Embracing Digital and Computational Pathology:  
A Calling for Pathologists as Leaders in Precision Medicine

Marilyn M. Bui, MD. PhD
Moffitt Cancer Center, Tampa, FL. USA
About the Presenter

No financial conflict of interest

Marilyn M. Bui, MD, PhD, FCAP
Email: Marilyn.Bui@Moffitt.org

Marilyn M. Bui | Moffitt Cancer Center
https://moffitt.org/providers/marilyn-bui/

@DrBuiPathology

• Senior Member/Professor of Pathology, Scientific Director of Analytic Microscopy Core, President of Medical Staff and Cytopathology Fellowship Program Director at the Moffitt Cancer Center https://moffitt.org in Tampa, Florida

• President of the Digital Pathology Association https://digitalpathologyassociation.org/


• Vice Chair of the CAP Digital Pathology Committee

• Editorial Board member of Journal of Pathology Informatics
Objectives

- Review the revolution of digital pathology (DP) and its impact on precision medicine
- Discuss lessons learned and challenges exist
- Identify resources, guidelines, opportunities and collaboration potential
- Highlight DPA recent accomplishments
A patient’s medical journey begins with their diagnosis...

Pathologists provide forecast of Diagnosis, Prognosis & Therapy.

Pathologists are natural leaders in precision medicine.
Pathologist Supply Down Relative to Diagnostic Demands

The number of pathologists in the United States decreased by 17.53% from 2007 to 2017, despite a corresponding 41.73% rise in diagnostic workload per pathologist, a study published online May 31 in *JAMA Network Open* shows.

*Medscape Medical News*

**Shortage of Histopathologists in the United Kingdom Now Contributing to Record-Long Cancer-Treatment Waiting Times in England**

Oct 31, 2018 | Laboratory Hiring & Human Resources, Laboratory Management and Operations, Laboratory News, Laboratory Operations, Laboratory Pathology, Laboratory Testing

*Only 3% of histopathology departments that responded to the Royal College of Pathologists’ workforce census reported enough staff to meet clinical demand*

The number of seniors applying for pathology positions dropped by 27.5% between 2008 and 2017, according to a study by Dr. Ryan Jajosky et al published in *Human Pathology* (March 2018, Vol. 73, pp. 26-32).

In its most recent workforce report, The Royal College of Pathologists is reiterating its call for:

- Increased funding for training;
- Better information technology (IT) for day-to-day work;
- Capital investment to implement digital pathology more widely; and,
- Development of advanced clinical practitioner apprenticeships to help more biomedical scientists become independent practitioners who would work alongside medically-qualified histopathologists.
One of the most promising fields of digital medicine

- Computational pathology/integrated pathology informatics
- Transform pathology data into clinically actionable knowledge

- Connectivity & accessibility
- Image analysis, artificial intelligence and automation
- Improved quality & efficiency
DP & AI - The Third Revolution in Pathology

Artificial Intelligence - The Third Revolution in Pathology

Manuel Saito-Teller, Perry Maxwell, Peter Hamilton
First published: 01 October 2018 | https://doi.org/10.1111/nis.12760
Digital pathology is not just the transfer of histopathological slides into digital representations. The combination of different data sources (images, patient records, and *omics data) together with current advances in artificial intelligence/machine learning enable to make novel information accessible and quantifiable to a human expert, which is not yet available and not exploited in current medical settings.

Augmented Pathologist

Explainable Artificial Intelligence in Digital Pathology by Holzinger, Malle, Kieseberg, Roth, Muller, Reihs, Zatloukal

Deep Learning in Breast Pathology

Automated classification of patients with metastatic breast cancer in lymph node


2. Peter Bandi, Oscar Geessink, Quirine Manson, et al. From detection of individual metastases to classification of lymph node status at the patient level: the CAMELYON17 challenge. IEEE-TMI (Early Access) DOI: 10.1109/TMI.2018.2867350

Downloading the data set

CAMELYON16 and CAMELYON17 data sets are open access and shared publicly on GigaScience, Google Drive and on Baidu Pan.
National Institutes of Health (NIH) grants-supported research

ARTIFICIAL INTELLIGENCE FOR COMPUTATIONAL PATHOLOGY

Image interpretation plays a central role in the pathologic diagnosis of cancer. Since the late 19th century, the primary tool used by pathologists to make definitive cancer diagnoses is the microscope. Pathologists diagnose cancer by manually examining stained sections of cancer tissues to determine the cancer subtype. Pathologic diagnosis using conventional methods is labor-intensive with poor reproducibility and quality concerns. New approaches use fundamental AI research to build tools to make pathologic analysis more efficient, accurate, and predictive. In the 2016 Camelyon Grand Challenge for metastatic cancer detection, the top-performing entry in the competition was an AI-based computational system that achieved an error rate of 7.5%. A pathologist reviewing the same set of evaluation images achieved an error rate of 3.5%. Combining the predictions of the AI system with the pathologist lowered the error rate to down to 0.5%, representing an 85% reduction in error (see image). This example illustrates how fundamental research in AI can drive the development of high performing computational systems that offer great potential for making pathological diagnoses more efficient and more accurate.
A deep learning approach for learning survival directly from histological images and creating a unified framework for integrating histology and genomic biomarkers for predicting time-to-event outcomes.

Systematically evaluated the prognostic accuracy of this approach in the context of the current clinical standard based on genomic classification and histologic grading of gliomas.

This approach rivals or exceeds the accuracy of highly trained human experts in predicting survival.

Improving the accuracy and objectivity of grading will directly impact patient care.
Classification and mutation prediction from non-small cell lung cancer histopathology images using deep learning

Nicolas Coudray, Paolo Santiago Ocampo, Theodore Sakellaropoulos, Navneet Narula, Matija Snuderl, David Fenyö, Andre L. Moreira, Narges Razavian and Aristotelis Tsimpogiannis

Visual inspection of histopathology slides is one of the main methods used by pathologists to assess the stage, type and subtype of lung tumors. Adenocarcinoma (LUAD) and squamous cell carcinoma (LUSC) are the most prevalent subtypes of lung cancer, and their distinction requires visual inspection by an experienced pathologist. In this study, we trained a deep convolutional neural network (inception v3) on whole-slide images obtained from The Cancer Genome Atlas to accurately and automatically classify them into LUAD, LUSC or normal lung tissue. The performance of our method is comparable to that of pathologists, with an average area under the curve (AUC) of 0.97. Our model was validated on independent datasets of frozen tissues, formalin-fixed paraffin-embedded tissues and biopsies. Furthermore, we trained the network to predict the ten most commonly mutated genes in LUAD. We found that six of them—STK11, EGFR, FAT1, SETBP1, KRAS and TP53—can be predicted from pathology images, with AUCs from 0.733 to 0.856 as measured on a held-out population. These findings suggest that deep-learning models can assist pathologists in the detection of cancer subtype or gene mutations. Our approach can be applied to any cancer type, and the code is available at https://github.com/coudray/DeepPATH.
Assessment of PD-L1 Expression & Immune Cell Infiltrates

**CELL-LEVEL ANALYSIS: T-CELL INFILTRATION**
- Colon cancer tissue (TMA)
- Cytokeratin (red)
- CD8 (brown)
- Nuclear
- Tumor cells
- CD8+ cells
- Analysis: 867 Tumor cells, 350 CD8+ T-cells

**SPATIAL PLOTTING**

**SPATIAL ANALYSIS**

Precision immunoprofiling by image analysis and artificial intelligence

Viktor H. Koelzer, Koruk Sirinukunwattana, Jens Rittscher, Kirsten D. Mertz

Received: 15 May 2018 / Revised: 6 November 2018 / Accepted: 9 November 2018 © The Author(s) 2018
Multiplex Biomarker Testing for Clinical Trials

Assessment of Immune Cells

Multiplex IF Stained Section

Courtesy of Susan McCarthy of Moffitt Cancer Center using Vectra in a CLIA lab for clinical trials
Pancreatic ductal adenocarcinoma (PDAC) has been refractory to immunotherapy and is characterized by a complex, stroma-rich tumor microenvironment. Most patients undergo treatment with aggressive chemotherapeutic regimens, which may alter the cellular composition and immunologic landscape within these tumors. To date, few studies have characterized the impact of chemotherapy on individual cellular compartments within PDAC tumors. We hypothesized that neoadjuvant chemotherapy may differentially modulate immune factors in the tumor, stroma and immune-cell rich regions of human PDAC tumors. We compared the spatial expression of 31 immuno-oncology targets across PDAC FFPE specimens from FOLFIRINOX and non-treated patients (n=5 each). Using the Digital Spatial Profiling technology from Nanostring®, we were able to identify FOLFIRINOX treatment results in significant spatially-distinct changes in protein expression.
Barriers to DP Adoption

- Regulatory
- Financial
- Technical
- Cultural
• Leading digital pathology companies have recently received **FDA approval** for a whole slide imaging system for primary diagnosis in US.

**Quality and reliability of the imaging system**

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**F.D.A. News Release**

**FDA allows marketing of first whole slide imaging system for digital pathology**

**For Immediate Release:** April 12, 2017

The U.S. Food and Drug Administration today permitted marketing of the Philips IntelliSite Pathology Solution (PIPS), the first whole slide imaging (WSI) system that allows for review and interpretation of digital surgical pathology slides prepared from biopsied tissue. This is the first time the FDA has permitted the marketing of a WSI system for these purposes.

"The system enables pathologists to read tissue slides digitally in order to make diagnoses, rather than looking directly at a tissue sample mounted on a glass slide under a conventional light microscope," said Alberto Gutierrez, Ph.D., Director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health. "Because the system digitizes slides that would otherwise be stored in physical files, it also provides a streamlined slide storage and retrieval system that may ultimately help make critical health information available to pathologists, other health care professionals and patients faster."
Breaking Financial Barriers

~ 12-13% (published) efficiency gain at pathologist level
~ Saving on retrieval of archived slides
~ Merger of departments/labs with flexible pathologist availability
~ Reduced turn around time changes patient pathways
  • reducing visits and in-patient time
  • better more efficient use of resources
~ Facilitates review improving diagnostic accuracy

J Pathol Inform

Research Article
Can Digital Pathology Result In Cost Savings? A Financial Projection For Digital Pathology Implementation At A Large Integrated Health Care Organization

Jonhan Ho, Stefan M. Ahlers1, Curtis Stratman2, Orly Aridor3, Liron Pantanowitz4, Jeffrey L. Fine4, John A. Kuzmishin1, Michael C. Montalto2, Anil V. Parwani1

Review
Future-proofing pathology part 2: building a business case for digital pathology
Bethany Jill Williams1, 2, David Bottoms3, David Clark4, Darren Treanor1, 2
Breaking Technical Barriers

- Image quality
- Open software solutions
  - Open to many scanners
  - Open to many image analysis suites
- System (LIS/LIMS) integration
- Speed, file storage and IT infrastructure
Breaking Technical Barriers

• **Integrating the Heath Care Enterprise (IHE) Pathology and Laboratory Domain (PALM)**
  An initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information; an international standards organization that bundles existing standards into profiles that solve particular medical communication problems

• **Digital Imaging and Communication in Medicine (DICOM)**
  The standard file format definition and communication profile for radiological and many other medical images

• **IHE/PLAM & DICOM collaborative digital pathology initiative starting in 2017 to create interoperability for digital pathology**
Breaking Cultural Barriers

Proven Phased Adoption Strategy

Phase 1
Planning

Phase 2
Scan Lab On-line

Phase 3
Retrospective Scanning

Phase 4
Review/Consult Scans

Phase 5
Primary Diagnosis

over ~18-24 months
OSU Wexner Medical Center Leads the Way

Digital pathology matchmaking: people, pixels

captodayonline.com/digital-pathology-matchmaking-people-pixels

Alternative approach

Dr. Anil Parwani and Dr. Wendy Frankel at OSU Wexner Medical Center, where pathologists are using digital
What’s next?

Developing value-added tools

- Cancer finding tool
- Region of interest finder tool
- Mitotic count tool
- Pre-screening of IHC slides with quantitative scores
- Bug finder (e.g. mycobacteria)
- More accurate, faster measurements
- Tumor grading tools
- Application of image analysis to routine practice
- Image capture and export to the report
Opportunities

The digitization of pathology in WSI will provide a huge source of data that will ultimately lead to computer-assisted diagnostics.

The integration of all the various data obtained in laboratories is the future of pathology.

The pathologist is a trained physician who has expertise in making the correct diagnosis, determining the likely prognosis, and, with the additional information derived from multiple tests, providing a consultative opinion about treatment approaches.

As laboratory testing plays an increasing role in the era of personalized medicine, the role of the pathologist increases, and the need for consolidated interpretive reporting becomes critical.

The depth of knowledge required to integrate these various ancillary technologies demands the insight of subspecialty pathology and promotes a critical role for pathologists in the implementation of precision medicine.
The Cancer Genome Atlas (TCGA)

- A collaboration between the National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI).
- Free public dataset with comprehensive, multi-dimensional maps of the key genomic changes in 33 types of cancer.
- Comprising more than two petabytes of genomic data.
- This genomic information helps the cancer research community to improve the prevention, diagnosis, and treatment of cancer.

https://wiki.nci.nih.gov/display/TCGA/Introduction+to+TCGA
http://cancer.digitalslidearchive.net/
Opportunities: TCGA Data

PanCancer insights from The Cancer Genome Atlas: the pathologist’s perspective

Lee AD Cooper, Elizabeth G Demicco, Joel H Saltz, Reid T Powell, Arvind Rao, and Alexander J Lazar

TCGA Tissue Procurement

TCGA Overview
Opportunities: TCGA Image Analysis
Future Collaborations

Future clinical demands will be best met by
• Dedicated research at the interface of pathology and bioinformatics, supported by professional societies
• Integration of data sciences and digital image analysis in the professional education of pathologists.
Institutional Collaboration Example

Abstract

Diagnostic pathology is the foundation and gold standard for identifying carcinomas. However, high inter-observer variability substantially affects productivity in routine pathology and is especially ubiquitous in diagnostician-deficient medical centres. Despite rapid growth in computer-aided diagnosis (CAD), the application of whole-slide pathology diagnosis remains impractical. Here, we present a novel pathology whole-slide diagnosis method, powered by artificial intelligence, to address the lack of interpretable diagnosis. The proposed method masters the ability to automate the human-like diagnostic reasoning process and translate gigapixels directly to a series of interpretable predictions, providing second opinions and thereby encouraging consensus in clinics. Moreover, using 913 collected examples of whole-slide data representing patients with bladder cancer, we show that our method matches the performance of 17 pathologists in the diagnosis of urothelial carcinoma. We believe that our method provides an innovative and reliable means for making diagnostic suggestions and can be deployed at low cost as next-generation, artificial intelligence-enhanced CAD technology for use in diagnostic pathology.
A Pathologist-level Interpretable Diagnosis System with Deep Learning

- Diagnosis of papillary urothelial carcinoma
- Collaboration of 17 board-certified pathologists with deep learning scientists
- A novel pathology computer-aided diagnosis system
Quality Improvement Opportunity

Preanalyticals Affect H&E
Quality Improvement Opportunity

Preanalyticals Affect Immunostains
**CAP Quality Improvement Opportunity**

**HistoQIP** is a quality assurance program for histopathology, jointly sponsored by the National Society for Histotechnology and the College of American Pathologists.

- To improve the quality of histologic preparations routinely performed in the histology laboratory through education.
- For each set of slides submitted, participants will receive an evaluation specific to their laboratory, an educational critique, and a participant summary report that includes peer comparison data, performance benchmarking data, and information regarding best-performing procedures and techniques.

### HQIP Whole Slide Image Quality Improvement Program (HQWSI)

<table>
<thead>
<tr>
<th>Stain/Tissue</th>
<th>Program Code</th>
<th>Challenges per Shipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>H&amp;E - Breast resection</td>
<td>HQWSI</td>
<td>A</td>
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<tr>
<td>H&amp;E - Lung resection</td>
<td>HQWSI</td>
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<tr>
<td>H&amp;E - Breast needle core biopsy</td>
<td>HQWSI</td>
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<tr>
<td>H&amp;E - Prostate needle core biopsy</td>
<td>HQWSI</td>
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<tr>
<td>H&amp;E - Colon resection</td>
<td>HQWSI</td>
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<tr>
<td>H&amp;E - Kidney resection</td>
<td>HQWSI</td>
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<tr>
<td>H&amp;E - Colon biopsy</td>
<td>HQWSI</td>
<td>A</td>
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<tr>
<td>H&amp;E - Skin punch biopsy</td>
<td>HQWSI</td>
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**Program Information**
- Participant laboratories may submit up to four stained coverslipped glass slides and upload their scanned whole slide images per mailing.
- Two shipments per year.

**11 recommendations**

- 7 recommendations (based on laboratory accreditation requirements)
- 4 expert consensus opinions
Quantitative Image Analysis of HER2 Immunohistochemistry for CAP HER2 QIA Guideline

Use of image analysis to ID HER2 status in breast cancer outlined on Cancer
Marilyn M. Buli, M.D., Ph.D., from the H. Lee Moffitt Cancer Center in Tampa, Florida, and colleagues developed evidence-based recommendations for the use of QIA in the interpretation of HER2 IHC...

Guide for HER2 Testing That's Not 'by Eye' - HCP Feed
QIA, on the other hand, electronically detects and tallies HER2 membranous immunohistochemical staining of invasive breast cancer cells and then provides a quantitative measure of that HER2 histologic feature. Guideline lead author Marilyn Buli, MD, PhD, Moffitt Cancer Center, Tampa, Florida, explained the importance of the new automated technology.

New Pathology Guideline Advances Accuracy in Breast Cancer

Quantitative Image Analysis of HER2 Immunohistochemistry for New Pathology Guideline Advances Accuracy in Breast Cancer
CAP.org/documents/summary...

NEW ONLINE RELEASE - archivesofpathology.org
www.archivesofpathology.org/doi/pdf/10.5868/arpa...
The guideline statements below, the discussion of the benefits and harms of the guideline statements are included in the supplemental digital content. Guideline Statements 1. Export Consensus Opinion. —Laboratories that choose to implement QIA for HER2 IHC interpretation for clinical testing should select a QIA system that is validated.

Quantitative Image Analysis of HER2 | College of American...
Updated CAP WSI validation guidelines

Clinical Guidelines for Telepathology
August 2014


http://www.jpathinformatics.org/article.asp?issn=2153-3539;year=2014;volume=5;issue=1;spage=39;epage=39;aulast=Pantanowitz

https://www.rcpath.org/uploads/assets/uploaded/d6b14330-a8b9-4f5e-bbe443f0d56de24a.pdf
Founded in 2009, the DPA is a nonprofit organization comprised of pathologists, scientists, technologists and industry representatives dedicated to advancing the field of digital pathology.

The organization’s mission is to facilitate awareness, education and adoption of digital pathology and AI applications in healthcare and life sciences.

Members are encouraged to share best practices and promote the use of the technology among colleagues in order to demonstrate efficiencies, share knowledge and its ultimate benefits to patient care.

1000+ active members across all membership categories

http://digitalpathologyassociation.org
DPA Officers and Staffs

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Our mission is to facilitate awareness, education and adoption of digital pathology and AI applications in healthcare and life sciences.
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Thoughts Leaders in
- Industry
- Pathology
- Academic Research
- Informatics
- Histotechnology
- Regulatory
- Imaging
- Histotechnology
- Residents/fellows
### Membership Levels

For a detailed list of all member opportunities and benefits, see our membership levels:

<table>
<thead>
<tr>
<th>Individual Membership Levels</th>
<th>Group Membership Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td>INDIVIDUAL</td>
<td>BENEFACtor</td>
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<tr>
<td>TECHNICIAN / TECHNOLOGIST</td>
<td>COUNCILOR</td>
</tr>
<tr>
<td>RESIDENT / FELLOW / PHD CANDIDATE / MD STUDENT</td>
<td>CHAMPION</td>
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<td>HOSPITAL / UNIVERSITY</td>
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<td>ALLIED SOCIETY</td>
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Committees and Task Forces

Membership

Michael Quick, Hologic (Chair)

The DPA Membership/Member Benefits Committee recommends policies, procedures, and strategies for enhancing the membership of the DPA. The Committee recommends initiatives to assure a growing and vital membership organization.

Education

Mike Isaacs, Washington University School of Medicine (Co-Chair)
Anil Parwani, The Ohio State University (Co-Chair)

The DPA Education Committee is responsible for the planning and execution of webinars, identifying white paper topics to be developed and presented on behalf of DPA membership at the annual conference, Pathology Visions as well as other educational opportunities. The Committee will ensure that all of the educational outreach opportunities of the various DPA committees and task forces have a similar direction and complement each other.

Reg. & Stan’rds

Esther Abels, PathAI (Co-Chair)
Joachim Schmidt, Roche (Co-Chair)

The mission of the Digital Pathology Association Regulatory and Standards Task Force is to advance digital pathology by bringing clarity to the regulatory pathway for digital pathology including its evolution and creating awareness thereof and working towards the development and adoption of standards as well as promoting interoperability in digital pathology for clinical use.

Program

Sylvia Asa, MD, PhD, University Health Network (Co-Chair)
Liron Pantanowitz, MD, UPMC (Co-Chair)

The DPA Program Committee is responsible for the planning and execution of the Pathology Visions Conference, including speaker and abstract selection and program development for the conference.

Website

Chris Garcia, LabCorp Diagnostics (Chair)

The DPA Website Task Force is responsible for keeping the Digital Pathology Association website current and providing resources to those who access it.

FDA holds public hearings, class III designated (2009)

Hosted FDA at DPA PathVisions

2011

DPA Formed Industry sub-subcommittee

DPA Hired external FDA regulatory firm to counsel DPA

DPA has face to face meetings with FDA and Alliances to clear regulatory pathway for AI

2012

DPA establish unified response to Draft guidance

First DeNovo Clearance of WSI for Primary Dx

2013

DPA pathologists meet w FDA to discuss risk/benefit,

2014

DPA actively engage FDA on classification clarity

2015

FDA reverse class III designation and decide on de novo pathway (class II)

2016

DPA clarifies special controls

2017

DPA in Advocacy for Regulatory Path Clarity

2018

2019
DPA in Interoperability with DICOM

- DPA hosted the first Connectathon at Pathology Visions 2017
- Formation of DICOM & Standards Task Force

"We learned more in this one event than we did in the past 7 years"

Dr. David Clunie, DICOM WG 26 Co-chair
Digital Pathology Association (DPA) https://digitalpathologyassociation.org/ in collaboration with NSH, developed the first ever certificate program for digital pathology.
Digital Anatomic Pathology Academy (DAPA)

- A web-based whole slide image teaching platform for pathology residents and fellows
- Prepare the next generation pathologists for the era of digital medicine
- Experienced pathologists, mostly academic pathologists are faculty
- High yielded cases that trainees must know before their certification exam
- Organized in organ systems for supervised and unsupervised learning
- Virtual multiscope lectures and didactic lectures are in development
- Free to all DPA members
Publication & White Papers

- Abstracts of all Pathology Visions presentation are published in the *Journal of Pathology Informatics* since 2017.
- Member publication posting on DPA website is available per request.
- Previous white paper presentations are on DPA website.
- Various new white papers are published or in progress.


WP3: Computational Pathology – Esther Abels/Cleo Kozlowski/Liron Pantanowitz
WP4: Business Case – Jennifer Quigley/Giovanni Lujan
WP5: IVM – Jeff Fine/Mark Zarella


Webinars & Blogs

- DPA members have access to all archived webinars.
- DPA members are welcome to post blogs.
SAVE THE DATE

2019 PATHOLOGY VISIONS

Celebrating the 10 Year Anniversary of the Digital Pathology Association!

Keynote Presenter:
Anil Parwani, MD, PhD, MBA | Ohio State University Wexner Medical Center

October 6-8
Hyatt Regency Orlando Orlando, Florida
Conclusions

• Digital pathology and artificial intelligence are here to stay and will continuously transform the delivery of precision medicine.

• Collaboration of pathologists, scientists and industry is important to move the field forward in an impactful way.

• Each individual can make a difference.

• Digital Pathology Association is your community.
• “In the long history of humankind (and animal kind, too) those who learned to collaborate and improvise most effectively have prevailed.”

• “It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is the most adaptable to change.” – Charles Darwin
No financial conflict of interest

Marilyn M. Bui, MD, PhD, FCAP
Email: Marilyn_Bui@moffitt.org

Marilyn M. Bui | Moffitt Cancer Center
https://moffitt.org/providers/marilyn-bui/

@DrBuiPathology

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