What to Expect for the Future of Regulation and Standardization of Digital Pathology

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DIGITAL PATHOLOGY ASSOCIATION MISSION

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

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

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 2019:

- Create clarity on AI regulatory pathway
  - DPA FDA meetings
- Inform community about regulatory status
- CPATH paper publication

STANDARDS Goals 2019:

- Create clarity on interoperability in DP using DICOM
  - Actively engaged in Connectathons
- Inform community about standardization
- DICOM paper publication

BACKGROUND

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

CDRH Mission

- To protect and promote the public health

Assure that patients and providers have timely access to medical devices/systems

Ensure that medical devices/systems on the market are safe and effective

History

PMA

COLLECTIVE deNovo


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


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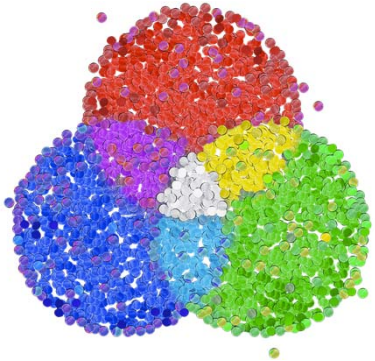
2nd WSI

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

FDA DPA information meeting

- Adoption of AI by DP could help accelerate the adoption of DP in both histopathology and cytopathology
- There are three categories of basic use: quantification, classification, and localization.
- AI could be beneficial, more accurate, more precise, and aid the pathologists in multiple ways.
- Discuss the regulatory pathway for image analysis applications for digital pathology products based on artificial intelligence.

Discussion items:

- IVD labeled scanner
- File format
- DICOM
- Standardized slide set
- Clinical Use – stand alone
- Compare to radiology
- Significant change
- GMLP

AI position paper

Questions to be addressed

Can we define general principles?

- How to evaluate AIs and algorithms in an initial standard, and how to conduct testing to this standard to determine what would be a ”substantial change" to an AI?
- How much can be borrowed from the radiology regulatory area to use for regulation of AI in DP?
- How to assess risk with AI in DP device?
- What kinds of studies are needed to substantiate the claims that will be made?

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?

- Memorandum
  - Objectives and goals
  - Efficient way of working
- Scope the mock
  - Who will be deciding on the scope
  - What will be the decision criteria for the scope: Low hanging fruit, majority vote , risk driven, and examples of scoping are file formats, stains, agnostic, interoperability,…