

# Discover our Hematological Malignancies Trial Portfolio with Cutting-Edge **Laboratory Solutions**

Since 2018, Cerba Research has conducted approximately 90 clinical trials in hematological malignancies, contributing to the market authorization or expansion of 16 therapies, including treatments for multiple myeloma.

These studies frequently involved highly specialized assays and led to the randomization of over 11,800 patients. Notably, Cerba Research played a key role in the regulatory approval of three CAR-T cell therapies, underscoring its leadership in advancing innovative treatments in hematology.



## Our Track Record



13,800+

Screened patients



11,800+

Randomized patients



MM

Most common indication



90

Hem trials since 2018



Over 60%

FCM performed in our Hem portfolio



45+

PBMC processing laboratories







176

Genes that can be detected with Cerba NGS Hematological Malignancies extended panel

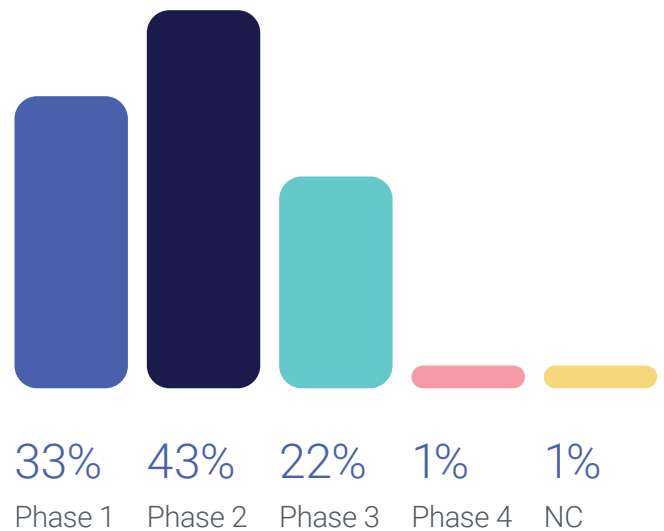
## Hematological Malignancy Indications

49%	Multiple myeloma
19%	Other hem
13%	Acute myeloid leukemia
8%	Non-Hodgkin lymphoma
5%	B-cell non-Hodgkin lymphoma
4%	Lymphoma
2%	Diffuse large B-cell lymphoma

## Therapy Class (2018–2025)

	36%	Small molecules
	34%	CGTs (e.g. CAR-T, NK cell therapy, etc)
	21%	Antibody therapy (e.g. mAbs)
	6%	Recombinant proteins (e.g. ADCs)

## Clinical Trial Phases Overview



## Case Study

# Large Pharma, Multiple Phases with a CAR-T and Other Assets in MM

### Overview



12 trials from FIH to registration



Safety and specialty projects



All regions globally



Projects Start 2010–now

### Challenge

Our sponsor was facing issues with poor quality of isolated cells when collecting bone marrow samples for downstream applications.

A crucial bottleneck for the project consisted of a shortage of samples which made FISH testing difficult. It proved difficult to identify FISH probes with relevant information for the indication.



### Solution

A lab protocol with the aim to optimize CD138 cell isolations.

A testing algorithm was developed specified to the amount and quality of the bone marrow.

In-depth gene sequencing analyses with a dedicated hematopathologist.

Implementation of cell isolation, FISH tests and centralized/ global testing was done in Paris. With the fragility of the cells in mind during turn-round times, the solution was transferred to Cerba Research's US-based laboratory.

### Outcome

Improved the cell quality and related downstream testing. Ultimately leading to enhanced data output of FISH testing.

Significant improvement of turn-around-times.

The provided solution was transferred to other MM trials.

# Flow Cytometry Expertise and Custom Solutions

## Customized Solutions

Customized assay design

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Fit-for-purpose validation (CLSI H62)

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Customized data analysis strategy

## Expertise

Scientists with extensive expertise in:

Panel design

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Assay validation

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Assay development

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Data analysis

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High-dimensional FCM

## Assays

Expertise in assay development to:

Monitor immunophenotyping and cell activation

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Monitor and characterize CAR-T cells

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Evaluate receptor occupancy of a drug

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Detect intracellular cytokine (ICS) production

Matrix:

PBMC (fresh and cryopreserved)

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Blood and BMA

## Global Footprint

Global FCM capability standardized assays through:

SOPs

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Assay transfer

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Validation process

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Instrument platform

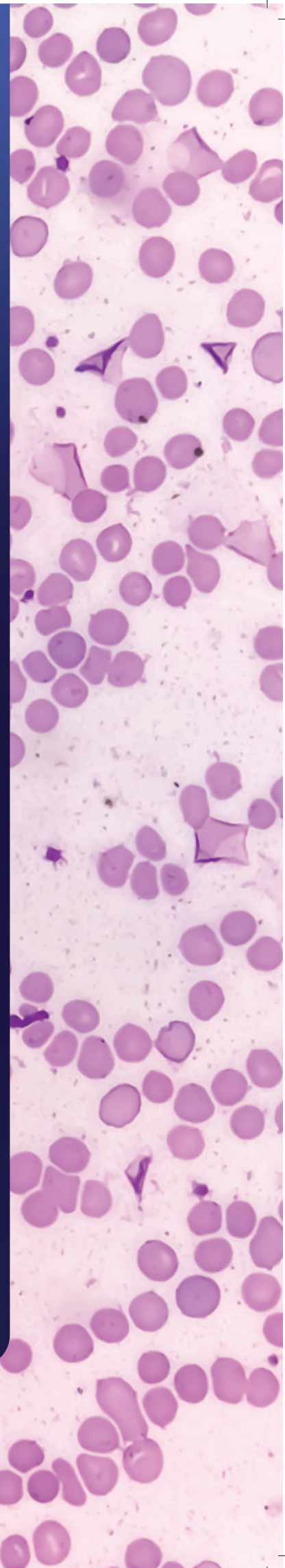
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Centralized data analysis and data review



# Cerba NGS Extended Panel for Hematological Malignancies (176 Genes)

ABL1	CDK7	FOXO1	KMT2D	PLCG2	SRP72
AKT1	CDKN1B	FUBP1	KRAS	POT1	SRSF2
AKT2	CDKN2A	GATA1	MAP2K1	PPM1D	STAG2
AKT3	CDKN2B	GATA2	MAX	PRDM1	STAT3
ANKRD26	CEBPA	GNA13	MBD4	PRPF8	STAT5B
ARID1A	CHD2	GNAS	MEF2B	PSMA1	STAT6
ASXL1	CHEK2	GNB1	MPL	PSMB5	SUZ12
ASXL2	CRBN	GRB2	MYC	PSMD1	TCF3
ATM	CREBBP	HRAS	MYD88	PSMG2	TENT5C
ATR	CRLF2	ID3	NF1	PTEN	TERC
ATRX	CSF3R	IDH1	NFE2	PTPN11	TERT
B2M	CSNK1A1	IDH2	NFKB2	PTPRD	TET2
BCL2	CUL4A	IDH3A	NFKBIA	RAD21	TGFBR2
BCOR	CUL4B	IFNGR2	NFKBIE	RB1	TLR4
BCORL1	CUX1	IGF1R	NOTCH1	RHOA	TNFAIP3
BIRC2	CXCR4	IGLL5	NOTCH2	RIT1	TNFRSF14
BIRC3	CYLD	IKZF1	NPM1	RPS15	TP53
BRAF	DDX41	IKZF3	NR3C1	RTEL1	TRAF2
BTK	DHX34	IL2RG	NRAS	RUNX1	TRAF3
CALR	DIS3	IL6	NSD2	SAMD9	U2AF1
CARD11	DNMT3A	IL6R	PAX5	SAMD9L	UBA1
CBL	EGFR	IL7R	PHF6	SAMHD1	WT1
CCND1	EGR2	IRF4	PIK3CA	SETBP1	XBP1
CD28	EP300	JAK1	PIK3CG	SF3B1	XPO1
CD37	ETNK1	JAK2	PIK3R1	SH2B3	ZBTB7A
CD38	ETV6	JAK3	PIK3R2	SMARCA4	ZRSR2
CD58	EZH2	KDM6A	PIM1	SMC1A	
CD79A	FBXW7	KIT	PIM2	SMC3	
CD79B	FGFR3	KLF2	PIM3	SOCS1	
CDK4	FLT3	KMT2A	PLCG1	SPI1	



# Global Uniform **PBMC Isolation Protocol** Using CPT Tubes



Blood sampling  
at sites



Centrifuge of tubes  
before transport



Transport to processing  
laboratory 15–25 °C



Transport to laboratory



Counting, aliquoting and  
cryo-preservation 8–24 hours



PBMC isolation



Storage LN2 at one of  
Cerba Research hubs



Assay development  
and lab testing



LIMS



Data export

45+ Network labs available globally  
(excluding Cerba Healthcare network)



# A Cerba Research Unique Offerings for Your **Liquid Tumor Trial**



## DNA/RNA

- NGS, oncopanels, broad panels, custom panels
- RNA seq, single-gene
- ctDNA-based panels
- ddPCR, qPCR
- Whole exome / whole genome
- HLA typing
- TCR / BCR seq
- NanoString®
- SNP-array
- DNA/RNA extraction
- Streck cell-free DNA BCT®
- PaxGene®, Qiamp kits



## Routine/Safety

- Coagulation
- Hematology
- Biochemistry
- Urinalysis pregnancy test
- COVID test
- Serology
- Thyroid function
- HbA1c
- All IMWG routine assays, such as sPEP, uPEP, sFLC



## Protein

- Multiplex cytokine
- Profiling (37-plex)
- Numerous ligand binding assays
- ELISA
- ELLA
- MSD
- ELISpot
- FluroSpot assays
- PK/ADA/Nab



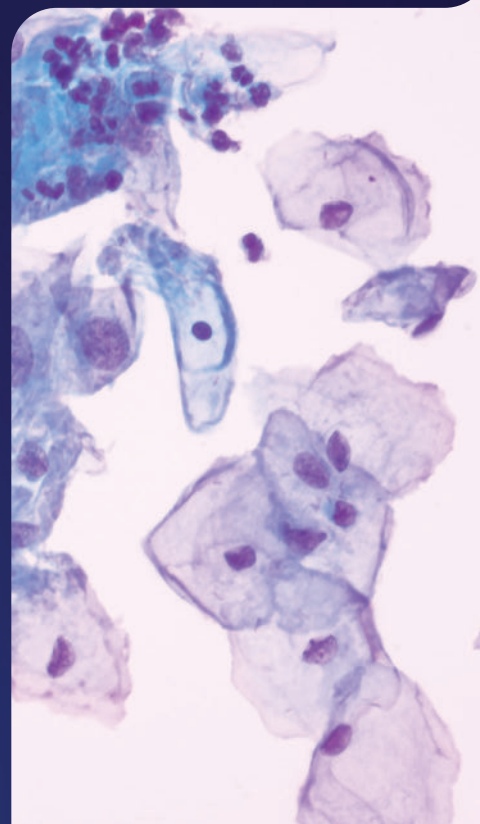
## Cell

- Flow Cytometry
- Cytex Aurora Immunophenotyping (including intra-cell markers)
- Receptor occupancy
- MRD detection (for MM by EuroFlow)
- CAR-T cell enumeration
- CAR-T cell phenotyping
- Intracellular cytokine detection
- PBMC isolation
- BMCC isolation
- Optical genome mapping, our next-generation cytogenetics
- PK/ADA/Nab



## Tissue

- Multiplex / simplex IHC
- 250+ biomarkers/protocols
- Full histopath service
- Halo®, Visiopharm®
- AI in image analysis
- Board certified pathologists
- Large biobank
- Strong immuno-oncology simplex and multiplex panels
- Spatial analysis of the tumor microenvironment
- NanoString® GeoMx, FISH, ISH



## About

# Cerba Research

Cerba Research is a leading laboratory services provider across all clinical development phases, to the life science industry (or pharmaceutical, biotechnology, medical device, government, and public health organisations). It combines the deep scientific expertise of specialist services with the capacity and breadth of a global central laboratory network. Cerba Research develops innovative solutions to unique challenges in research and drives operational agility at scale for multiple therapeutic areas, with world recognised expertise in virology and oncology. It is part of the Cerba HealthCare Group with 15,000 employees on five continents, driven to advance health diagnosis.

## Interested in How We Can Shape Your Laboratory Strategy for Better Outcomes?

Get in touch today and see how Cerba Research will support your next program.

[cerbaresearch.com](https://cerbaresearch.com)



### Cerba Research Data In-House:

NGS: Next-generation sequencing, ctDNA: Circulating tumor DNA, HLA: Human leucocyte antigen, TCR: T cell receptor, MSD: Mesoscale discovery, Flow Cytometry, PBMC: peripheral blood mononuclear cell, BMM: Bone marrow mononuclear cell, PK/ADA/Nab: Pharmacokinetic/antibody-drug antibody/neutralizing antibody, IHC: Immunohistochemistry, FISH: Fluorescence in situ hybridization, ISH: In situ hybridization.