



# The DPA and the Alliance

Esther Abels and Scott Blakely  
Nov 4, 2019

# A puppy or a bagel?



# Digital Pathology Association Statement

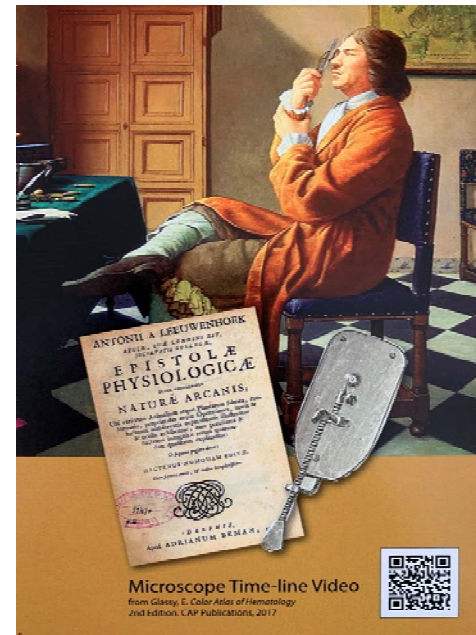
The Digital Pathology Association (DPA) is a not-for-profit organization comprised of pathologists, scientists, technologists and representatives from industry that focus on developing education and awareness of digital pathology applications in healthcare, life sciences and artificial intelligence

# The what, how and why?

- Driving adoption
- Central repository for key information
- Domain knowledge
- Education and sharing
- Collaborating with the FDA on equipment approvals and addressing technology regulations
- Shorten time to market of innovative products

# Background and History

- The Digital Pathology Association (DPA) was founded in 2009, goals included
  - supporting digital pathology education initiatives,
  - defining best practices,
  - influencing standards and interfaces,
  - organizing an annual conference that addresses diverse needs within the industry, and more.
- The DPA represents a collaboration between healthcare professionals and industry leaders
  - consisting of pathologists, scientists, technologists and industry representatives.
  - creating a more productive workplace for pathologists and healthcare institutions as well as enhancing patient care.
- The DPA continues to support these goals and looks towards the future for the needs of pathologists and are active in creating standards and interoperability for the users and producers of this technology.



# Committees

- Education Committee
  - Whitepapers
  - Webinar: SAVE THE DATE Dec 4, 2019
- Program Committee
  - Pathology Visions
- Website Committee
  - Blogs
  - Archives
  - WSI repository
- Regulatory & Standards Taskforce committee

## DPA White Papers

Computational pathology definitions, best practices, and recommendations for regulatory guidance: a white paper from the Digital Pathology Association

Esther Abels, Liron Pantanowitz, Famke Aeffner, Mark D. Zarella, Jeroen van der Laak, Marilyn M. Bui, Venkata NP Vemuri, Anil V. Parwani, Jeff Gibbs, Emmanuel Agosto-Arroyo, Andrew H. Beck, Cleopatra Kozlowski  
2019; Published in the Journal of Pathology

Introduction to digital image analysis in whole-slide imaging: A white paper from the Digital Pathology Association  
Erratum: Introduction to Digital Image Analysis in Whole-slide Imaging: A White Paper from the Digital Pathology Association

Famke Aeffner, Mark D. Zarella, Nathan Buchbinder, Marilyn M. Bui, Matthew R. Goodman, Douglas J. Hartman, Giovanni M. Lujan, Mariam A. Molani, Anil V. Parwani, Kate Lillard, Oliver C. Turner, Venkata N. P. Vemuri, Ana G. Yuil-Valdes, Douglas Bowman  
2019; Published in the Journal of Pathology Informatics

A Practical Guide to Whole Slide Imaging: A White Paper From the Digital Pathology Association

Mark D. Zarella, Douglas Bowman, Famke Aeffner, Navid Farahani, Albert Xhona, Syeda Fatima Absar, Anil Parwani, Marilyn Bui, Douglas J. Hartman  
2018; Published in Archives of Pathology & Laboratory Medicine



search

MEMBER LOGIN

NON-MEMBER LOGIN

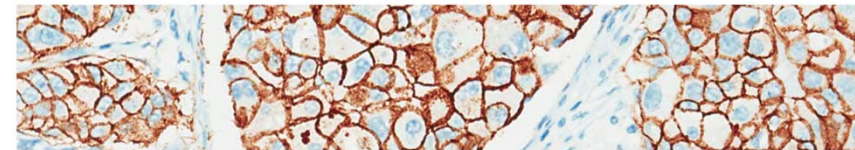
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PATHOLOGY VISIONS

RESOURCES

MORE



## Whole Slide Imaging Repository

### Resources

[About Digital Pathology](#)

Thank you for visiting the DPA's Whole Slide Imaging Repository. This web page lists whole slide and static image examples. Our goal is to create a resource of image repositories.

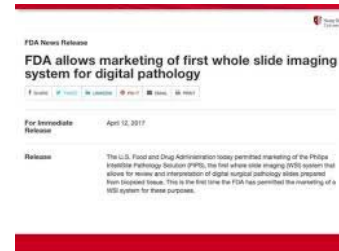
# Regulatory and Standards Taskforce

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



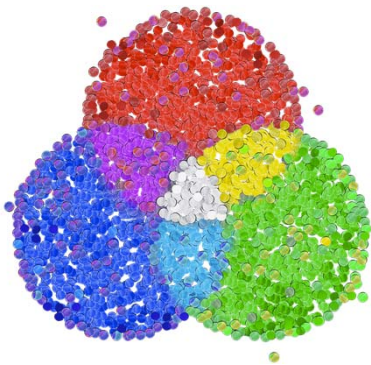
# History

PMA



2009    2011    2013    2014    2/2015    12/2015    04/2016    04/2017    10/2017    03/2019    05/2019    07/2019

PMA



**grand**  
RE-OPENING

*Contains Nonbinding Recommendations*  
**Technical Performance Assessment  
of Digital Pathology Whole Slide  
Imaging Devices**

**Guidance for Industry and Food  
and Drug Administration Staff**

Document issued on: April 20, 2016

The draft of this document was issued on February 25, 2015

For questions about this document, contact the Division of Molecular Genetics and Pathology at 301-796-6179 and Nicholas Anderson at 301-796-4310 or [nicholas.anderson@fda.hhs.gov](mailto:nicholas.anderson@fda.hhs.gov) or Aldo Badano at 301-796-2534 or [aldo.badano@fda.hhs.gov](mailto:aldo.badano@fda.hhs.gov).



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of *In Vivo* Diagnostics and Radiological Health  
Division of Molecular Genetics and Pathology  
Molecular Pathology and Cytology Branch

2017 **PATHOLOGY**  
**VISIONS**  
connectathon





# REGULATORY & STANDARDS TASK FORCE

Creating clarity on AI, interoperability and regulatory pathways

Regulatory and Standards are closely connected  
DPA has expanded scope to address both

## REGULATORY Goals 2020:

- Define general principles for Clinical Validation of AI
- Define general principles for Change Control of locked down AI
- Define a roadmap to interoperability for WSIs, PACS, AIs

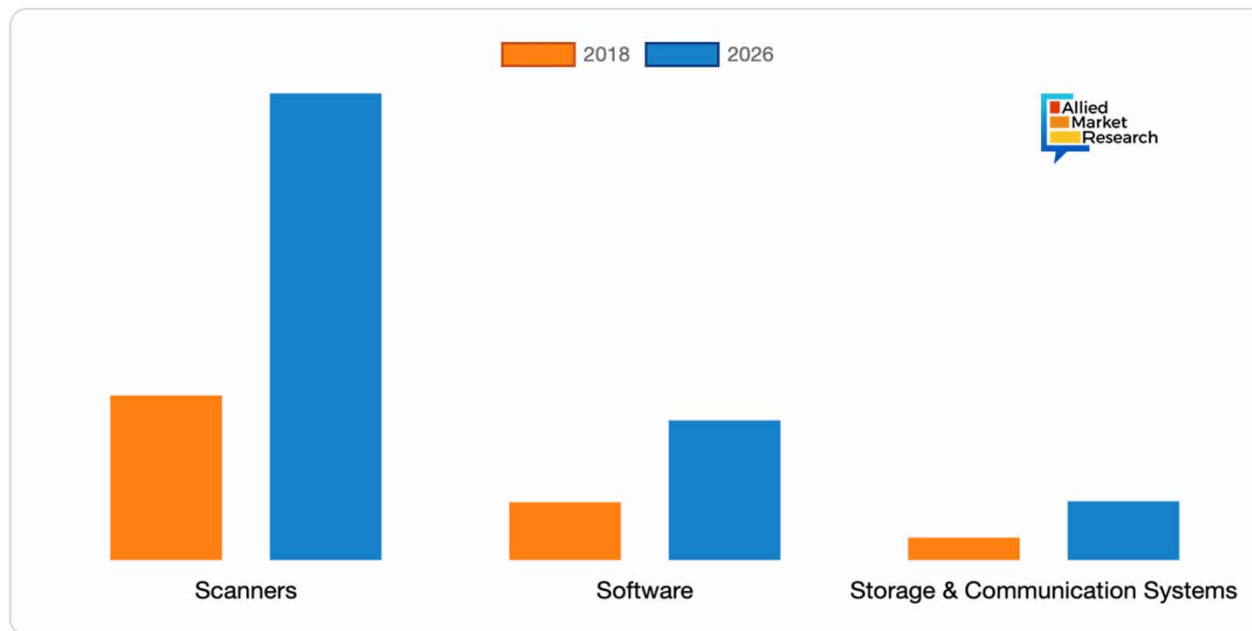
## STANDARDS Goals 2020:

- DICOM paper publication
- DICOM PaLM IHE DP Workflow guidelines & Connectathon
- Define a roadmap to image compatibility

# Why now?

## Digital Pathology Market

### By Products



The digital pathology market accounted for \$512 million in 2018, and is expected to reach \$1,390 million by 2026, registering a CAGR of 13.3% from 2019 to 2026.

**Scanners** is projected as one of the most lucrative segment.

# DPA supports Alliance

- Mutual interest to drive DP helping patients
- Collective approach
- Ultimately, the deliverables of the alliance need a home which can be accessed by everybody

# Opportunities

DPA is especially interested in regulatory pathway, MDDTs and would like to explore if a mock submission could support clarity in the regulatory pathway

- Guidelines around creating and using an MDDT
- Phantom



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Thank you