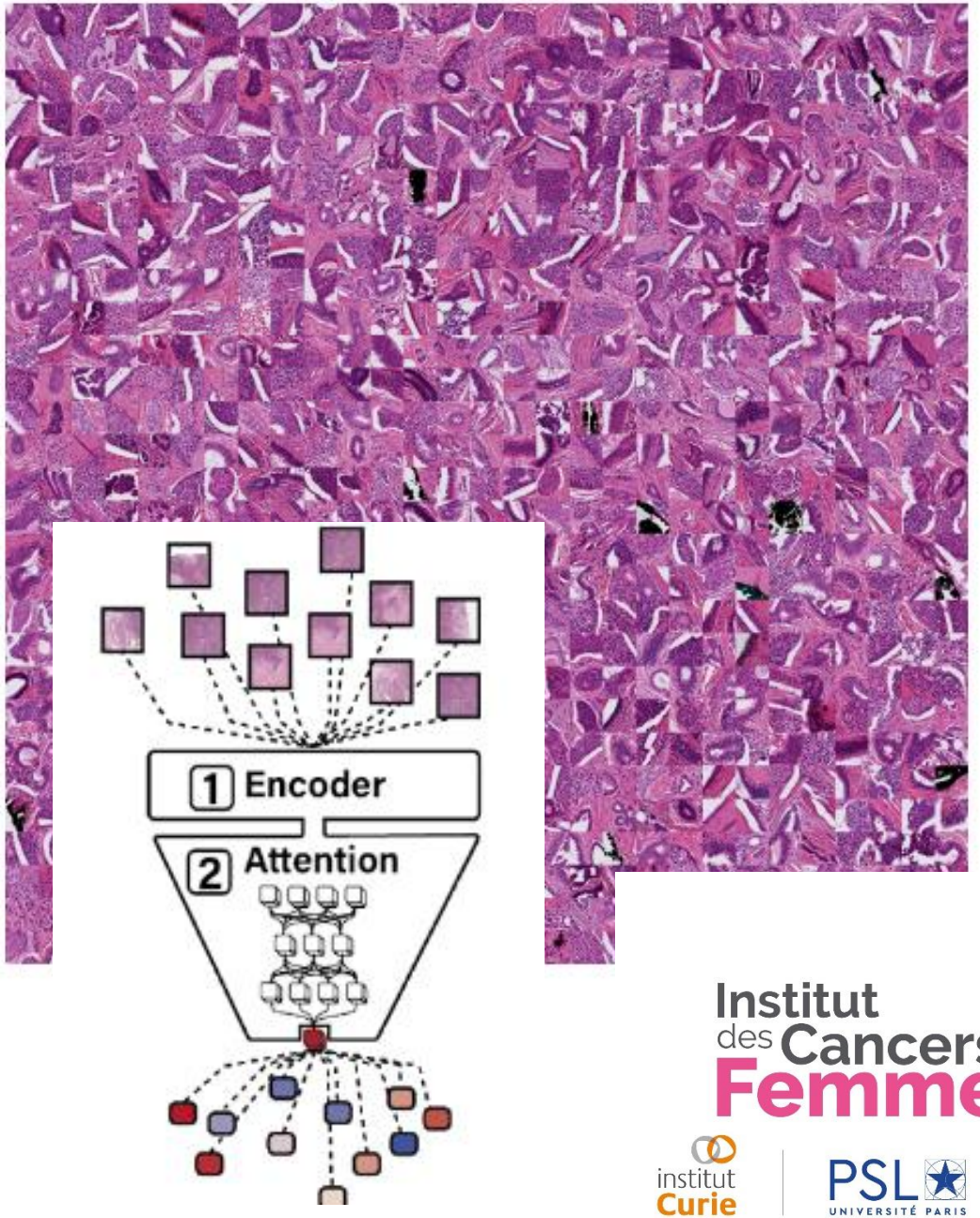
Pr Anne Vincent-Salomon
Department of Pathology
Institut CURIE Paris and PSL University, France

Digitalization of Pathology Department and the Use of Artificial Intelligence in Practice



ENSEMBLE, PRENONS
LE CANCER DE VITESSE

Institut des Cancers des Femmes

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My disclosures in relation with this presentation

- Ibex Medical Analytics: grant for research, honoraria, stock options, travel supports
- Astra-Zeneca: grants for research, travel supports, honoraria
- Daiichi-Sankyo: honoraria for lectures
- MSD and MSD Avenir: grant research
- Owkin: grant for research
- Primaa: grant for research
- Myriad: honoraria

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Outlines of my talk

1- Introduction

2- Diagnosis of breast cancer using AI

3- Prediction of Homologous Recombination Deficiency (HRD) in breast cancers using AI

4- Digital transition of Institut Curie's pathology department

5- Perspectives

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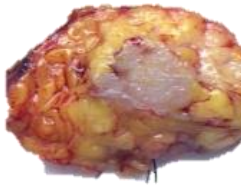
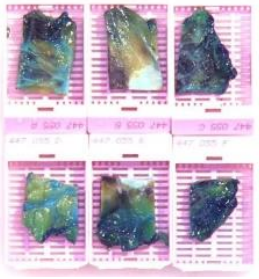
DIGITAL PATHOLOGY





Surgical specimen

Health Data Wharehouse
- **Whole slide images**
- **Clinical and pathological datas**

- Transformation of a **glass** slide into a **digital** slide (Whole slide images, WSI): generated by digital scanners

  → **An additional step** in the pathology technical workflow

  - Scanners
  - Image management system + Laboratory Management System
  - WSI Storage capacities

What can computer vision scientists do for pathologists ?

AI Diagnostic tools to help pathologists in time consuming tasks

- **Diagnosis of lymph node metastases**
- **Diagnosis of breast cancer**
- **Mitotic count**
- **Quantification of markers assessed by immunohistochemistry**

Development of predictive and prognostic surrogate markers from digitalized H&E slides

- **Molecular classes status (without IHC)**
- **Genomic status of *BRCA1 or 2***
- **To predict response to neoadjuvant therapy**
- **To define prognosis**

Etc….

•Improve pathologists workflow and reduce turn around time
• Increase accuracy, reduce inter-observer variability
• "**Second reads**" before final sign out to ensure clinically significant lesions have not been missed (QA)

Steiner et al, Am J Surg Pathol 2018; Sandbanck et al, NPJ Breast Cancer 2022; Saha et al, Nature scientific reports 2017; Diao et al Nat Com 2021; Lazard et al Cell Report Medicine 2022

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AI TOOLS IN PATHOLOGY:

Developped by pathologists with computational vision scientists +++

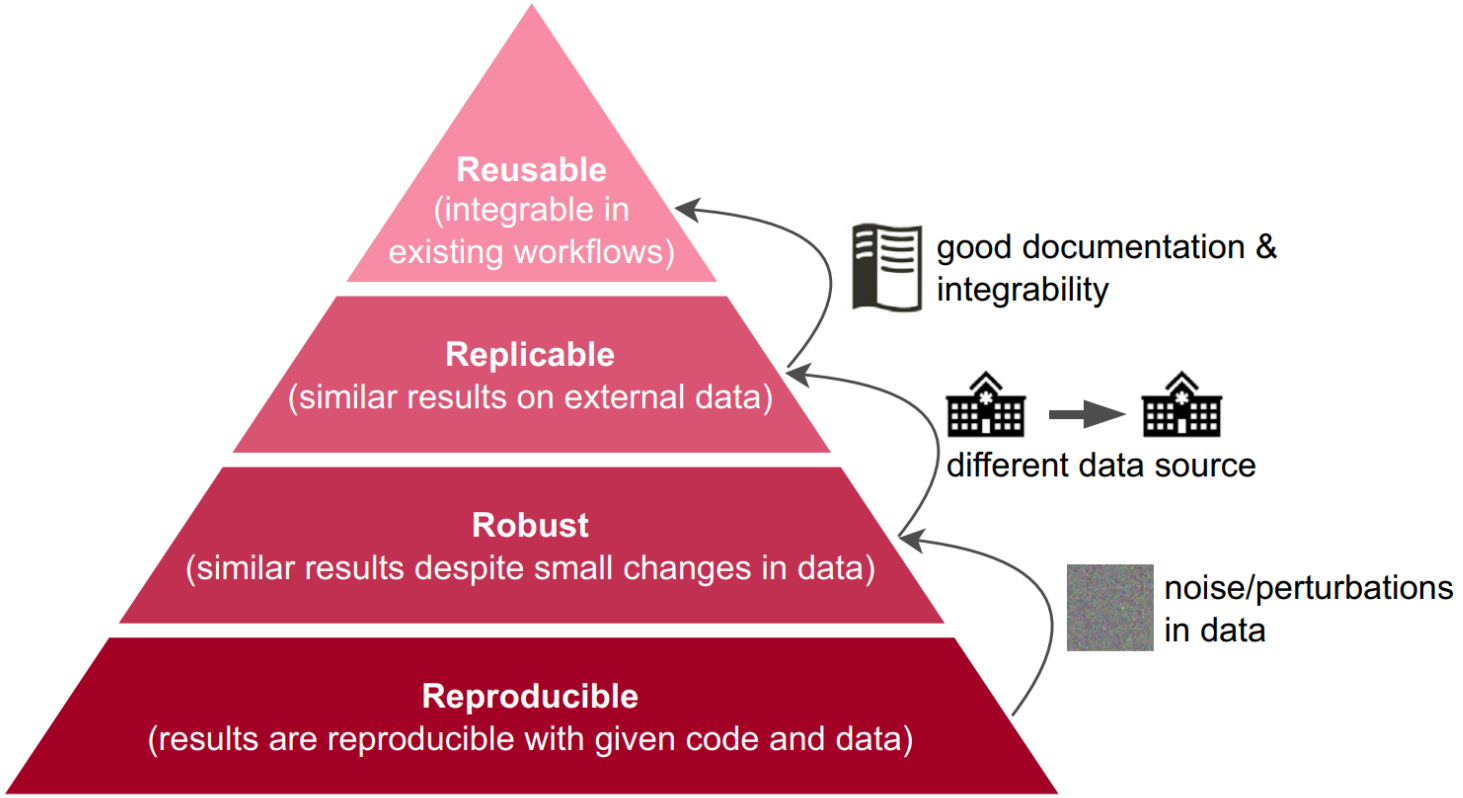

Figure 2.
Reproducibility, robustness, replicability, and reusability in the context of deep learning algorithms for computational pathology.

Sophia J. Wagner et al. / Mod Pathol 37 (2024) 100350

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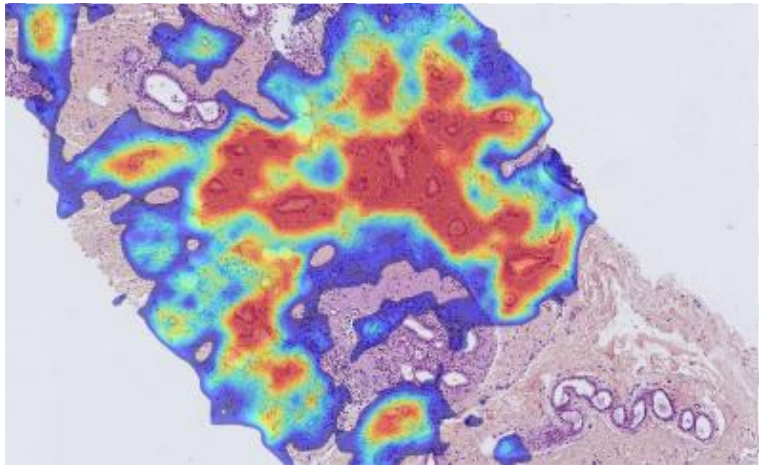
Validation and real-world clinical application of an artificial intelligence algorithm for breast cancer detection in biopsies

Judith Sandbank[1,2], Guillaume Bataillon[3,7], Alona Nudelman[1], Ira Krasnitsky[2], Rachel Mikulinsky[2], Lilach Bien[2], Lucie Thibault[3], Anat Albrecht Shach[4], Geraldine Sebag[2], Douglas P. Clark[2], Daphna Laifenfeld[2,8], Stuart J. Schnitt[5,6], Chaim Linhart[2], Manuela Vecsler[2] and Anne Vincent-Salomon[3]✉

NPJ Breast cancer 2022



Internal training Set (n=2167 cases)

Set	Analysis	Number of cases	AUC* [95% CI]	Specificity [95% CI]	Sensitivity [95% CI]	PPV NPV
Internal test set (MHS)	Invasive vs. non-invasive	1090 (173 invasive, 917 non-invasive)	0.998 [0.996;1.000]	98.27% [95.03%;99.41%]	99.02% [98.15%;99.48%]	95.0%, 99.7%
	DCIS vs. benign/ other	908[a] (27 DCIS, 881 benign)	0.999 [0.997;1.000]	98.64% [97.56%;99.30%]	100% [84.50%;100%]	69.3%, 100%
	IDC vs. ILC	169[b] (156 IDC, 13 ILC)	0.932 [0.862;1.000]	NA[c]	NA[c]	NA[c]

* **AUC – area under the ROC** curve**

The **Receiver Operator Characteristic (ROC) curve plots the **True Positive Rate** against **False Positive Rate** at various threshold values and shows the performance of a classification model at all classification thresholds.

IBEX

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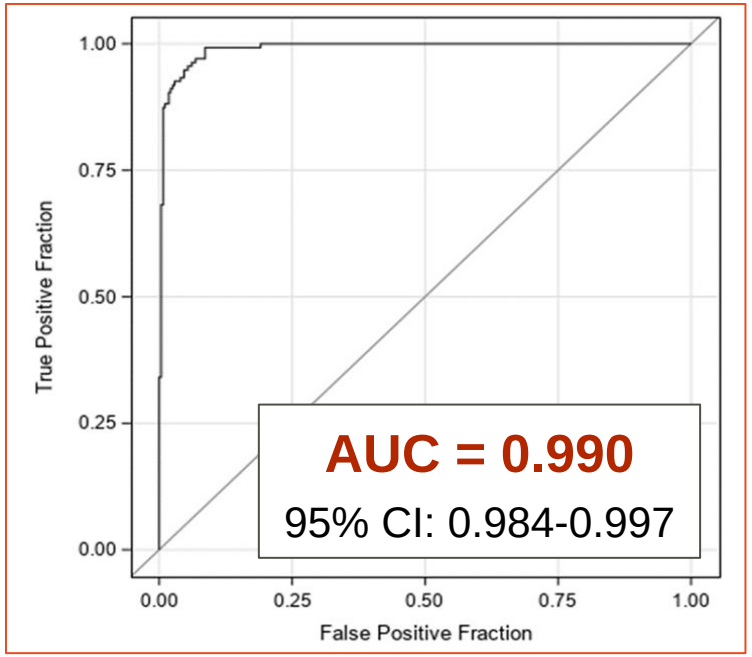
Galen Breast AI Validation study: Invasive Carcinoma Detection

N=436 cases* (156 invasive; 135 DCIS/ADH; 145 benign)**

Performance		95% Confidence Limits	
Sensitivity	95.51%	91.03%	97.81%
Specificity	93.57%	90.07%	95.90%
PPV	89.22%	83.61%	93.07%
NPV	97.40%	94.73%	98.73%

PPV – positive predictive value
NPV- negative predictive value

ROC CURVE



AUC – area under the ROC curve; Galen Breast invasive probability score versus the ground truth diagnosis after discrepancy review

**** 34 rare invasive carcinomas types: fusiform metaplastic, tubular, apocrine, mucinous, micropapillary, acinic cells carcinomas**

* Performance on consecutive biopsies is expected to be higher

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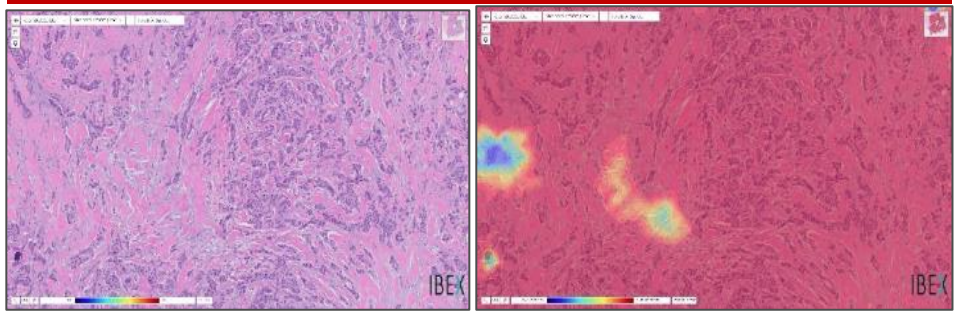
Galen Breast detection of Invasive lobular carcinoma

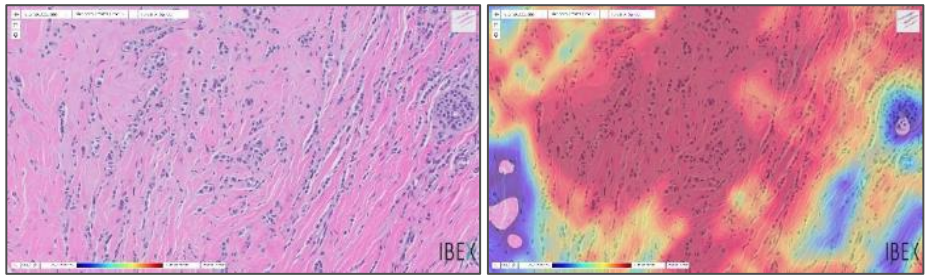
N= 153 cases (98 IDC; 55 ILC)

Performance		95% Confidence Interval	
AUC	0.973	0.996	0.948
Sensitivity	92.9%	97.1%	85.8%
Specificity	92.7%	97.1%	82.7%
PPV	95.8%	98.3%	89.6%
NPV	87.9%	95.0%	76.7%

Heatmaps display:
low probability in blue
high probability in red

IC-NST





Invasive Lobular carcinoma

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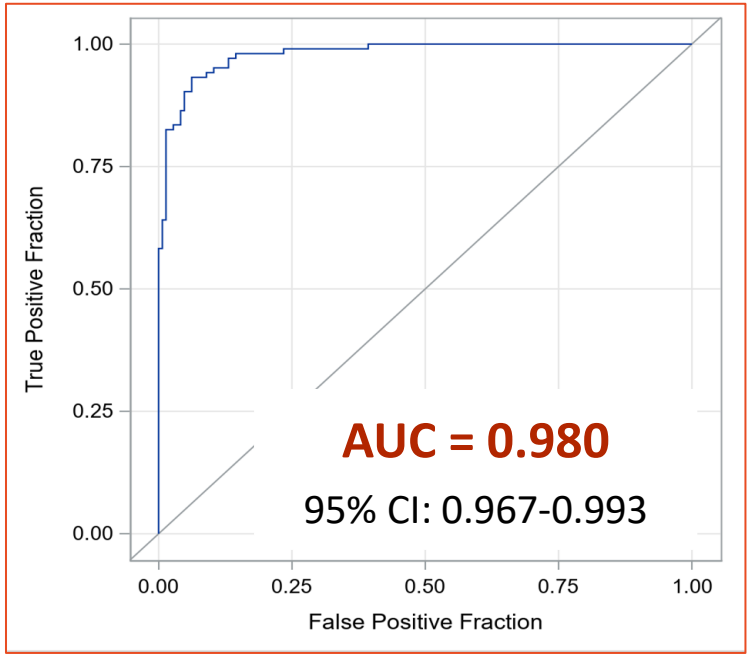
Galen Breast AI Validation study: In Situ Ductal Carcinoma Detection

N= 248 cases (103 DCIS; 145 benign/other)

Performance		95% Confidence Limits	
Sensitivity	93.79%	88.63%	96.70%
Specificity	93.20%	86.63%	96.67%
PPV	91.4%	84.51%	95.43%
NPV	95.1%	90.24%	97.61%

Performance for DCIS and ADH detection versus benign is AUC=0.949, Sensitivity=87.41%, Specificity=86.9%

ROC CURVE



AUC – area under the ROC curve; Galen Breast in-situ probability score versus the ground truth diagnosis after discrepancy review

**cohort enriched with low grade DCIS ; Performance on consecutive biopsies is expected to be higher

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Galen Breast identification of DCIS nuclear grade

(Intermediate and High) grade DCIS versus (ADH and Low) Grade DCIS

N= 134 cases (88 IG/HG DCIS; 46 LG DCIS/ADH)

Performance		95% Confidence Interval	
AUC	0.921	0.965	0.878
Sensitivity	84.1%	90.3%	75.1%
Specificity	84.8%	92.4%	71.8%
PPV	91.4%	95.8%	83.2%
NPV	73.6%	83.6%	60.4%

Note: These studies do not represent a typical case distribution in a lab, since low grade and ADH were **enriched** in order to allow sufficient statistical power for various analyses;
Performance on consecutive biopsies is expected to be higher

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TILs Detection in invasive carcinomas (cut-off: > 30% TILs for heatmap)

In pure invasive carcinomas

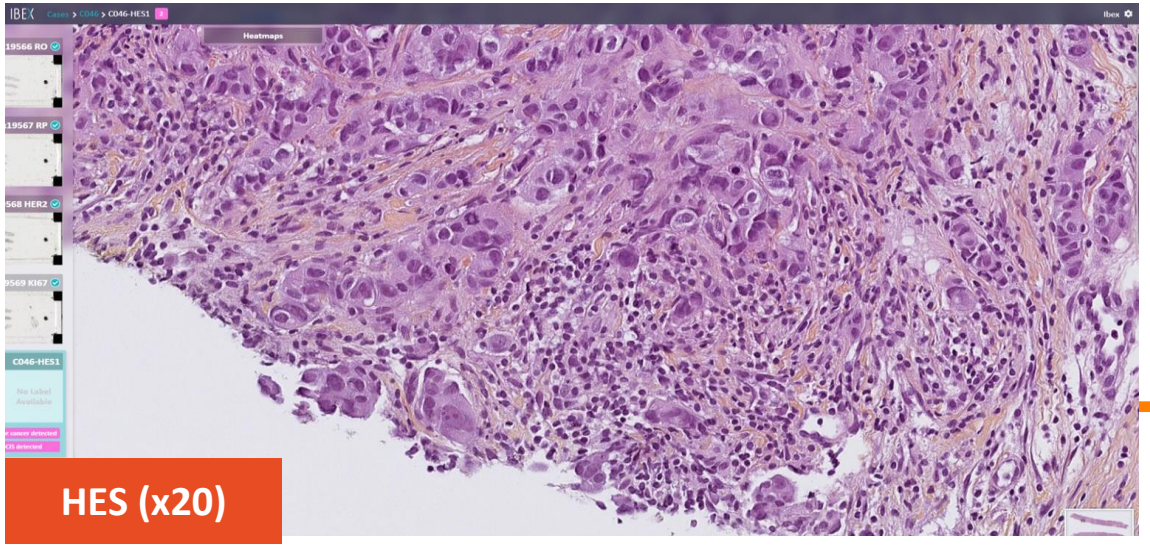
N= 47 cases (19 TILs positive; 28 TILs negative)

Performance		95% Confidence Interval	
AUC	0.953	0.892	1.0
Sensitivity	94.7%	73.5%	99.9%
Specificity	85.7%	67.9%	94.9%

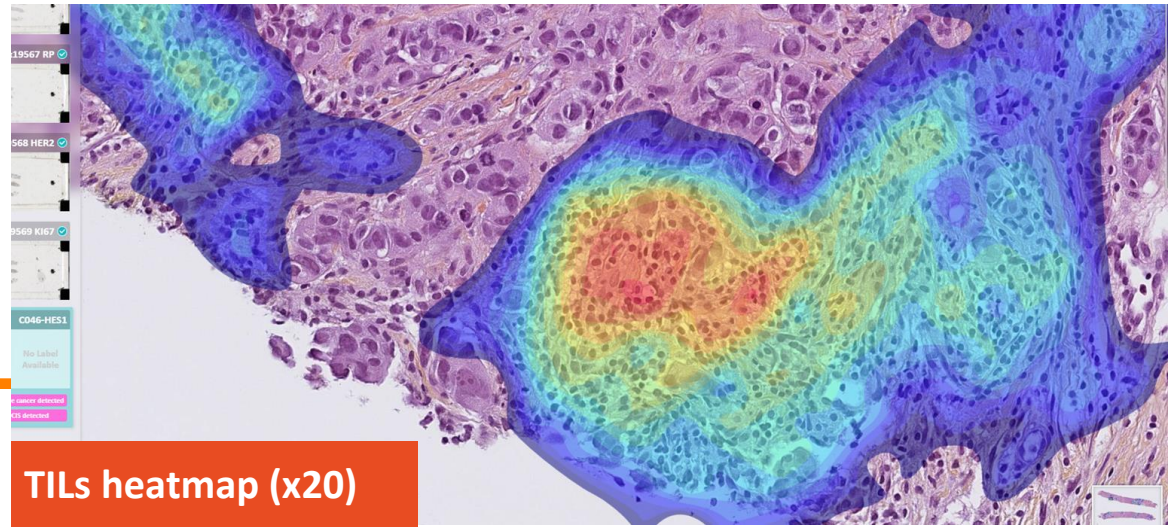
in Invasive carcinomas associated with DCIS

N= 109 cases (32 TILs positive; 77 TILs negative)

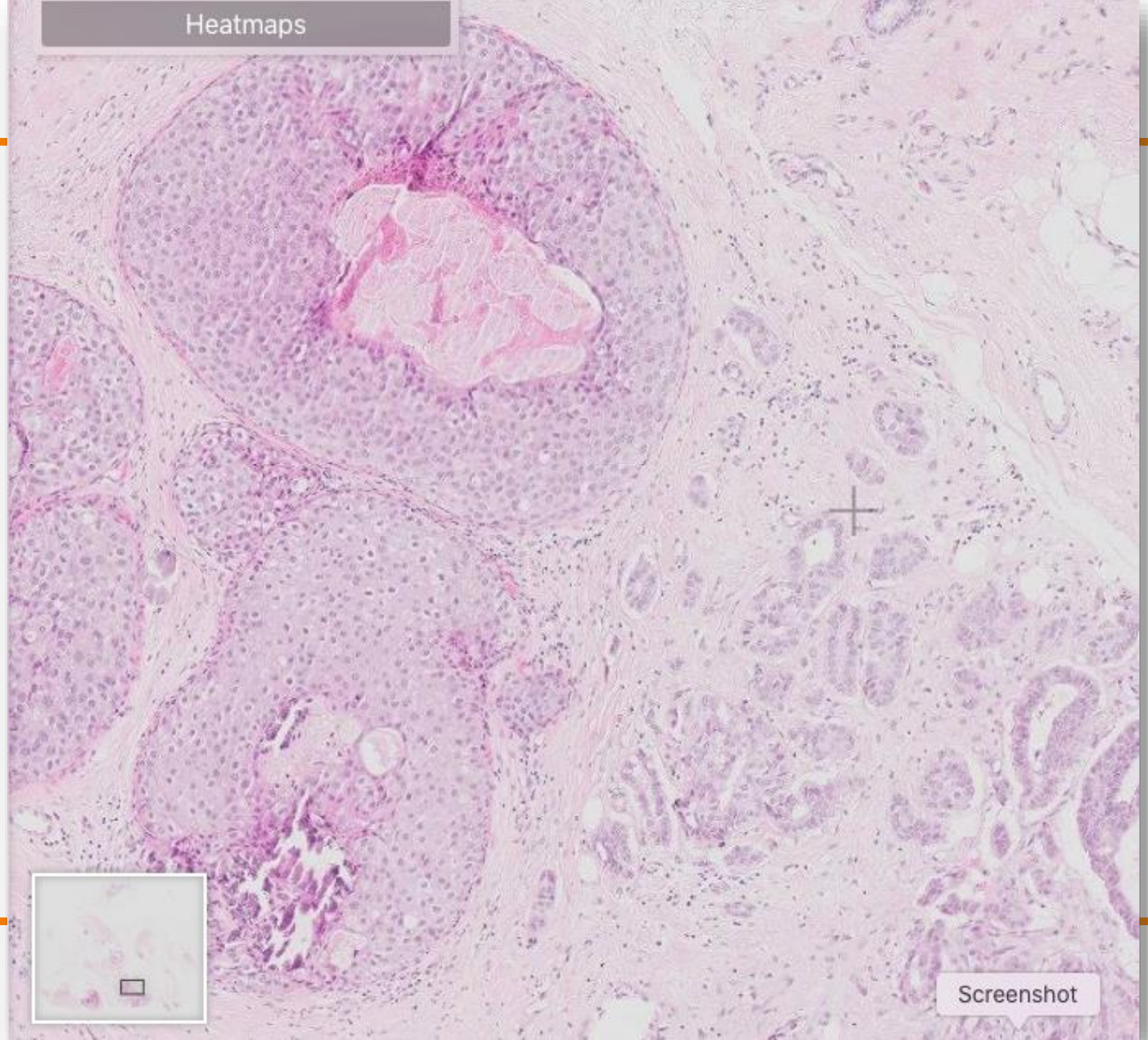
Performance		95% Confidence Interval	
AUC	0.965	0.934	0.996
Sensitivity	93.8%	78.8%	99.3%
Specificity	85.7%	76.3%	92.0%



HES (x20)



TILs heatmap (x20)



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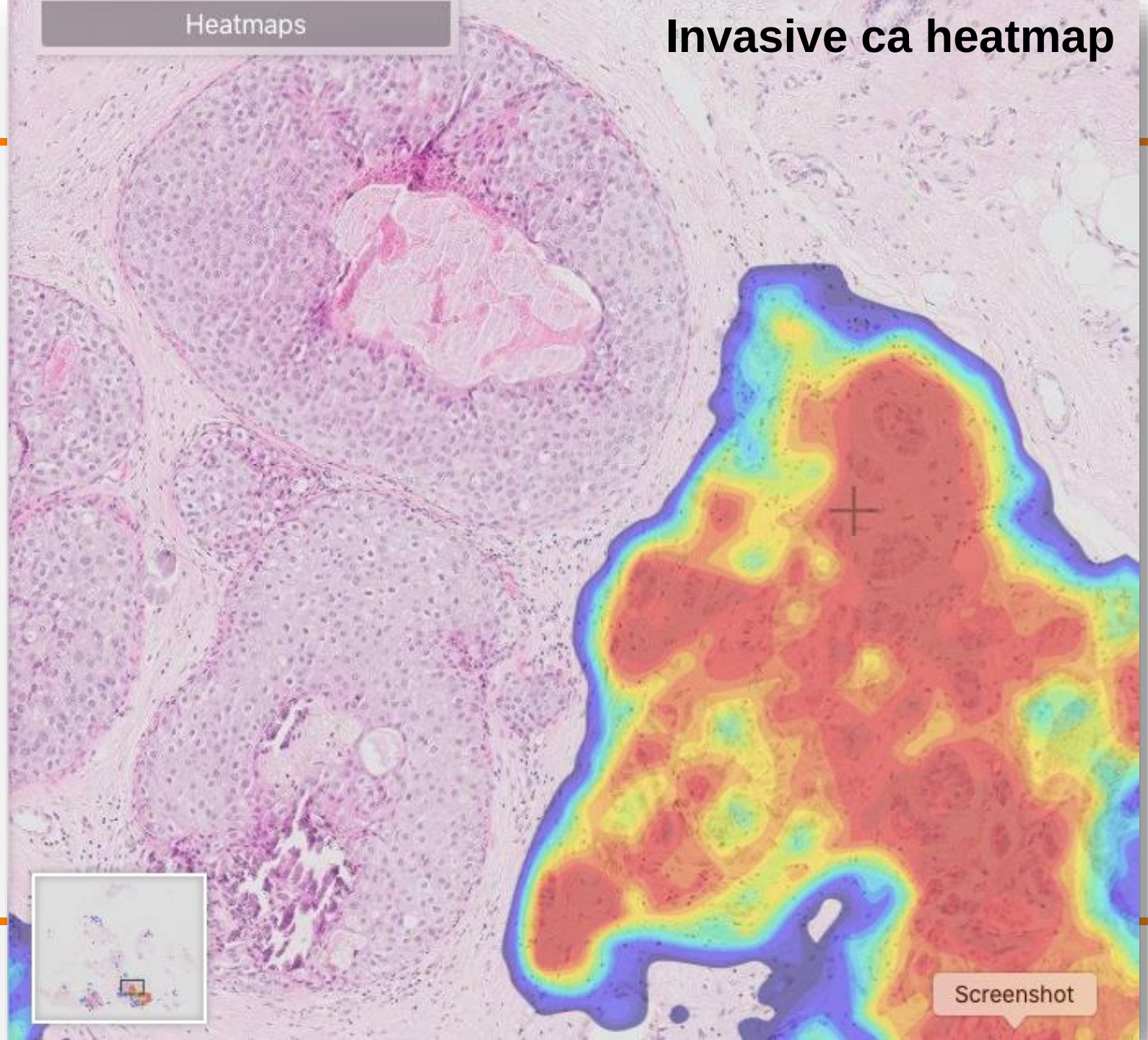
Invasive ca heatmap



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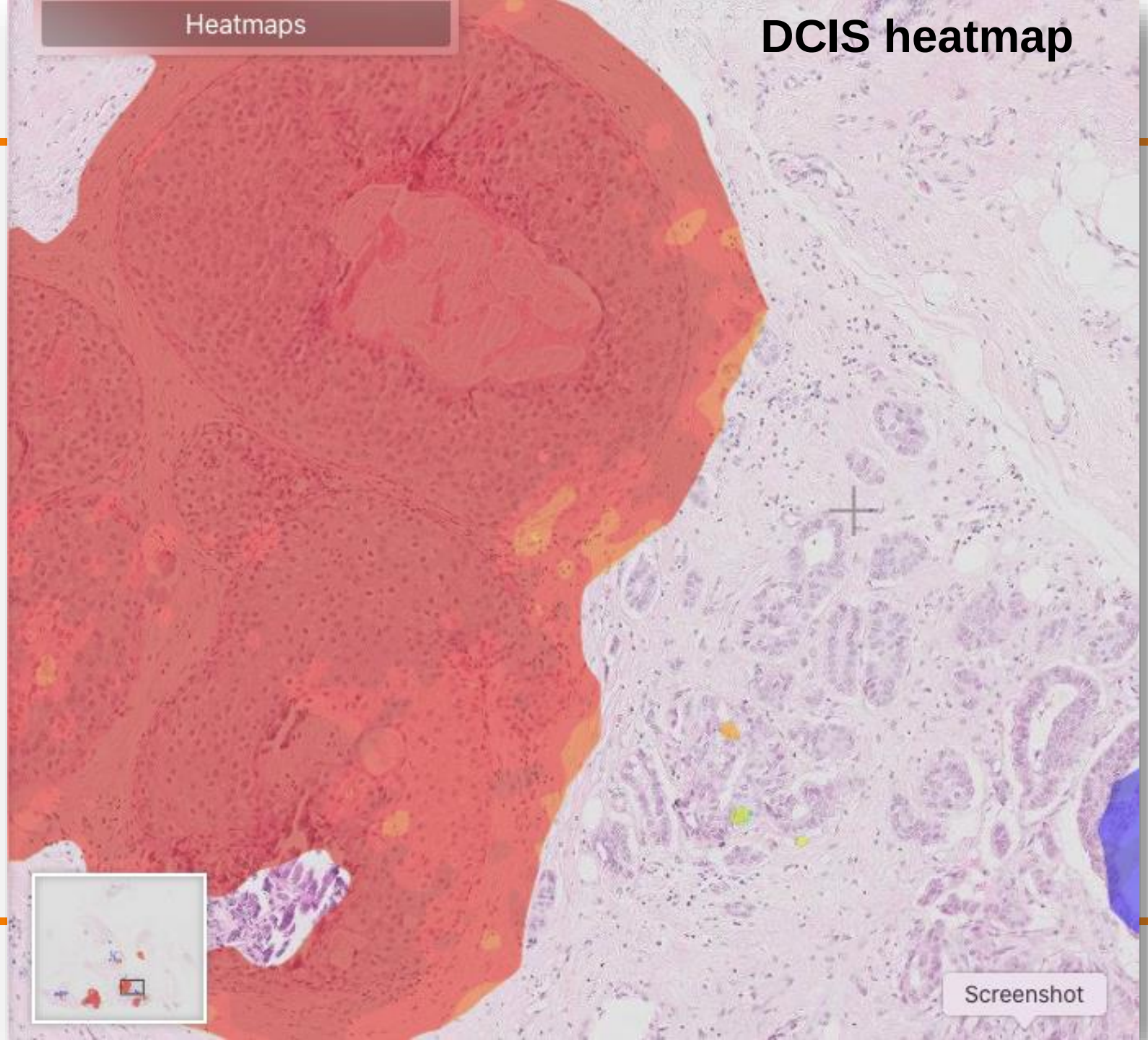
DCIS heatmap



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GALEN BREAST ALGORITHM: PERFORMANCES IN 5 INDEPENDENT STUDIES FROM DIFFERENT LABS AROUND THE WORLD (different scanners, different stainings…)

	Number of Cases	Specimen Type	Invasive Ca AUC	DCIS AUC
Sandbank, 2022 *Test Set*	**1998**	**CNB**	**0.998**	**0.999**
Sandbank, 2022 *Validation set*	**684**	**CNB**	**0.990**	**0.980**
Assaad, 2023*	**475**	**CNB**	**0.98**	**0.99**
Shaker, 2024*	**108**	**CNB**	**0.976**	**0.975**
Lami, 2024	**100**	**CNB**	**0.997**	**0.975**
Broeckx, 2023*	**248**	**Excisions**	**0.986**	**0.994**

*meeting abstracts
Lamy et al, Pathology 2024

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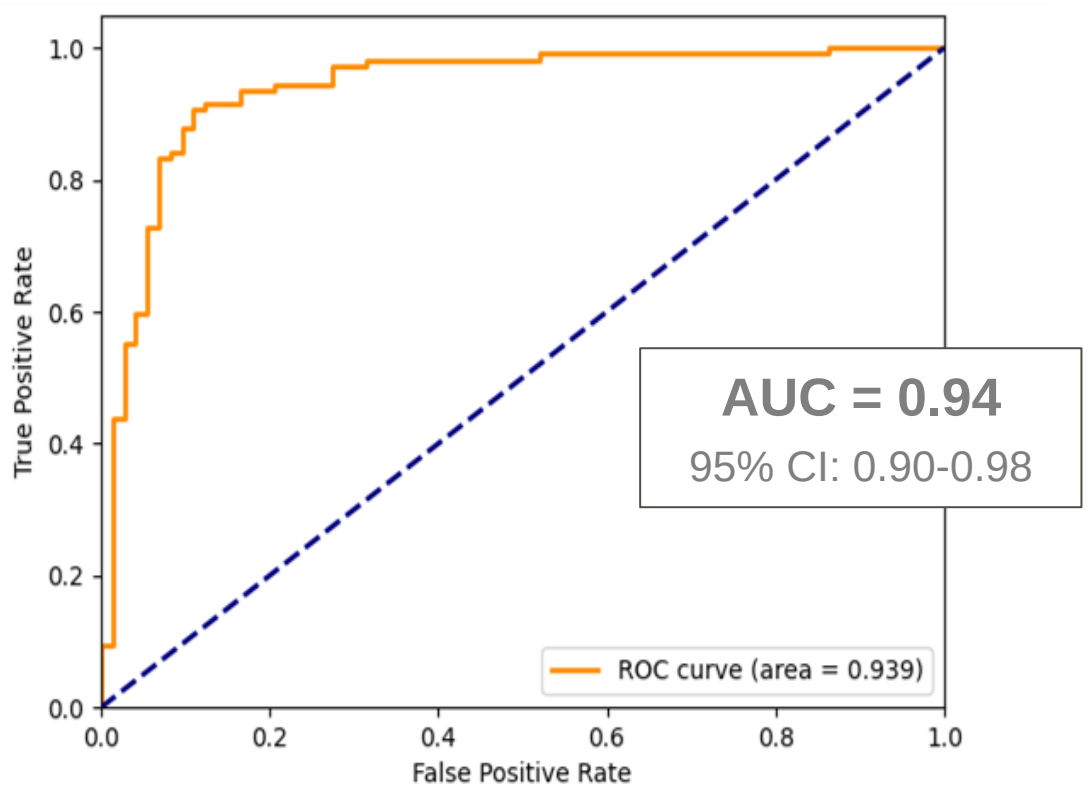
GALEN BREAST PERFORMANCE IN ANOTHER VALIDATION SET TO IDENTIFY IDC VERSUS ILC

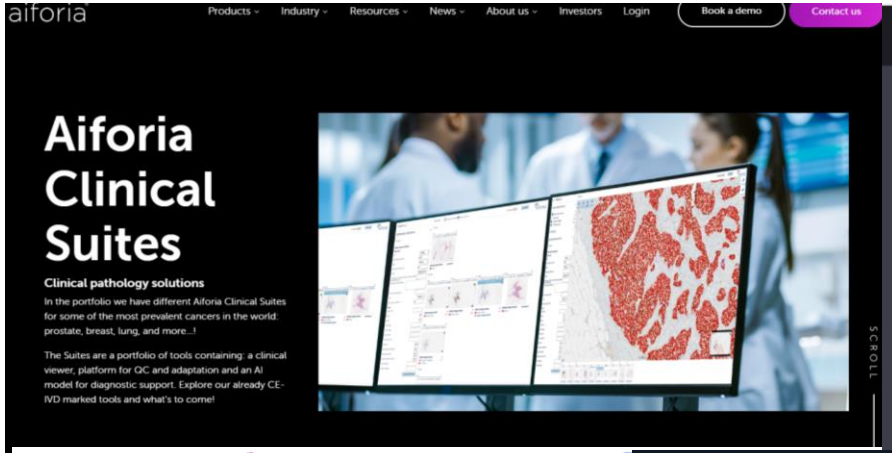
N= 180 cases (107 IDC; 73 ILC)

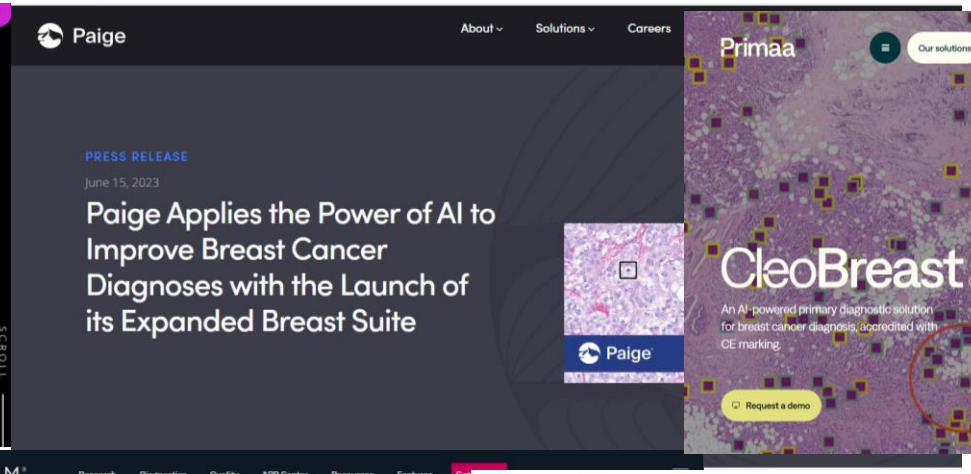
Performance	
Sensitivity	90.7%
Specificity	89%
PPV	92%
NPV	87%
AUC (95% CI)	0.94 (0.90, 0.98)

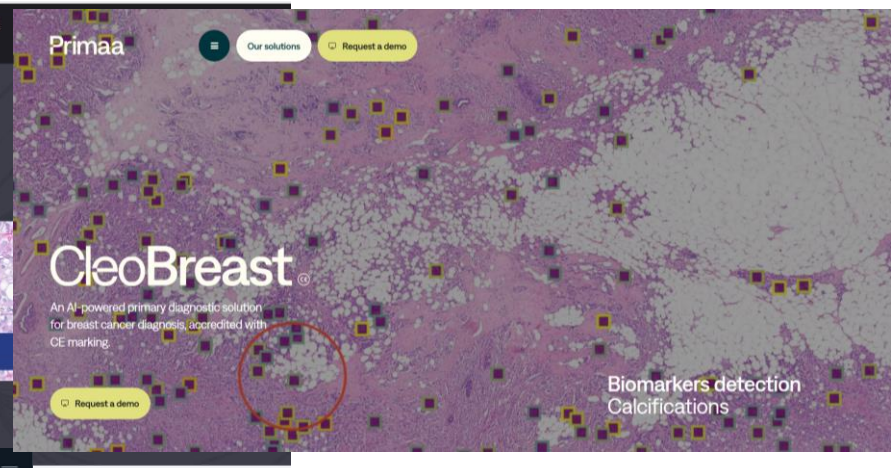


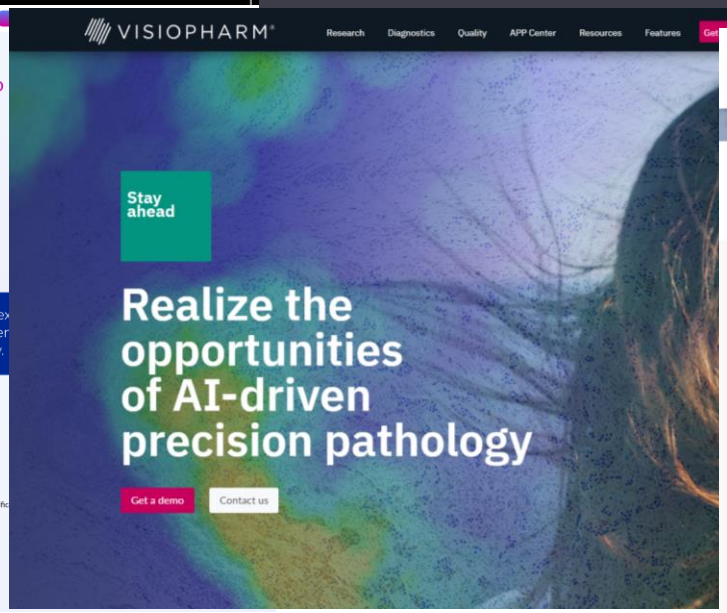
Assaad, USCAP 2023

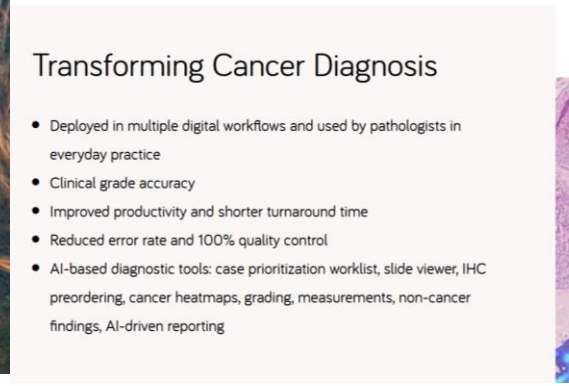
AI to quantify biomarkers: many AI tools available on the market

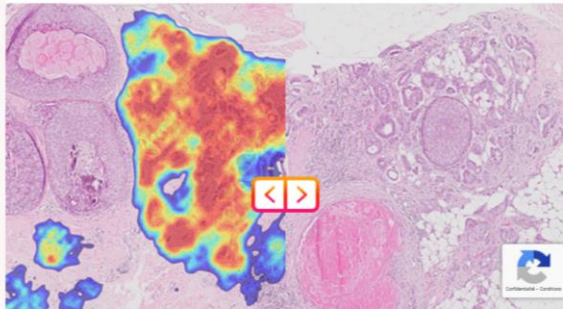












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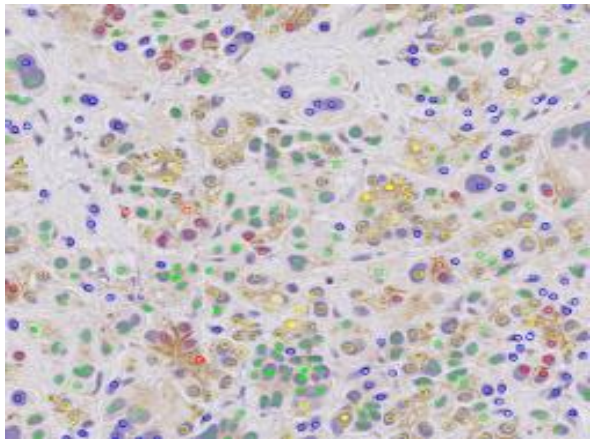
AI to quantify biomarkers: the example of HER2 with Ibex Breast

Automatic identification of infiltrating cells

+ Classification and scoring according to ASCO/CAP guidelines



HER2 evaluation at a cell level

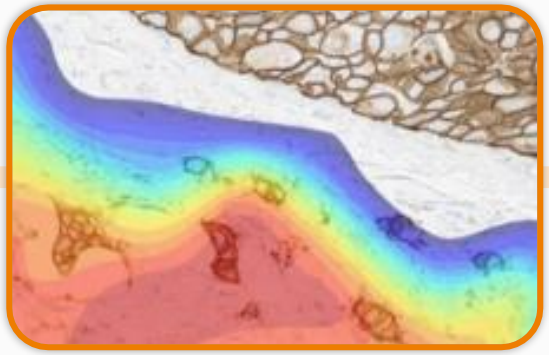
- Not invasive
- Not stained
- Faint incomplete
- Moderate incomplete
- Intense incomplete
- Faint complete
- Moderate complete
- Intense complete

- **Fully automated pipeline.**
- **The pathologist does not select the area of interest**
- **"Transfer Learning Reading" technology uses H&E algorithms to train IHC reading algorithms.**
- **Combining infiltrative versus *in situ* diagnostic analysis and quantification of stainings**

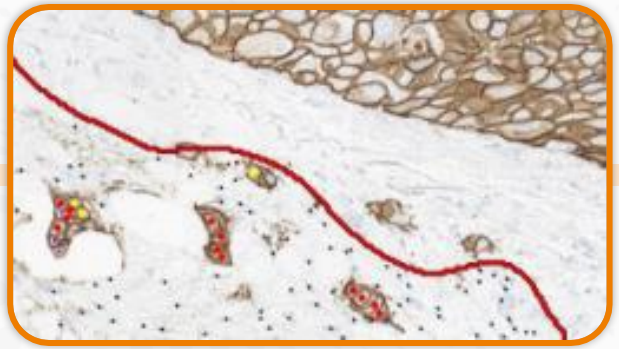
AI Solution for Evaluation of HER2 Immunostain: IBEX Breast HER2

Regions Model

Invasive area detected



Cells Model



Detects cells and staining pattern:
Intense Complete: 12 cells = 80%
Moderate Complete: 3 cells = 20%

2018 ASCO/CAP guidelines

HER2 score: Score = 3+

Globerson *et al.* SABCS 2022

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Germline (and somatic) *BRCA1 & 2:*

- **A*n* approved biomarker for**
  - **TNBC and ER+ HER2- metastatic breast cancers**
  - **High-risk early breast cancers**
- **In the NCCN and ESMO guidelines**

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Detection of *BRCA1 or 2* mutation by a systematic sequencing approach

- Is feasible for Triple Negative Breast Cancers:
  - That represent 15 to 18% of all breast cancers
  - Knowing that the identification of a *BRCA1* mutation is found in only 15% of TNBC

- May be difficult to extend to all luminal Breast Cancers because of:
  - The volume & logistics
  - The costs

We aimed at developing an AI algorithm that would predict HRD directly from whole slide images and that could become a **screening tool for triage of tumors more likely to be mutated**

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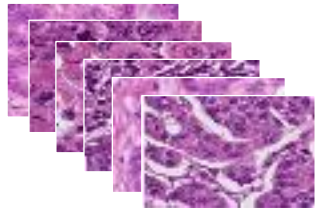
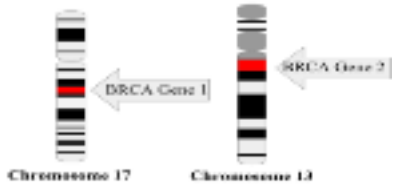
Collaboration between 3 teams from the Institut CURIE hospital and research center

Pathologists



BATAILLON Guillaume
VINCENT-SALOMON Anne
Department of pathology

Geneticists

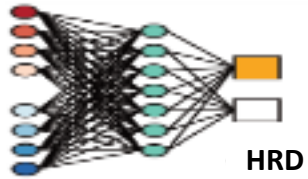


Inserm
La science pour la santé
From science to health

STERN Marc-Henri
INSERM U830

STOPPA LYONNET Dominique
Department of genetics

Computational scientists



HRD

MINES ParisTech

PSL UNIVERSITÉ PARIS

WALTER Thomas
LAZARD Tristan (PhD)
INSERM U900

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Two datasets for HRD prediction

- **The Curie dataset: 715 of luminal and TNBC breast cancers patients HE slides** (surgical specimens, no neoadjuvant treatment)

- **Known Homologous Recombination status (ground truth):**
  - **309** Homologous recombination proficient **(HRP)** tumors
    - assessed with the Large State Transition (LST) method
  - **406** Homologous recombination deficient **(HRD)** tumors
    - Germline *BRCA1 & 2*
    - Sporadic *BRCA1 & 2* (49 cases)

- **the TCGA dataset:**
  - **800 cases (slides and genomic analyses by SNP6.0)**
  - **Homologous Recombination status determined by the LST method**

Popova *et al* Cancer Research 2019

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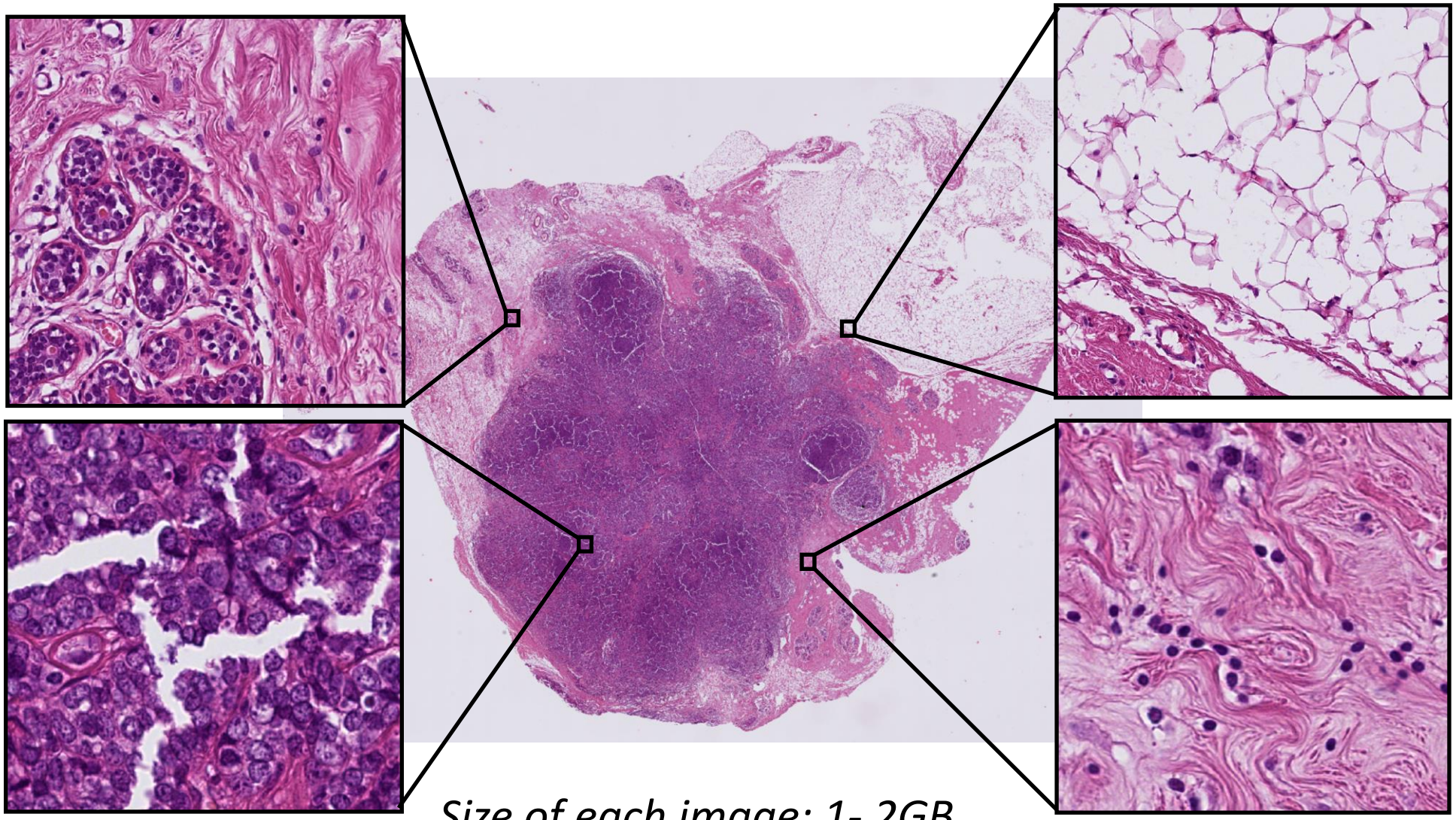
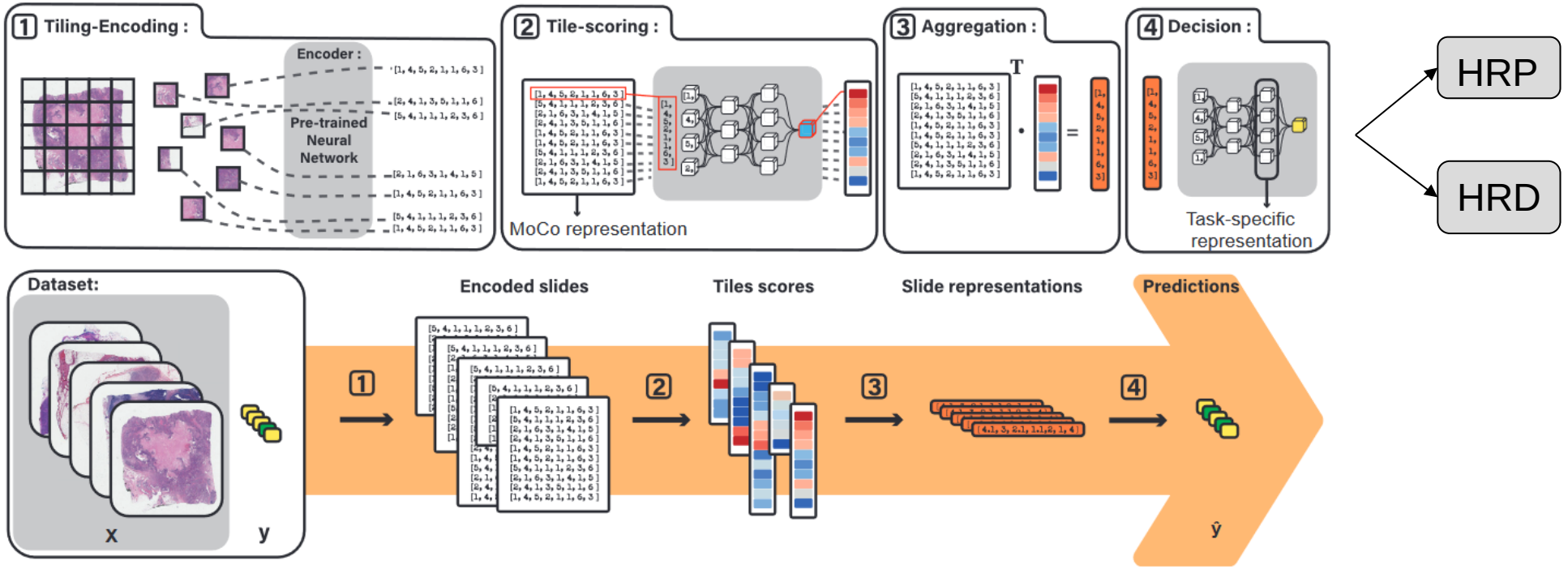
Computational challenge: one slide = many images



Size of each image: 1- 2GB

~ 50.000 images (256x256)

Methods: End to End pipeline and Multiple Instance Learning



WSI divided into tile images (224 x 224 pixels)

Tiles are encoded into a vector using the self-supervised technique momentum contrast (MoCo)

The slide representation are classified by the decision module into HRP or HRD

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Performance of the algorithm on the TCGA dataset & the Curie dataset

Prediction of HRD

	AUC		B_{Acc}	
	Mean	SD	Mean	SD
$TCGA_{raw}$	0.71	0.10	0.59	0.08

⟹ Consistent with previous published analyses showing an AUC = 0.74*

	AUC		B_{Acc}	
	Mean	SD	Mean	SD
$Curie_{raw}$	0.88	0.03	0.81	0.02

(*Diao *et al* Nat Com 2021)

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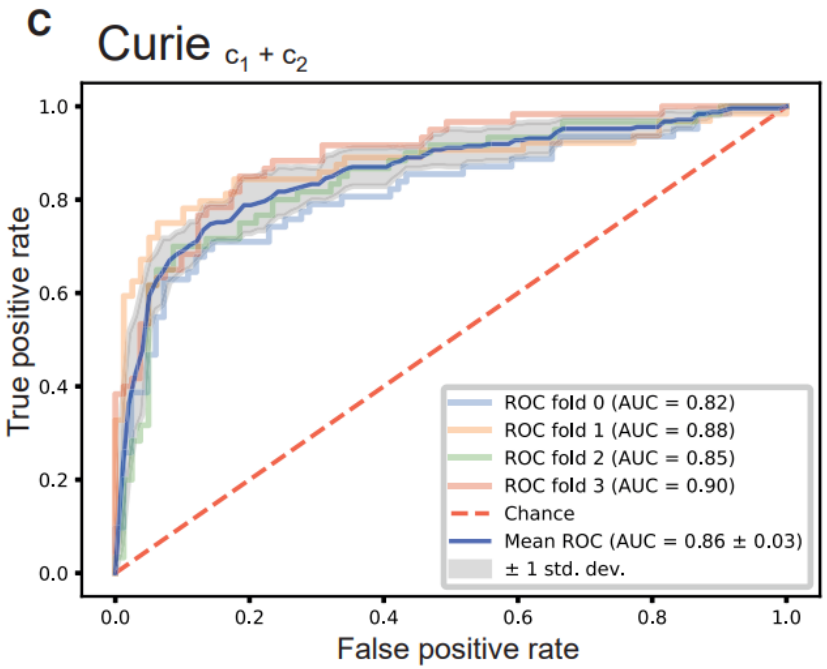
Performance of the algorithm on the Curie series after technical biases correction

Tumor blocks from Curie data set were prepared over a period of 25 years
(During this time, protocols for block preparation have changed)

Table 1. Classification performances

	AUC		B_{Acc}	
	Mean	SD	Mean	SD
$Curie_{raw}$	0.88	0.03	0.81	0.02
Curie c_1 + c_2	0.86	0.03	0.78	0.04



The **Receiver Operator Characteristic (ROC)** curve plots the **TPR** against **FPR** at various threshold values and shows the performance of a classification model at all classification thresholds.

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Performance of the algorithm on the TCGA dataset after correction of the biological confounder "molecular class"

Prediction of HRD	AUC		B_{Acc}	
	Mean	SD	Mean	SD
$TCGA_{raw}$	0.71	0.10	0.59	0.08
TCGA c_3*	0.63	0.08	0.54	0.02

*C3: bias of the molecular class

This result suggested that a NN trained on the entire BC cohort of TCGA for HRD prediction without stratification or bias correction might actually predict to a large extent the molecular subtype

Prediction of Molecular classes in the TCGA with our algorithm: AUC = 0.89

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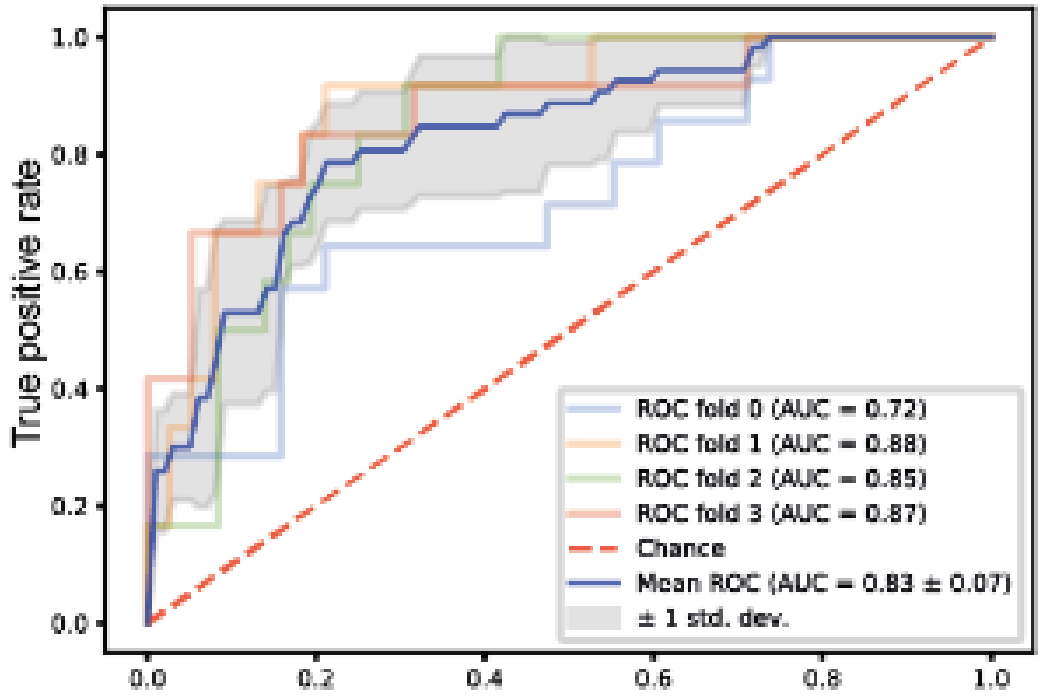
Results for luminal breast cancer patients after correction of technical bias

251 Luminal WSI (188 HRD, 63 HRP)



AUC = 0.83

Sensitity: 88%
Specificity: 57%
Positive predictive value: 86%

	Ground Truth = genomic status	
	Luminal (n= 251)	
AI Prediction	**HRD**	**HRP**
HRD	**166**	**27**
HRP	**22**	**36**
Total	**188**	**63**

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Opening the black box for pathologists is important !

To visualize and understand the TILE features that weighted in the algorithm and that weighted the most to predict the label

- To pave the way for MACHINE TEACHING !

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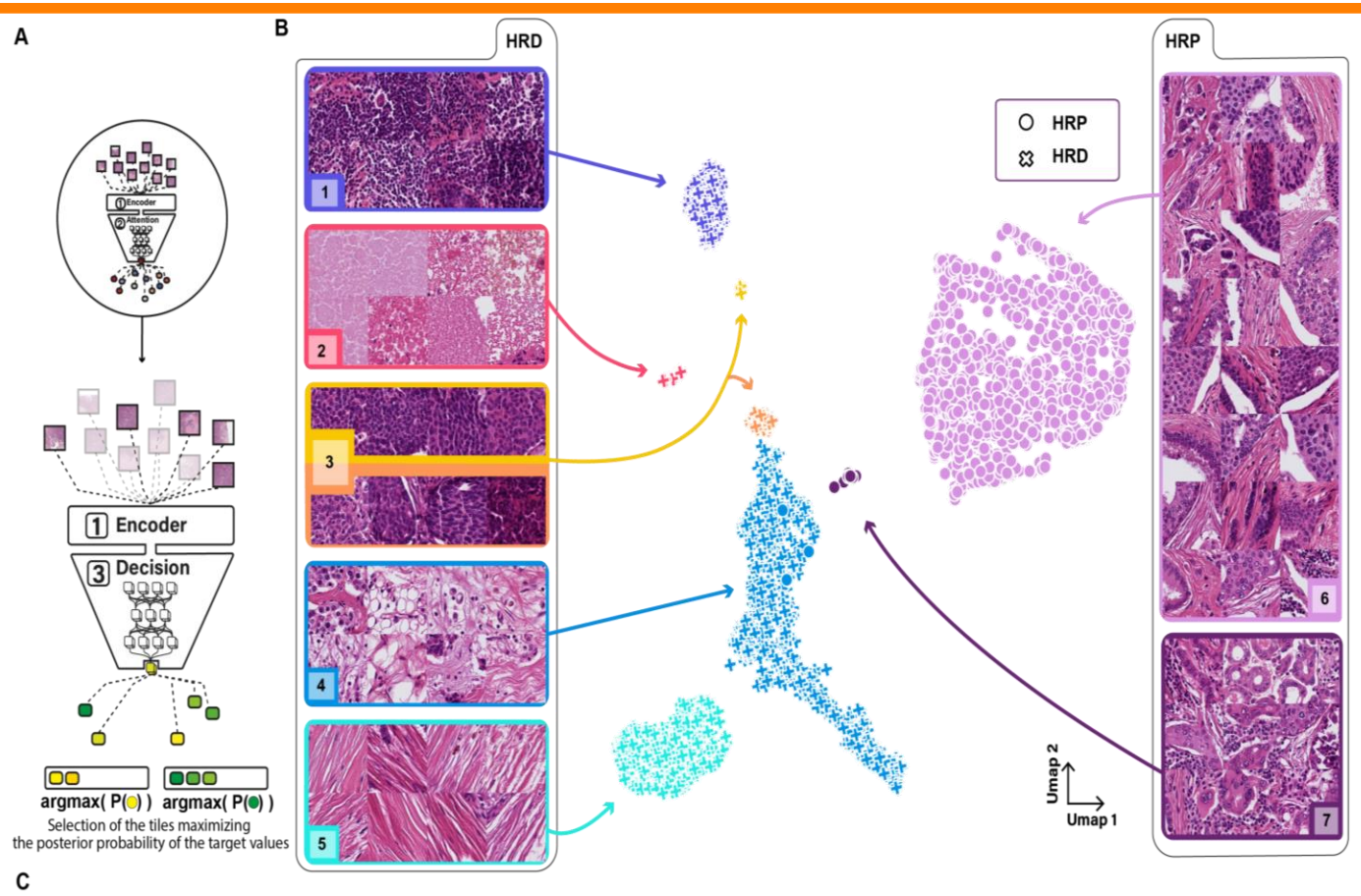
Visualization of TILE features that weighted in the algorithm



Clusters corresponding to different tumors tissue pattern with a clear relation with HRD or HRP

1. High density of Tumor Infiltrating Lymphocytes TILs
2. Hemorragic suffusion associated to necrotic tissue
3. Basal/hyperchromatic carcinomatous cells with nuclear atypia
4. Adipose tissue with inflammatory changes associated with clear tumor cells
5. Laminated fibrosis
6. Low tumor cell density and clear spaces around cell nests
7. Clear space surrounding apocrine cell nests

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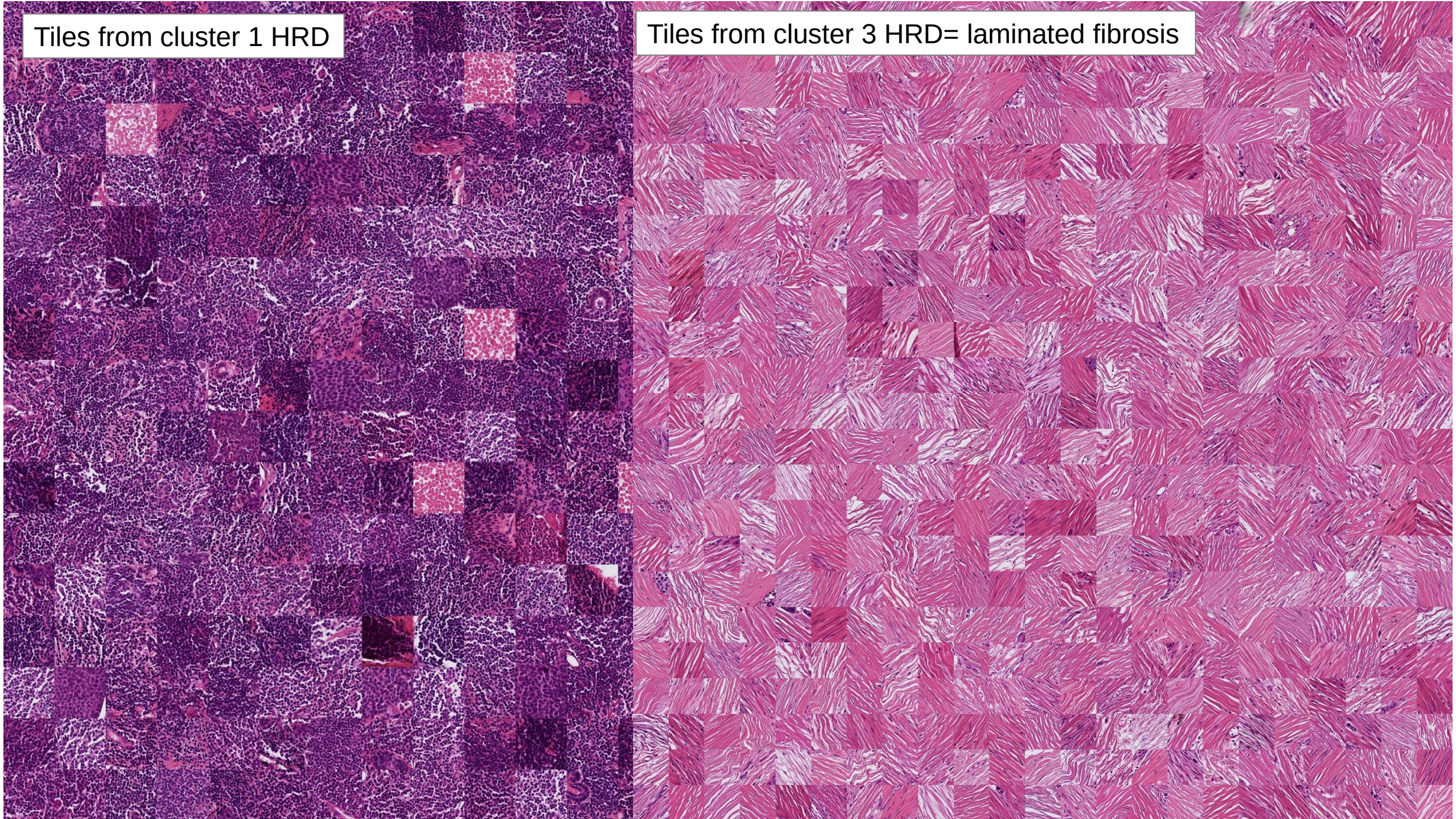
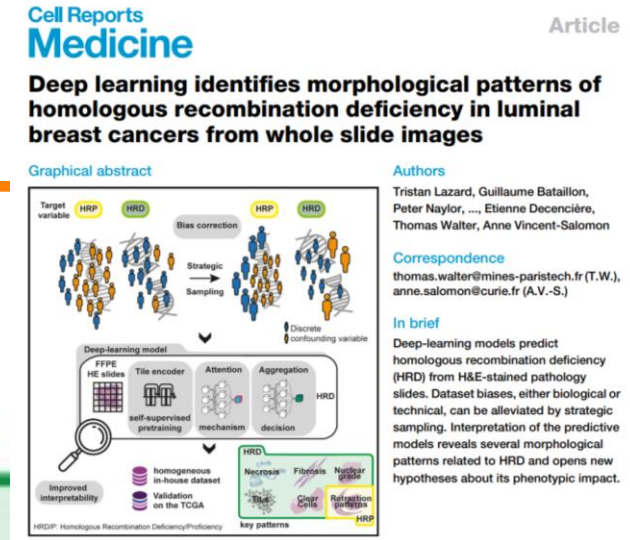
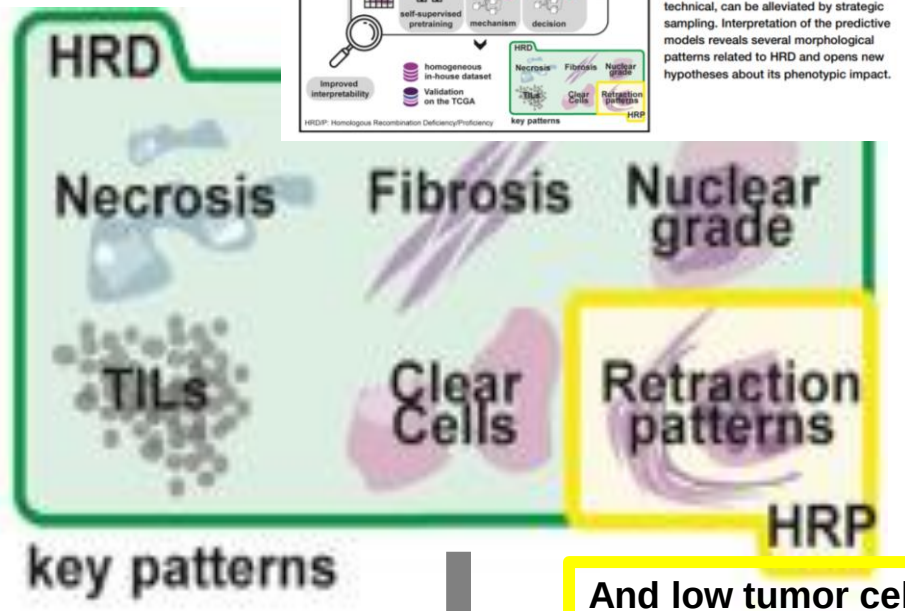

Tiles from cluster 1 HRD
Tiles from cluster 3 HRD= laminated fibrosis

Conclusions from this study

- Homologous recombination deficiency is predictable from H&E slides with high accuracy (0.83)
- **Biases** in computational pathology data can be alleviated by strategic sampling (the method of choice)
- We identified five HRD and two HRP-related morphological patterns

→ A biological in vitro validation needed before using it





And low tumor cell density

"Machine teaching"

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Future steps:

- Validation with external cohorts is on going
  - PhD Thesis of dr Raphaël BOURGADE (CHU de Nantes, France, Dr Loussouarn)
  - under the supervision of Prs Walter (INSERM 900 & Ecole des Mines-PSL University, and myself)

- It will be soon applied on HES from our patient Institut CURIE

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Outlines of my talk

1- Introduction

2- Diagnosis of breast cancer using AI

3- Prediction of Homologous Recombination Deficiency (HRD) in breast cancers using AI

4- Digital transition of a pathology department

5- Perspectives

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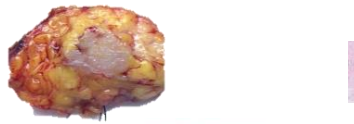
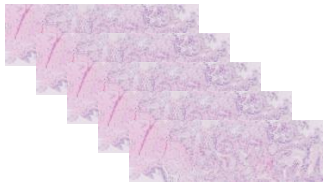
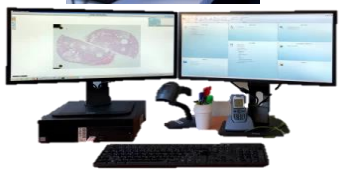
Transition to a digital lab at Institut Curie, France: from gross sampling to an Health Data Wharehouse







Gross sampling images

Institut Curie Health Data Wharehouse

1- It’s a long process
2- This transition needs perseverance
3- The success of the digital transition: it’s a team success
4- Integration of AI tools is an additional challenge

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Successful Digital Transformation of a pathology department

- **Take the time** to **define the needs** adapted to our practice

- **Associate the team, pathologists and technicians, to choose scanners and IMS**
- **Human resources needed to set up the project (IT department and in pathology)**
- **Distribution of the glass slides in parallel to the digitalized slides to let the time to pathologists to get used to digitalized slides (for 6 months)**

- **Anticipate the Storage needs (costs +++)**
  - "Short-term" storage: 220 To (approx. 10 weeks workload)
  - "Long-term" storage: 25 To/year (approx. 1 slide/sample)

- **IT Security issues & interoperability of the LIMS & IMS, solved thanks to the Data Protection Officer and the IT department**

- **Financial and institutional support**

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Pathology department of Institut Curie:

- **2 pathology units**
  - one in St CLOUD west part of Paris; and one in the Center of Paris
  - within one hour of public transportation

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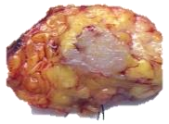
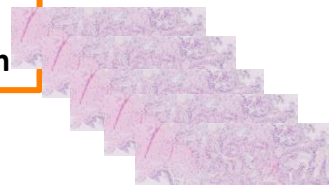
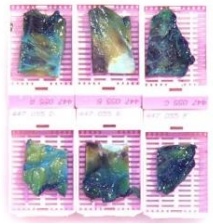
Implementation of digital pathology for diagnosis at Institut Curie



Tissue-section Slides preparation





Institut Curie Health Data Wharehouse

Gross sampling (specimen images)
- Macropath, Milestone
- VZ-R, Ipevo

Gross specimen pictures

Whole Slide Images production (H&E and FISH)
- 4 LEICA GT450
- 1 HAMAMATSU Nanozoomer 360
- 2 Pathscan EXCILONE

SCANNERS

WSI examination by pathologists

SECTRA IDS7

Image management system (IMS)

- Structured standardized pathological reports
- ARIANE sx® Dedalus
- Electronic health records

Laboratory information management system (LIMS)

- H&E: 350 000 slides /yr
- 300 Mo-5Go per WSI
- Storage of all slides/case for 3 months
- Permanent storage for 1 referent slide

STORAGE

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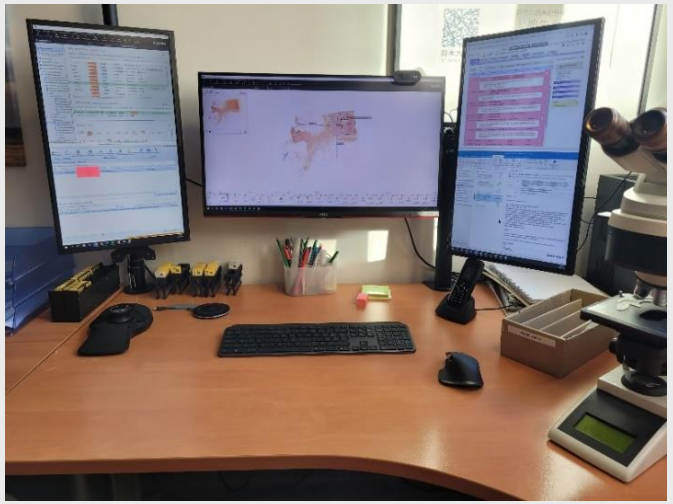
Workstation for the best confort of the pathologist

- **Specifications provided by SECTRA (IMS editor)**
  - Infrastructure
    - **Bandwidth**
    - **Latency**
  - Workstation
    - **Processor**
    - **Graphics card**
    - **Monitors**
      - Resolution
      - Refresh rate



Review Article

Display Characteristics and Their Impact on Digital Pathology: A Current Review of Pathologists' Future "Microscope"

Jacob T. Abel[1], Peter Ouillette[1], Christopher L. Williams[2], John Blau[3], Jerome Cheng[1], Keluo Yao[4], Winston Y. Lee[1], Toby C. Cornish[5], Ulysses G.J. Balis[1], David S. McClintock[1]

[1]Department of Pathology, University of Michigan, Ann Arbor, MI, USA, [2]Department of Pathology, University of Oklahoma Health Sciences Center, Oklahoma City, OK, USA, [3]Department of Pathology, University of Iowa, Iowa, USA, [4]Departments of Pathology and Laboratory Medicine, University of California San Francisco, San Francisco, CA, USA, [5]Department of Pathology, University of Colorado School of Medicine, Aurora, CO, USA

Submitted: 01-May-2020 Revised: 22-May-2020 Accepted: 28-May-2020 Published: 11-Aug-2020

- **Choice by the pathologists**
  - 3D mouse
  - Screen choice (price, quality of the image and confort)

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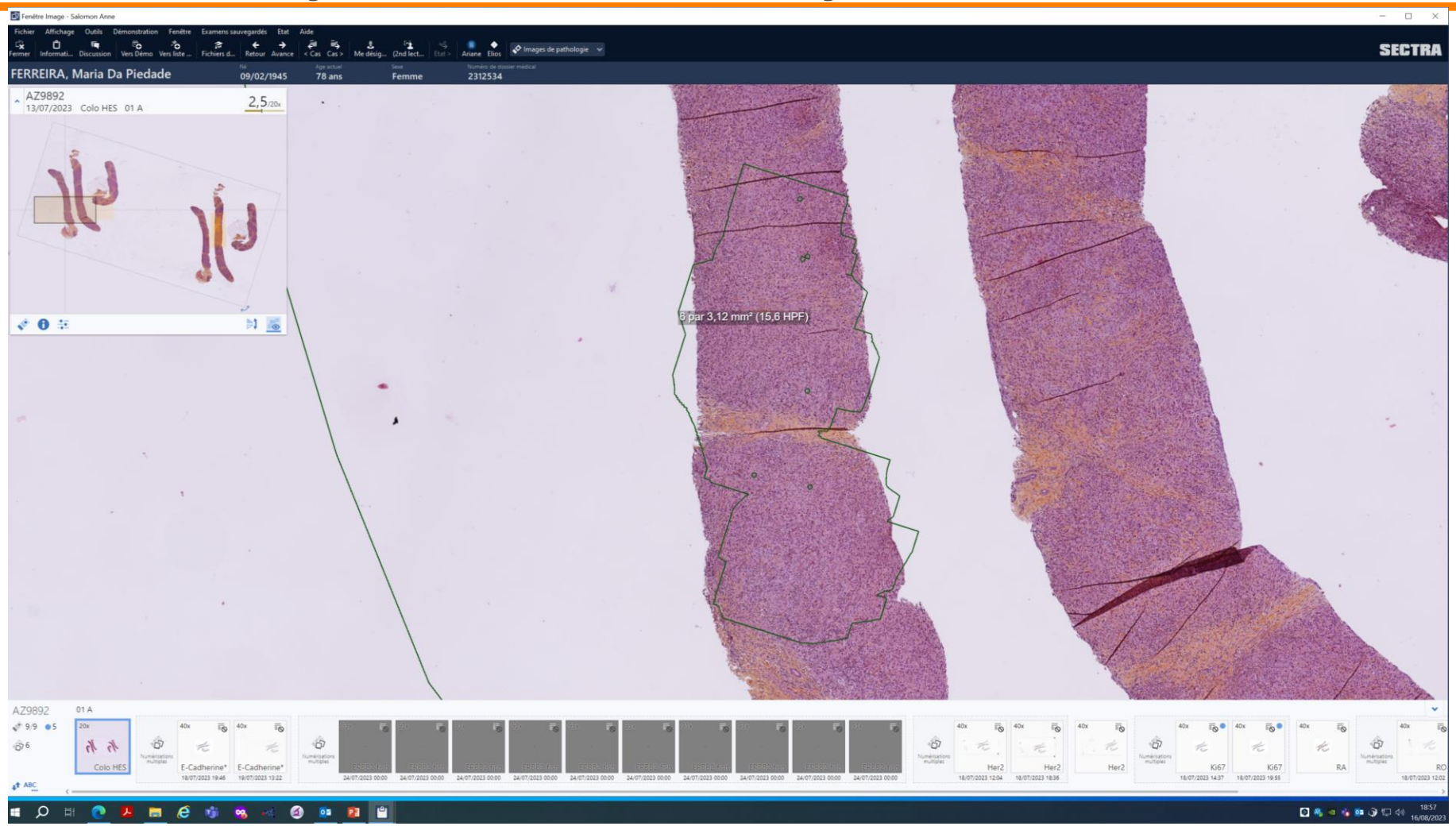
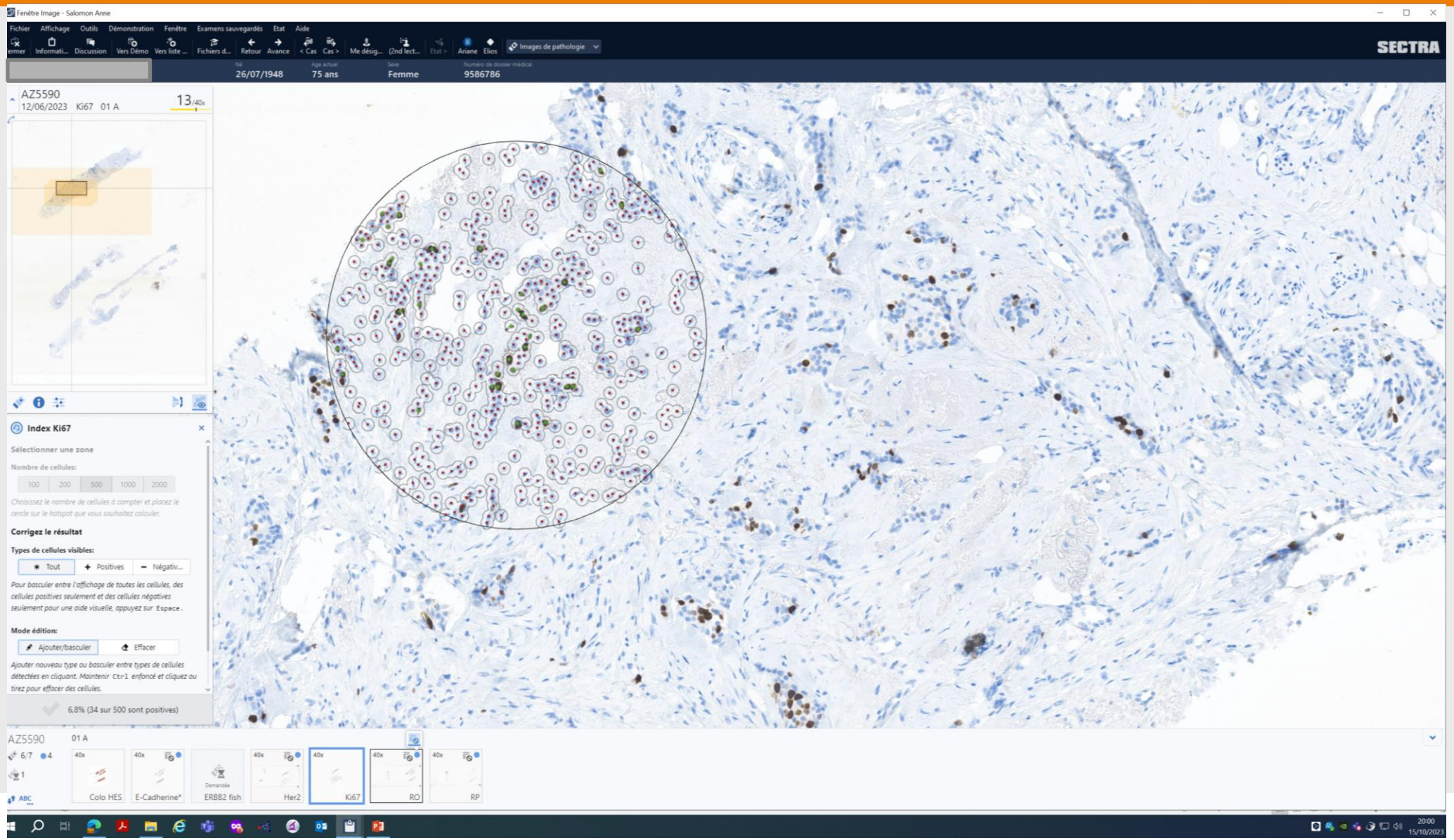
Mitotic count: IDS7 by Sectra makes it easy to do !



Evaluation of KI67 using the Sectra tool



IDS7; Sectra

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Outlines of my talk

1- Introduction

2- Diagnosis of breast cancer using AI

3- Prediction of Homologous Recombination Deficiency (HRD) in breast cancers using AI

4- Digital transition of a pathology department

5- Conclusions

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Conclusions (1)

- Numerous algorithms are currently being developed by start-ups or academic research labs together with pathologists and to help pathologists:
  - For the diagnosis of breast cancer and axillary lymph node metastasis,
  - To increase reproducibility in biomarkers assessment,

- Economic models for the application of AI remains to be identified in many countries

- The generalization of digital transformation for pathology labs is needed for the use of AI, and is underway.

- Breast pathologists will use AI if it's **easy to use, time-saving, highly accurate and if it's facilitate their work !**

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Conclusions (2)

- Computational pathology: a dynamic field that makes fast tchnological progresses
- Algorithms before their use into clinical practice have to solve **bias** issues, their availiability on the market takes time.
- Common responsability between computational scientists and pathologists to develop performant and robust tools to facilitate our work and to better diagnose our patients
- Long term collaboration between pathologists and computational scientists
- From academic research to clinical practice: who does fill the gap?

  → Efficient tech transfer

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Foundation models: can determine the biomarkers status without any immunos

- Creation of large-scale deep neural network
- Trained on very large data sets (> 1 million slides)
- Algorithms named “self supervised” that do not necessitate pathologist annotations
- Diagnose frequent as well as rare cancers
- Can predict biomarkers

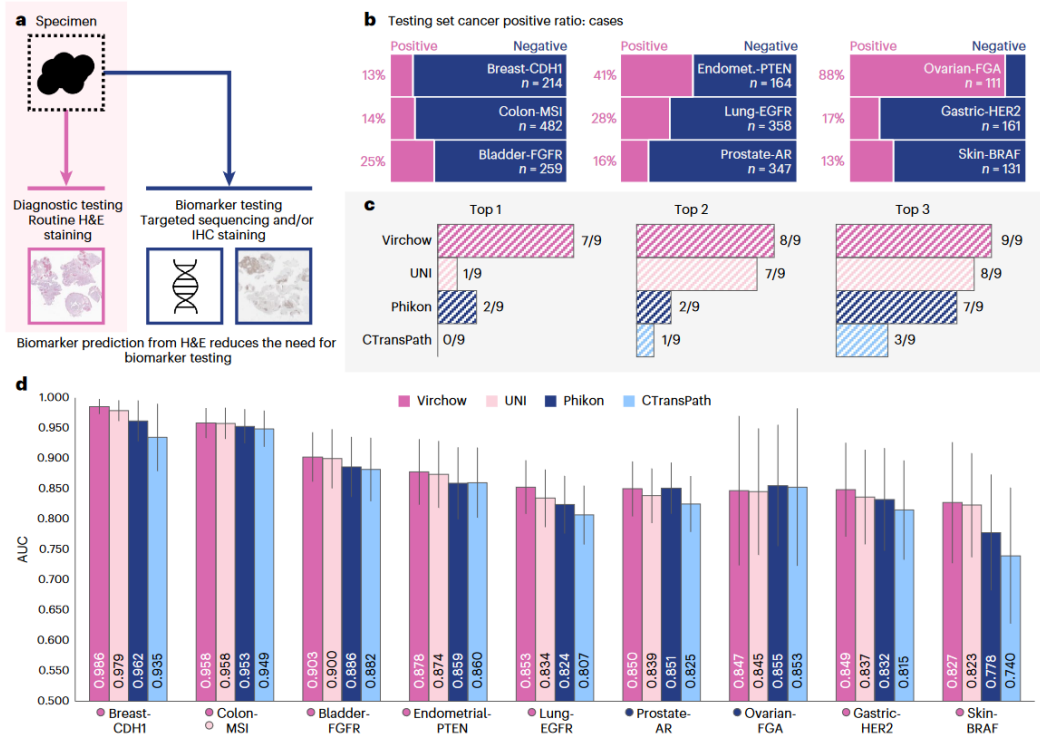

Fig. 4 | Biomarker prediction results. a, Virchow embeddings help predict the ranking across many biomarkers. **d**, Biomarker detection performance as

Vorontsov *et al*, Nature Medicine, Oct 24

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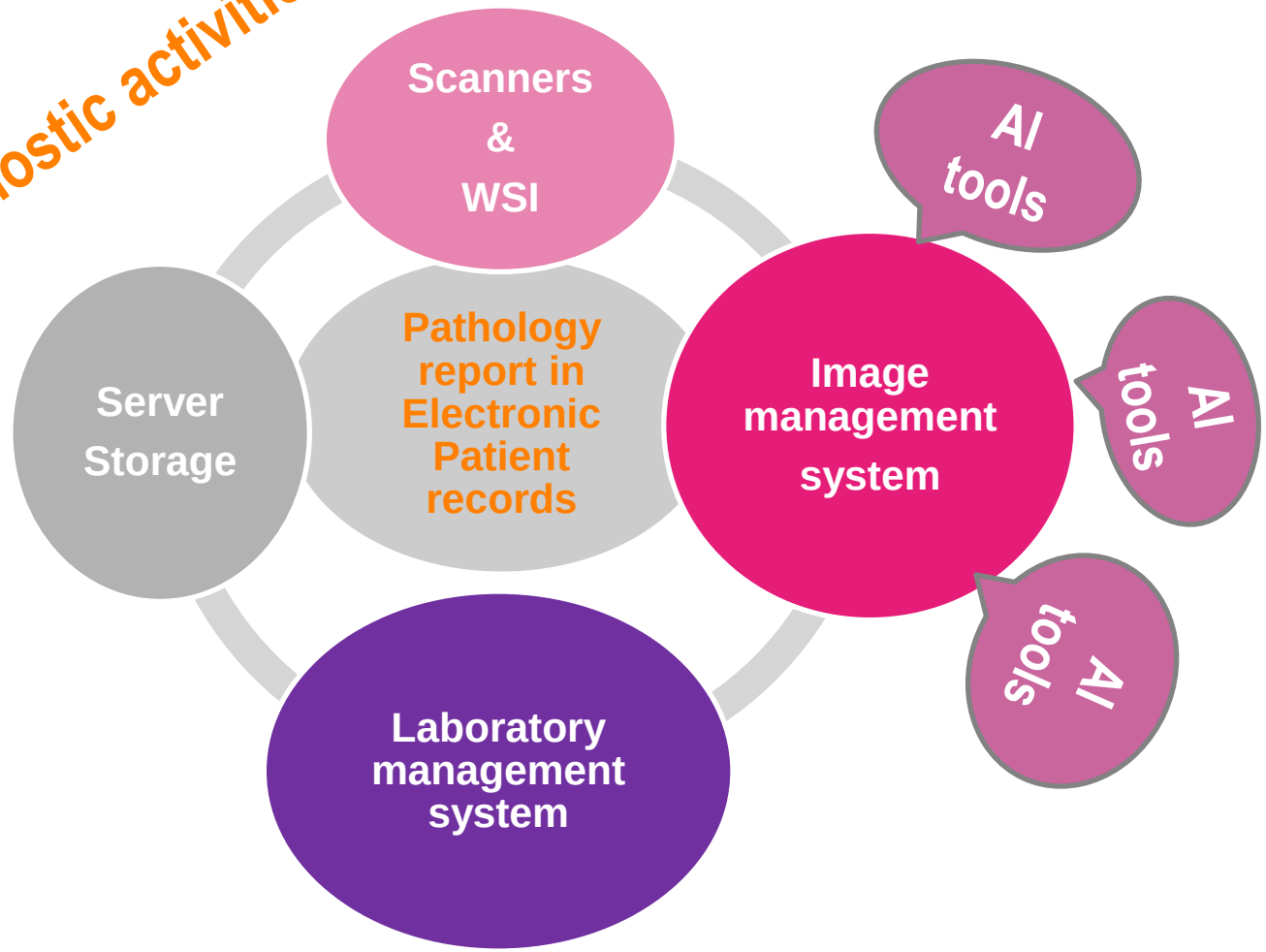
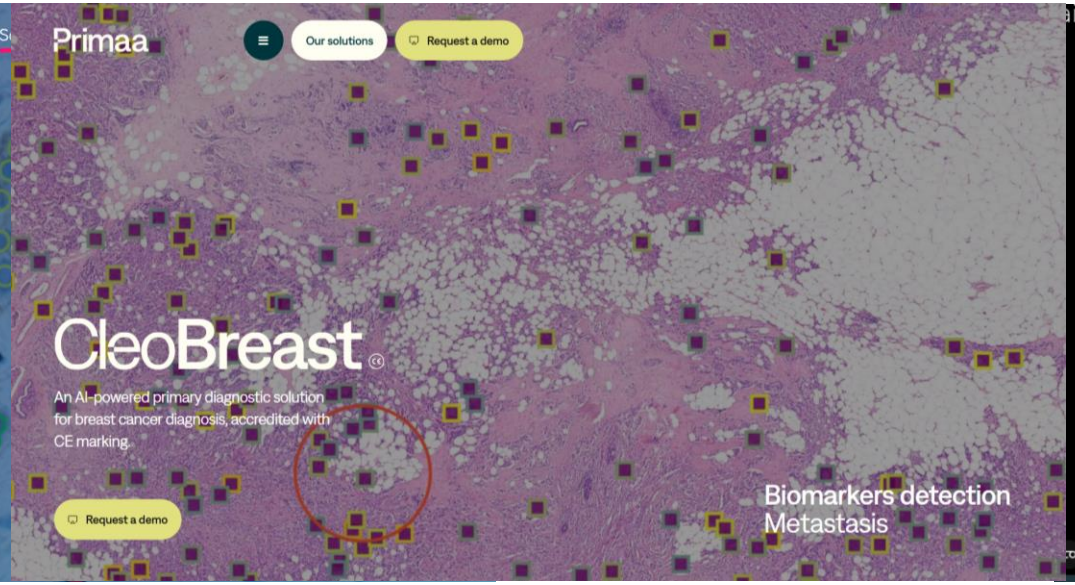
AI IN BREAST PATHOLOGY TO ASSIST THE PATHOLOGISTS FOR DIAGNOSTIC ACTIVITIES

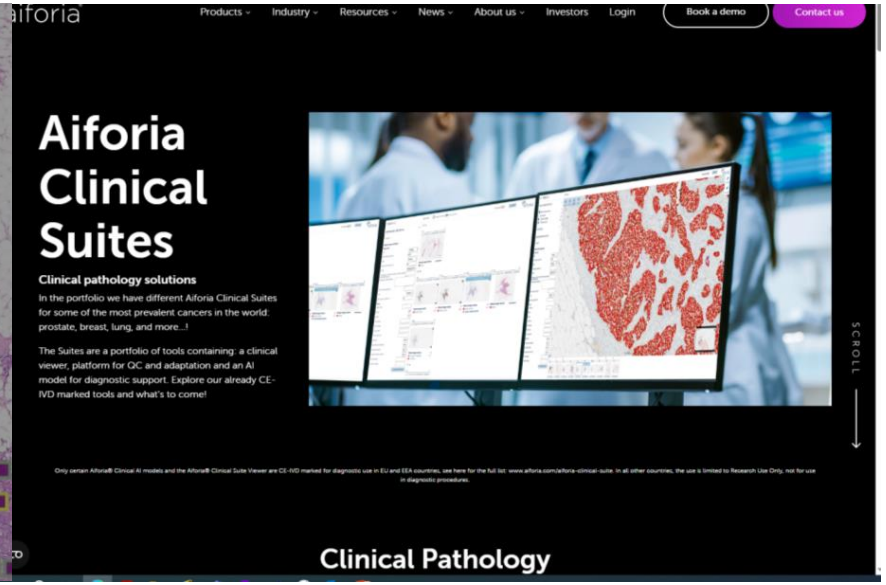
BREAST (core needle biopsies and surgical specimen)	Ibex Galen Breast	Primaa Cleo Breast	Aiforia Breast Cancer Clinical Suite
Invasive carcinoma	available	available	available
DCIS	available	available	available
architure score	planed	unavailable	avai
Nuclear grade	available	planed (Q1 20	ble
Identification of mitosis and mitotic score	-		available
Identification of µcal	-	ailable	available
Vascular invasion		available (CE label on going)	available
Axillary met	planed	available	-
E R quantification	planed	planed (Q1 2025)	available
HER2 quantification	available	planed (Q1 2025)	available
KI67 quantification	-	planed (Q1 2025)	available
TILS quantification	available	planed (Q1 2025)	-

Today, one AI solution does not fit to all diagnostic activities….



At Institut Curie:





Ibex prostate and Breast go live next week !

In January 25

In June 25

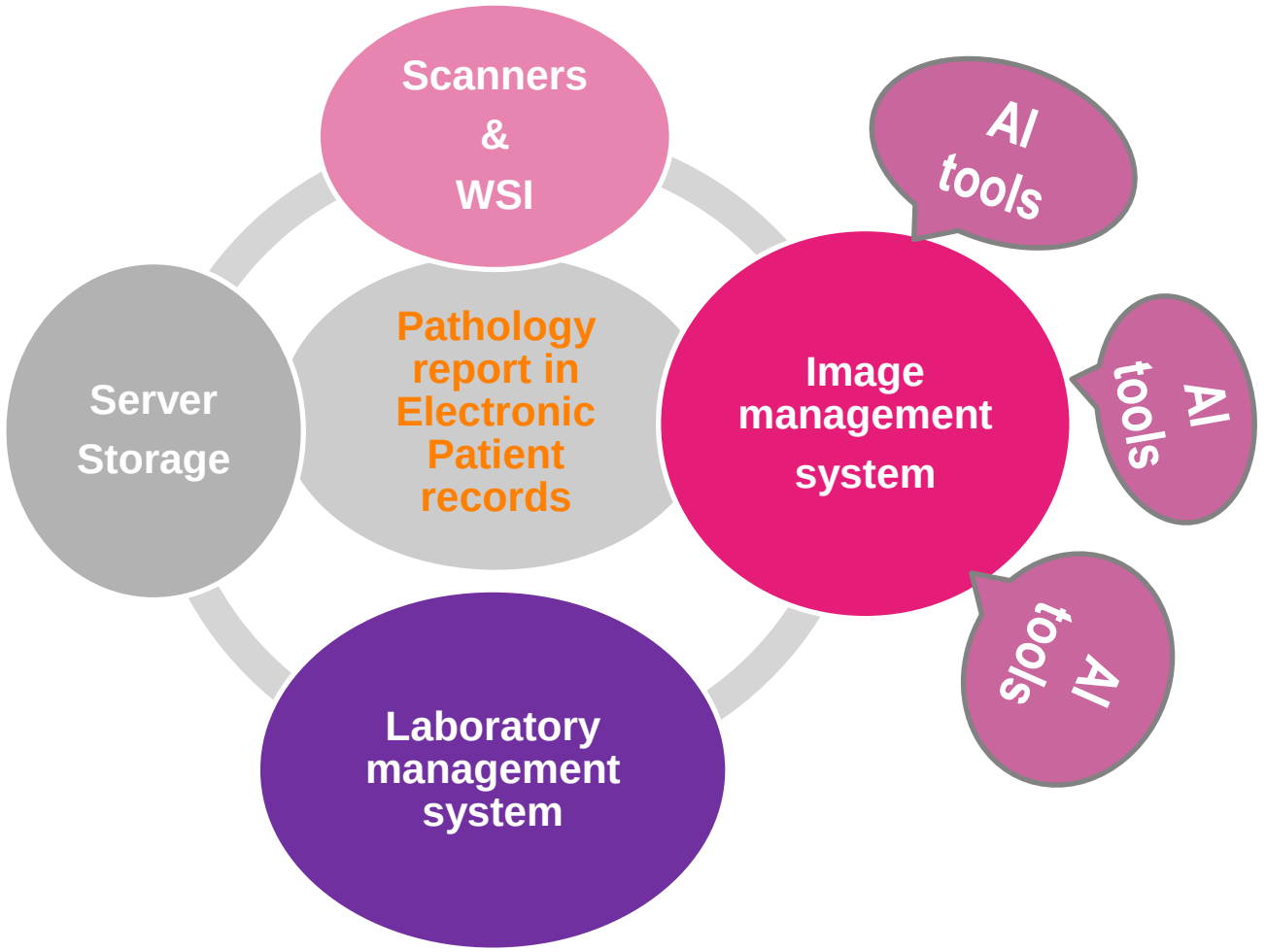
We will welcome a master student in social sciences & economy who will help us during one year

- To evaluate the ergonomy of each tool, to list tasks performed by the solution
- To summarize all steps needed to acquire and deploy an AI tool in an hospital
- To identify the security issues and the IT requirements to implement the tools
- To evaluate the cost and the benefit of using these AI tools

CONCLUSIONS & TAKE HOME MESSAGES

AI solutions in breast pathology

- **INTEROPERABILITY:**
  - Between informatics tools to set up digital pathology (Dicom format is becoming the standard)
- **SECURITY issues:** AI solutions accessible from clouds or on premise
- **ERGONOMY:** AI tools should be easy to use for pathologists
- **AI TOOLS ROBUSTNESS**: Involvement of pathologists; Control the bias; External validation
- **HUMAN GUARANTEE !**



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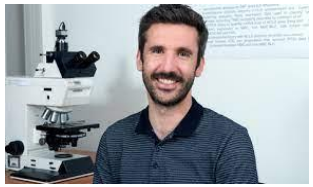
TARIS Corinne, LAMY Anne Florence
MENET Emmanuelle, ALLORY Yves
& Department of pathology



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Department of Genetics

STERN Marc-Henri
POPOVA Tatiana
INSERM U830

WALTER Thomas
LAZARD Tristan (PhD)
NAYLOR Peter
& INSERM U900

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