



Breast Cancer Awareness month

Breast cancer touches us all.

Family, friends, colleagues.



This October, we act

Enhancing Breast Cancer Treatment Decisions with Artificial Intelligence: A Reliable Approach to Ki-67 Scoring

*Precision Medicine:
Redefining the Future of Healthcare*

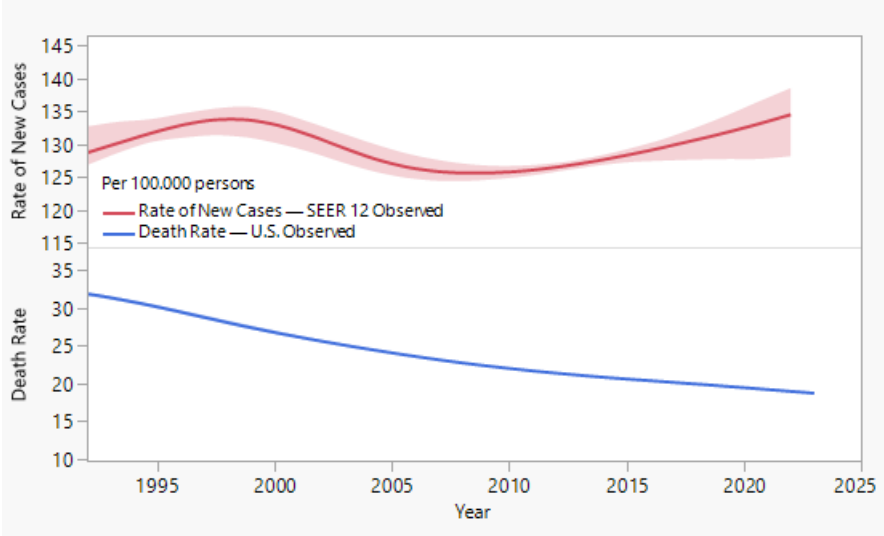
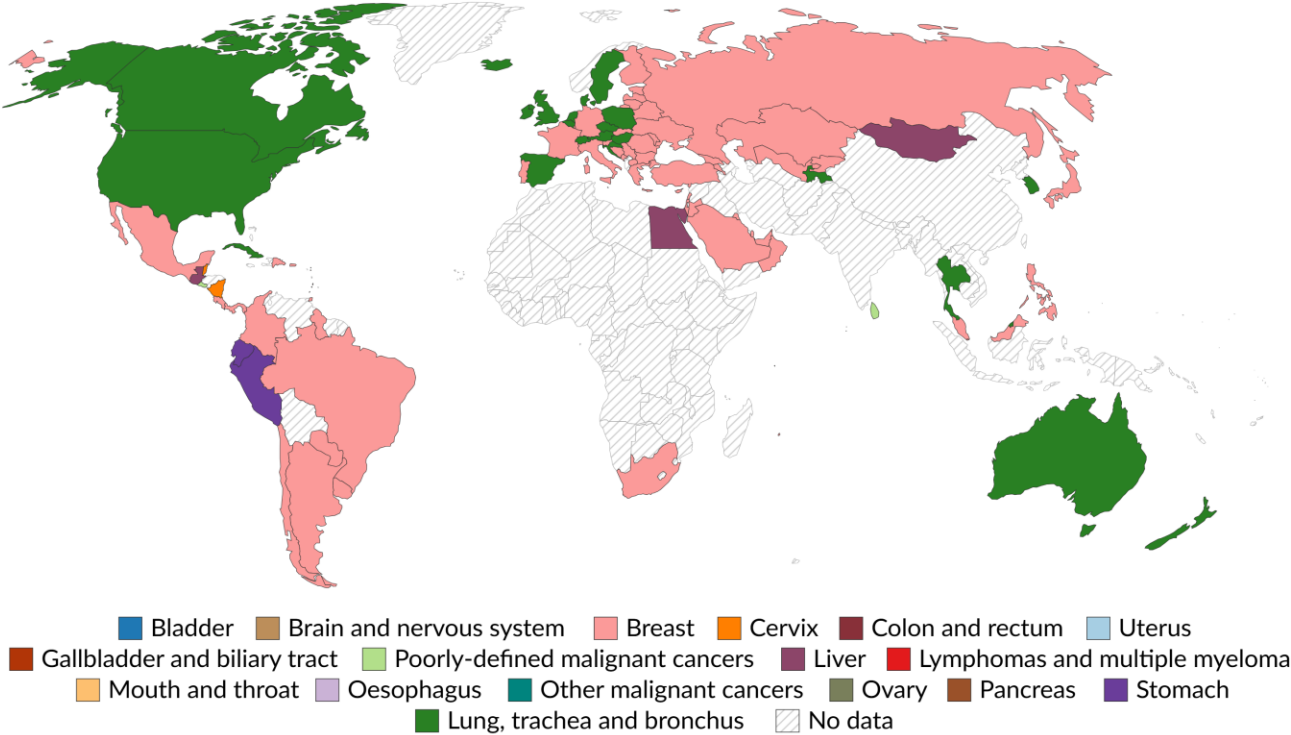
27 - 28 October 2025 | San Francisco, CA

Breast Cancer

Leading cancer types causing death in women, 2023

The most common cause of cancer¹ deaths in women, based on the underlying cause² listed on death certificates.

Our World
in Data



Data from seer.cancer.gov/statfacts/html/breast.html

Data source: WHO Mortality Database (2025)

OurWorldinData.org/cancer | CC BY

Note: Only shown for countries with sufficient levels of death registration³.

<https://ourworldindata.org/grapher/leading-cancer-types-causing-death-in-women>

Breast Cancer Subtypes

Molecular subtypes	Biomarkers	Frequency of cases (%)	Histological grade	Prognosis	Response to therapies
Luminal A	ER+ HER2- PR+ Ki67 low	40-50	Well differentiated (Grade I)	Good	Endocrine
Luminal B [HER 2+] [HER 2-]	ER+ HER2+ PR+/- Ki67 low/high	20-30	Moderately differentiated (Grade II)	Intermediate	Endocrine Chemotherapy Target therapy
	ER+ HER2- PR- Ki67 high				Endocrine Chemotherapy
HER 2+	ER- HER2+ PR- Ki67 high	15-20	Poorly differentiated (Grade III)	Poor	Chemotherapy Target therapy
Triple negative	ER- HER2- PR- Ki67 high	10-20	Poorly differentiated (Grade III)	Poor	Chemotherapy PARP inhibitors

ER: estrogen receptor, PR: progesterone receptor, HER2: human epidermal growth factor receptor 2

Based on the expression of ER, PR, HER2 and proliferation status as assessed by Ki67, different molecular subtypes of breast cancer have been identified that have distinct prognostic features and responses to therapies

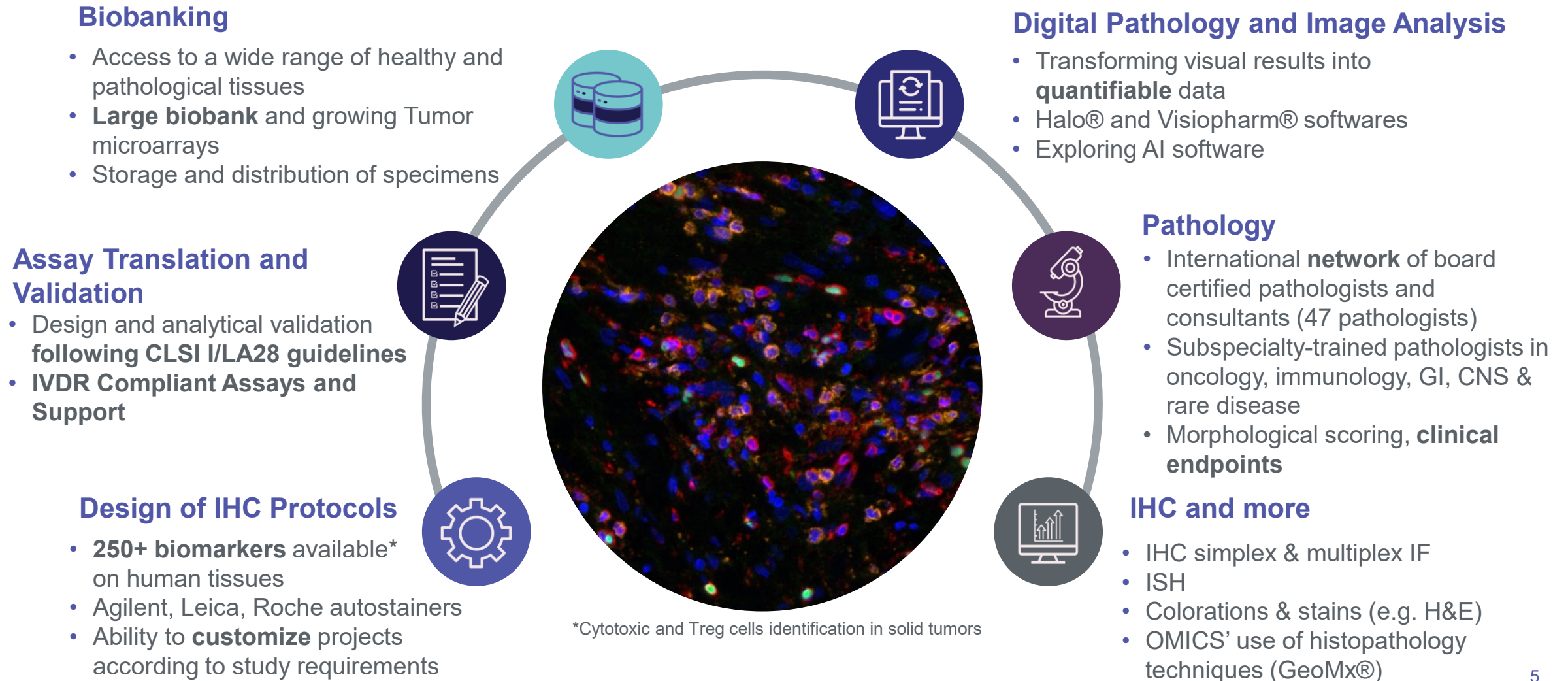


Cerba Research

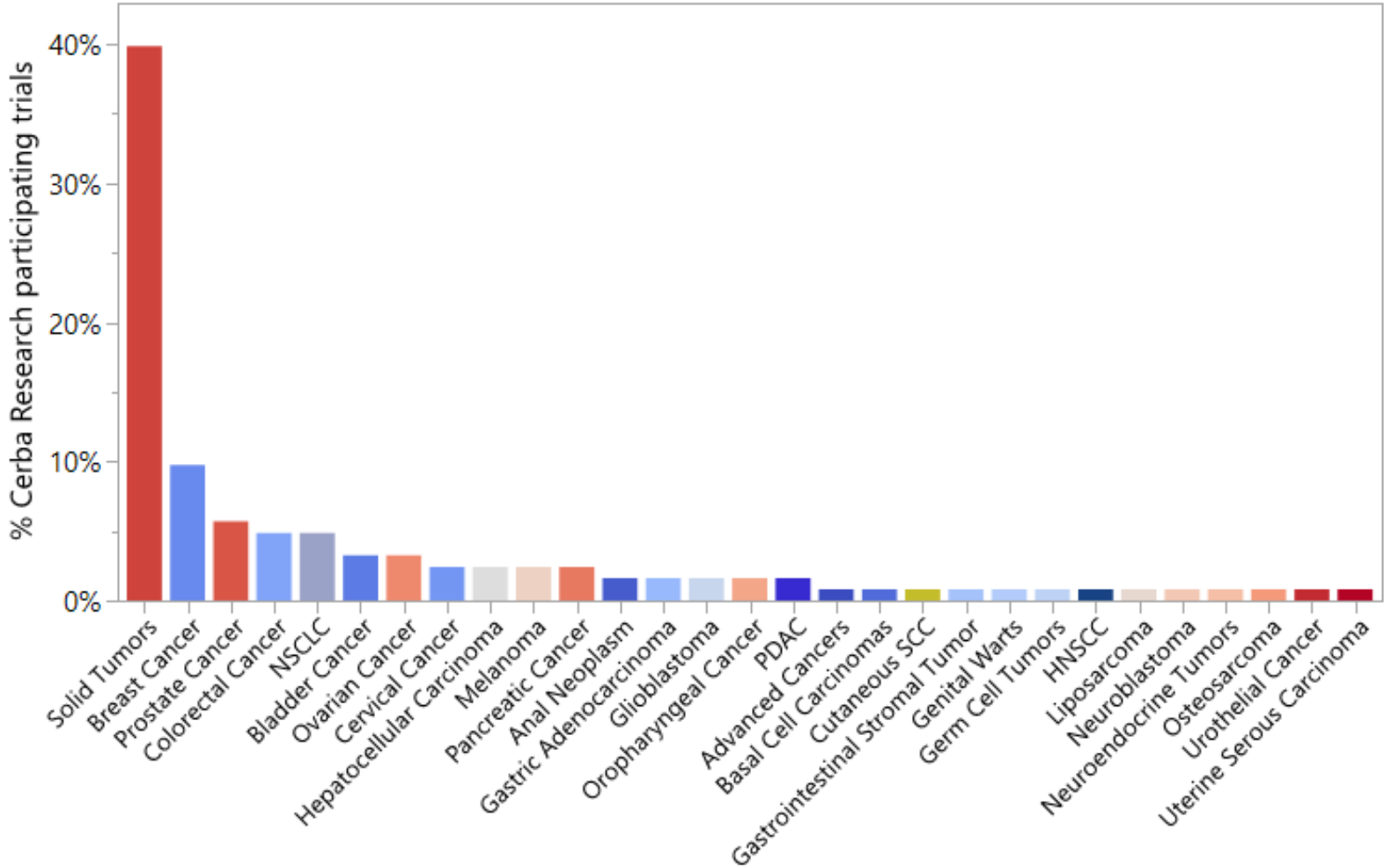
Breast Cancer Expertise at Cerba Research

Histopathology in Oncology

A fully integrated process



Cerba Research Implication in Solid Tumors Trials since 2018



Market Authorization / Expansion



32

Market authorizations / expansions

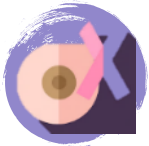


Approved Indications

- RRMM
- **Metastatic Breast Cancer**
- Neuroblastoma
- And more...

Trials grouped under “Solid tumors” indication are phase I-FIH for the most part which have no specific indication
NSCLC: Non Small Cells Lung Cancer, PDAC: Pancreatic Ductal Adenocarcinoma, SCC: Squamous Cell Carcinoma, HNSCC: Head and Neck Squamous Cell Carcinoma

What Are Breast Cancer Guidelines Proposing? Aligned with Cerba Research Offerings



Breast Cancer Biomarkers	Most commonly deployed*	May also be deployed*	Cerba Research NGS**	Cerba Research IHC**	Cerba Research FISH**
HER2	IHC	ISH (reflex), FISH (reflex)	x	x	x
ER	IHC	NA		x	
PR	IHC	NA		x	
PD-L1	IHC (22C3 Ab)	NA		x (clones 22C3, SP142, SP263, multiplexed)	
Ki67	IHC	NA		x	
PKI3CA	NGS, PCR, liquid biopsy	NA	x		
NTRK fusions	NGS, FISH, PCR	NA	x		x
TMB-H	NGS	NA	x		
MSI-H/dMMR	NGS, IHC, PCR	NA	x	x	
BRCA1/BRCA2	Germline sequencing	NA	x		
RET fusions	NGS	NA	x	x	
ESR1	NGS, PCR	ddPCR	x		

*NCCN guidelines 2024; **Cerba Research Data In-house mostly available through the ACTOnco®/Cerba France/Cerba US NGS panels or CR Montpellier (IHC) or Cerba France (FISH); TMB-H=tumor mutational burden-high; MSI-H=microsatellite instability-high; dMMR= mismatch repair deficient; IHC=immunohistochemistry; NGS=next-generation sequencing; FISH=fluorescence *in situ* hybridization; PCR=polymerase chain reaction; ESR1=estrogen receptor 1; ISH=*in situ* hybridization

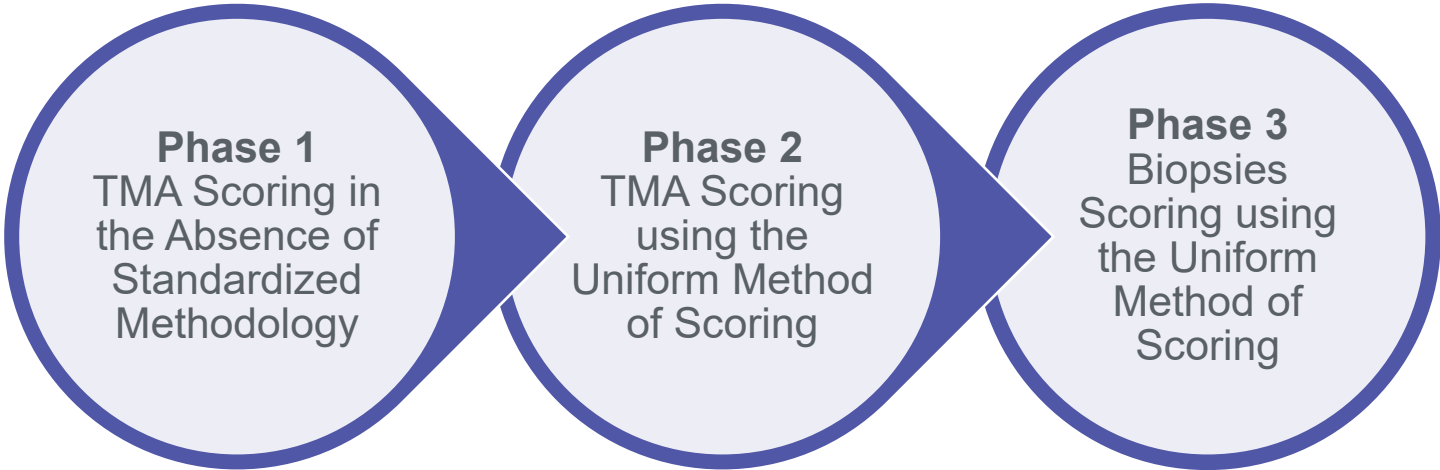


Cerba Research

Ki67 Project

Use of Artificial intelligence to improve Ki67 scoring

Efforts for Ki67 scoring standardisation by the IKWG



Intra-Laboratory	ICC: 0.94	/	/
Inter-Observer	ICC: 0.71	ICC: 0.92 95% CI: 0.88-0.96	/
Inter-Laboratory	ICC: 0.59	/	ICC: 0.87 95% CI: 0.81-0.93

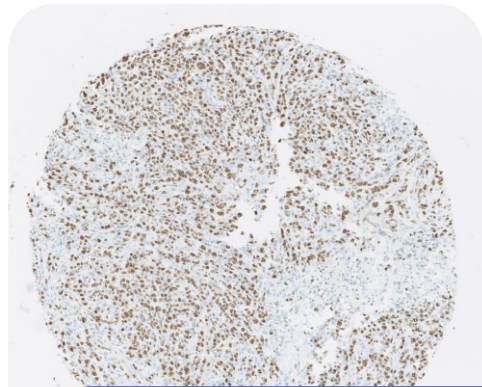
IKWG = International Ki67 in Breast Cancer Working Group
From Nielsen, T. O. et al. Assessment of Ki67 in Breast Cancer: Updated Recommendations From the International Ki67 in Breast Cancer Working Group. J Natl Cancer Inst 113, 808–819 (2020).

Project aim

How can we improve reliability and effectiveness of Ki-67 scoring ?

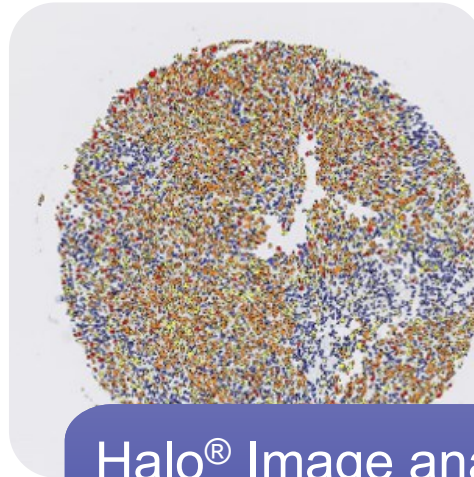
Project workflow

114 breast cancer tumors stained with for Ki-67 [MIB-1] using the Dako Omnis platform.



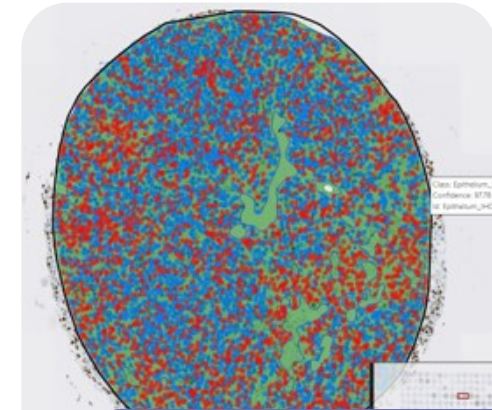
Pathologists assessment

- IKWG scoring training session with 2 pathologists
- Full scoring Ki-67
- 2nd read three weeks later by 1 pathologist (intra-reader variability)



Halo® Image analysis

- Halo® random forest classifier segmentation (tumor vs non-tumor vs background)
- Pathologist validation
- Ki-67⁺ assessment

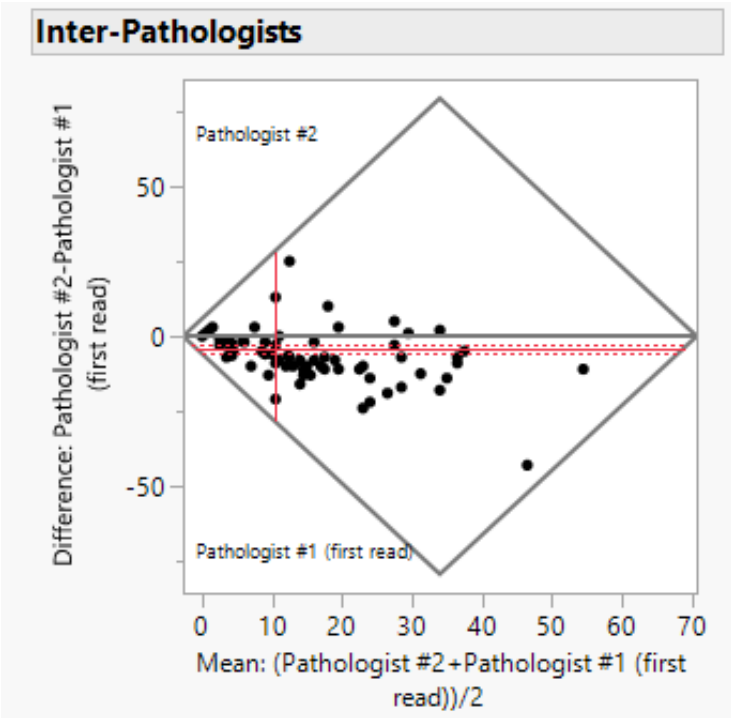
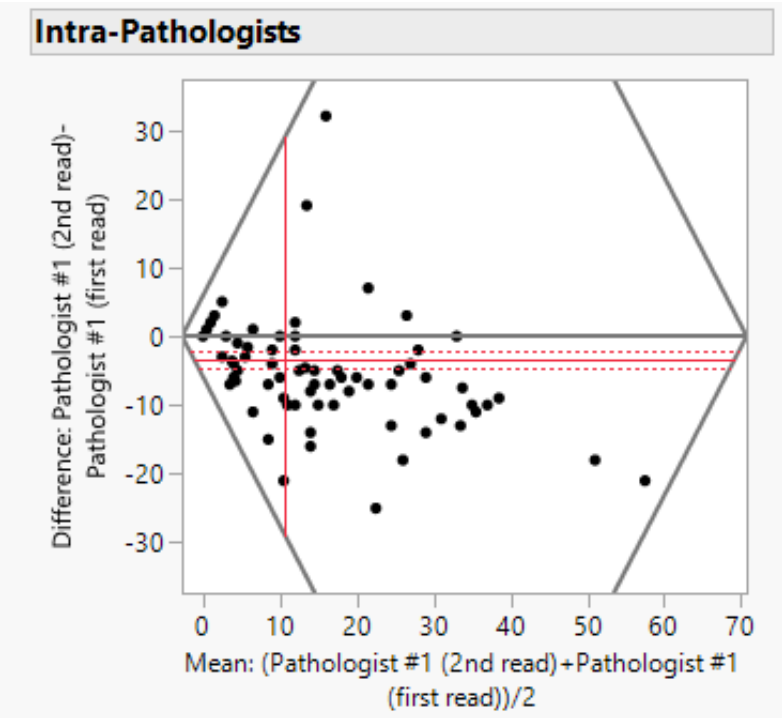


AiForia® Image analysis

- Aiforia® Ki-67 AI model
- Calibration including AI model training
- Ki-67⁺ assessment

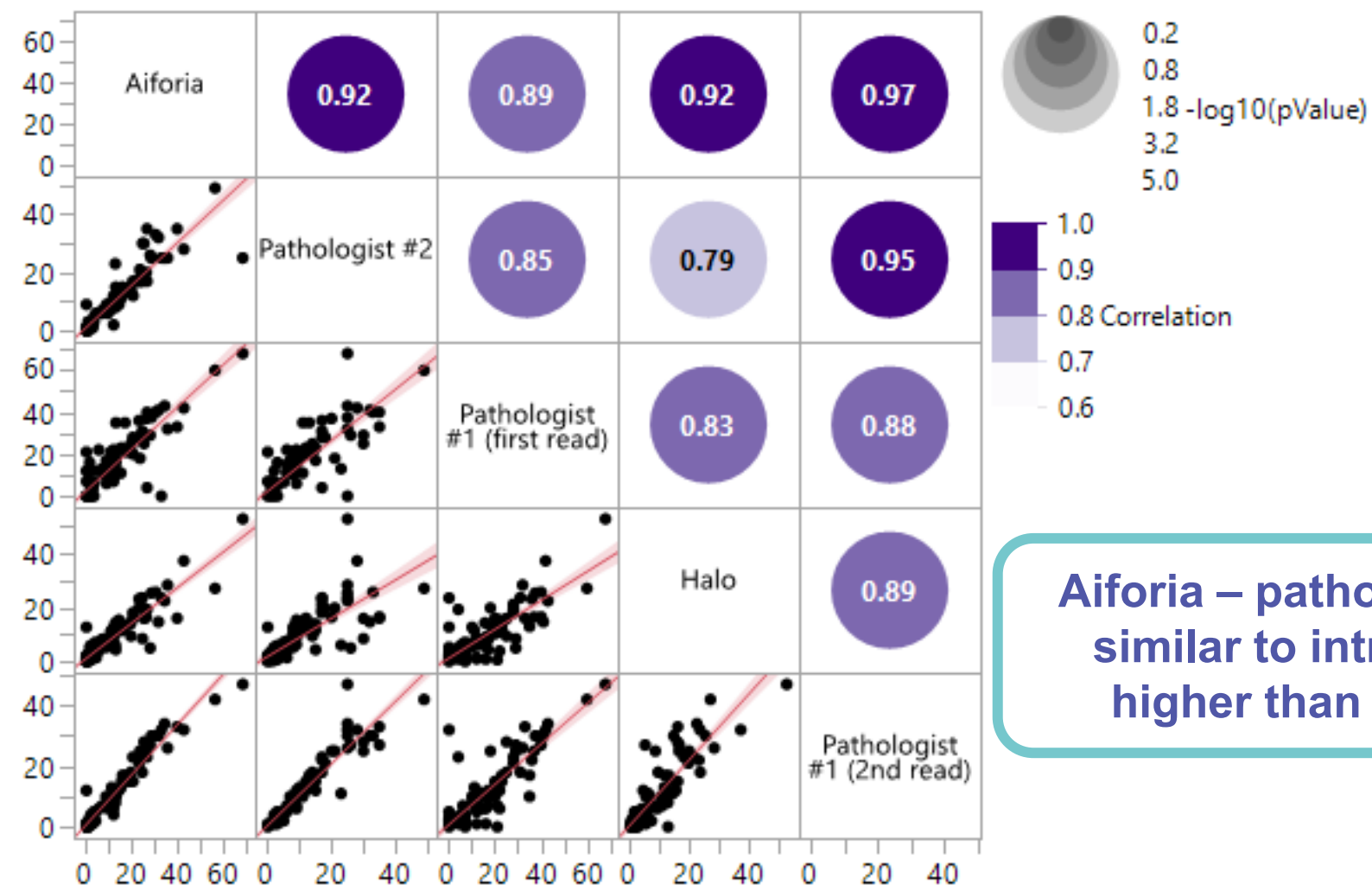
Percentage of Ki67+ cells Matched pairs analysis
Analysis time

Project Insights – Pathologist Variability



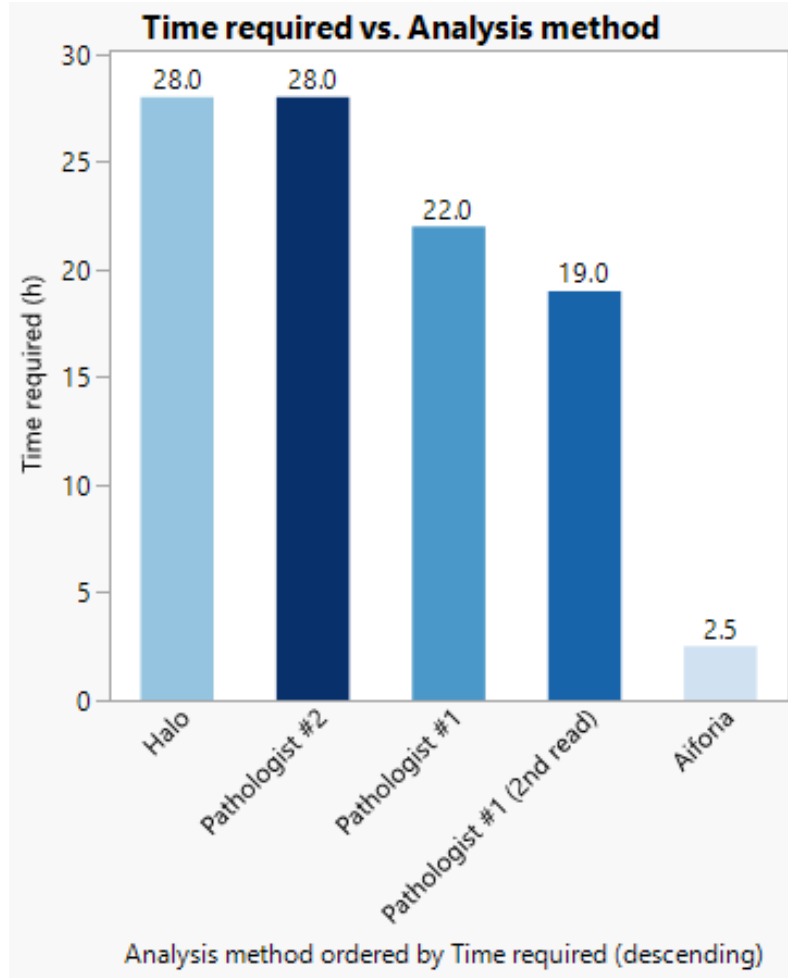
Variability Test	Correlation	Prob > t
Intra-Pathologist	88.1%	<0.0001
Inter-Pathologist	85.3%	<0.0001

Project Insights



Aiforia – pathologists correlation (89-97%) is similar to intra-pathologist one (88%) and higher than inter-pathologist one (85%).

Project Insights



2 MINUTES

This is the time needed for the Aiforia® platform to analyse all the samples.

The deep learning AI approach is by far the fastest.

Image analysis solution using Halo application development is about the same time than the pathologist analysis.

Project Takeaways

- Deep learning assisted image analysis using Aiforia solution allows to get data similar to the pathologist reading
- Deep learning assisted image analysis using Aiforia solution allows to reduce analysis time by nearly 10 times

**Cerba Research Histopathology department
investigates the best method for your samples**



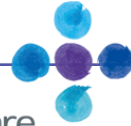
Cerba Research

Cerba Research – a specialty lab

Strong healthcare track record and financial stability

Private equity owned

Cerba HealthCare



Cerba Research



Cerba Healthcare

€1.9bn 2024 turnover
15,774 employees
90 Nationalities

48M Patients per year

170 Technical platforms
1,360 Laboratories
2,500+ types of tests
200,000+ tests performed every day
1,200 pathologists
1,000 clinical publications to date



Division of Cerba Healthcare

950 employees
1400+ Clinical trials since 2018
10 Technical platforms
45 Laboratories
>300 customers
~30 Peer-reviewed publications per year

Therapy areas:

- Oncology
- Anti-Infectives/Vaccines
- Immunology
- CGT

Accreditations and regulatory experience



Delivering global solutions with extended laboratory network

Local operations for efficiency and risk mitigation

Belgium

Routine, Molecular Biology,
Bioanalytical Lab, Flow
Cytometry, Microbiology

France (Paris & Montpellier)

Genetics/NGS, Molecular Biology,
IVD, Flow Cytometry,
Histopathology/IHC,
Virology, Biorepository, BSL3

North America & Canada

Routine, Genetics/NGS,
Molecular Biology, IVD, Flow
Cytometry, Bioanalytical Lab/PK,
Histopathology/IHC, Virology

South Africa (Johannesburg)

Routine, Genetics/NGS, Molecular
Biology, Virology, Microbiology,
BSL3, Biorepository

The Netherlands

BSL3, Pre-clinical, Molecular
Biology, Genetics/NGS,
Pathology, Virology

China (Shanghai)

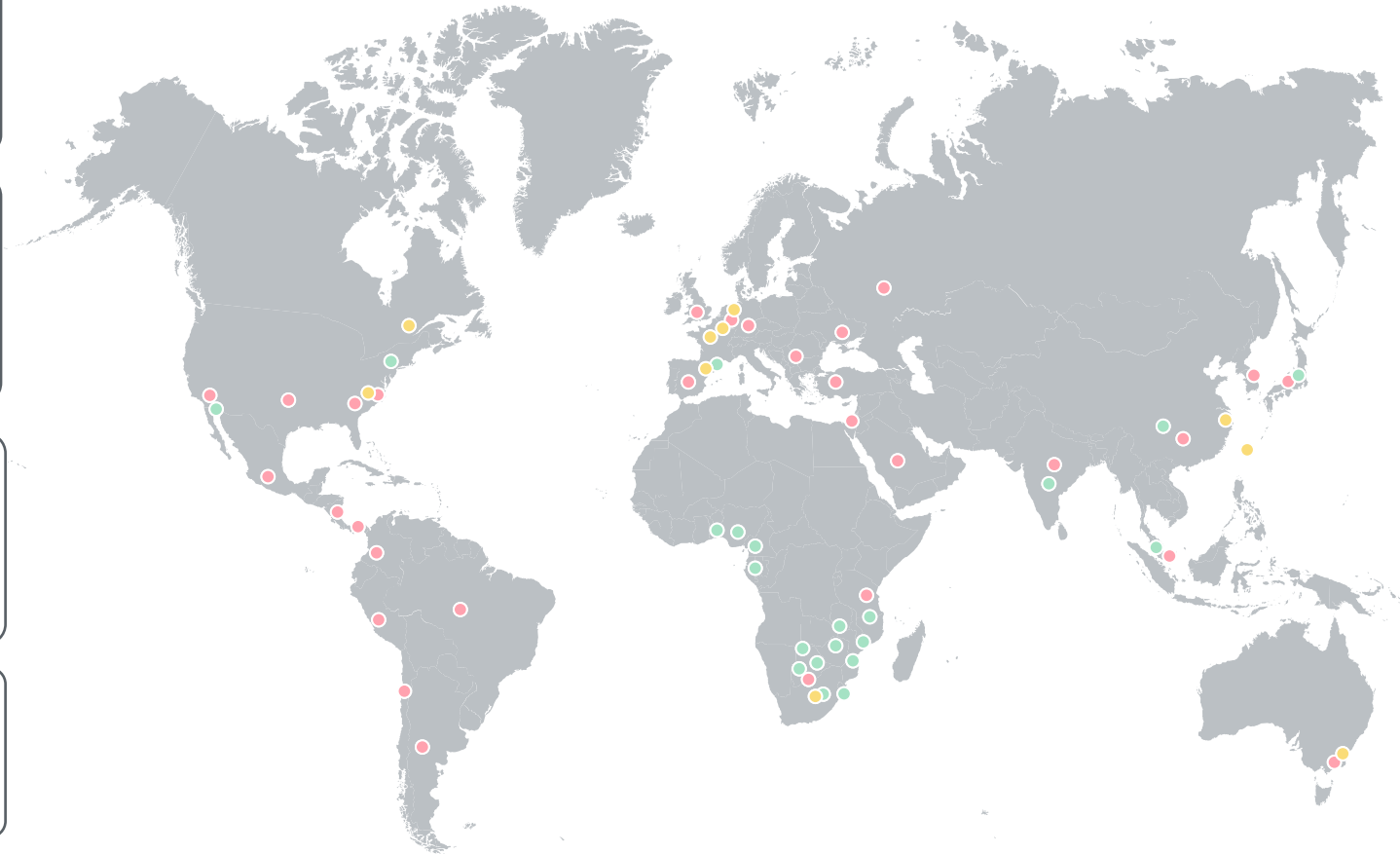
Routine, Genetics/NGS, Molecular
Biology, Flow
Cytometry, Bioanalytical Lab/PK,
Histopathology/IHC

Taiwan (Taipei)

Routine, Genetics/NGS, Flow
Cytometry, Histopathology/IHC
Lab,

Australia (Sydney)

Routine, Molecular Biology,
Flow Cytometry, Virology



- Office Locations and Specialty Laboratories
- Pre-Processing Laboratories
- Research & Partner Laboratories

Cerba Research – Where Innovation Meets Expertise in Clinical Trials



Global Specialty Network: Centers of Excellence

- Integrated specialty and routine testing laboratories across Europe, North America, Africa, and Asia.
- Deliver consistent, high-quality results to support global clinical trials.



Science-Led. Results-Driven.

- Development and validation of context-specific assays that translate complex science into actionable insights
- Accelerating clinical development with confidence.
- Early scientific engagement drives smarter study design and stronger outcomes



Beyond the sample to insights

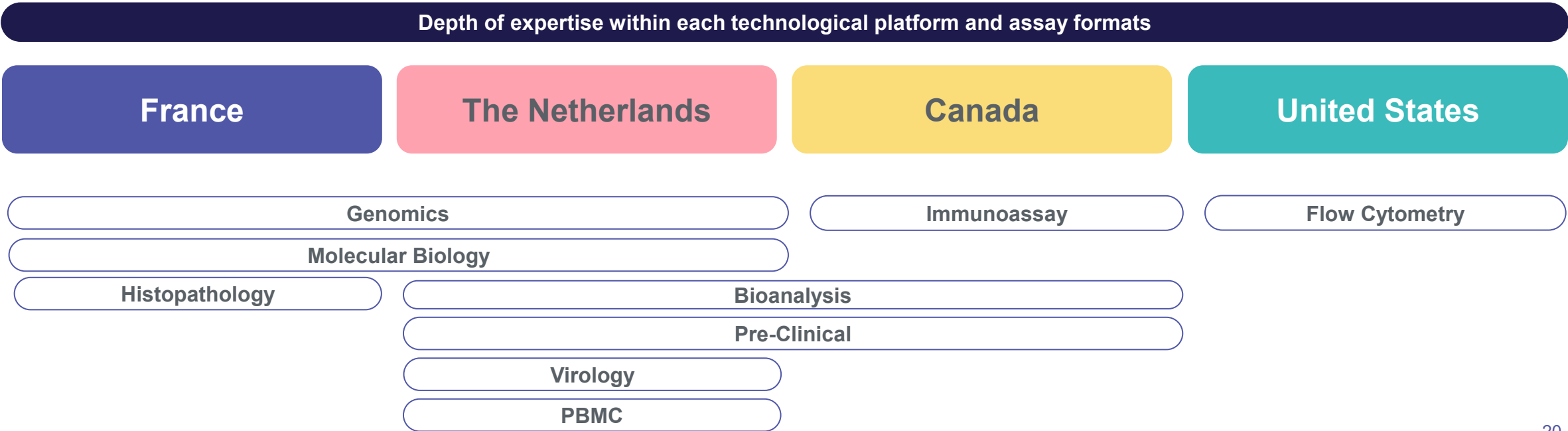
- Integrated scientific approach ensures every step is driven by precision, enabling faster, smarter decisions in complex clinical development

Centre of Excellence: Driving scientific rigor and innovation

Platform/Geographic Location

Key Roles of Cerba Research CoE:

- Centralizes **test development** and **method validation**
- Ensures **scientific accuracy**, **standardization**, and **regulatory compliance**
- Acts as the **reference point** for platform-specific knowledge and innovation
- Oversees **technology transfer** to Applicative Centers
- Provides **training**, **documentation**, and **support** to ensure successful implementation





Cerba Research

Come to
see us
at
Booth #5

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