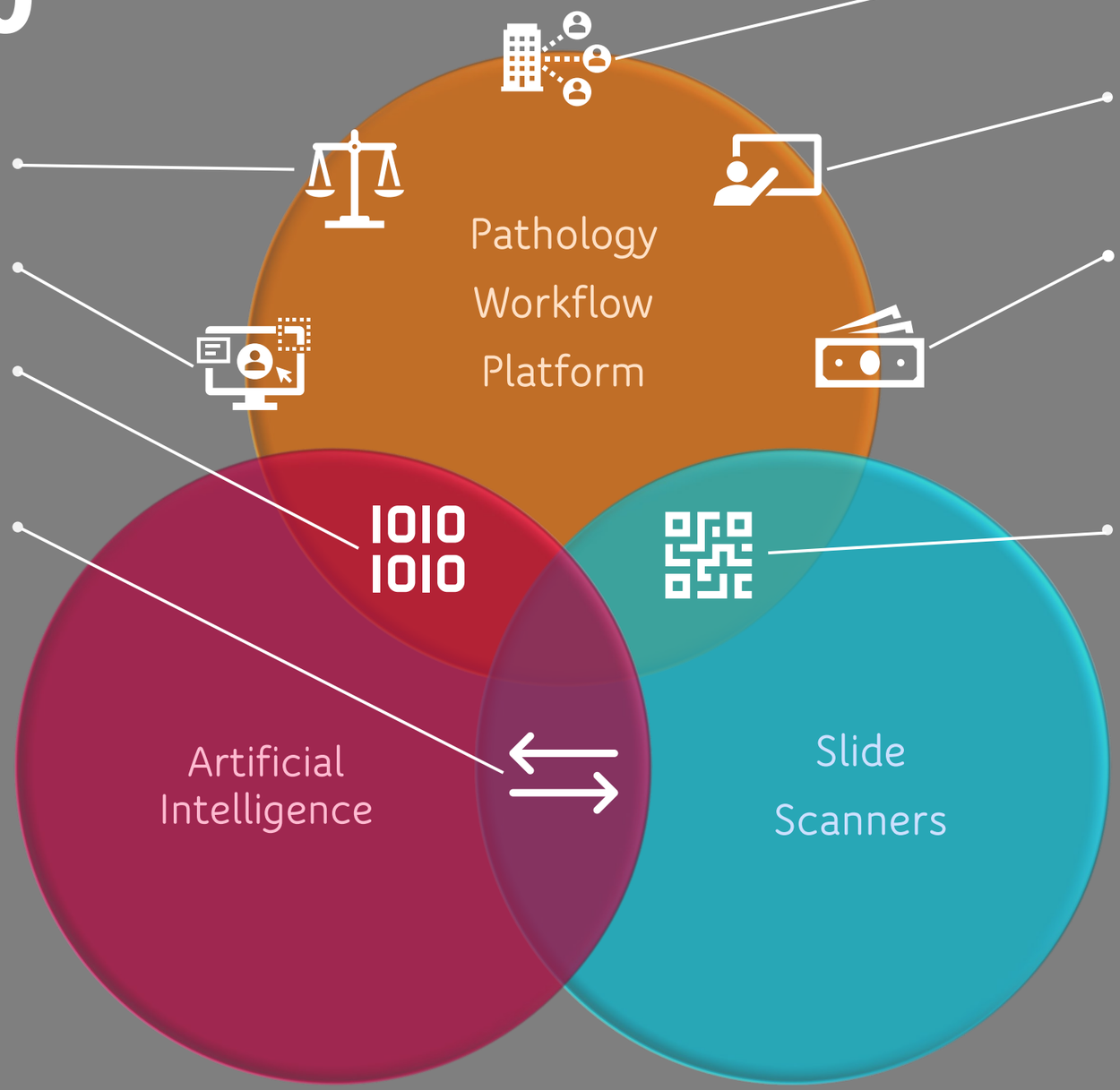
- **University of Puerto Rico**
  - AP/CP Residency
  - Cytotechnology Program

Committed to Education



Workflow Optimization Platform

WSI 2.0



Load balancing

Enhanced user experience

Receive AI-generated diagnostic information

Exchange automation to AI environment

Remote sign-out

Interactive peer review

Revenue Cycle Management automation

Physical media (barcodes)

Questions

What is your view regarding the impact of the new digital pathology codes in accelerating the adoption of digital pathology in routine clinical practice? Will it accelerate, or will it lead to a slow and steady increase in adoption?

Questions

What is the biggest obstacle that practices can face in adopting digital pathology in academic and community practices?

Questions

Digital pathology codes currently pertain to surgical pathology practice;

where are we with codes for digital cytopathology?

Questions

Audience Questions

Thank You

The DCPC will be producing more digital pathology educational content in 2023.

- **In addition to webinars the committee will produce podcasts on digital pathology implementation and will create a digital pathology frequently asked questions (FAQ) section for our updated and enriched website.**
  - **DCPC Website**

We are also updating the Digital Pathology Resource Guide. Please reach out if you are interested in assisting with this effort.

To become a DCPC member please apply during the upcoming committee appointment cycle.