

## TITLE: Lessons from the first FDA Approval of an AI Tool in Diagnostic Pathology

A regulatory science event collaboratively jointly organized by Plcc and DPA with participation from Paige, and the FDA

### SUMMARY:

Artificial intelligence applications have the opportunity to unlock the full potential of digital pathology. From a *regulatory* perspective, the first milestones in digital pathology have been accomplished – and the first approval of an AI tool to aid in the diagnosis of prostate cancer represents a leap forward.

From a *regulatory science* perspective, the publicly available decision summary (DEN200080) provides an interesting insight into the design requirements for an AI review and authorization.

Given the broad interest in the field of pathology and regulatory science for integration of AI tools in diagnostics, this webinar will outline some of the key aspects in the decision summary.

### WHEN JOINING THIS EVENT, YOU WILL LEARN

- to appreciate the structure and content of an FDA decision-summary
- to recognize the regulatory science and data components that support the approval of an AI tool
- to emphasize the potential of regulatory science collaborations

### AGENDA

#### Introduction – Joe Lennerz MD, PhD, Plcc (2 min)

- Scope of the meeting, Agenda
- Anti-trust monitoring, Code of conduct

#### Introduction cont'd – Esther Abels MSc, DPA (3 min)

- Thank you to FDA and Paige

#### Decision summary – Peter Yang PhD, FDA, Office of Regulatory Policy, Office of Product Evaluation and Quality (10 min)

- Structure and content of a decision summary
- What can you use decision summaries for?
- Decision summaries for AI

#### The first AI algorithm in pathology submission - Emre Gulturk MSc, Paige, Regulatory Affairs & Quality (15 min)

- Overview of the submission process
- Key components and importance of wording (examples from DEN200080)
- Workflow diagrams and illustrating the intended use

#### An approach to review decision summaries – Jansen Seheult MB BCh BAO, MSc, MS, MD, Mayo Clinic (5 min)

- What to look for in a decision summary
- Identifying validation a lab needs to do
- An interesting fact in the Paige decision summary

#### The clinical outlook for AI in pathology – David Klimstra MD, Paige, Founder (10 min)

- Outlook computational and diagnostic pathology
- What does FDA approval for AI-driven diagnostic pathology?

- FDA approval and what now.

Moderated discussion (Joe Lennerz) (10-15 min)

- The importance of disparities in AI algorithm validation
- Open questions

Adjourn