

# Advancing Cell & Gene Therapy Trials With Confidence

Cerba Research is uniquely positioned to support your Cell and Gene Therapy trial with a wide range of in-house laboratory services, supported by bespoke logistics solutions.

We are also able to support sponsors with their assay development, including our regulatory and IVDR certification capabilities.

One IVDR example is related to AAV (ADA) ELISA assay.



## Our Track Record



85%

Trials include specialty testing



~60%

In hematological malignancies



50+

CGT trials since 2018



40%

CAR-T driven



~6K

Patients screened



4.8K+

Randomized patients



5

Market authorizations/expansions

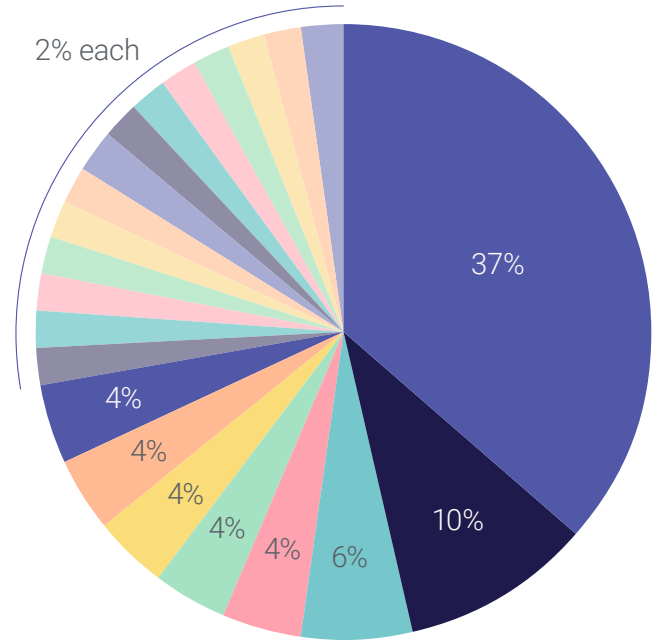


AAV

Adeno-associated virus assay development

## CGT Trials by Indications Since 2018

37%	Multiple Myeloma
10%	Acute Myeloid Leukemia
6%	Solid
4%	Non-Hodgkin Lymphoma
4%	Epidermolysis bullosa
4%	Colorectal cancer
4%	Gastric Adenocarcinoma
4%	Stargardt Disease
2%	B-cell malignancies
2%	Acute or Chronic Liver Failure
2%	Acute Lymphoblastic Leukemia
2%	Macular Degeneration
2%	Hemophilia A
2%	Hematologic Malignancies
2%	Leukemia
2%	Neuropathy
2%	Osteoarthritis
2%	Pancreatic Ductal Adenocarcinoma
2%	Pompe Disease
2%	Rod-Cone Dystrophy
2%	Spinal Muscular Atrophy
2%	Wilson Disease



## Sponsor Type

60%	Biotech/Pharma
35%	Large Pharma
4%	Midsized Pharma
2%	Other

## Clinical Trial Phases

31%	Phase 1
48%	Phase 2
15%	Phase 3
4%	Phase 4
2%	NC

# HLA Typing Vs Anti-HLA Antibodies Vs HLA Class I and II

Available at Cerba Research



01.

**Cerba NL:** 2 HLA typing NGS kits (CareDx® AlloSeq™ Tx17 and GenDx HLA Typing)



02.

**Cerba Paris:** HLA typing used for both routine and clinical trials use (AllType™ FASTplex NGS)



03.

**Our US lab (CA)** which is CAP/CLIA, also offers the CareDx® AlloSeq™ Tx17 and GenDx HLA typing

## Project Type

Type of Tests Requested

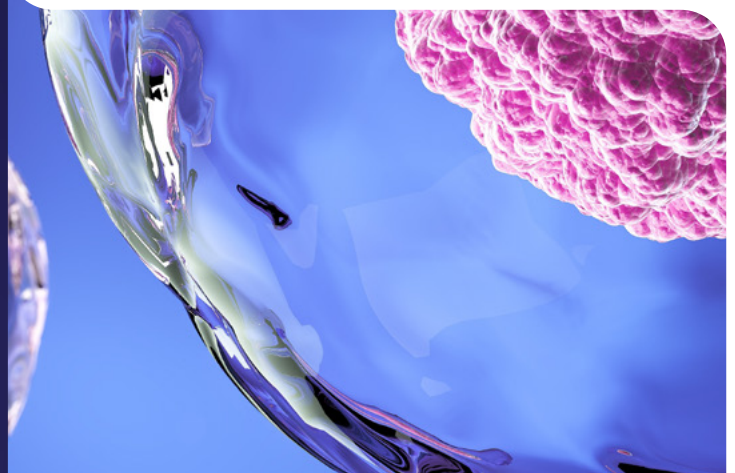
65%	Specialty
21%	Routine and Specialty
6%	Validation
4%	Routine
4%	Supplies Only

## Asset Class

44%	CAR-T
21%	NK Cell Therapy
19%	Cell Therapy
10%	Gene Replacement Therapy
4%	Autologous T Cells
2%	Engineered Donor Grafts

## Therapy Area

58%	Oncology - Hemato
17%	Oncology - Solid
10%	Other (e.g. Rare)
6%	Inflammatory
6%	Metabolics
4%	Neurology



# Our Off-the-Shelf 37-plex MSD Panel

## CRS Is Critical For Pharmacodynamics Within CGT Trials

Many diseases are characterized by inflammatory processes. Cytokines, as mediators of inflammation may serve as biomarkers (PD) to characterize disease progression and therapy response. The 37-plex MSD panel is also relevant for cytokine release syndrome (CRS) safety assessment for CGT trials. CRS may include fatal or life-threatening reactions occurring following treatment with investigational CGTs.

### 37-plex panel MSD (matrix : EDTA plasma/serum)



#### Proinflammatory

- TNF- $\alpha$
- IFN- $\gamma$
- IL-1 $\beta$
- IL-2
- IL-4
- IL-6
- IL-8
- IL-10
- IL-12p70
- IL-13



#### Chemokine

- Eotaxin
- Eotaxin-3
- MIP-1 $\alpha$
- MIP-1 $\beta$
- IP-10
- MCP-1
- MCP-4
- MDC
- TARC



#### Cytokine

- GM-CSF
- IL-5
- IL-7
- IL-12/IL23p40
- IL-15
- IL-16
- IL-17A
- TNF- $\beta$



#### Angiogenesis

- VEGF-A
- VEGF-D
- Tie-2
- Flt-1
- PlGF
- bFGF



#### Vascular

- SAA
- CRP
- VAM-1
- ICAM-1

## 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)



### Acronyms

AAV: Adeno-associated viruses, ADA: Antibody-drug antibody, CA: California, CAR: Chimeric antigen receptor, CAR-T: Chimeric antigen receptor T cell, CGT: Cell & Gene Therapy, CRP: C-reactive protein, CRS: Cytokine release syndrome, EDTA: Ethylenediaminetetraacetic acid, HLA: Human leukocyte antigens, MSD: Mesoscale discovery, NGS: Next-generation sequencing, NK: Natural killer, Seq: Sequencing, US: United States.

