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An ASCO Direct™ Conference

Feasibility of Using AI in Clinical Practice

PRESENTED BY

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Professor & Chair of Pathology, University of Pittsburgh

DISCLOSURE

Consultant for AiXMed, Hamamatsu & NTP

Medical advisory board for Ibex

Co-founder of LeanAP Innovators & Placenta AI

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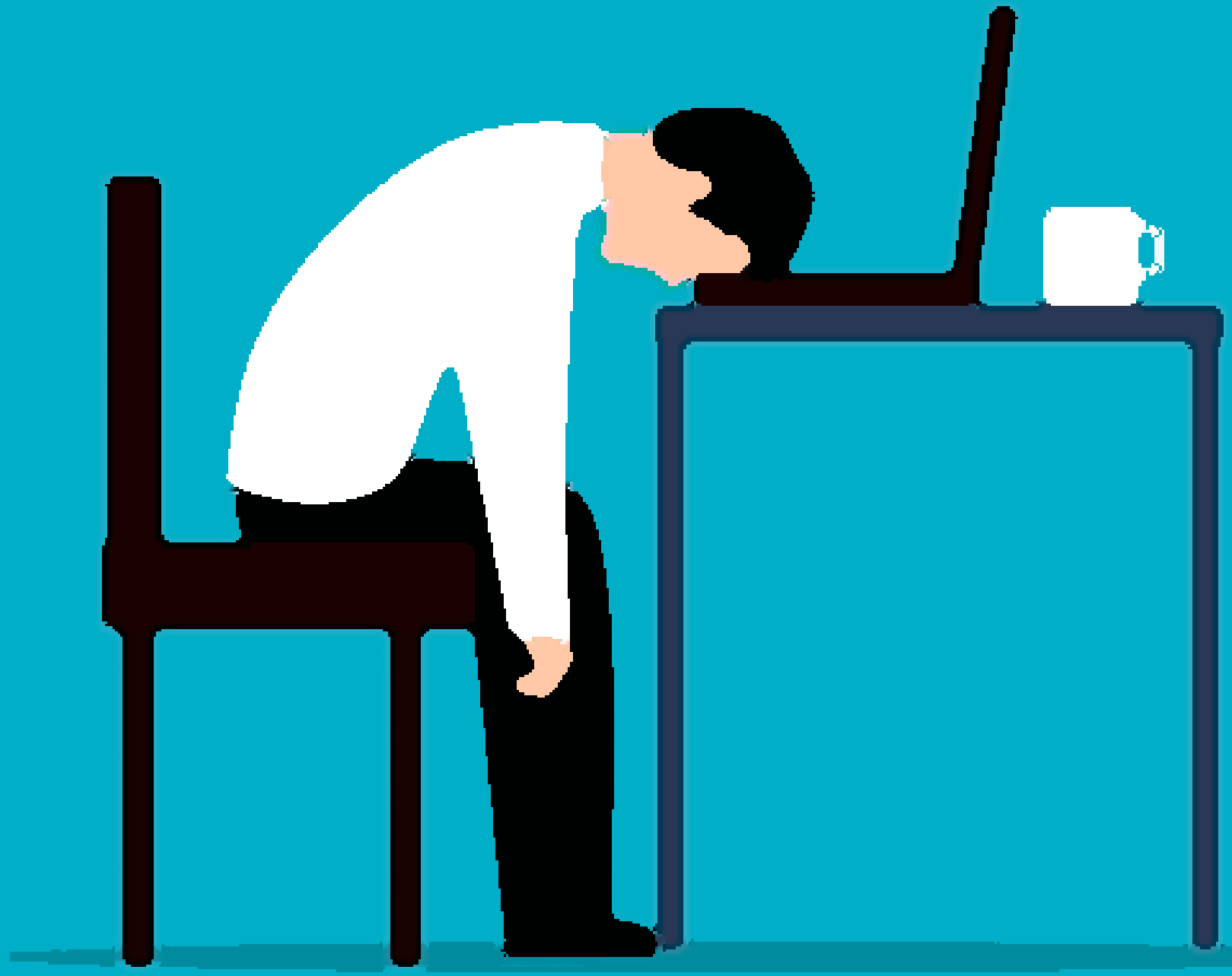


Unmet Needs

Increasing workload

Greater case complexity

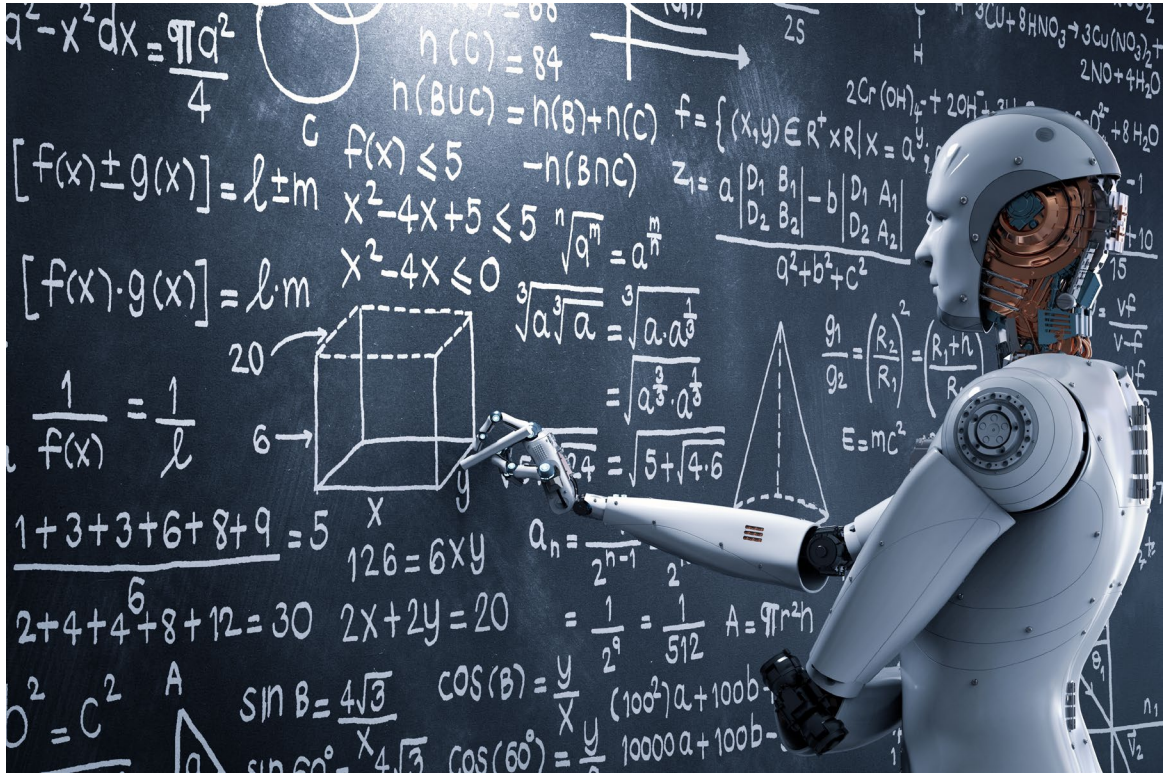
Workforce shortage

Less experts/specialists

Advances in medicine

Burnout persists

Can AI Solve Our Problems?



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Story of Elevator Operators

When elevators first became commercially available in the U.S. around 1853, almost everyone still used stairs.

To get people to trust elevators, operators were required.

They were important because there was nothing yet automatic about the operation of elevators. Operators were even tested & given licences.

As technology improved, operators did less until they were not needed at all.

However, operators became obsolete when:

-They went on strike (workforce shortage), &

-People had to use stairs, as the buildings got taller (workload increased).

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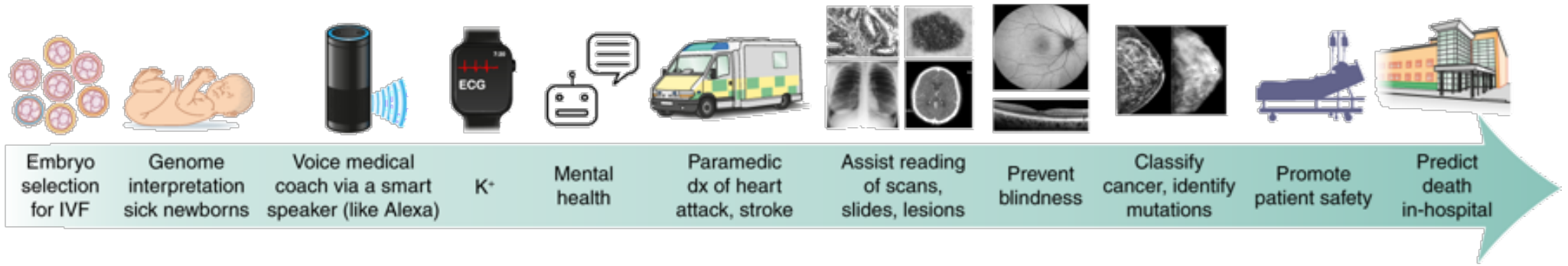
Womb to Tomb

Examples of AI Applications Across the Human Lifespan



Topol EJ. Nat Med. 2019; 25(1):44-56

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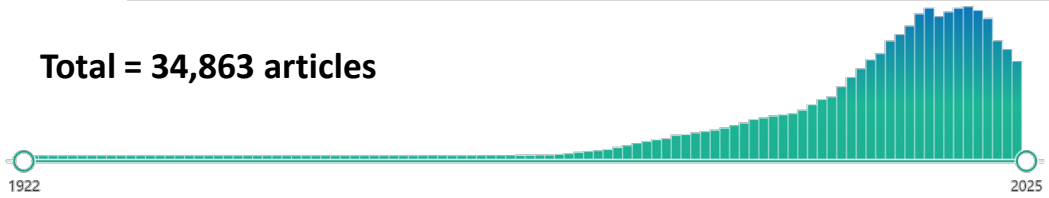
Computational Pathology Literature

PubMed®

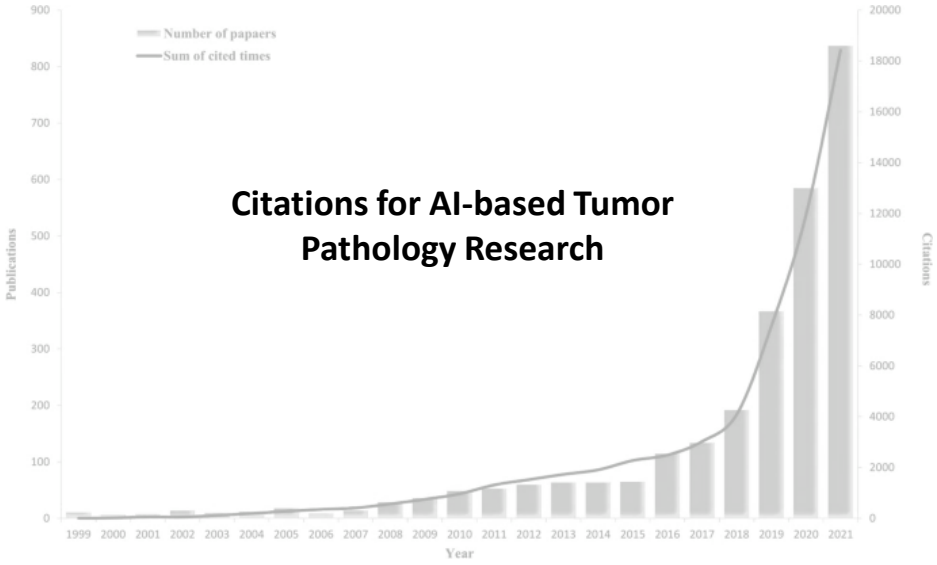
Total = 34,863 articles



1944 = 1 paper

2019 (peak) =19,464 results

2024 (so far) = 12,235 papers



Citations for AI-based Tumor Pathology Research

Shen et al. J Transl Med 2022; 409

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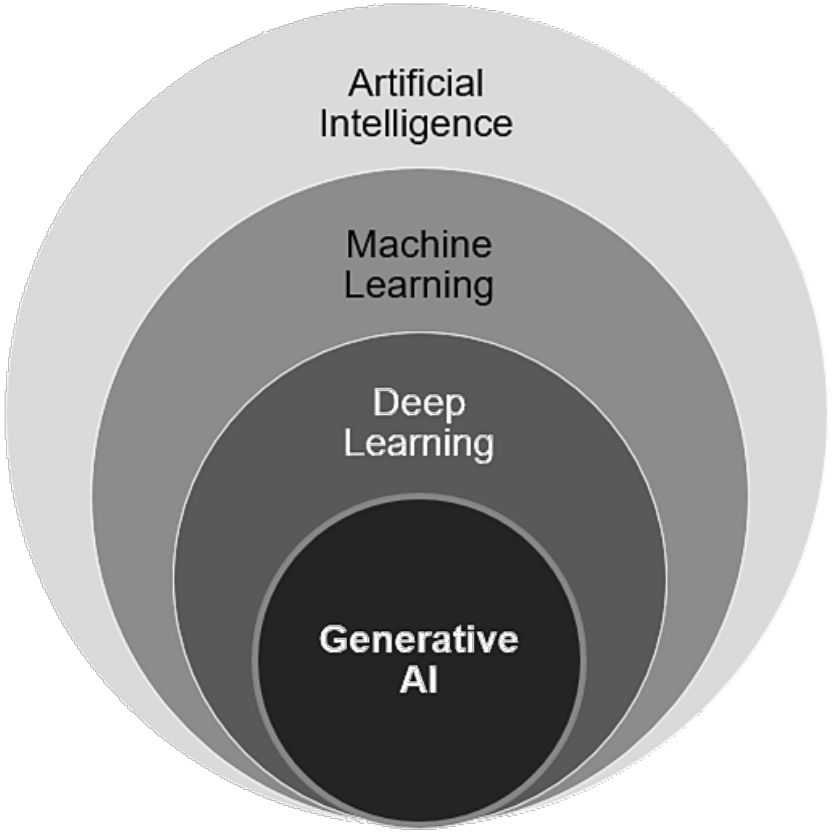
The AI Landscape



AI = The development of computer systems that can perform tasks that typically require human intelligence (e.g. decision support).

ML = A subfield of AI that involves training models on data to make decisions without being programmed (instructed), but instead identifying patterns to make these decisions.

DL = Subset of ML where computers use layers of artificial neurons within a neural network (e.g. CNN) to learn complex patterns from large amounts of data. These models have become the gold standard for image and text analysis in Pathology.

Gen AI = Refers to AI models that create/generate new content, like text & images, based on the data they have been trained on (e.g. ChatGPT).

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Explainable AI

Heat Maps

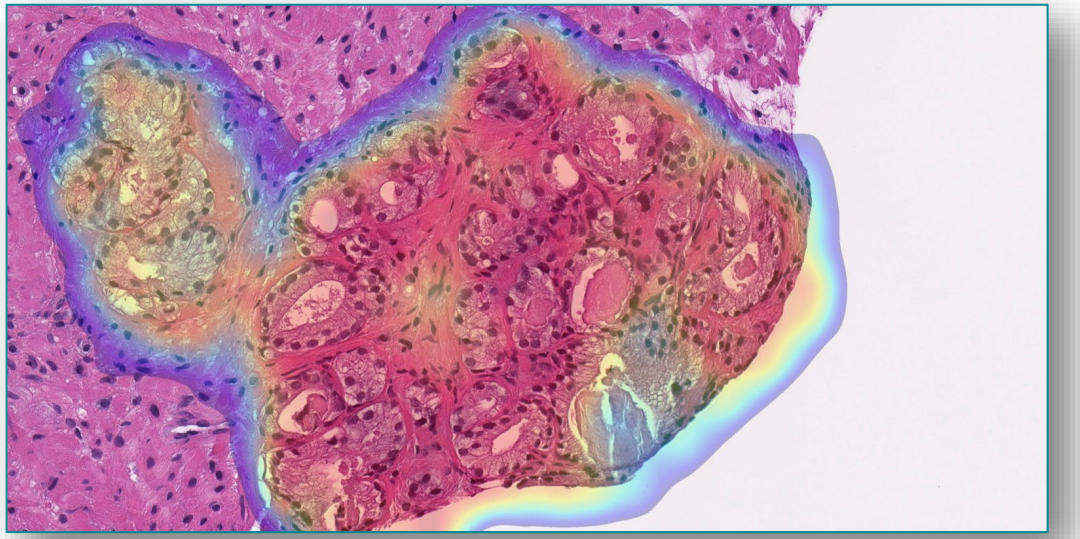
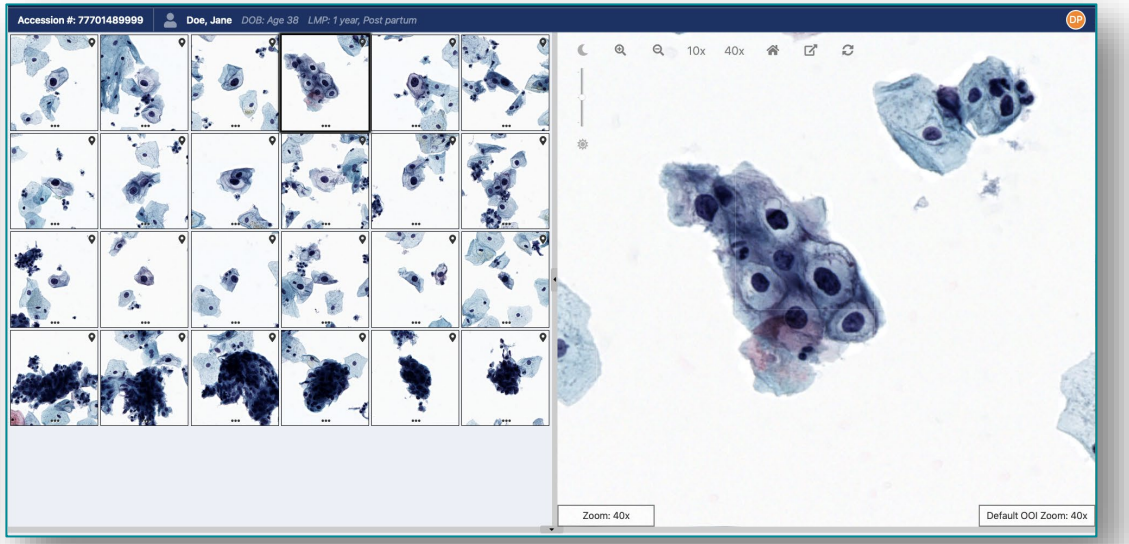


Image Galleries



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Current Uses of AI in Radiology

Rajpurkar P & Lungren MP. NEJM 2023; 388:1981-90

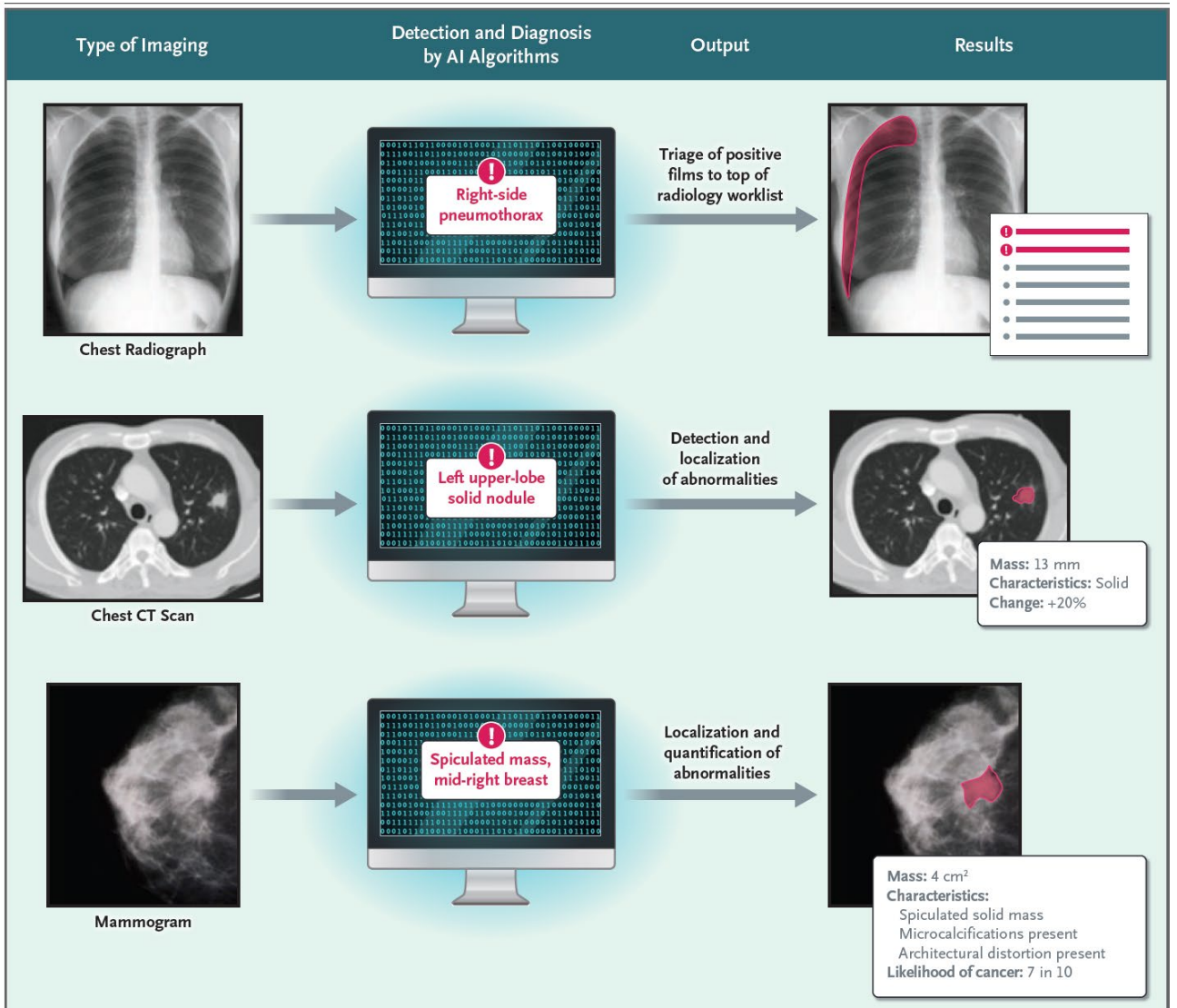

Figure 1. Current Uses of Artificial Intelligence (AI) in Radiology.

Shown are common clinical AI solutions for the functions of triage, detection, and diagnosis with CADt (computer-aided detection for triage), CADe (computer-aided detection for characterizing abnormalities), and CADx (computer-aided detection for diagnosis). Other AI applications for radiology include image reconstruction and noise reduction. Applications for nonimaging tasks are not shown. CT denotes computed tomography.

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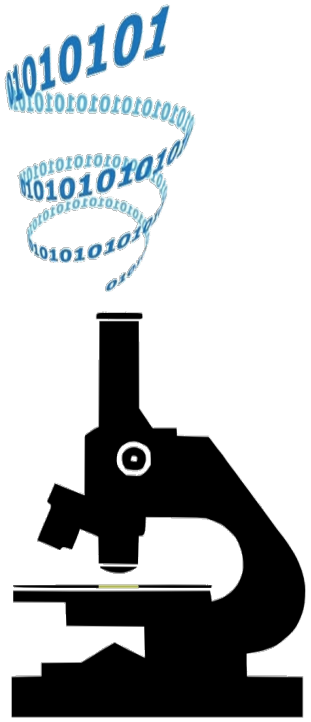
Applications of AI Pathology



- Detect rare events (e.g. microorganisms, cancer)
- Automatically quantify features in digital images
- Diagnose diseases (e.g. cancer) from digital slides
- Make prognostic predictions by analyzing pixels
- Discovery (e.g. biomarker research, clinical trials)

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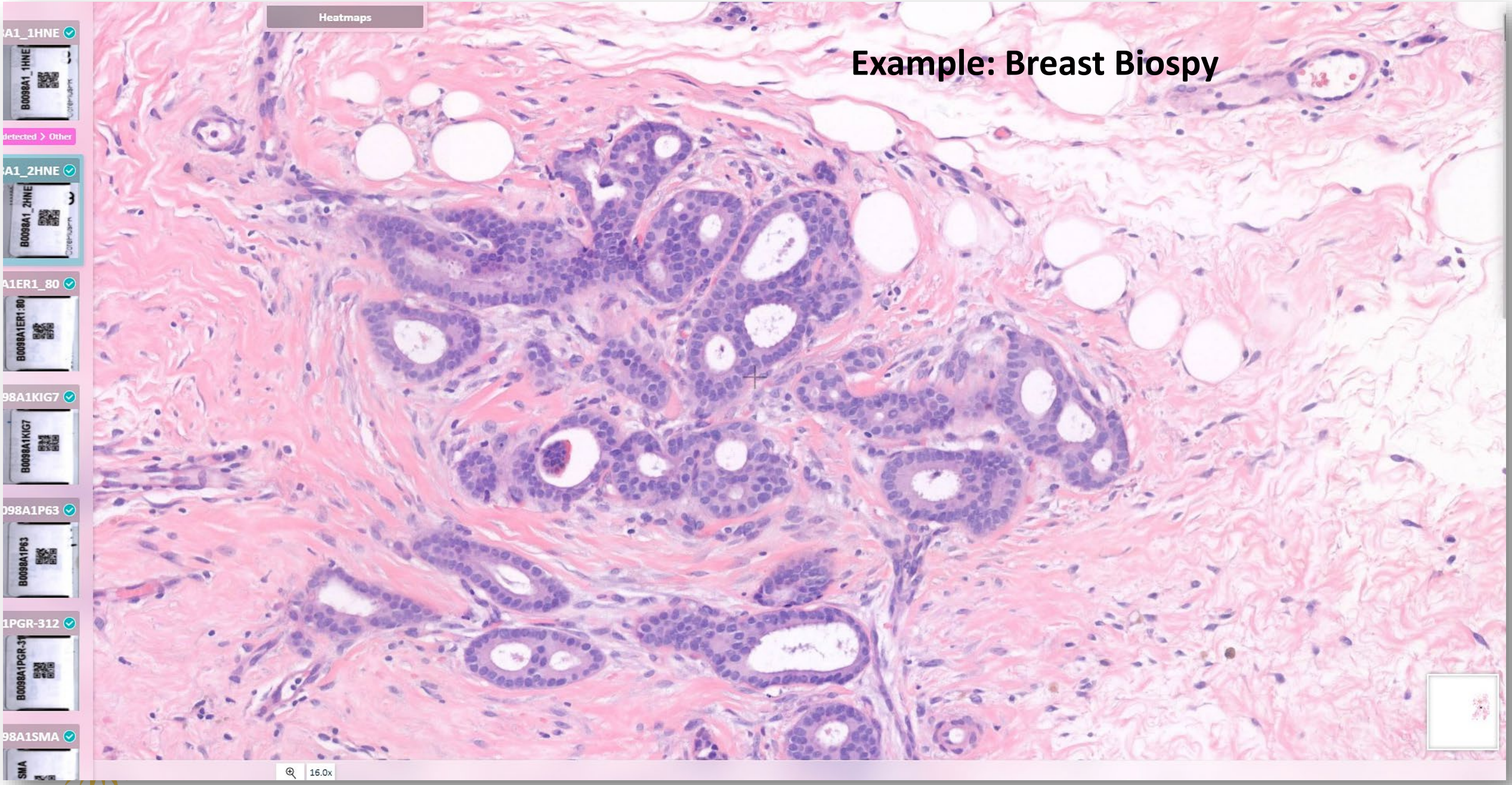
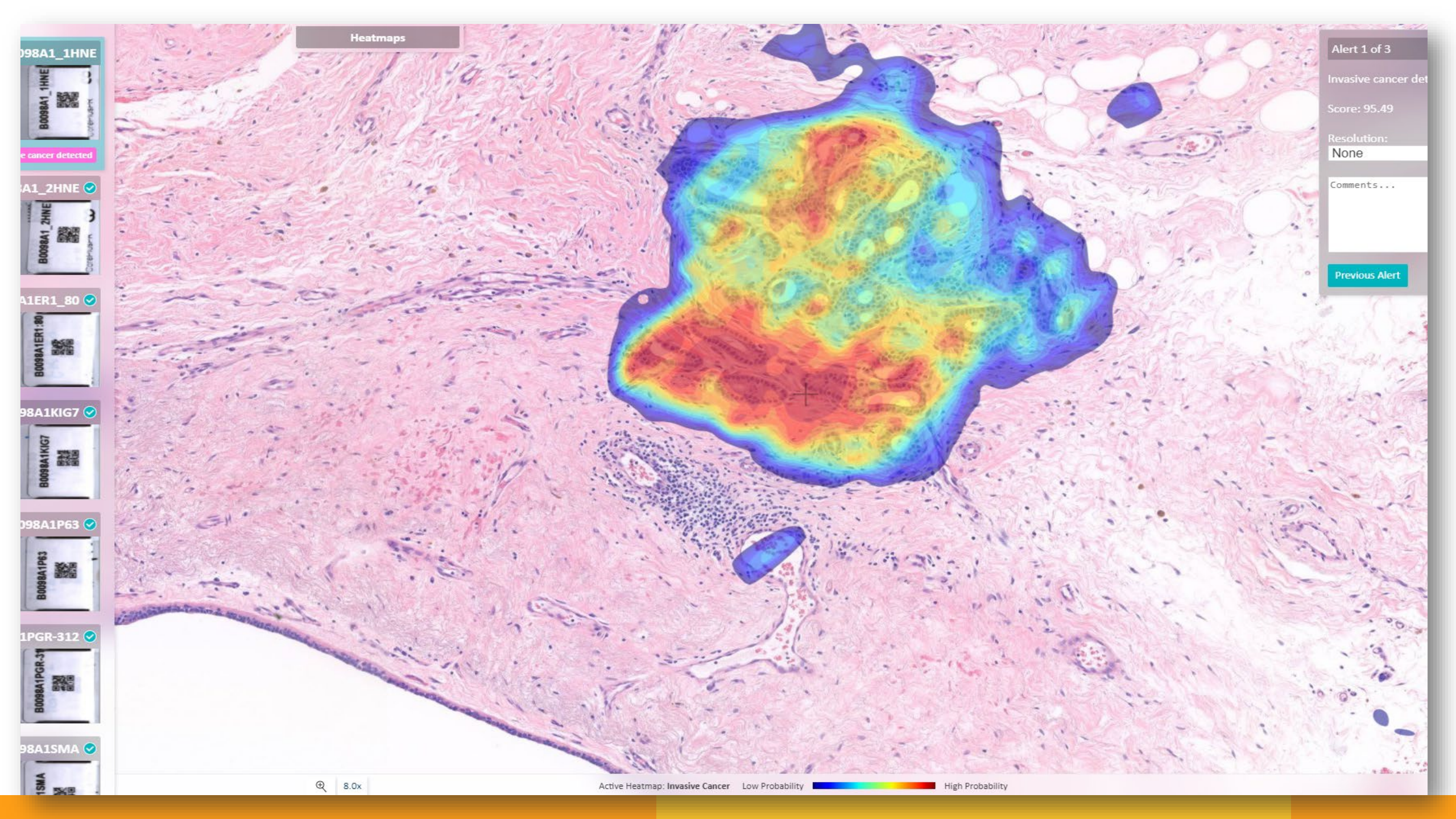
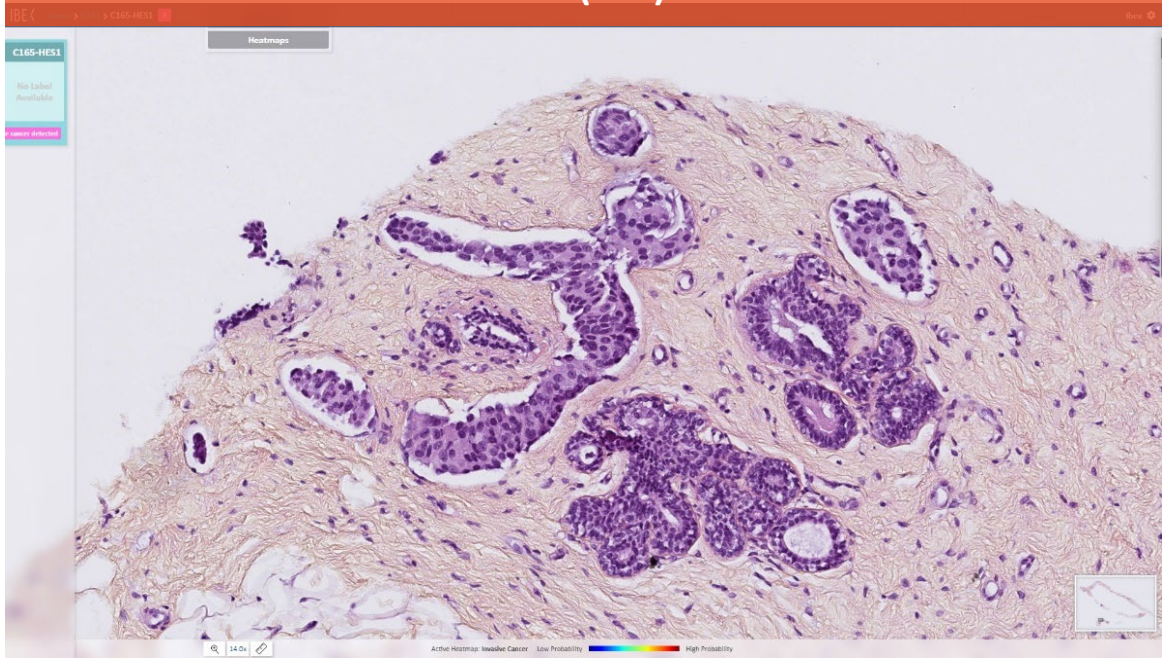

Heatmaps
Example: Breast Biospy
16.0x

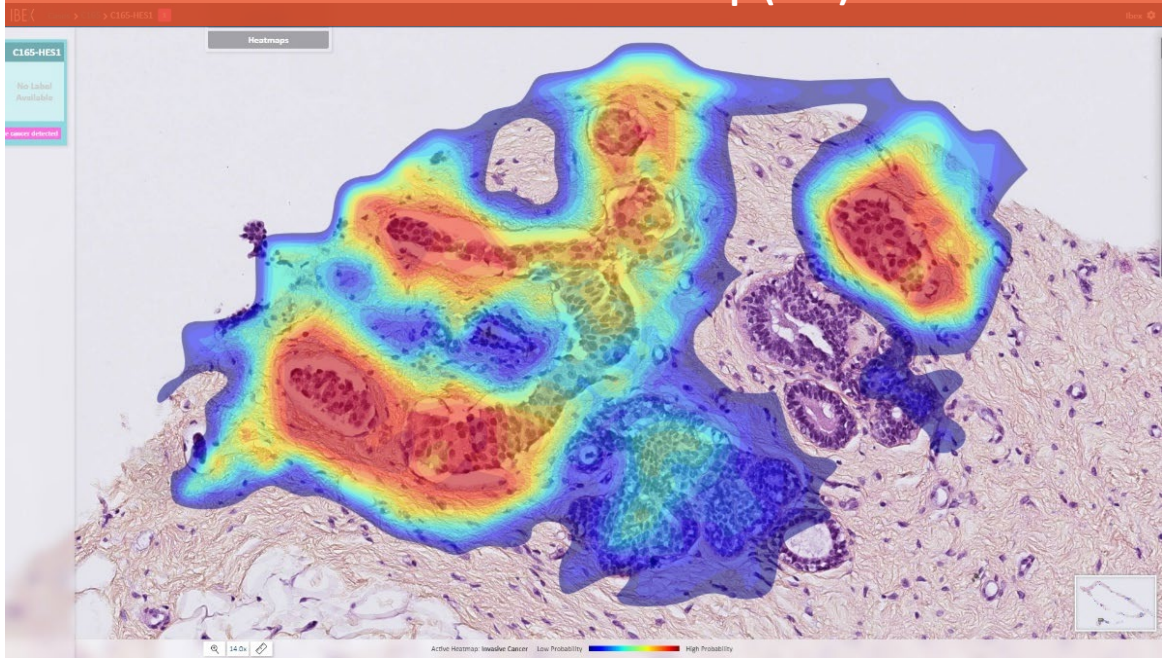

Heatmaps
098A1_1HNE
e cancer detected
A1_2HNE
A1ER1_80
98A1KIG7
098A1P63
1PGR-312
98A1SMA
Alert 1 of 3
Invasive cancer det
Score: 95.49
Resolution:
None
Comments...
Previous Alert
8.0x
Active Heatmap: Invasive Cancer
Low Probability
High Probability

Lymphovascular Invasion (LVI) Detected

HES (x14)



Invasive cancer heatmap (x14)



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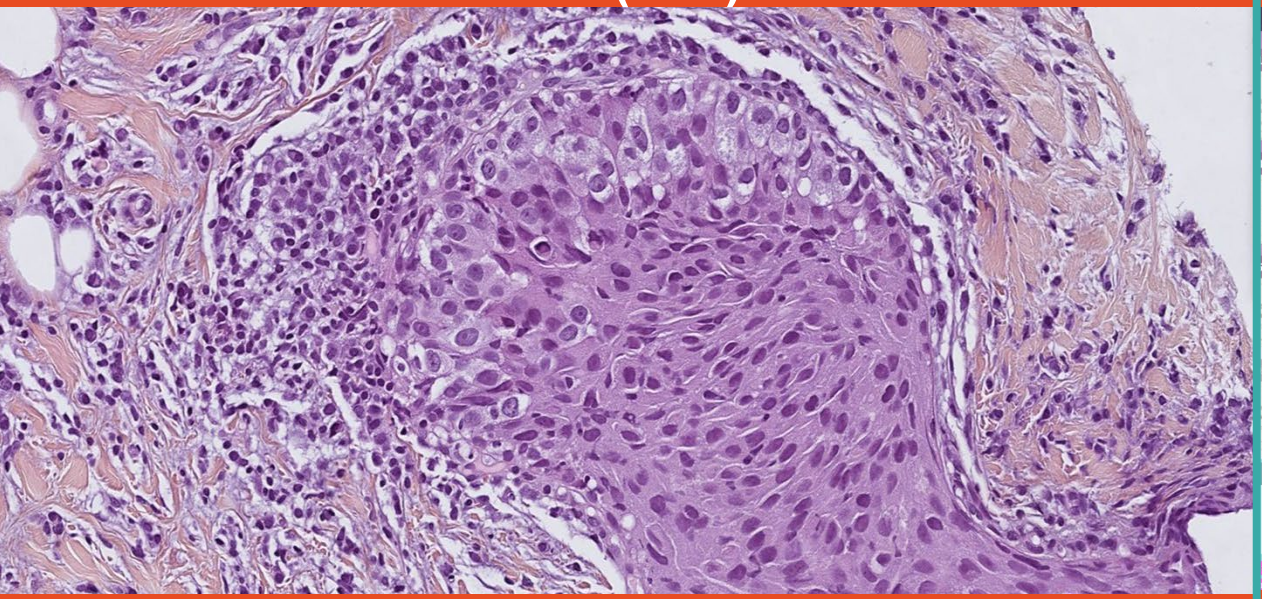
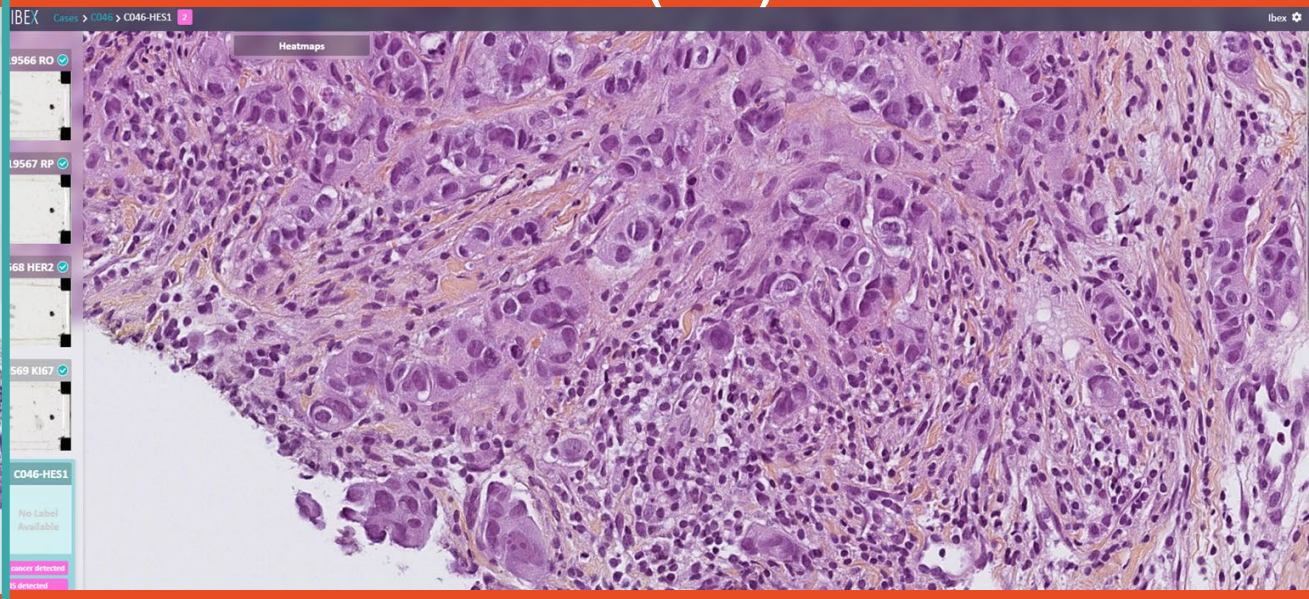
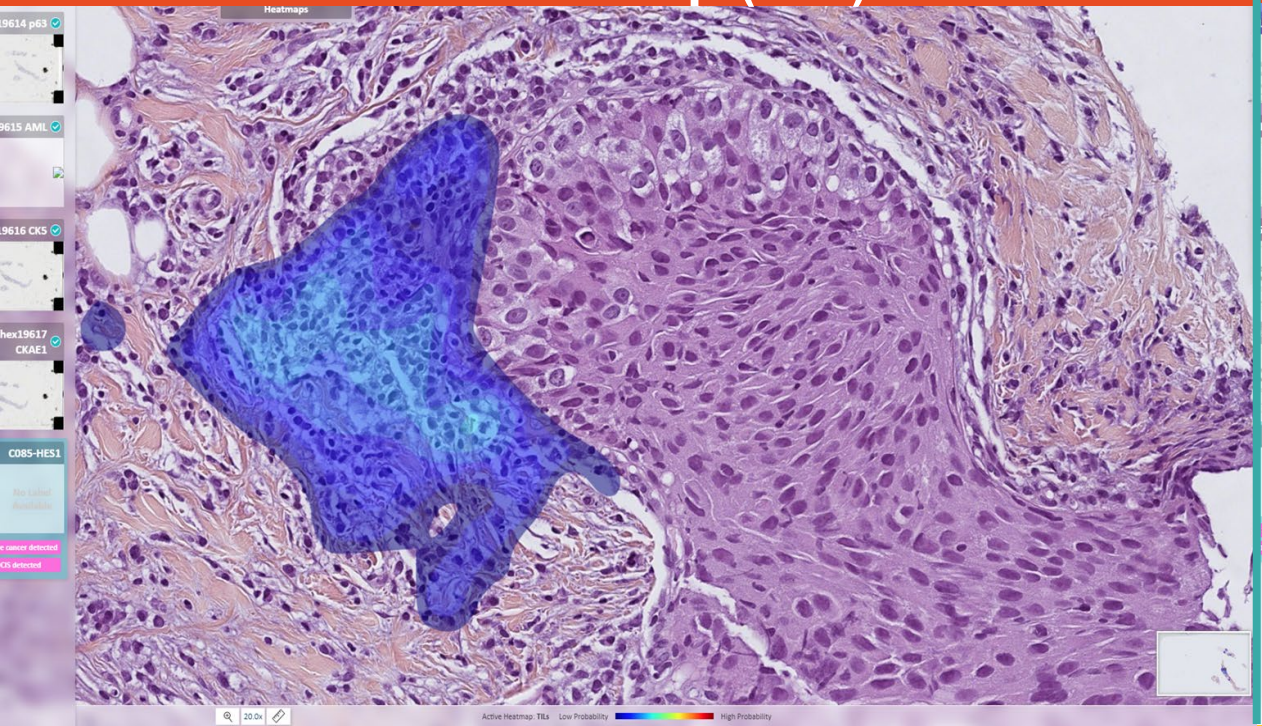
DCIS (x20)



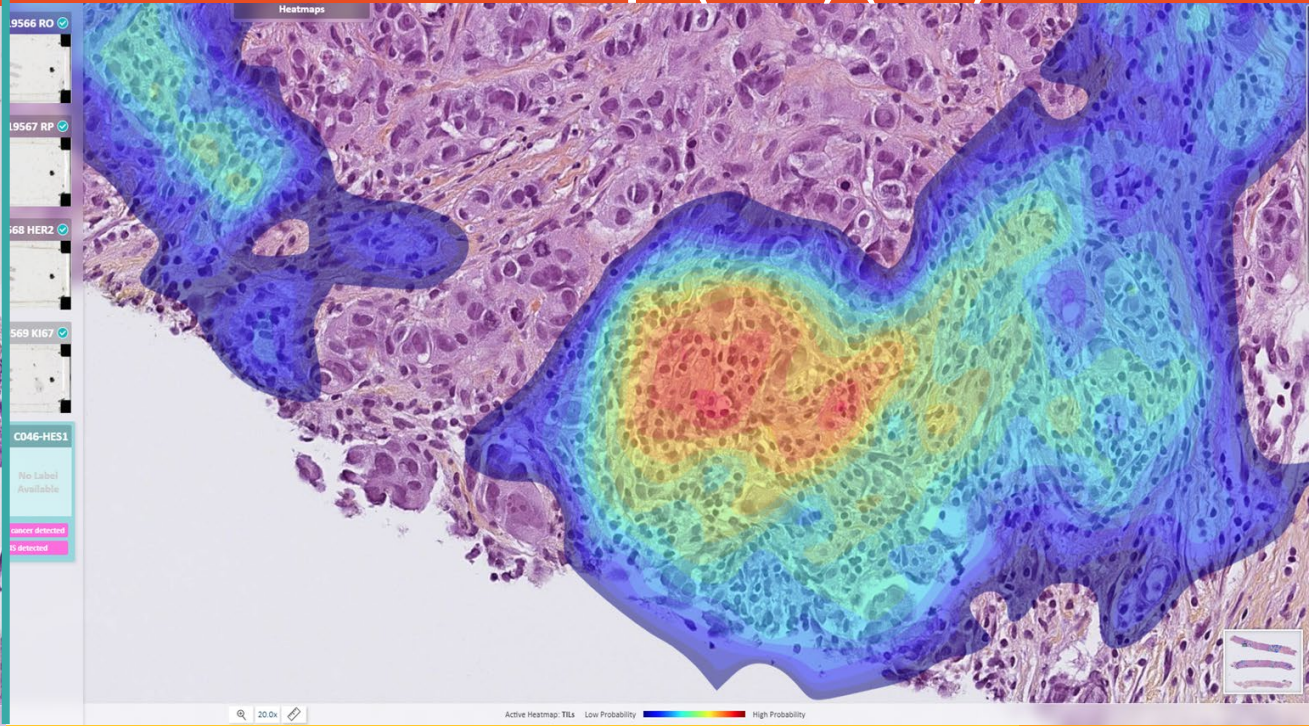
IDC (x20)



TIL heatmap (x20)

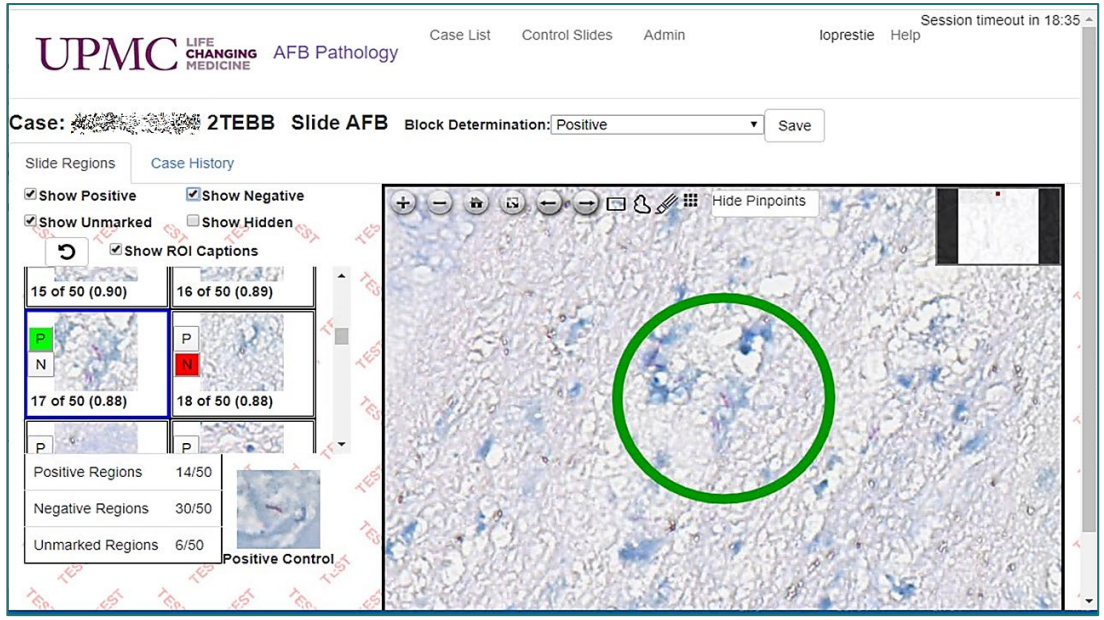


TIL heatmap (30%) (x20)



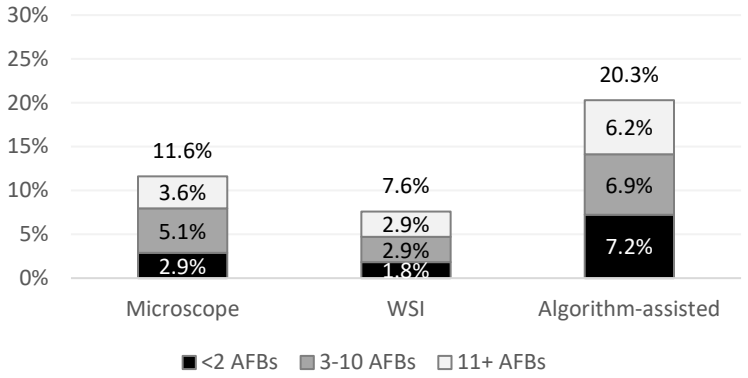
AI-Assisted AFB Screening

Web Portal

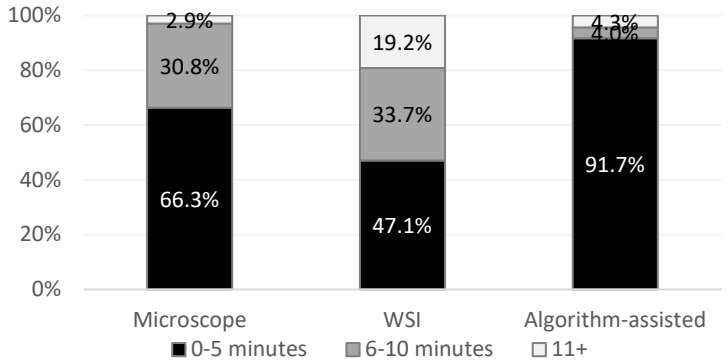


Pantanowitz et al. AJCP 2021; 156(1):117-128

More Accurate



Much Quicker



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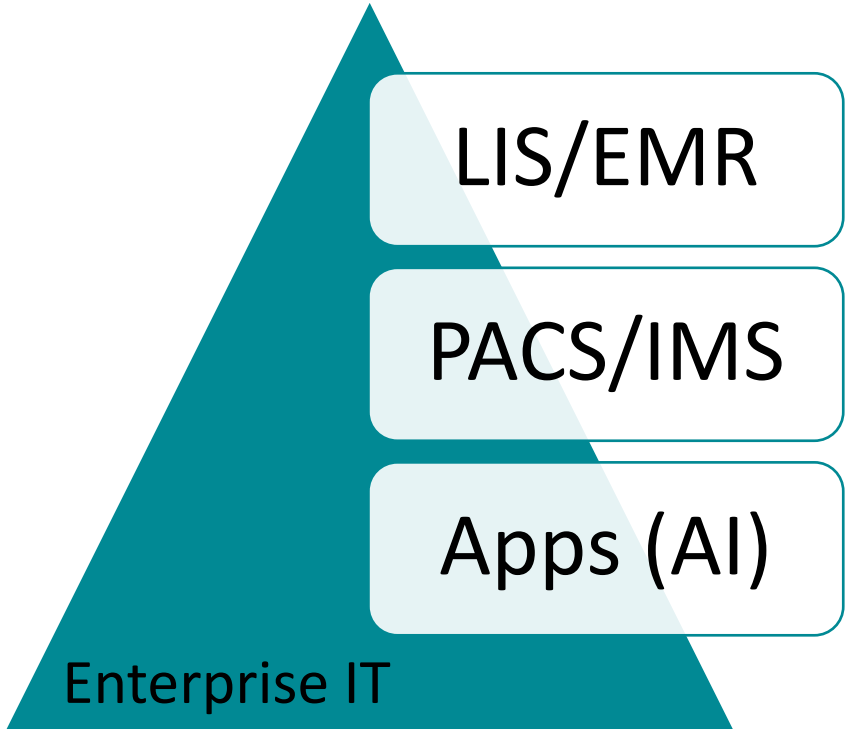
Digital Ecosystem



- **On-prem, edge vs cloud**
- **System interoperability**
- **DICOM image standard**
- **Going “fully” digital**
- **Loss of app functionality**
- **IT analyst support**

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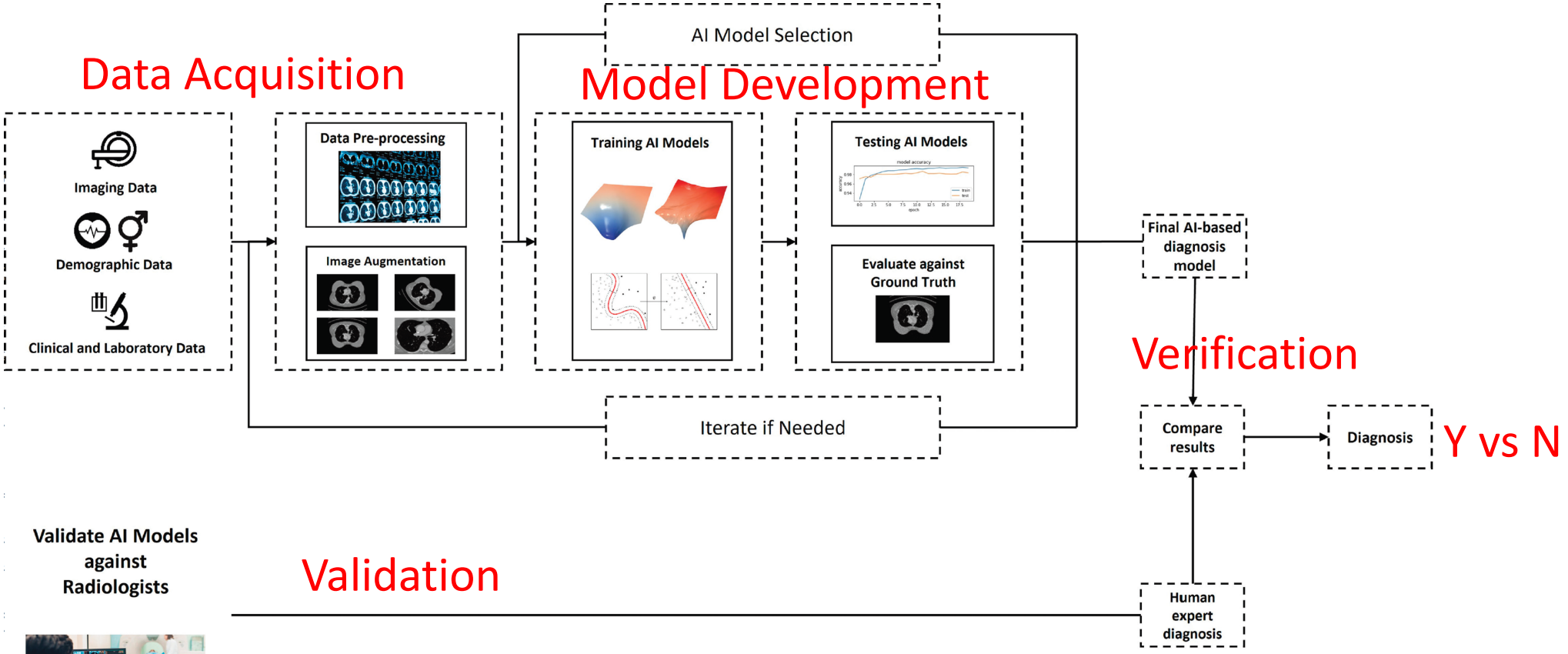
AI Deployment for Clinical Use



Dack E et al. Invest Radiol. 2023; 58:602-609

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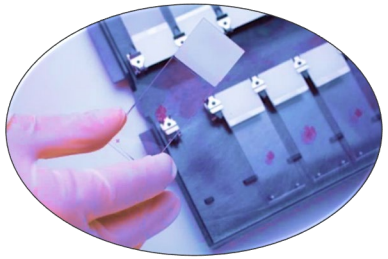
Where to Insert AI Tools?



Scanning

First read: AI to rescan, triage cases, screen, pre-order, pre-diagnose, sign-out negative cases

Primary Diagnosis

AI for running QA in the background

Second read: AI to perform tasks only when directed (grade, confirm diagnosis, offer a differential)

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GIGO Principle

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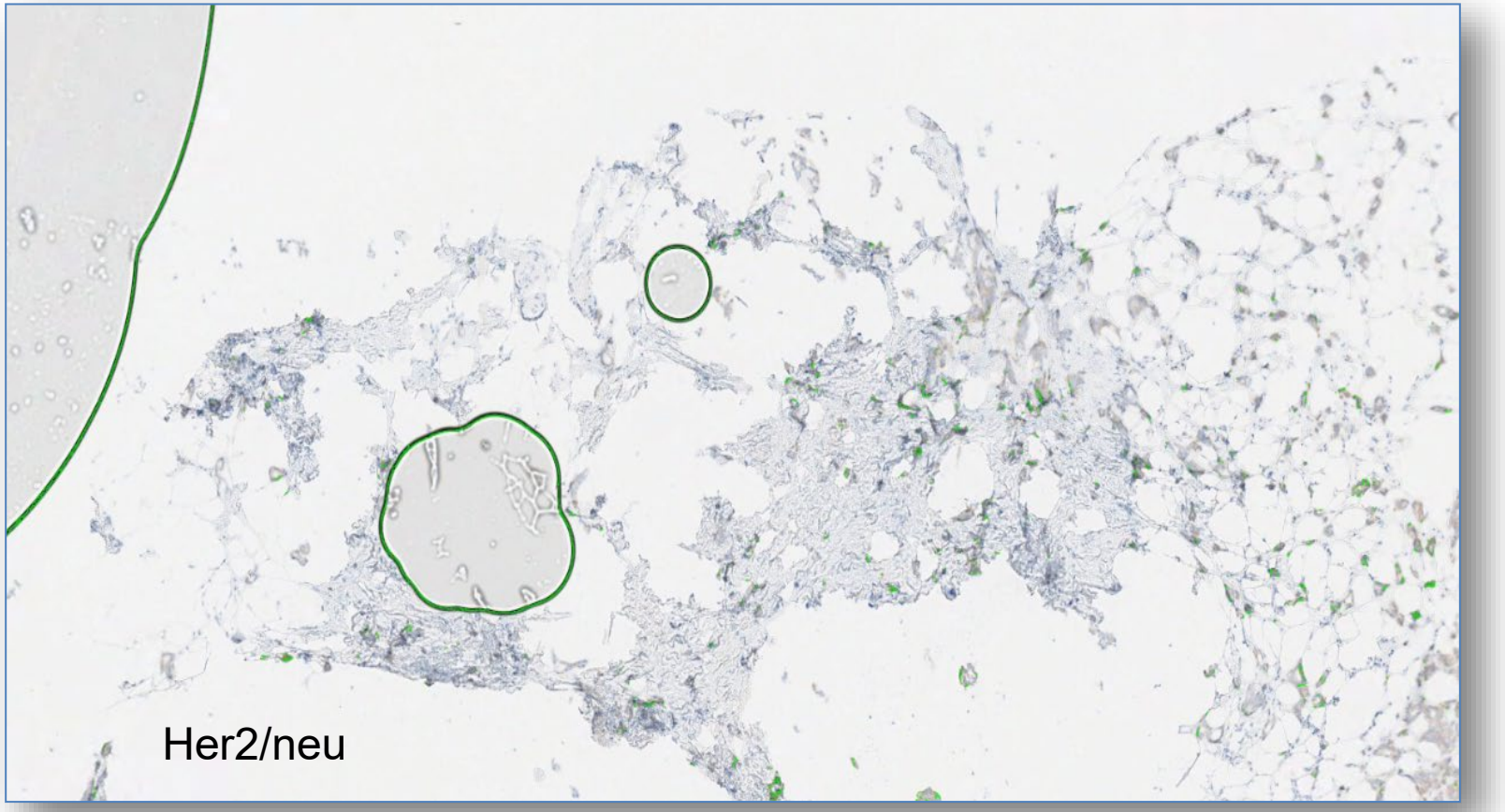
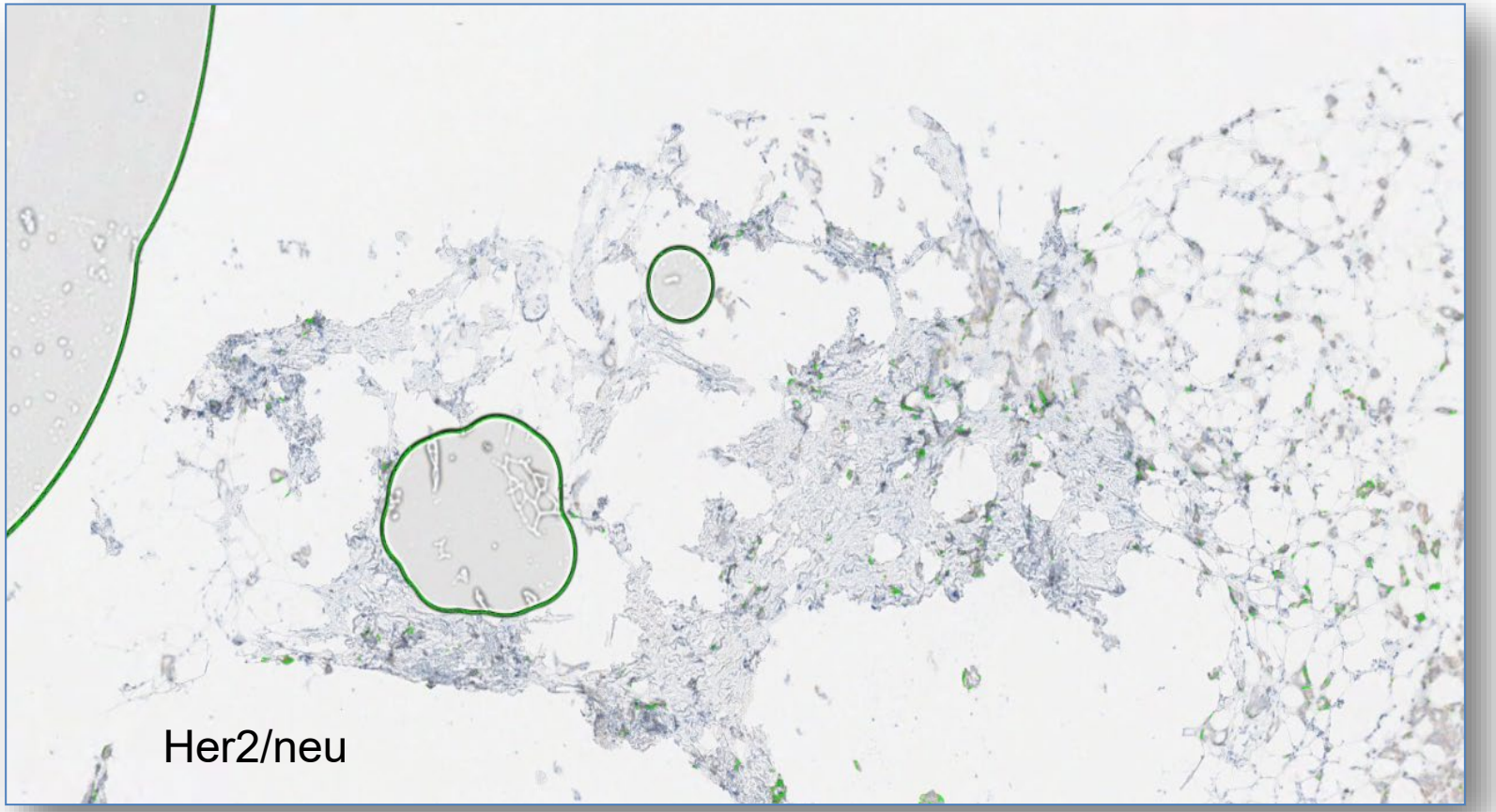
Artifact = False Her2+ Result



Artifact = False Her2+ Result



Safeguards:

Large (unbiased), and heterogenous datasets for training

Clinical validation

Human-in-the loop

Post-deployment monitoring

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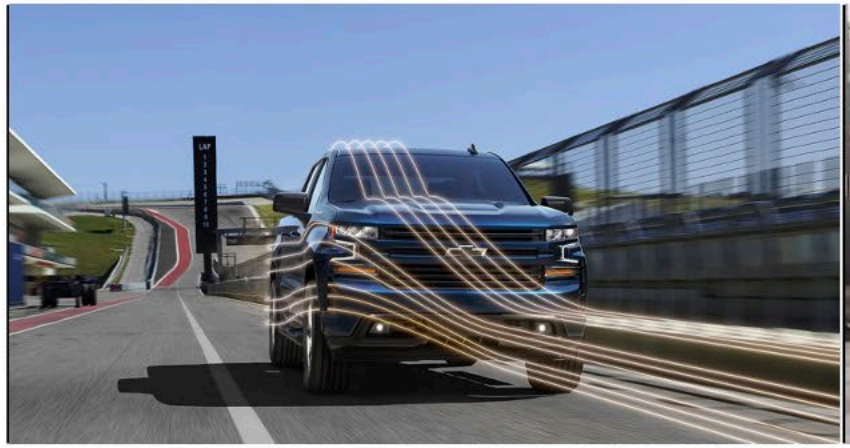


Analytical Validation	Technical Verification	Clinical Validation
○ Technical	○ Technical	○ Clinical
○ Vendor responsible	○ Vendor + Lab effort	○ Lab liable
○ Tool development step	○ Tool calibration	○ “Test drive”
○ Large (hold-out) dataset	○ Small dataset	○ Medium dataset
○ App development	○ Fine tuning	○ Locked algorithm
○ Regulatory standards	○ External evidence	○ Compliance

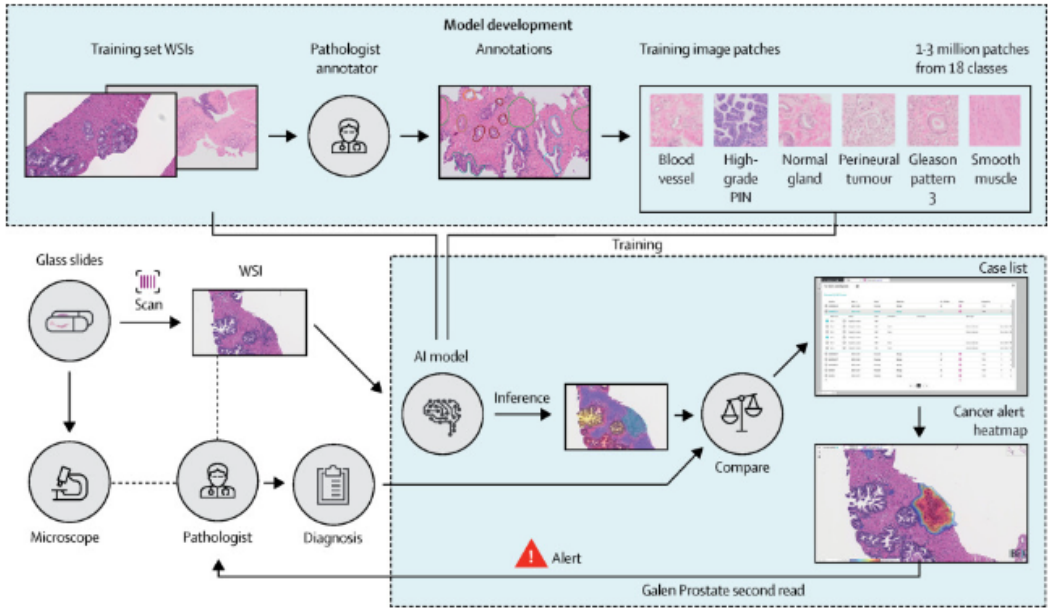
THE LANCET Digital Health

ARTICLES | VOLUME 2, ISSUE 8, E407-E416, AUGUST 01, 2020

PDF [1

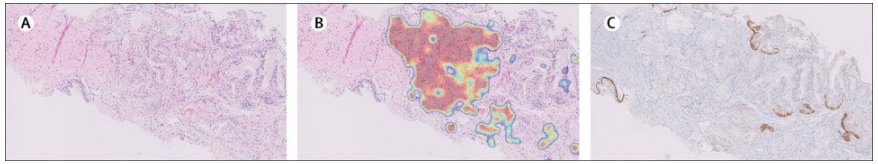
An artificial intelligence algorithm for prostate cancer diagnosis in whole slide images of core needle biopsies: a blinded clinical validation and deployment study

Liron Pantanowitz, MD • Gabriela M Quiroga-Garza, MD • Lilach Bien • Ronen Heled • Daphna Laifenfeld, PhD • Chaim Linhart, PhD • et al. Show all authors



Pathologists' misdiagnoses identified by the algorithm

	False positive	False negative
Adenocarcinoma	1 benign, 2 ASAP	2 cancer, 2 ASAP
Gleason score 7–10	2	4
Gleason pattern 5	0	1
Perineural invasion	1	2



Missed cancer case originally diagnosed as benign

The Lancet Digital Health 2020 2e407-e416DOI: (10.1016/S2589-7500(20)30159-X)

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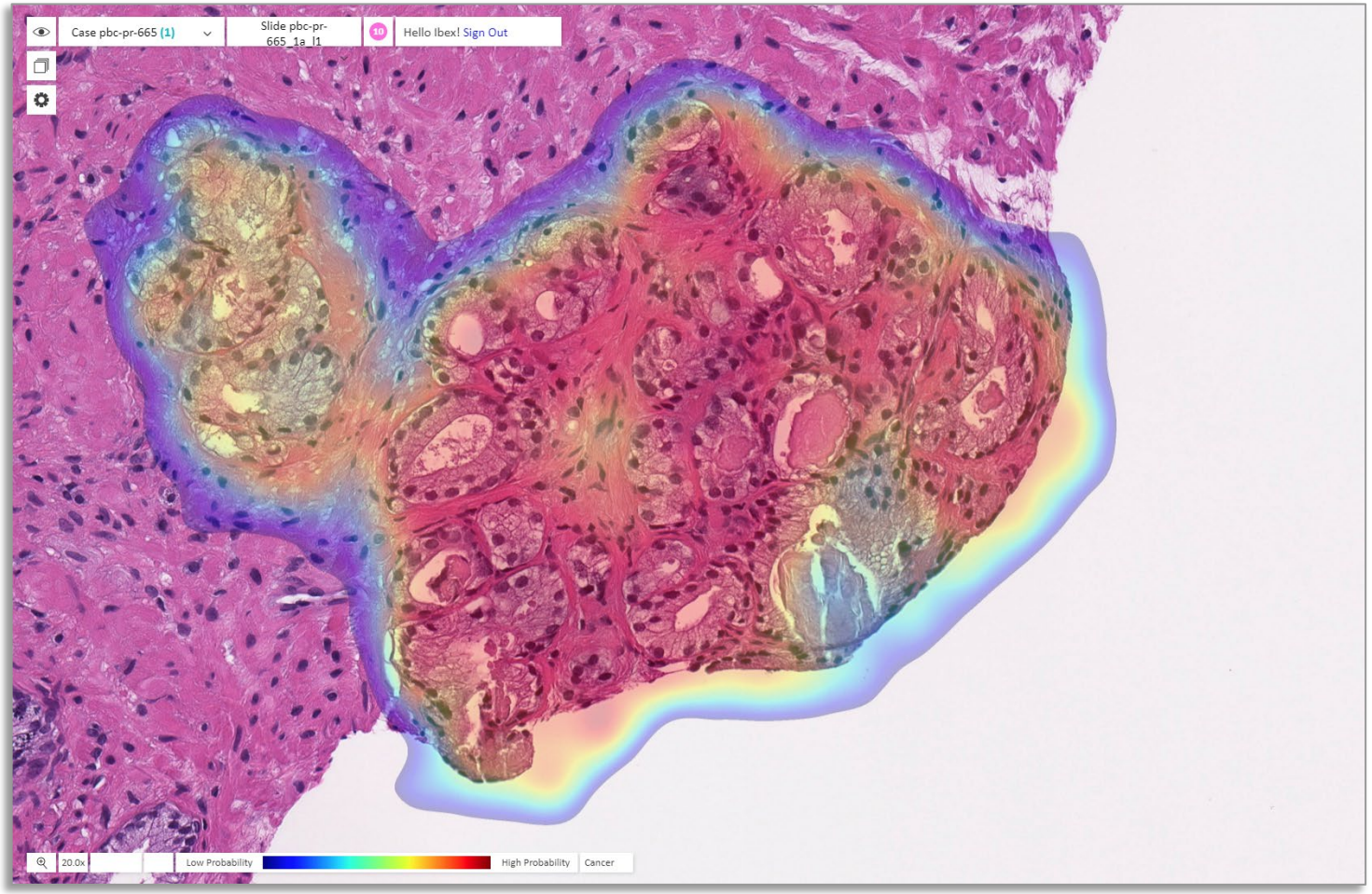
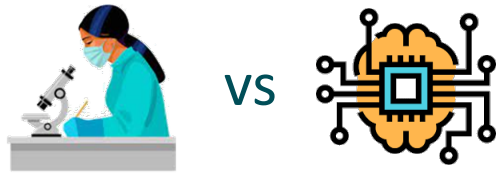


Prostate CNB with cancer heatmap

Blue = low probability
Red = high probability

The original diagnosis of benign was changed to cancer G3+3 following review.



The Lancet Digital Health 2020 2e407-e416DOI: (10.1016/S2589-7500(20)30159-X)

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Business Use Case

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Academic Medical Centers

What they have

Moderate case volume

High case complexity

Subspecialty experts

What they need

Automation & efficiency

Standardization of care

Time for academics

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Community Pathology Practices

What they have

Low case volume

Low case complexity

Generalists

What they need

Quick & ease of use

Diagnostic assistance

Less referrals

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Can AI do MORE than I can with my (micro)scope?

Do we train algorithms to just replicate what we can do with a microscope (e.g. train to interpret cases that fit into existing classification systems), or should we instead train AI systems to predict outcomes (e.g. underlying genotype from phenotype, prognosis, response to therapy)?

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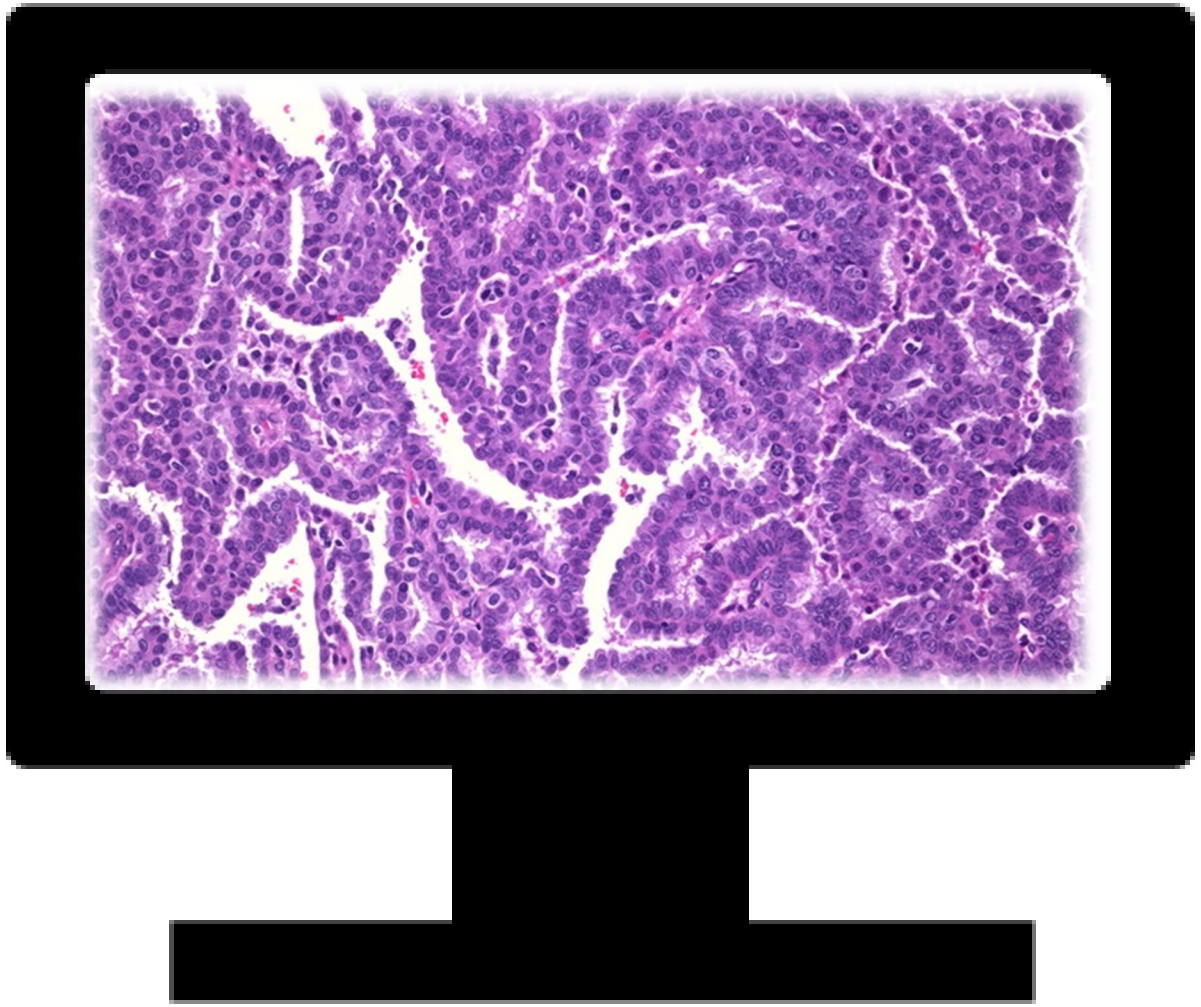

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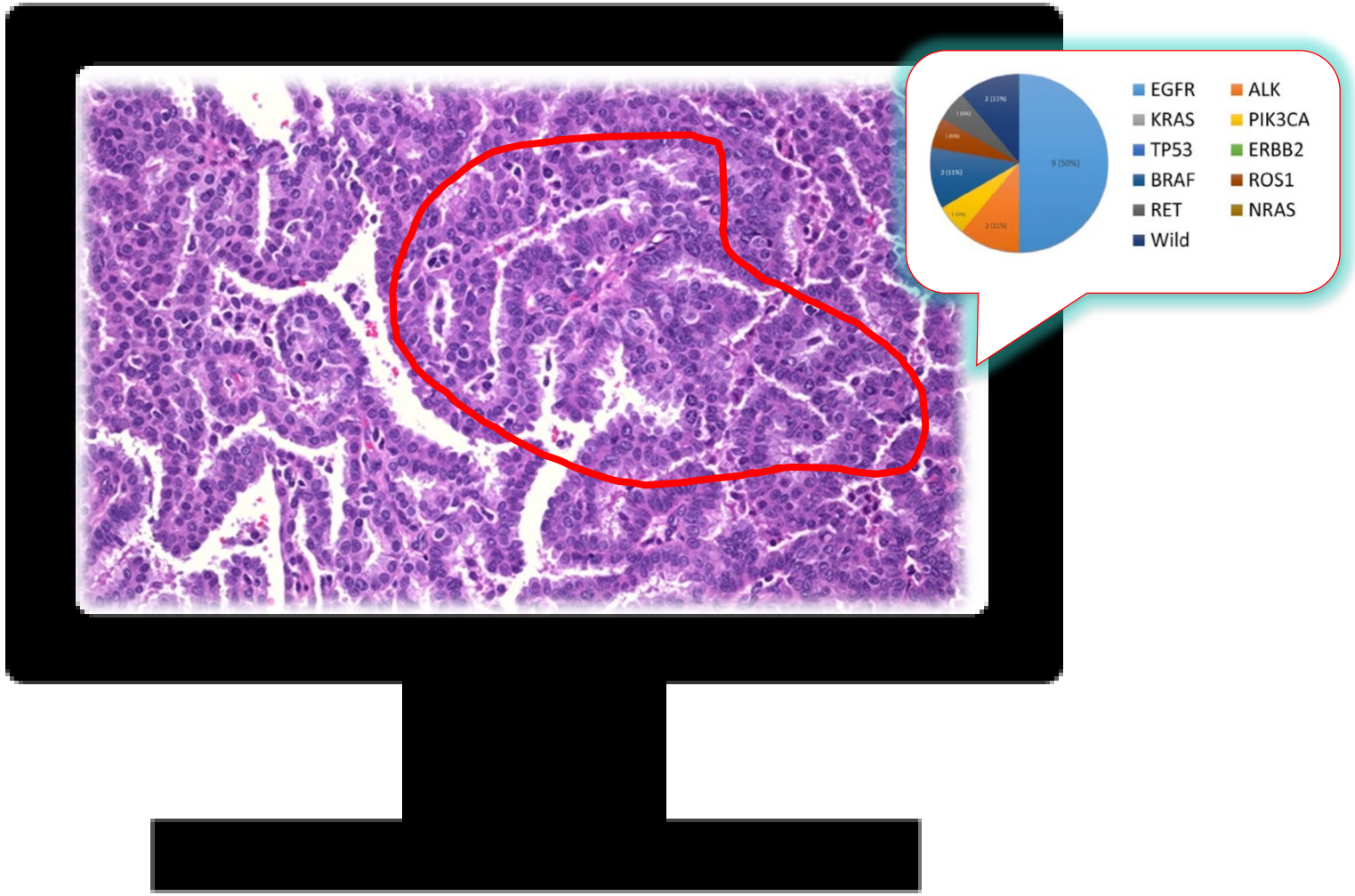

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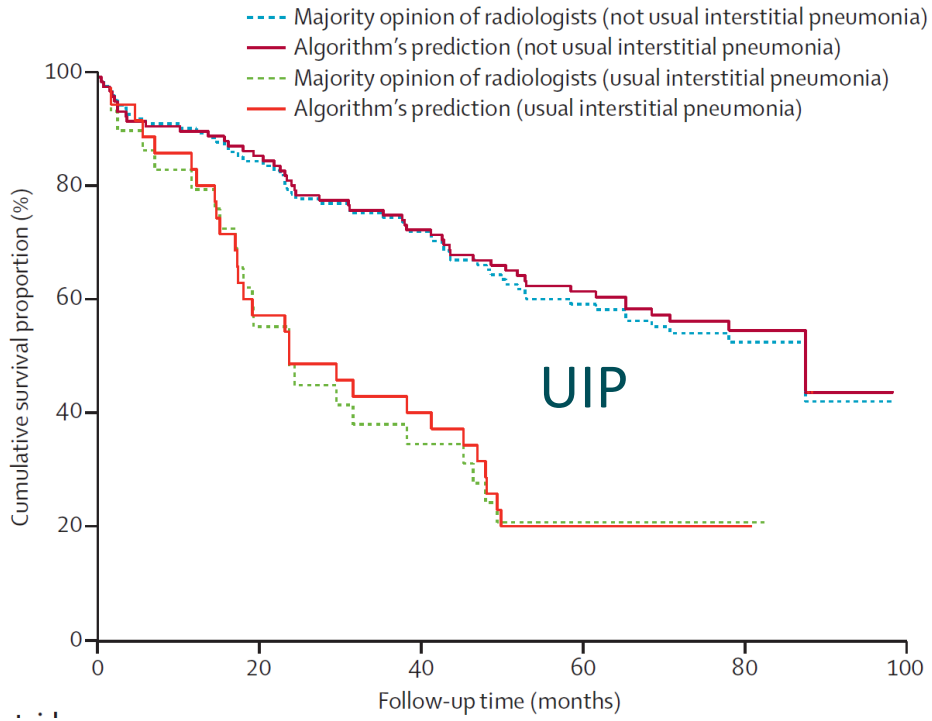
AI & Survival Analysis

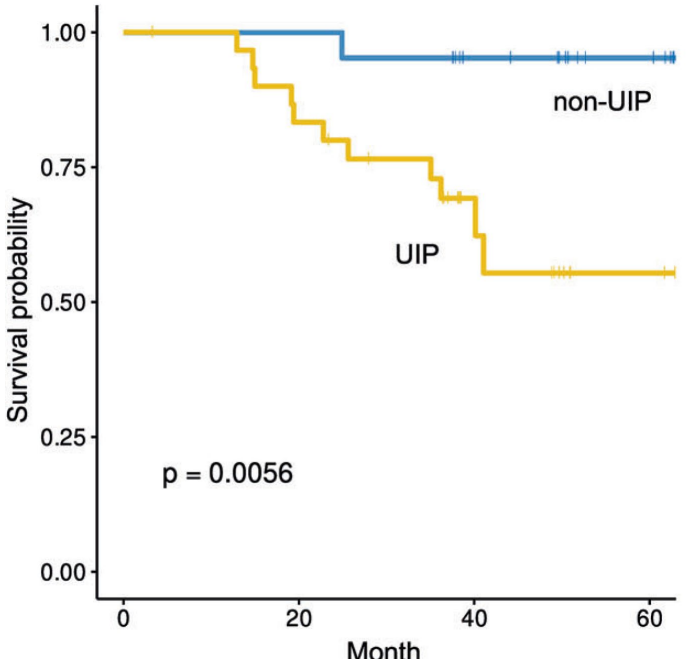
Cases predicted as UIP had a significantly worse prognosis than those predicted as non-UIP

Radiology (HRCT)



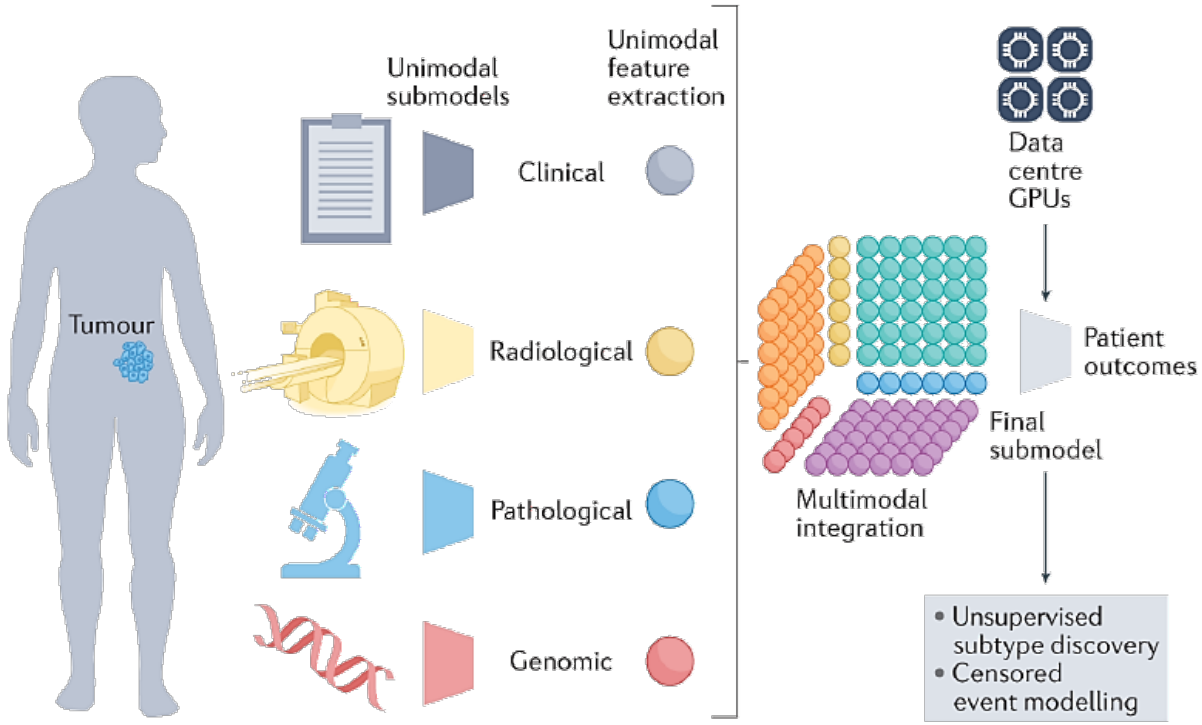
Walsh SLF et al. Lancet Respir Med 2018; 6:837–45

Pathology (Histopathology)



Uegami W et al. Mod Pathol. 2022; 35:1083-1091

Multimodal AI Models



- Advanced ML models designed to process, integrate and link multiple data types (modalities).
- Allows more comprehensive & contextually aware decisions, to improve AI-based diagnostics & predictions.

Boehm KM et al. Nat Rev Cancer 2022; 22(2):114-126

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Generative AI

- AI capable of generating text, images, code or other media
- E.g. ChatGPT (GPT = generative pretrained transformer)
- Common uses: Creative writing, summarize text, translation, producing code, data mining, categorization, etc.
- Clinical uses: Automate report generation, diagnosis classification, synthetic (fake) data, etc.
- Challenges: Bias, ethics (e.g. deepfake), hallucinations

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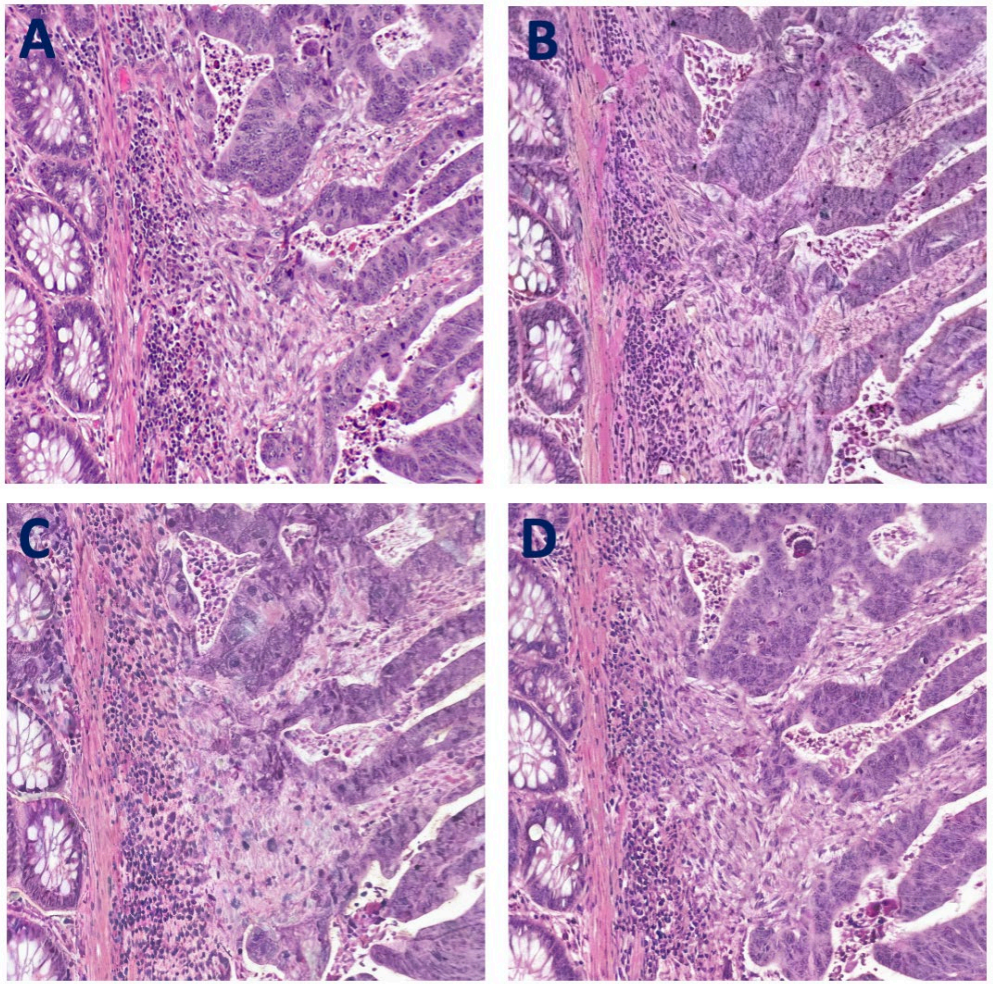
Which Digital H&E Recut is Fake?



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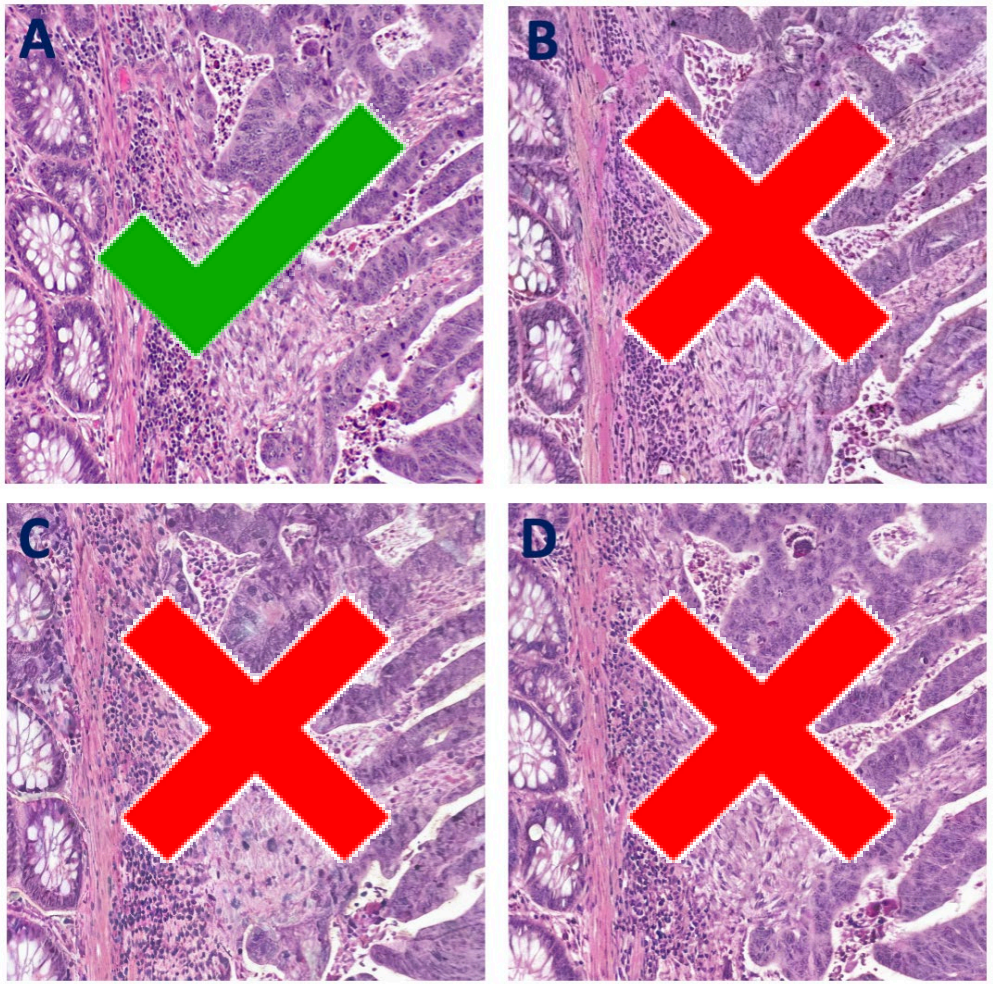

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Questions About Using AI in Healthcare

- What are the right tasks for AI in Medicine (i.e. killer app)?
- What is the right evidence for using AI (FDA, publications)?
- How do we pay for AI tools and get reimbursed (CPT code)?
- How do trainees interact with AI (will they be deskilled)?
- What are the emerging ethics & regulatory concerns?

FDA & AI/ML-enabled Medical Devices Marketed in the US

Artificial Intelligence and Machine Learning in Software as a Medical Device | FDA

Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices | FDA

04/30/2024	K232923	Ethos Treatment Management (3.0); Ethos Treatment Planning (2.0)	Varian Medical Systems Inc.	Radiology	IYE
04/29/2024	K240062	ARVIS® Shoulder	Insight Medical Systems, Inc.	Neurology	OLO
04/26/2024	K232799	syngo.via RT Image Suite	Siemens Medical Solutions USA, Inc.	Radiology	MUJ
04/26/2024	K240406	Sonio Detect	Sonio	Radiology	IYN
04/26/2024	K233673	uMR Jupiter	Shanghai United Imaging Healthcare Co., Ltd	Radiology	LNH
04/25/2024	K232331	InVision Precision LVEF (LVEF)	InVision Medical Technology Corporation	Radiology	QIH
04/24/2024	K240850	EPIQ Series Diagnostic Ultrasound Systems; Affiniti Series Diagnostic Ultrasound Systems	Philips Ultrasound LLC	Radiology	IYN
04/23/2024	K240058	AEYE-DS	AEYE Health Inc.	Ophthalmic	PIB
04/22/2024	K233582	Rapid	iSchema View Inc.	Radiology	LLZ
04/22/2024	K234068	ART-Plan (v.2.2.0)	Therapanacea SAS	Radiology	MUJ
04/19/2024	K240781	SKOUT® system	Iterative Scopes, Inc.	Gastroenterology-Urology	QNP
04/17/2024	K233186	uOmnispace.MR	Shanghai United Imaging Healthcare Co., Ltd.	Radiology	QIH
04/16/2024	K232202	Aperio GT 450 DX	Leica Biosystems Imaging, Inc.	Pathology	PSY
04/15/2024	K240773	VisAble.IO	Techsomed	Radiology	QTZ
04/12/2024	K240238	Vantage Fortian/Orian 1.5T, MRT-1550, V9.0 with AiCE Reconstruction Processing Unit for MR	Canon Medical Systems Corporation	Radiology	LNH

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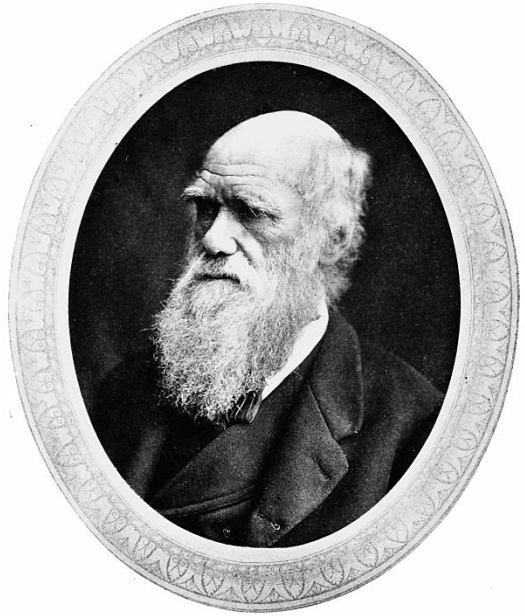
AI Tool ➡

It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is the most adaptable to change.



Charles Darwin

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