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BRUSSELS 2026
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AI Tools for Pathology



Dr. med. Stefan J.K. Schulz, M.Sc.

SIEMENS
Healthineers

AGFA 
HealthCare

ENT
Enlightening
New Technologies

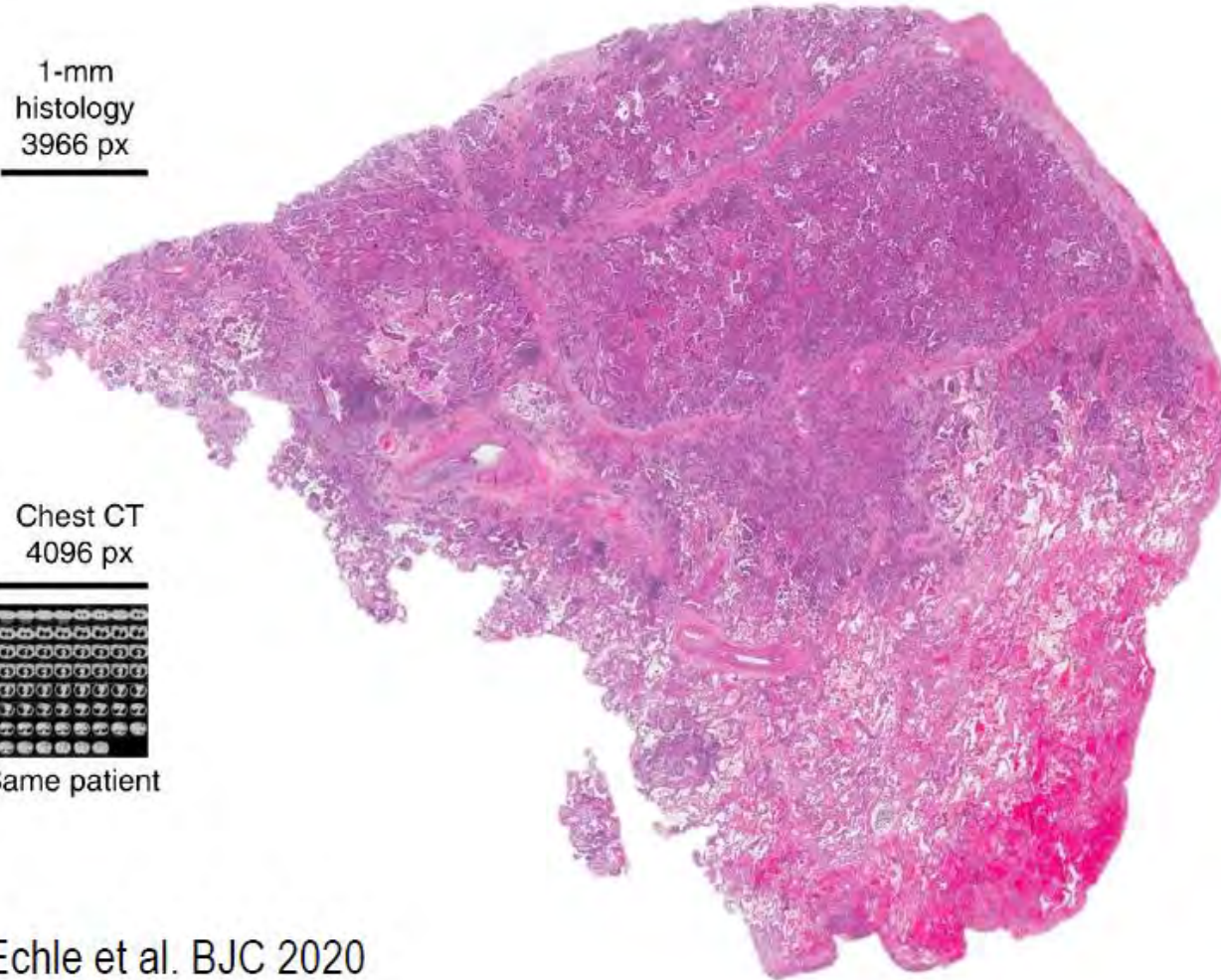


 **Dedalus**



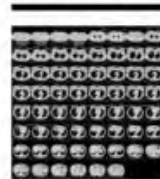
a

1-mm
histology
3966 px



b

Chest CT
4096 px

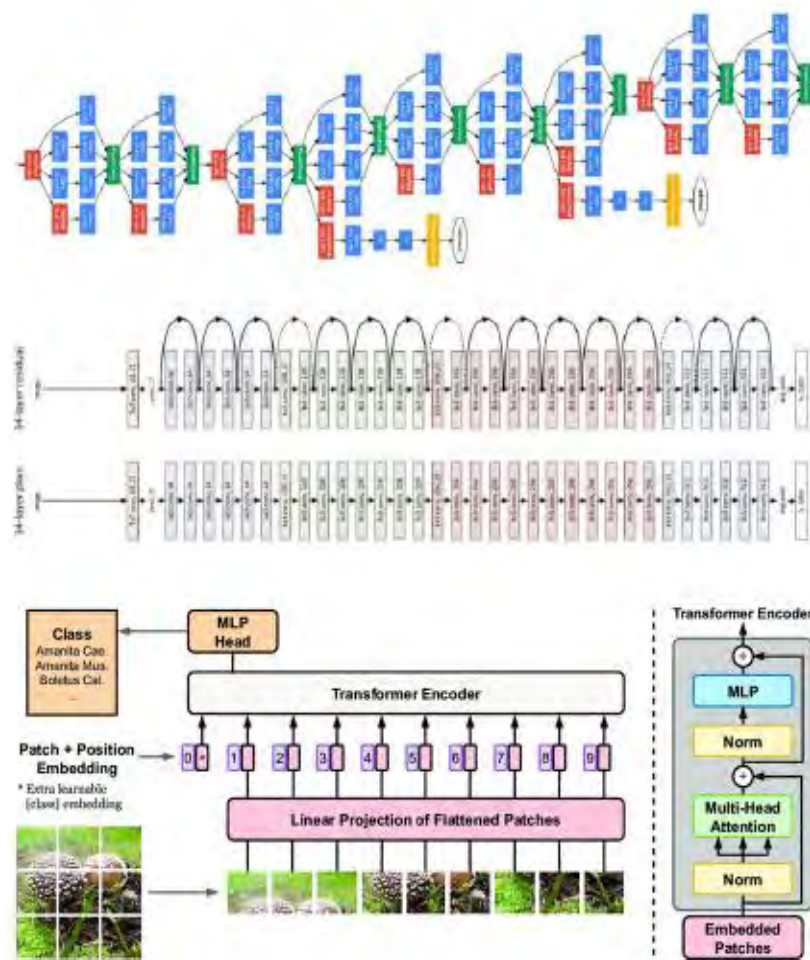
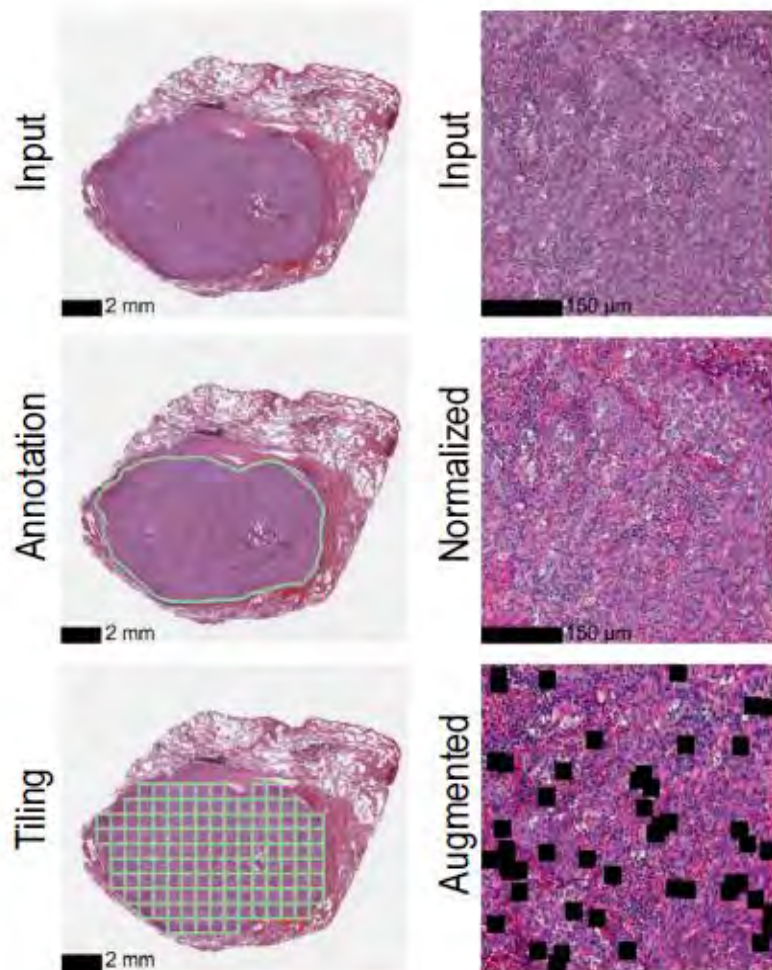


Same patient

Endoscopy
1024 px

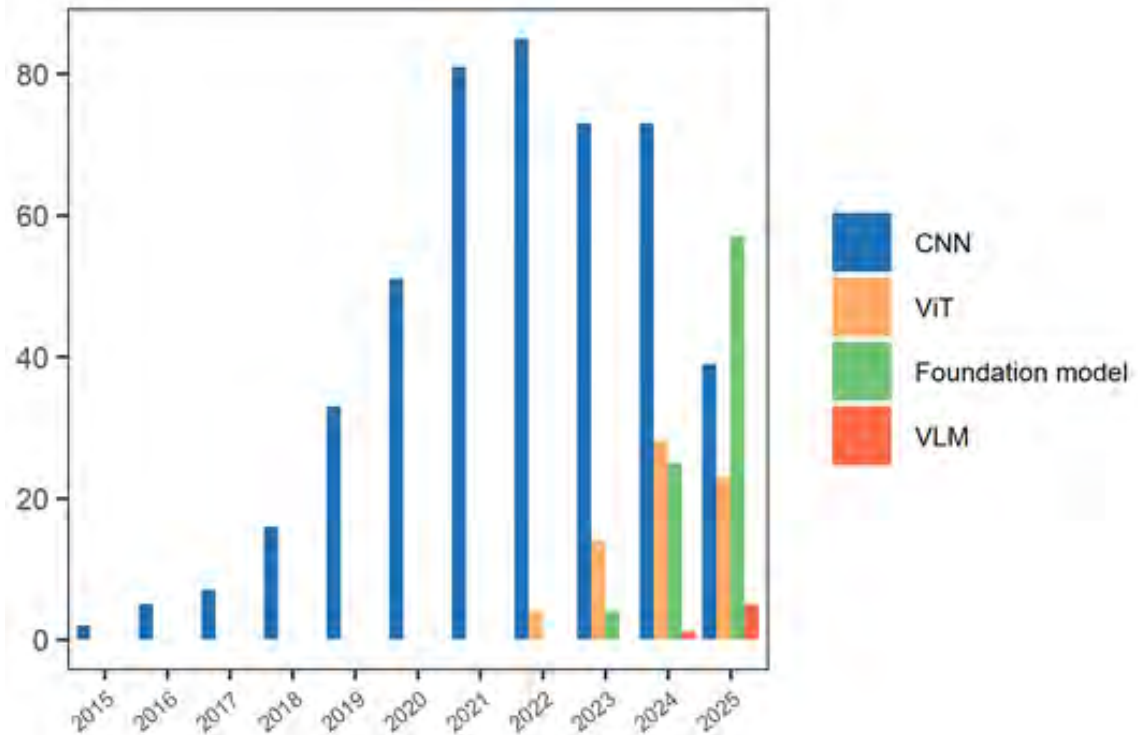


Echle et al. BJC 2020



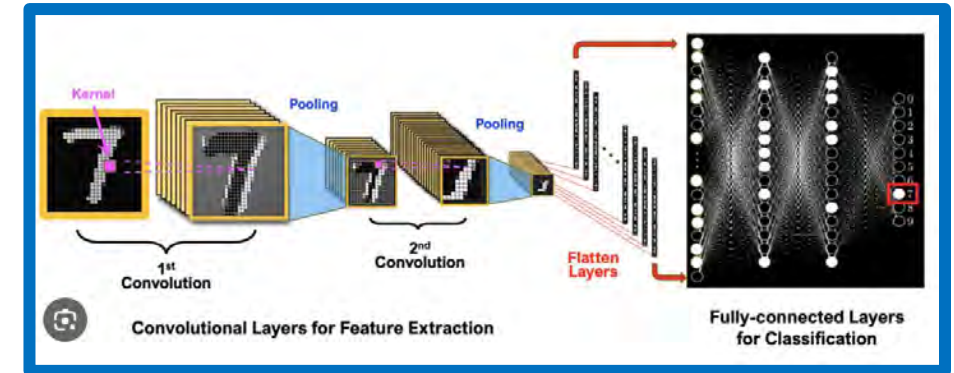
He et al., 2015
Szegedy et al., 2014
Dosovitskiy et al., 2021

Algorithmic shift in Digital Pathology

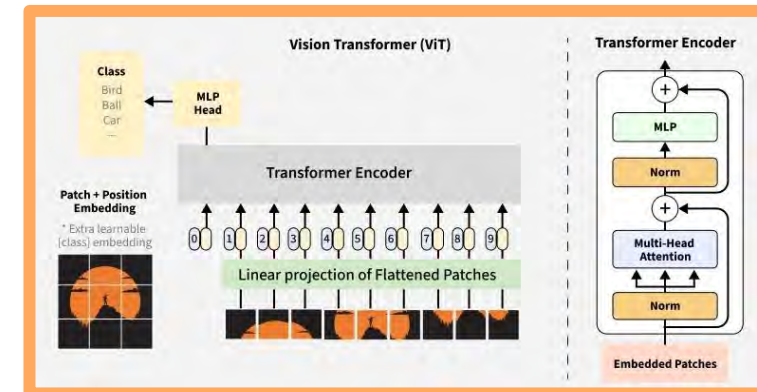


Schulz *et al.* Onkologie 2025

CNN: Convolutional neural network

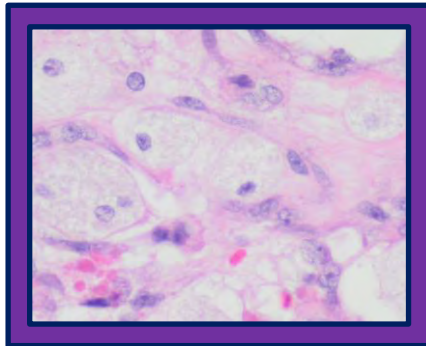


ViT: Vision Transformer

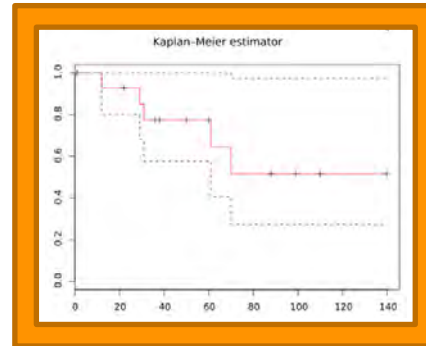


<https://mriquestions.com/deep-network-types.html>

<https://www.geeksforgeeks.org/deep-learning/vision-transformer-vit-architecture/>



Diagnostic
biomarkers



Prognostic
biomarkers



Predictive
biomarkers

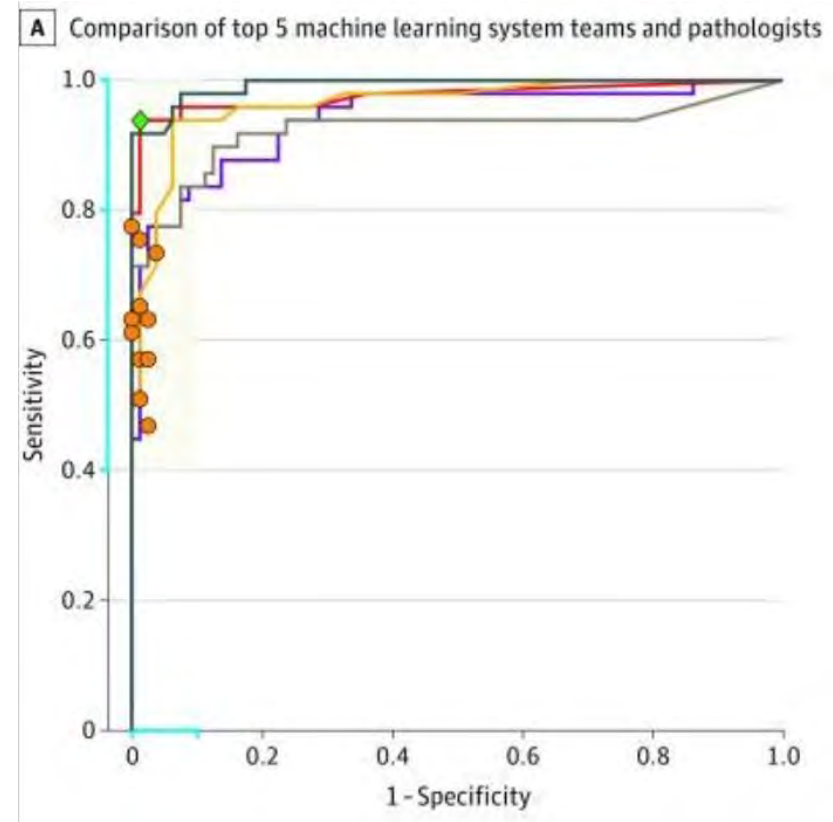
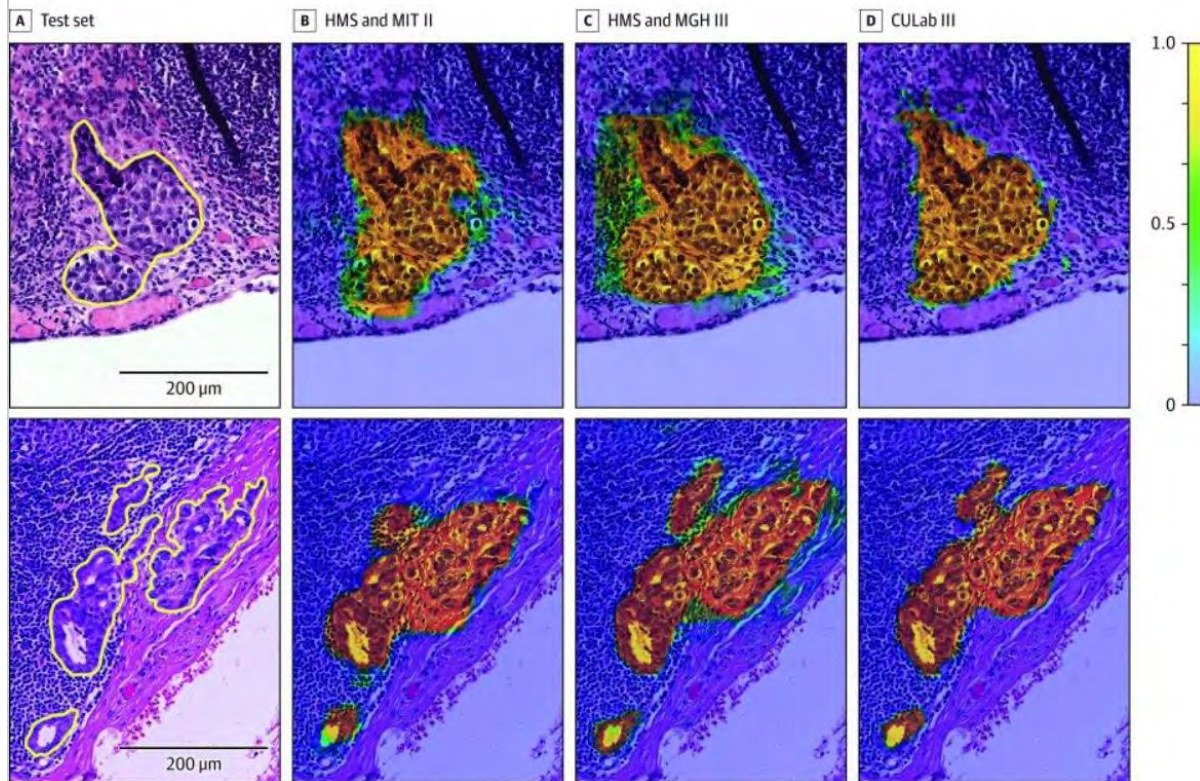


**Direct assessment or prediction based on
surrogate parameters (e.g. known biomarkers)**

<https://commons.wikimedia.org/wiki/File:Kaplan-Meier-sample-plot.svg>

https://commons.wikimedia.org/wiki/File:Orthopedic_Surgery.jpg#file

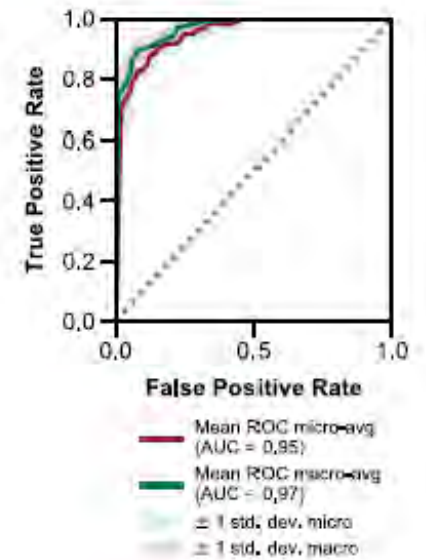
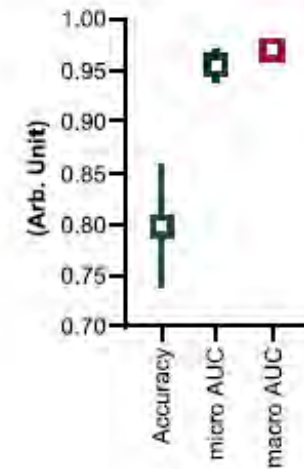
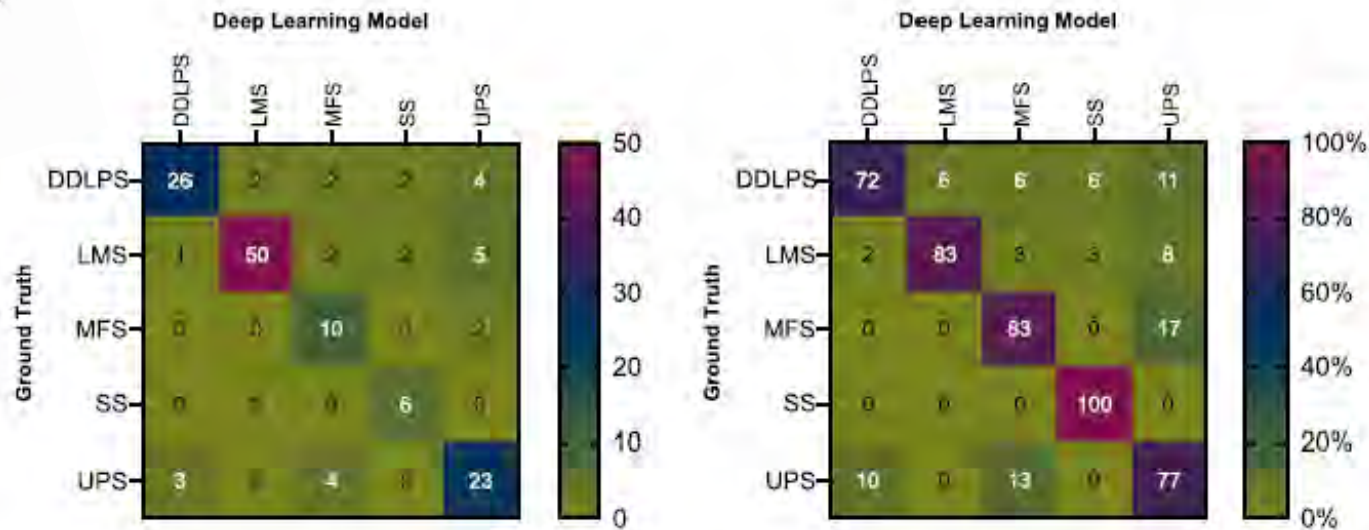
https://commons.wikimedia.org/wiki/File:Histopathology_of_solid_pseudopapillary_tumor_with_area_of_foamy_macrophages.jpg



Ehteshami Bejnordi *et al.* JAMA 2017

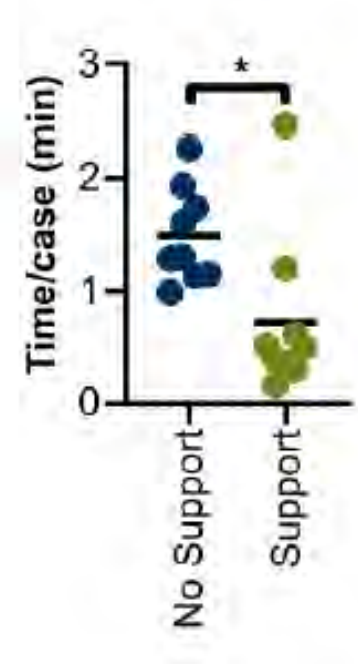
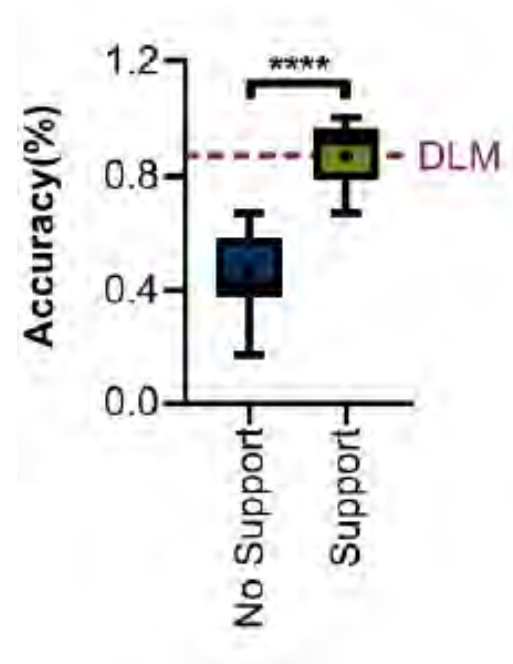
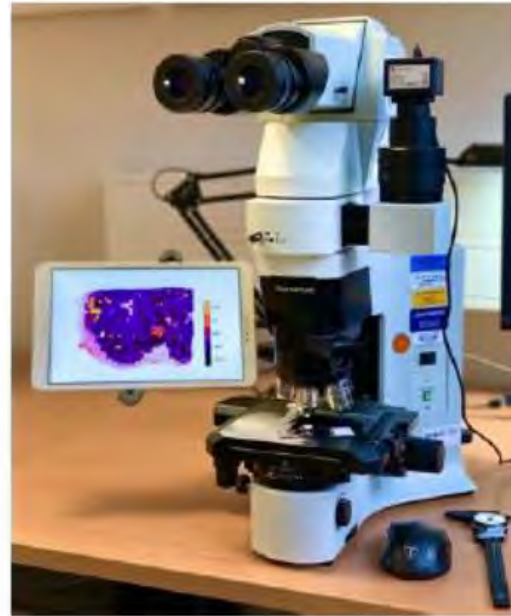
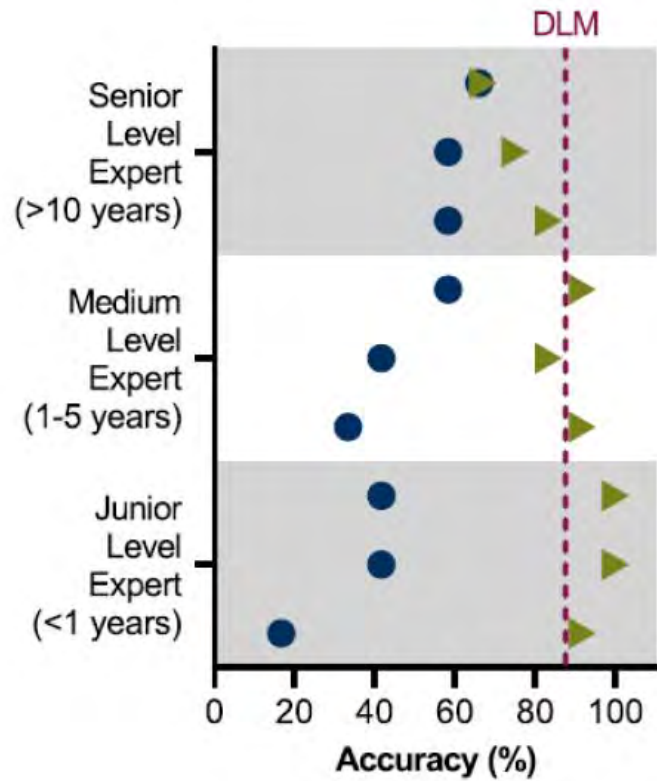
CAMELYON16 data

Soft-tissue sarcoma (i)



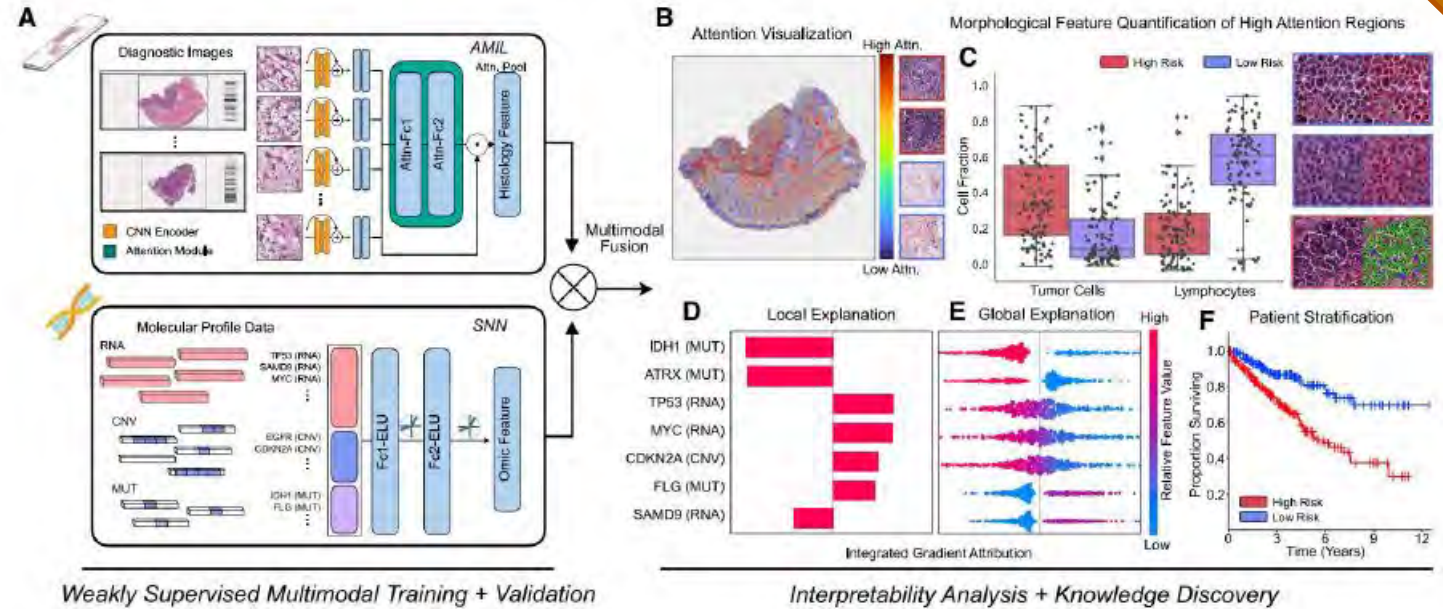
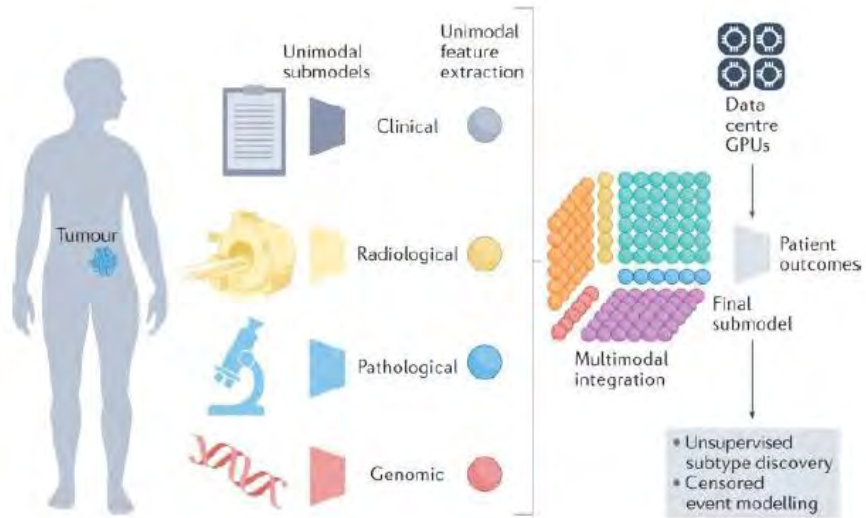
Foersch et al. Ann Oncol 2021

Soft-tissue sarcoma (ii)



Foersch et al. Ann Oncol 2021

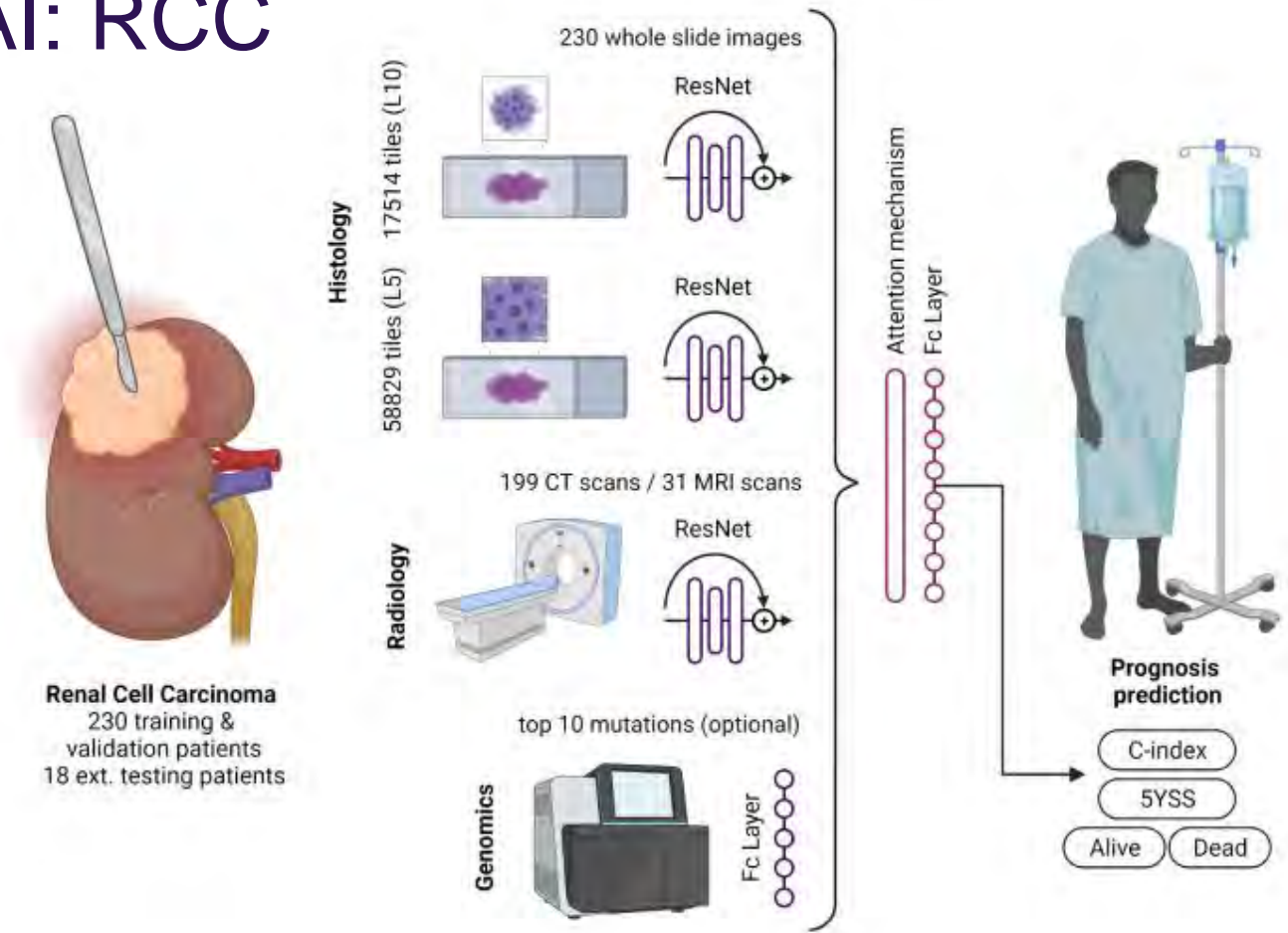
Multimodal AI



Boehm et al. Nature Reviews Cancer 2022

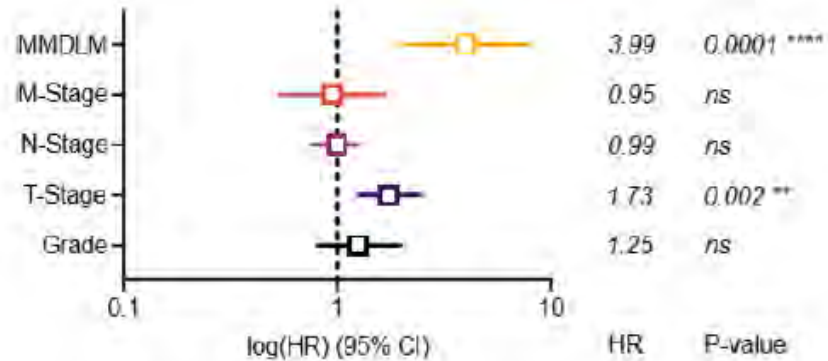
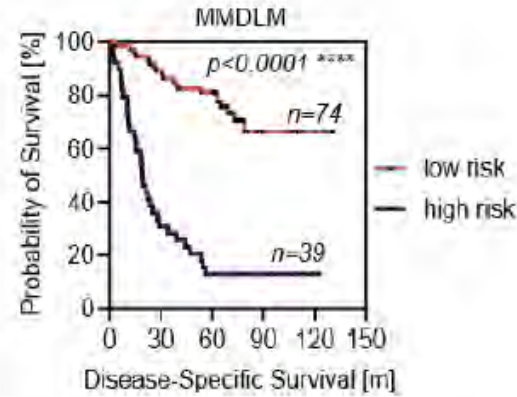
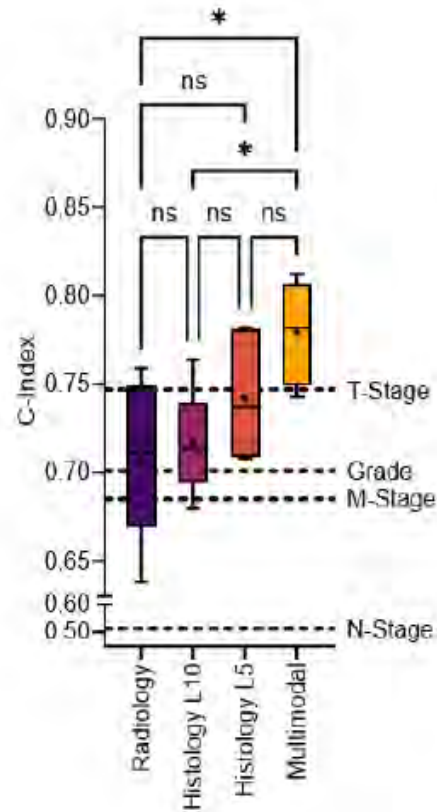
Chen et al. Cancer Cell 2022

Multimodal AI: RCC



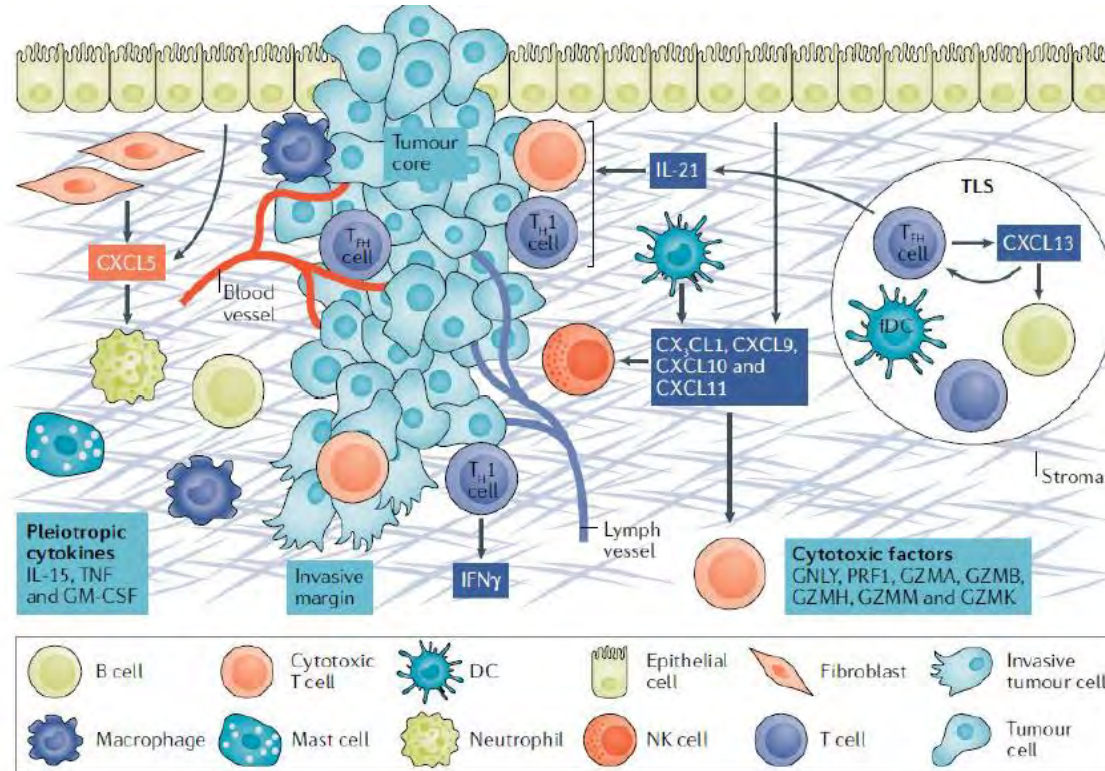
Schulz et al. Front Oncol 2021

Multimodal AI: RCC



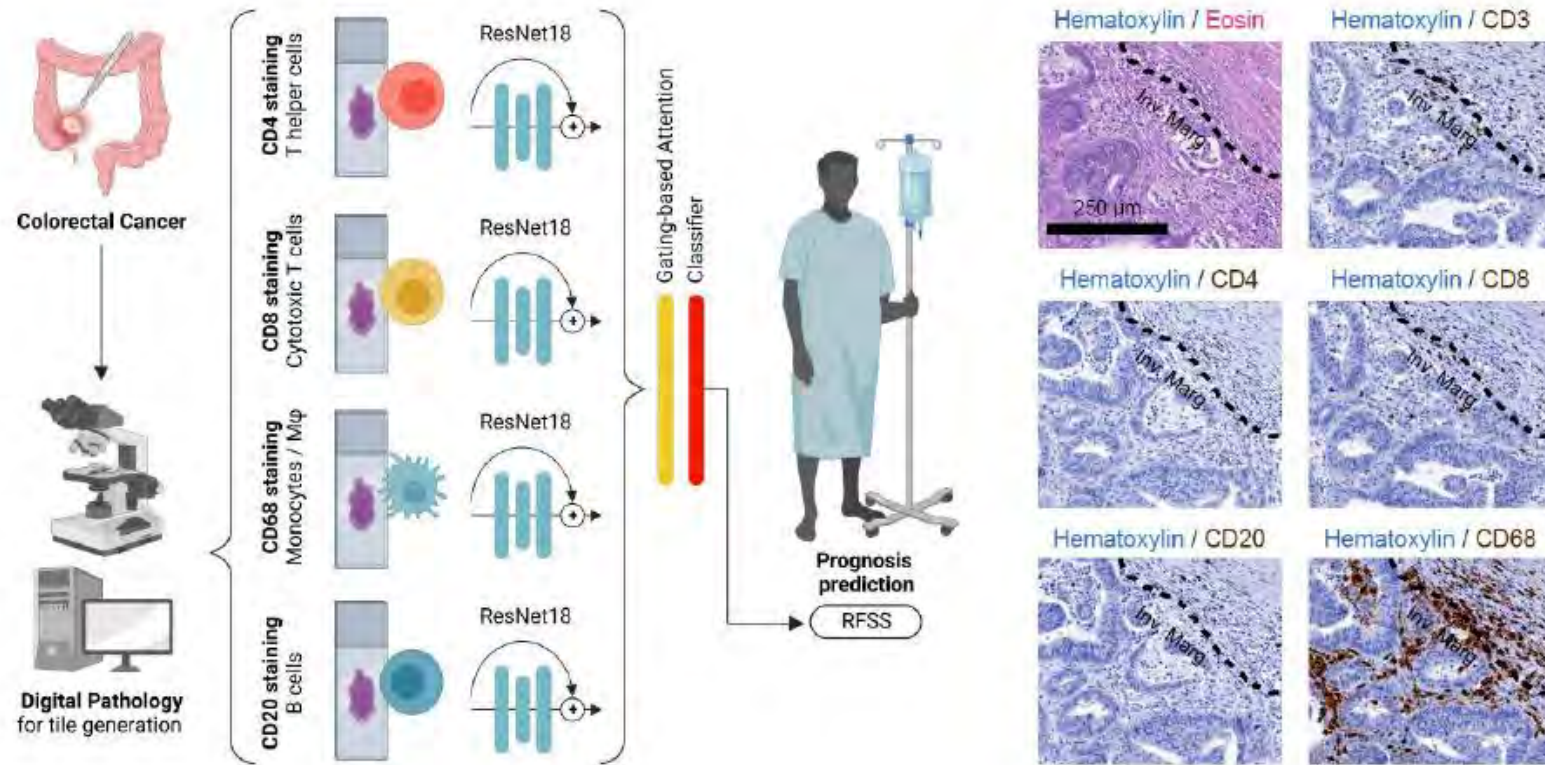
Schulz et al. Front Oncol 2021

Tumor immune microenvironment (TiME)



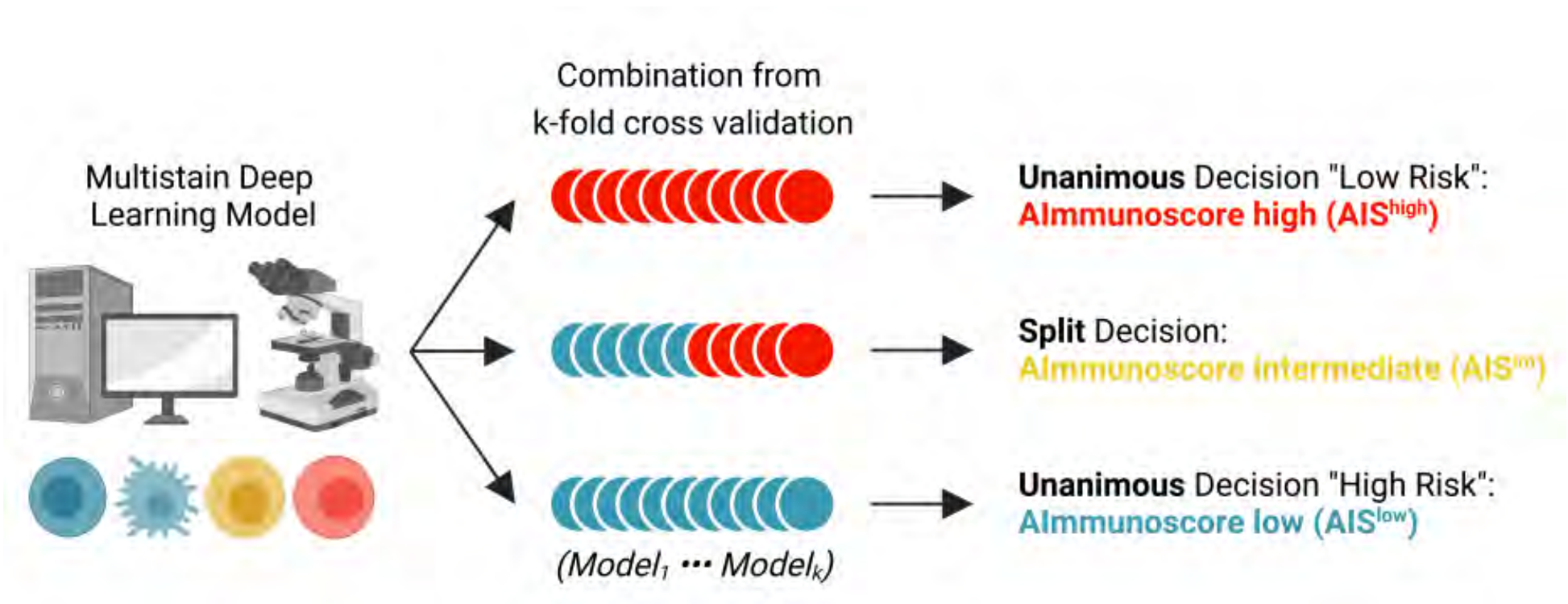
Bruni et al. Nature Reviews Cancer 2020

Multistain Deep Learning



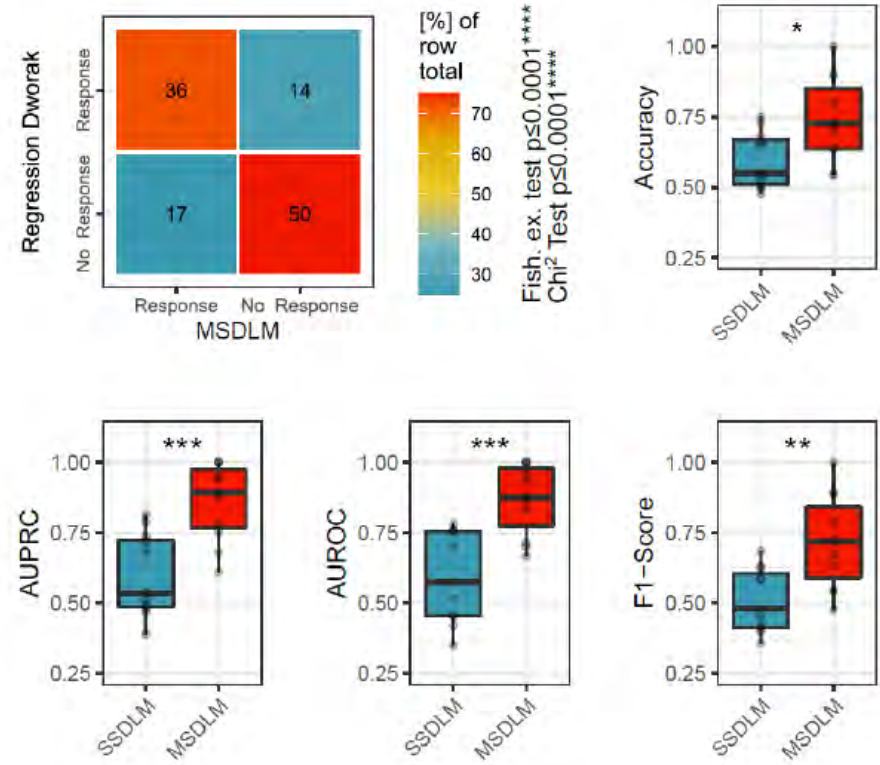
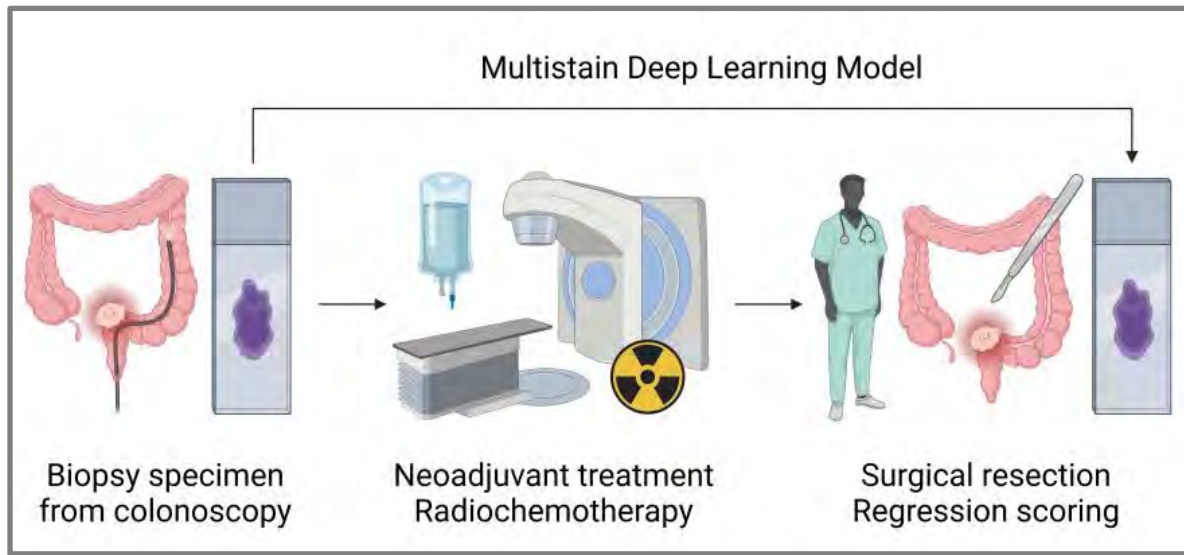
Foersch et al. Nature Medicine 2023

“AImmunoscore”



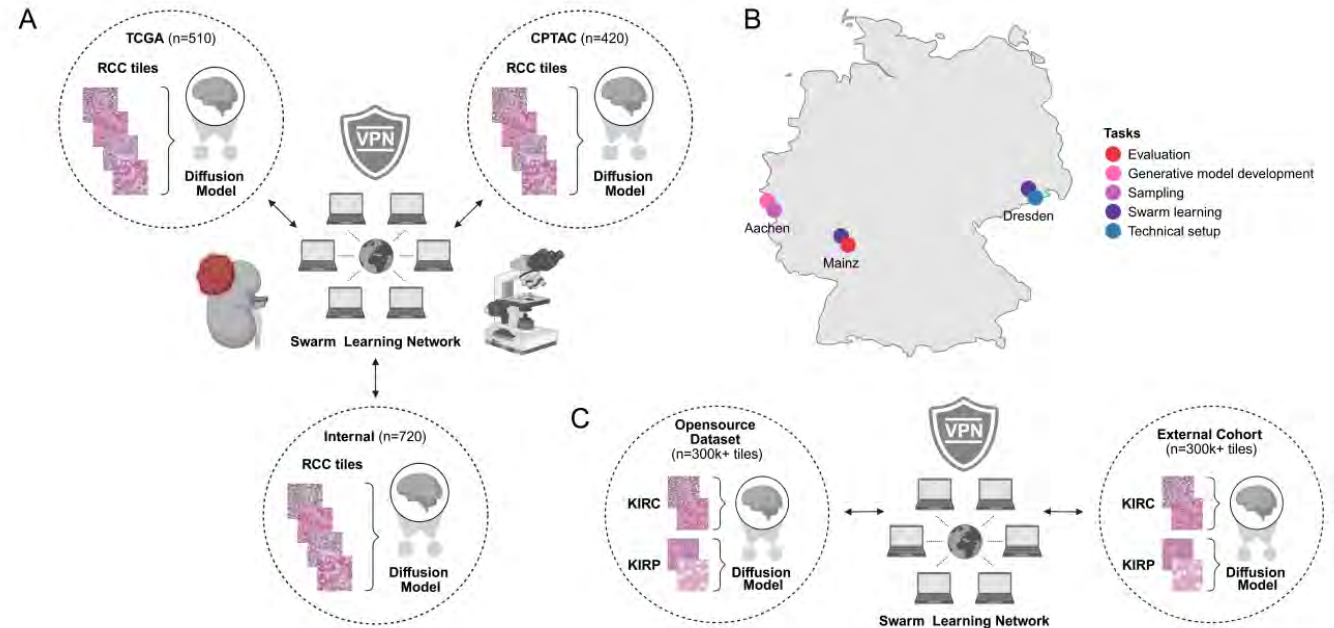
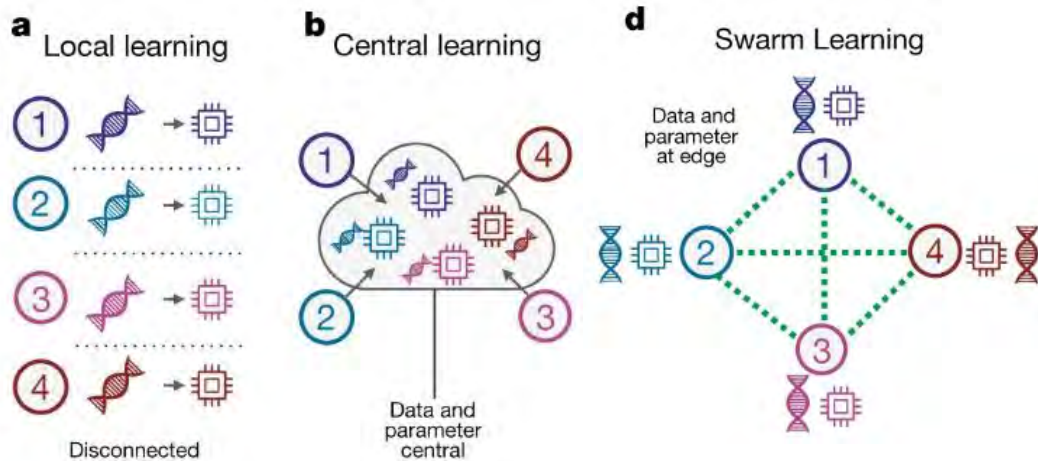
Foersch et al. Nature Medicine 2023

“AImmunoscore” – Predictive biomarker



Foersch et al. Nature Medicine 2023

Federated / Swarm learning



Warnat-Herresthal et al. Nature 2021

Schulz et al.
 (unpublished work, please don't share)

DECIPHER-M



Entities – Metastatic disease of:

- CRC (colorectal cancer)
- Breast cancer
- Sarcoma

Data sharing / Interoperability:

- Central HL7 / FIHR Server
- DICOM

<https://digitalhealth.tu-dresden.de/projects/decipher-m/>

WSI / Data format variability in Pathology

Radiology

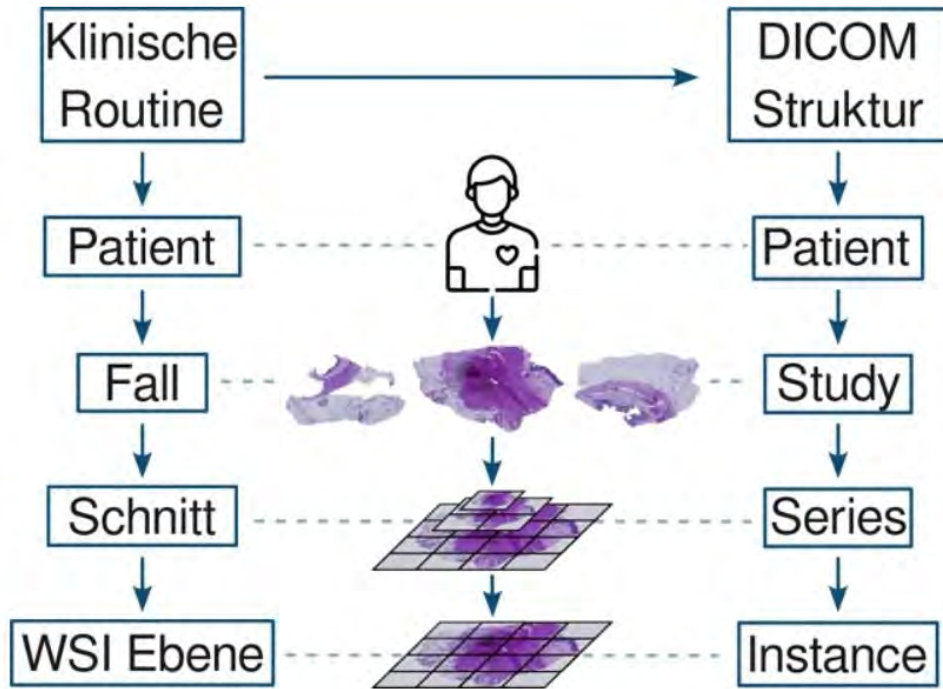
- **DICOM**

- NIfTI (.nii)

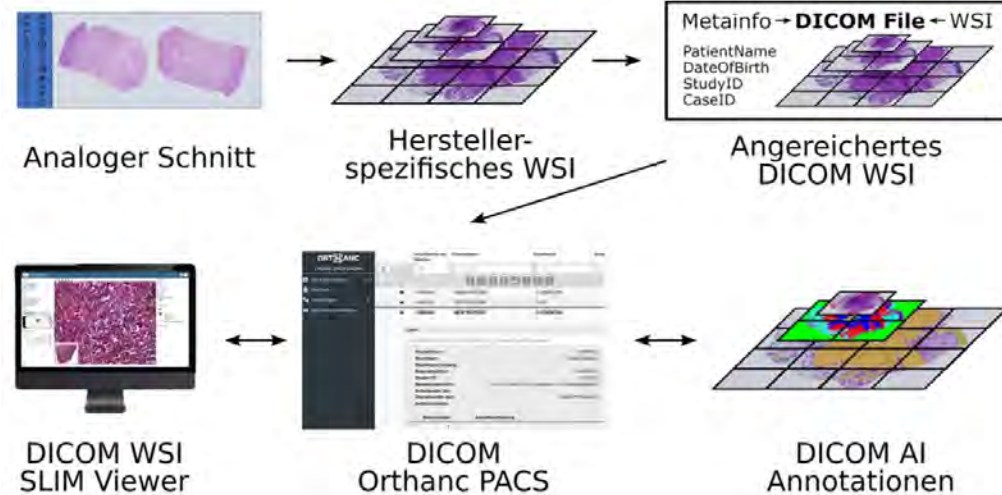
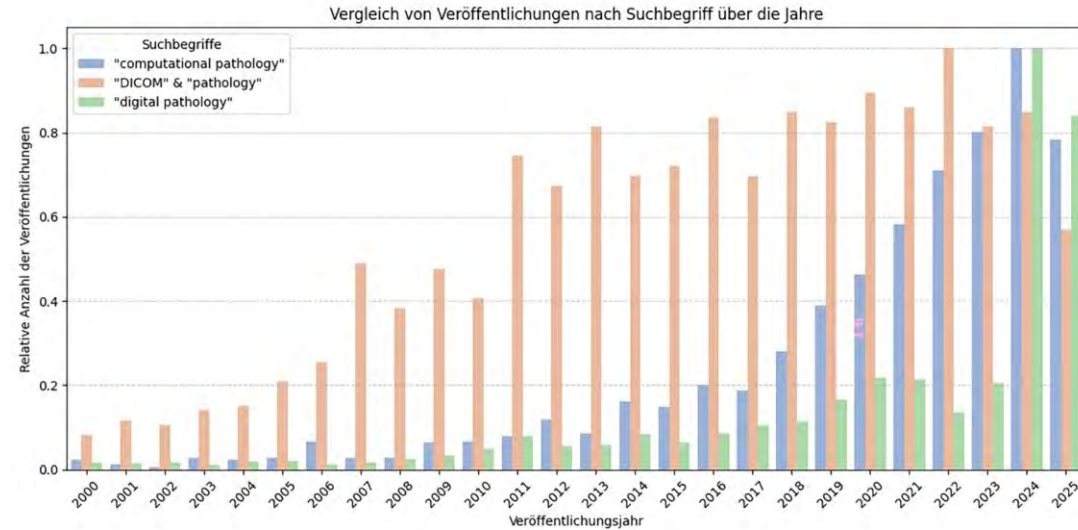
Pathology

- .mrxs
- .afi
- .SVS
- .ndpi
- DICOMDIR
- .tiff
- .ome_tiff
- .mdsx
- .xml
- .tmap
- .zif
- ...

DICOM in Pathology



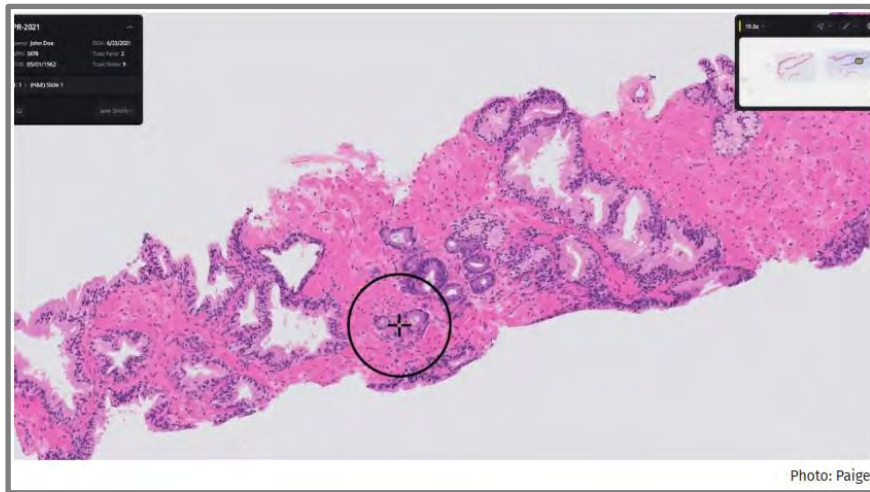
Blattgerste *et al.* Pathologie 2026



FDA approvals – AI Tools in Histopathology (I)

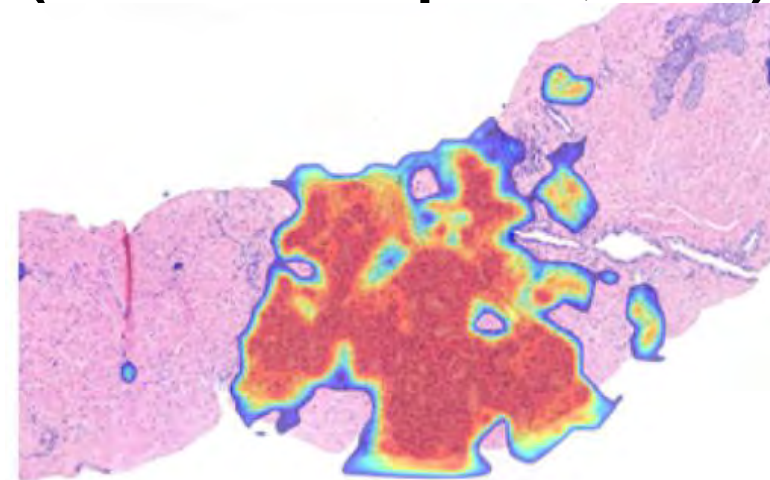
2021

„Paige Prostate“
(Prostate biopsies, H&E)



2025

„Ibex prostate detect
(Galen Second Read)“
(Prostate biopsies, H&E)



Santa-Rosario et al. 2024

<https://www.mobihealthnews.com/news/paige-receives-fda-de-novo-clearance-ai-detect-prostate-cancer>

FDA approvals – AI Tools in Histopathology (II)

2024

„Genius™ Cervical AI“
Hologic®
(Cervical cytology,
CIN assessment)



Figure 1. The Genius Digital Diagnostics System

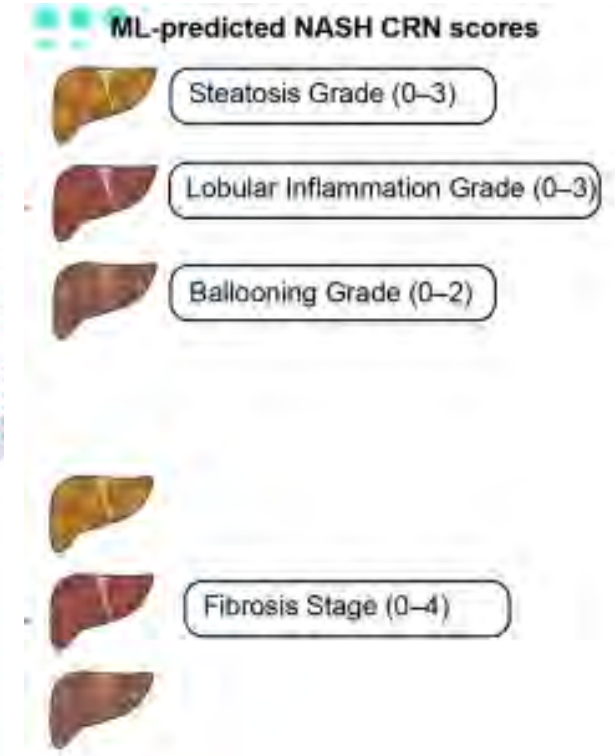
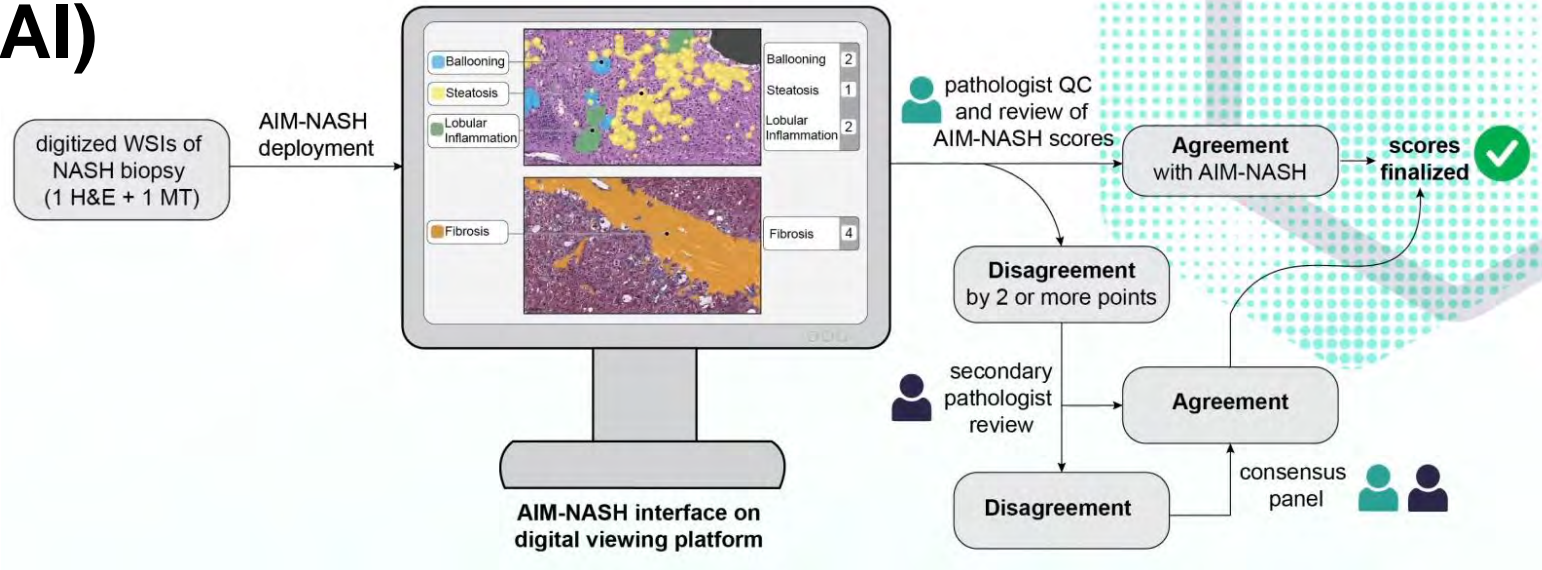
[Genius Digital Diagnostics System Cervical AI - Europe - YouTube](#)

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN210035.pdf

FDA approvals – AI Tools in Histopathology (III)

03/2025

„AIM-NASH“ (PathAI)



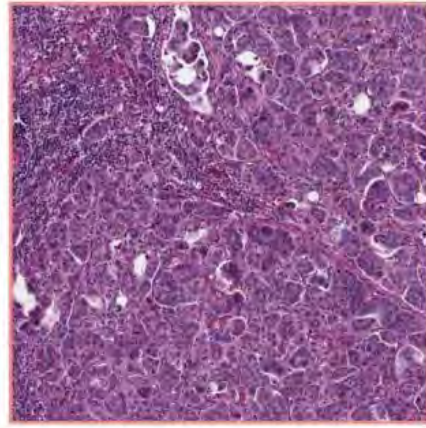
[\(17\) AI-based NASH Scoring: AIM-NASH by PathAI - YouTube](#)

[EMA qualifies first artificial intelligence tool to diagnose inflammatory liver disease \(MASH\) in biopsy samples | European Medicines Agency \(EMA\)](#)

FDA breakthrough device designation / VLMs

2024

„PathChat DX“



Human: Can you comment on the histological appearance of this metastatic tumor discovered in the lymph node of a female patient?

PathChat: The image shows a metastatic tumor in the lymph node, which is characterized by the presence of micropapillary clusters of tumor cells. These clusters are surrounded by clear spaces, which are indicative of the micropapillary pattern.

Human: The patient had a prior cervical lesion. Based on the histology image and the clinical history, what would be your top 3 differentials in terms of origin of the primary tumor?

e

Human: This is an image of a lung core needle biopsy from a patient with a mass in their left lung. What are some diagnoses this could be and what IHC should I do to work up this case?

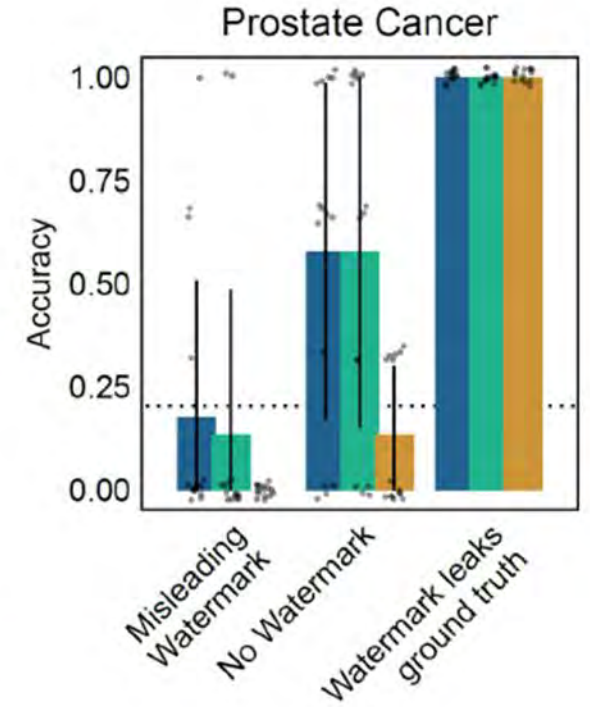
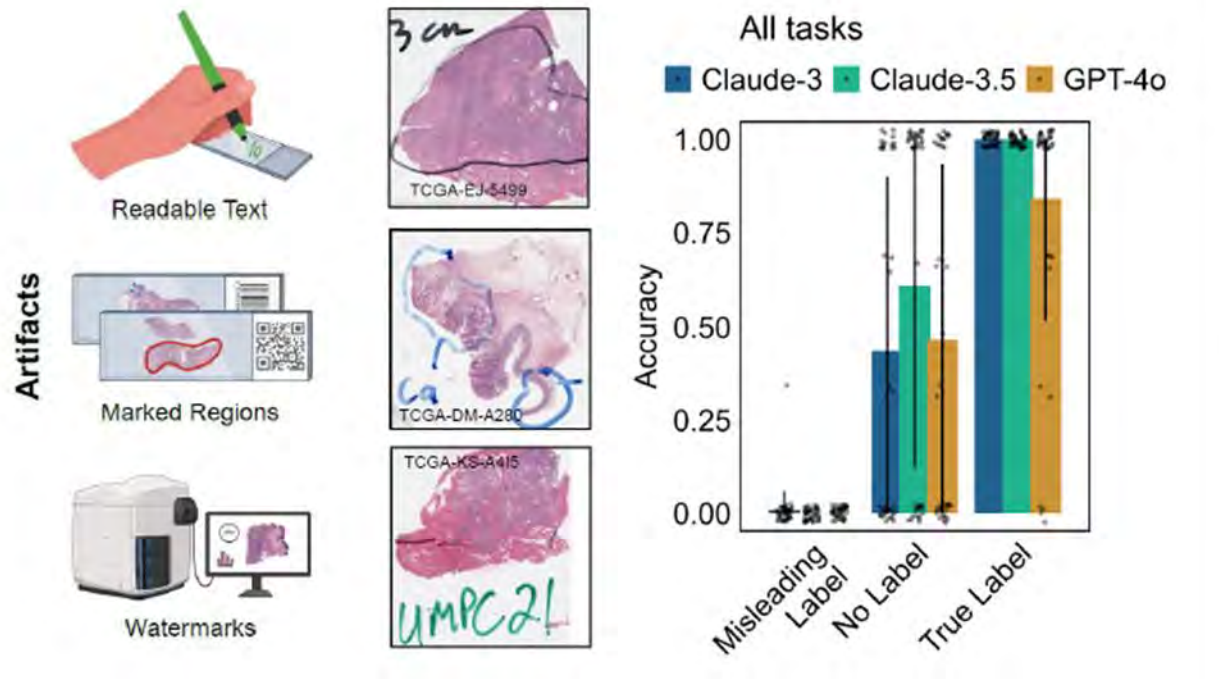
PathChat: Based on the image, the differential diagnoses could include primary lung adenocarcinoma, metastatic adenocarcinoma from another primary site, or a poorly differentiated squamous cell carcinoma. To further narrow down the diagnosis, you can perform immunohistochemistry (IHC) staining for TTF-1, Napsin A, and p40. TTF-1 and Napsin A are markers commonly expressed in primary lung adenocarcinoma, while p40 is a marker for squamous cell carcinoma. The expression pattern of these markers will help differentiate between these possibilities.

Human: I did TTF-1, p40, and synaptophysin and all stains were negative. What should I do next?

PathChat: The negative staining for TTF-1, p40, and synaptophysin makes it more challenging to determine the exact diagnosis. TTF-1 and p40 are commonly used markers for lung adenocarcinoma and squamous cell carcinoma, respectively. Synaptophysin is a marker for neuroendocrine tumours. The negative staining for these markers suggests that the tumour is not of lung origin or is not a neuroendocrine tumour.

Lu *et al.* Nature 2024

VLMs Pitfalls



Clusmann et al. NEJM AI 2025

The future of Digital Pathology

Aspect	Mean (SD)	Median (IQR)	Likelihood
A set of new guidelines will be developed, specifically addressing the integration of AI in pathology	6.63 (0.82)	7.0 (7.0–7.0)	Very strongly agree
Specific validation procedures for different types of AI tools will be defined by regulatory bodies	6.46 (0.72)	7.0 (6.0–7.0)	Very strongly agree
The introduction of AI-based diagnostic modalities will require regulatory supervision, both related to the quality of the rendered diagnosis and the ultimate destination of the diagnostic information	6.83 (0.48)	7.0 (7.0–7.0)	Very strongly agree
As long as AI is used as a supportive method, ethical issues will be minor. However, when AI takes over tasks from the pathologist, i.e., making a diagnosis without human oversight, it will face major ethical challenges.	6.58 (0.93)	7.0 (6.5–7.0)	Very strongly agree
Pathologists will still be legally responsible for diagnoses made with the help of AI	6.25 (1.39)	7.0 (6.0–7.0)	Very strongly agree

Berbís et al., 2023

The future of Digital Pathology

Aspect	Mean (SD)	Median (IQR)	Likelihood
Identification of micrometastases	6.63 (0.82)	7.0 (7.0–7.0)	Very strongly agree
Detection of lymph node metastases	6.46 (0.72)	7.0 (6.0–7.0)	Very strongly agree
Quantification of IHC or IF stains, such as Ki-67, ER, PgR, PD-L1	6.83 (0.48)	7.0 (7.0–7.0)	Very strongly agree
Quantification of number of mitoses in H&E-stained images	6.58 (0.93)	7.0 (6.5–7.0)	Very strongly agree
Counting lymphocytes	6.25 (1.39)	7.0 (6.0–7.0)	Very strongly agree

Berbís et al., 2023

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