The DPA and the Alliance

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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

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

COLLECTIVE deNovo


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


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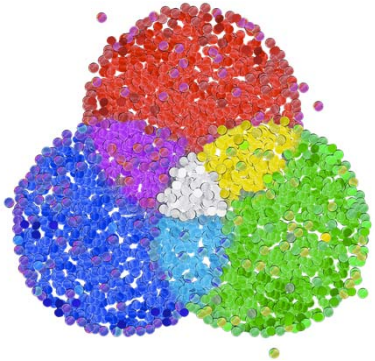
FDA allows marketing of first whole slide imaging system for digital pathology

2nd WSI

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 or Aldo Badano at 301-796-2534 or 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 Vitro* Diagnostics and Radiological Health
Division of Molecular Genetics and Pathology
Molecular Pathology and Cytology Branch

2017 PATHOLOGY VISIONS connectathon

MDIC COLLEGE of AMERICAN PATHOLOGISTS DPA Association of Directors of Anatomic and Surgical Pathology apii FDA IHE DICOM USCAP CMS

REGULATORY & STANDARDS T ASK FORCE

Creating clarity on AI, interoperability and regulatory pathways

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

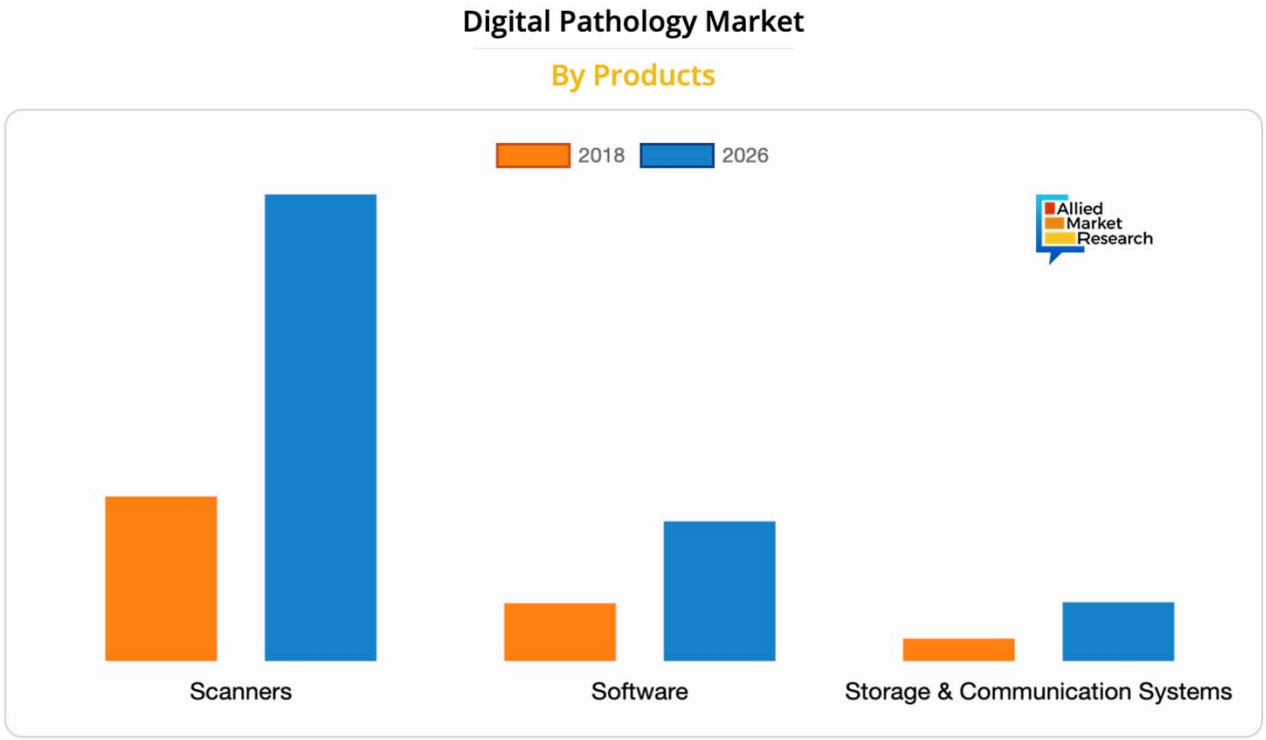
REGULATORY Goals 2020:

- 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?



Scanners is projected as one of the most lucrative segment.

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.

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

Thank you