

Decision Summary

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

Featuring



Paige[®]

MAYO
CLINIC



Jointly presented by



DIGITAL
PATHOLOGY
DPA
ASSOCIATION

Pathology Innovation Collaborative Community **PIcc**

- Regulatory science initiative
- Facilitate Innovation
- Advance safety and effectiveness evaluations
- Harmonize approaches to speed delivery to patients
- Collaboration in the **pre-competitive space**
- Open to all stakeholders

Antitrust monitoring is needed

These meetings need to stay within protected subject matters and need to be monitored so that they do not stray off into inappropriate areas, such as:

- Pricing and price terms
- Sales and service territories for particular products
- Customers and customer territories
- Each company's individual decisions regarding selection of suppliers or customers
- Marketing plans and especially future marketing plans or new product offerings
- Other proprietary or competitively sensitive information

Plcc provides the infrastructure to connect all stakeholders



You value
Collaborations



You have a
Regulatory
Science Project



You propose
your project
to Plcc



You present
to steering
committee



Plcc helps
organize the
project



Plcc is a network
to find interested
collaborators

Focus is NOT on
competitive
product development

Plcc does NOT
actively participate
in your project

DIGITAL
PATHOLOGY



ASSOCIATION



Mission: facilitate awareness, education and adoption of digital pathology and AI applications in healthcare and life sciences.



DPA fosters an exchange of ideas helping members understand, navigate, and influence the future of pathology.



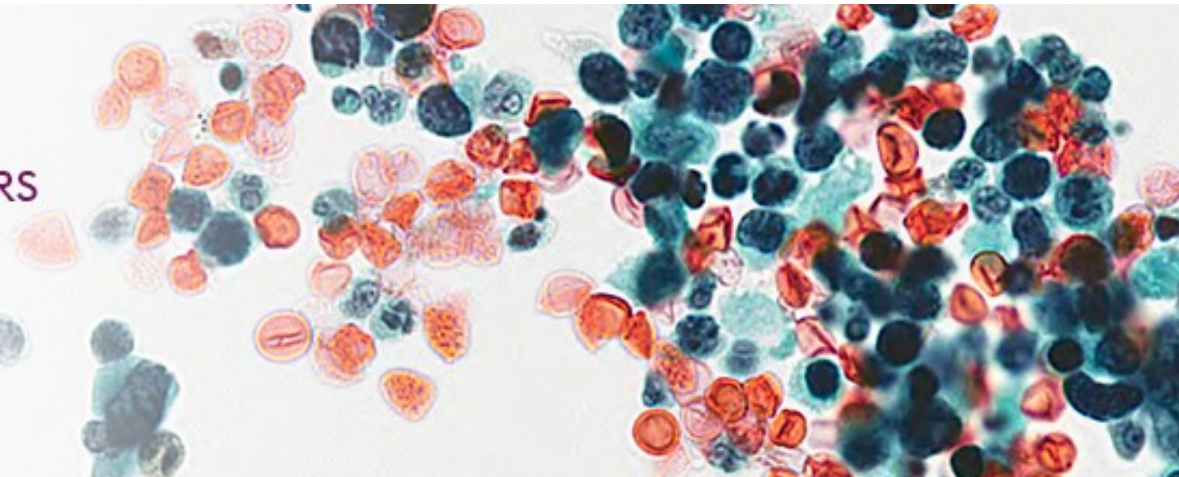
JOIN OUR COMMUNITY & CONNECT WITH 2,600+ DIGITAL PATHOLOGY PROFESSIONALS!

DPA COLLABORATE
The online community for members to connect, innovate, and learn.
Share ideas, pose questions, and network with your peers

LOG IN

The banner features a light blue background with a pattern of small white dots. On the left, there is a large red circle. On the right, there are overlapping green and blue circles. The text is in a mix of bold purple, blue, and green fonts.

DIGITAL ANATOMIC PATHOLOGY ACADEMY (DAPA)
WSI EDUCATIONAL PLATFORM PROVIDED BY THE DPA FOR ITS MEMBERS
Cloud-based platform provides annotated digital slides with diagnosis and relevant information of morphology and ancillary testing



MEMBER LOGIN

DIGITAL PATHOLOGY
DPA
ASSOCIATION

Beyond the Scope
a podcast focusing on the hot topics in digital pathology

Listen on
Apple Podcasts

Listen on
Spotify

The banner has a blue background with a subtle pattern of vertical lines. On the left is the DPA logo. On the right are two black buttons with white text and icons for Apple Podcasts and Spotify.

THE LENS OF INNOVATION
OCTOBER 16-18 | MGM GRAND | LAS VEGAS, NV

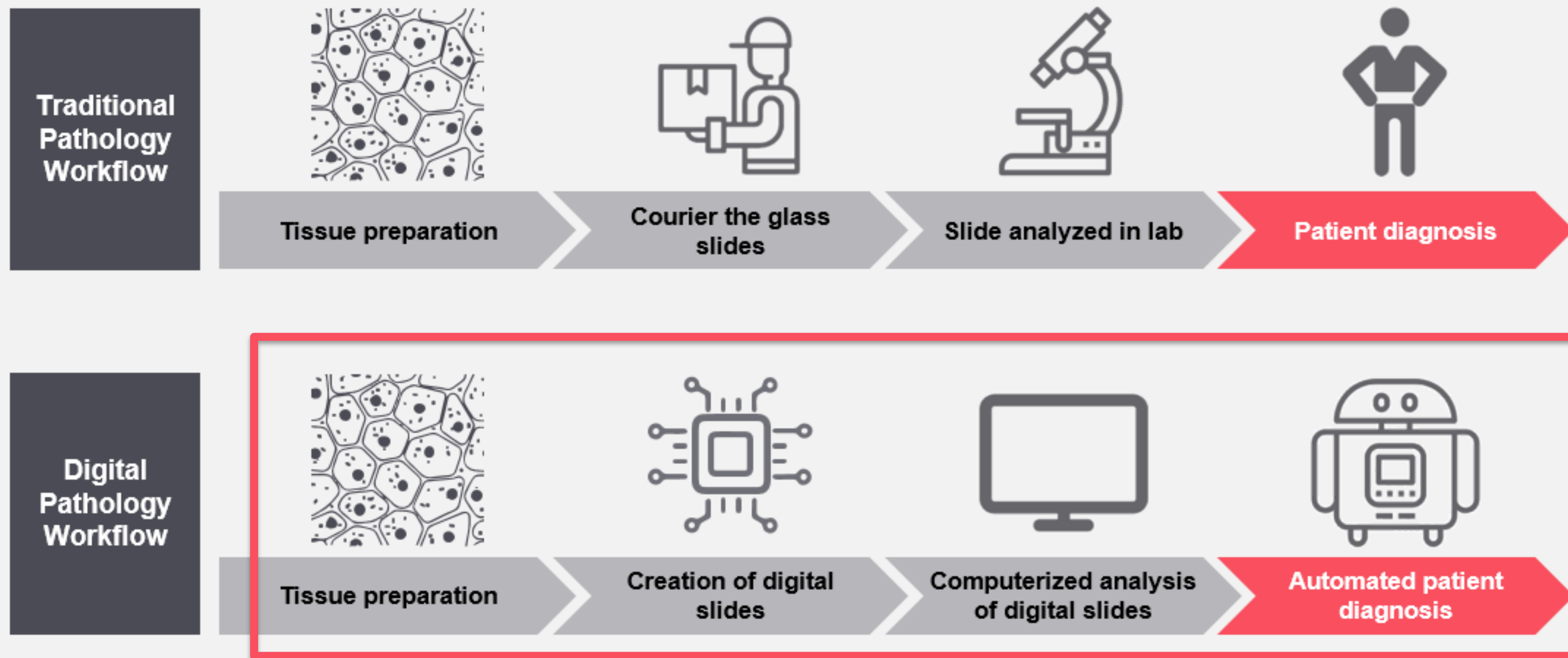
#PathVisions22

NON PATHOLOGY
VISIONS

The banner features a light blue background with a pattern of small white dots. On the left, there is a large red circle. On the right, there is a large, colorful, abstract lens-like graphic. The text is in bold purple and blue fonts.

Keep it simple

EXHIBIT 1: Comparison between Manual Approach and Digitalization followed in Pathology



Source: Pathkids.com



Decision Summary

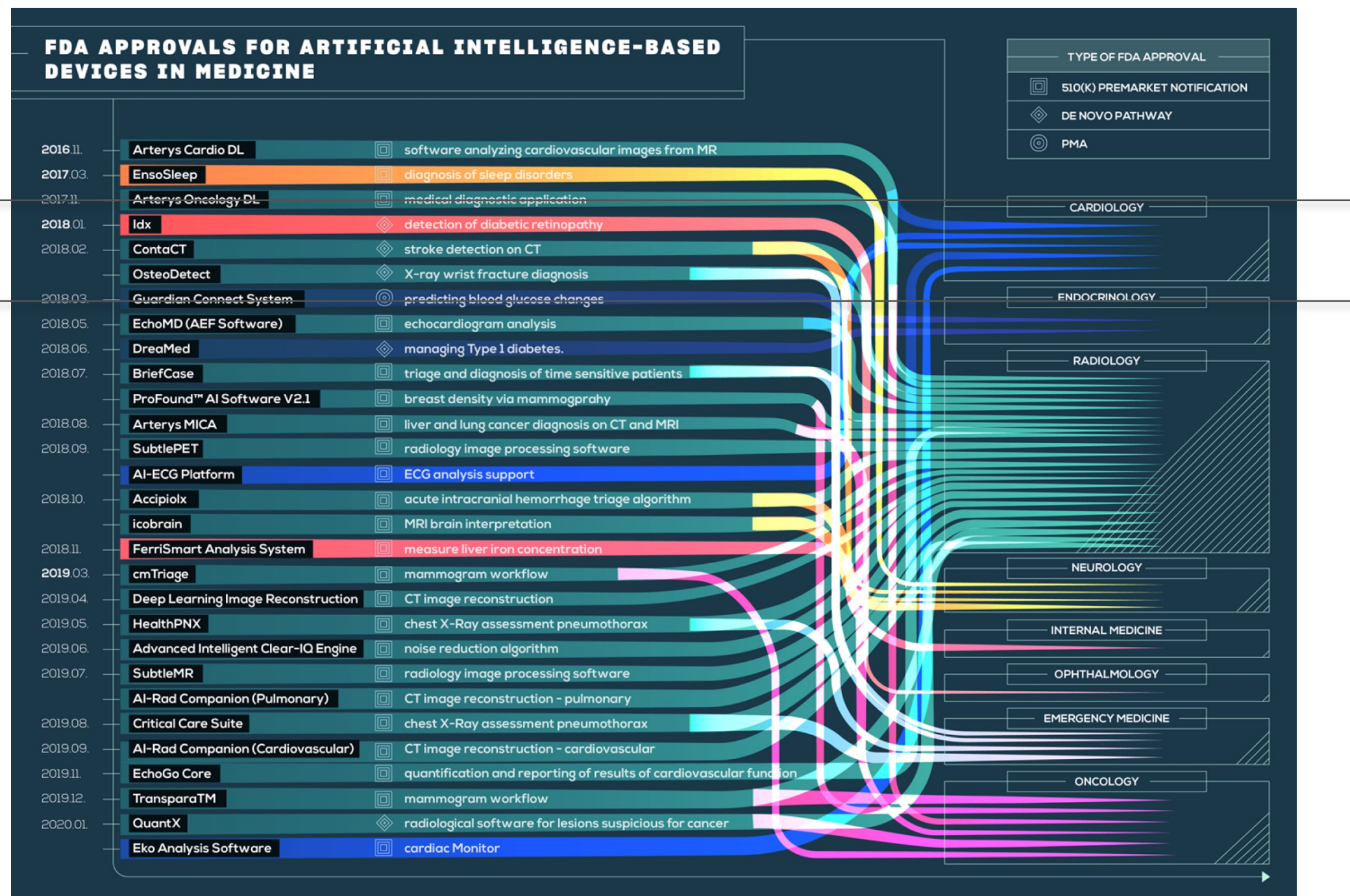
Number of FDA approvals with AI-based algorithms is increasing – currently >80 algorithms

ARTICLE OPEN

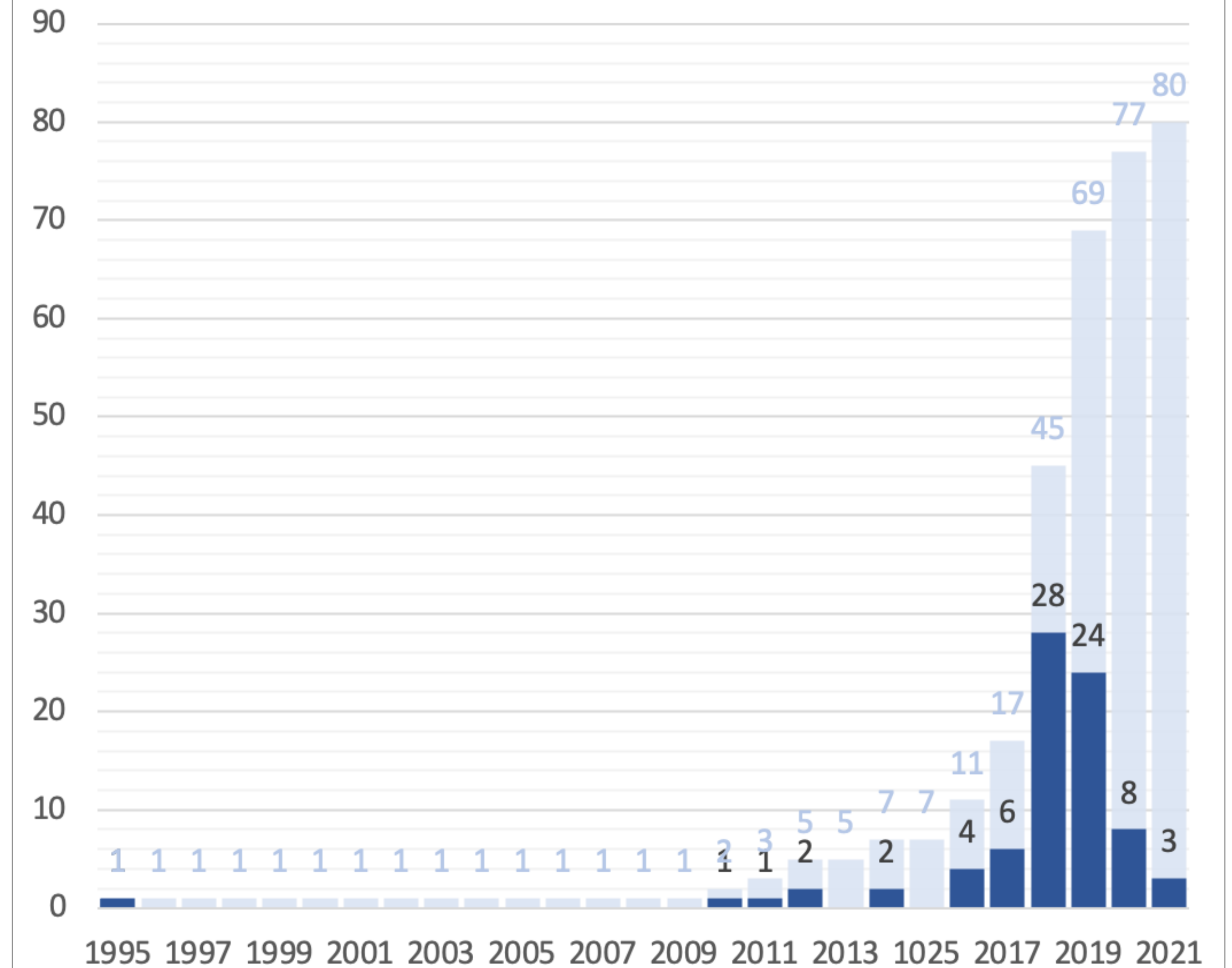
Check for updates

The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database

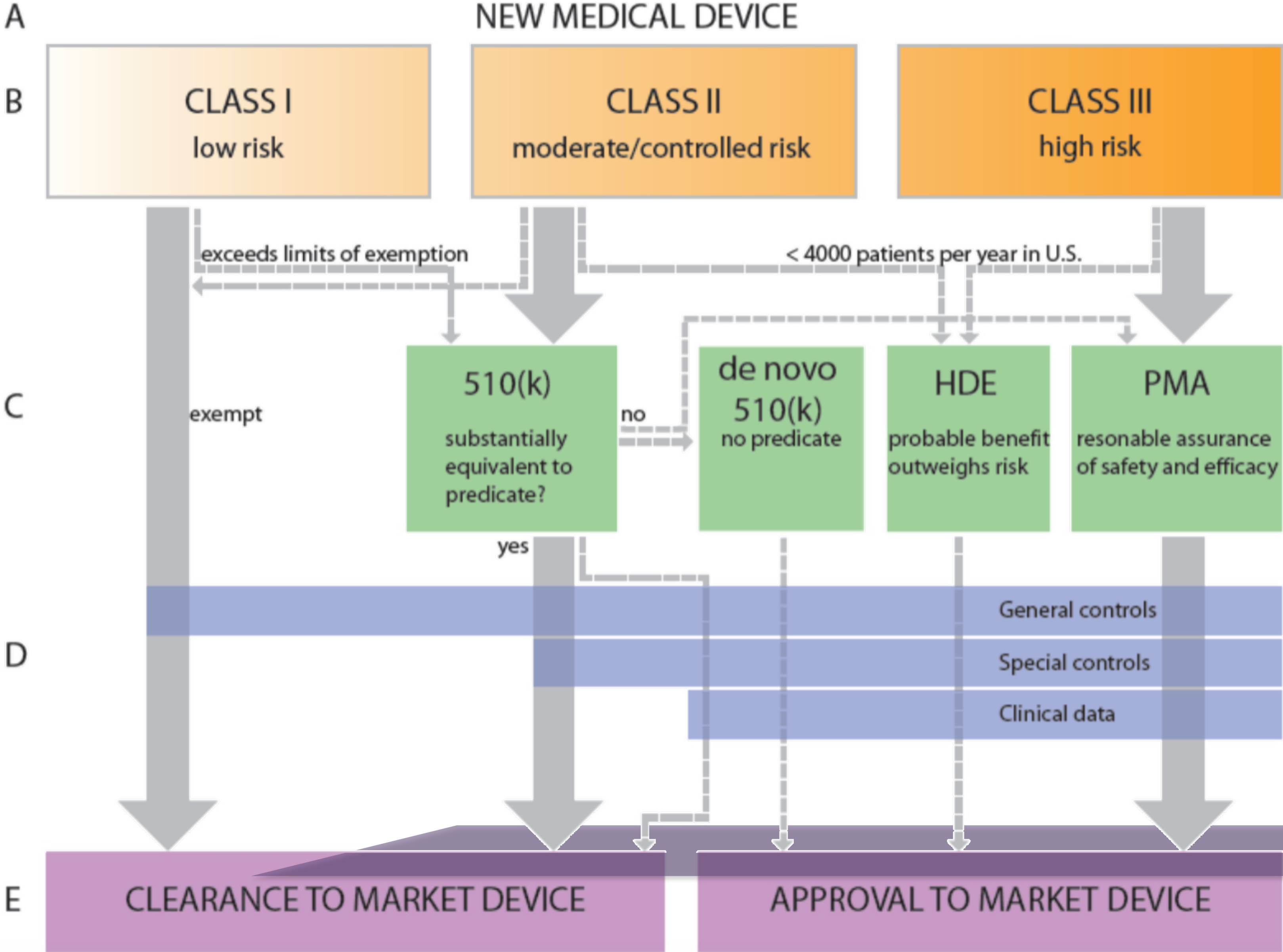
Stan Benjamins^{1,2}, Pranavsingh Dhunoo³ and Bertalan Meskó^{3,4}



FDA approved AI-based algorithms



Decision Summary is one of the Authorization Documents



Authorization Documents

- Approval Letter
- **Decision Summary**
- Summary of Safety and Effectiveness
- Patient Labeling
- PMA Database Entry
- ...



DECISION SUMMARY

Peter Yang, PhD

Office of Regulatory Programs, Office of Product Evaluation and Quality,
Center for Devices and Radiological Health, FDA