eurofins | Clinical Trial Solutions

Cell & Gene Therapy Clinical Development Testing

Cell therapy and gene therapy are overlapping fields of drug research, with both emerging as some of the most promising approaches to treating cancer as well as other genetic and acquired diseases.

These rapidly evolving fields carry complexities that create challenges to developing and implementing applicable bioassays for evaluating their safety and efficacy as part of the clinical trial process. With so many unique therapies in development, there is also an increased need for specialty assays; and the requisite scientific expertise to understand how to apply the best technology to develop, validate, and implement custom methods for clinical studies. Securing the right CRO partner to help navigate these complexities is critical.

At Eurofins Clinical Trial Solutions, we draw upon the broad expertise of our scientists, and a comprehensive portfolio of analytical technologies, to provide customised solutions that help accelerate the clinical development of our clients' innovative cell and gene therapies.

Whether your approach involves gene addition, gene editing, RNA-based, or adoptive cell therapy; you can rely on our deep knowledge and experience to tailor the right bioanalytical methods to ensure the success of your research.

Gene Therapy Assays

Molecular Bioanalysis & Biomarkers:

- qPCR/dPCR to measure transgene expression, viral shedding, biodistributions, and persistence
- NGS to identify gene signature correlated with clinical outcomes
- NanoString: Enables gene expression profiling
- RNA Sequencing: Provides insights into cellular responses
- Quantitative analysis (qPCR & dPCR for replication competence for retroviral vectors (RCL/RCR)

Pharmacokinetics (PK):

- qPCR/dPCR

Immunogenicity:

- Assays for measuring Anti-Drug Antibodies (ADA) against viral vectors
- Neutralizing Antibody (NAb) assays to test for neutralizing activity against the therapy vector
- Cell-based functional assays using flow cytometry and Enzyme-linked Immunosorbent spot (ELISpot) to assess immune response

Efficacy:

- Flow cytometric detection of the target protein

CELL & GENE THERAPY TECHNOLOGIES

Next-generation Sequencing (NGS)

nanoString

Polymerase Chain Reactor (PCR)

Flow Cytometry

ELISpot

Immunoassay

EUROFINS BIOINFORMATICS CENTER OF EXCELLENCE

Our team of bioinformaticians, data scientists, and IT specialists provide a range of services to support C&GT development, including analysis of molecular and phenotypic data from:

- NGS data processing
- Metagenomics
- Transcriptomics
- Structural-biology
- Flow Cytometry

Cell & Gene Therapy Clinical Development Testing

Cell Therapy Assays

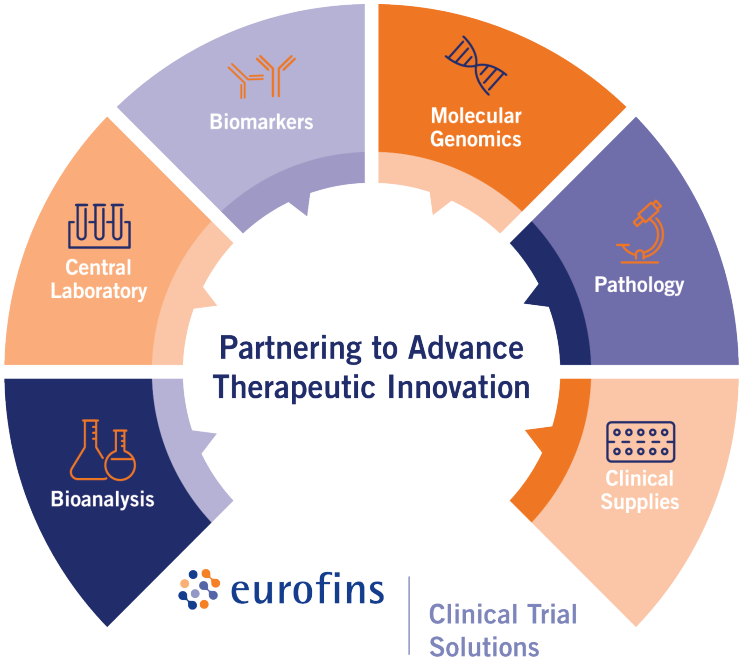
Immunogenicity and PK/PD Assessment:

- Flow cytometric phenotyping of immune cell populations, including modified immune cells (e.g., CAR-T cells)
- Flow cytometric enumeration (Lyse/No Wash Whole Blood)
- Enzyme-linked Immunsorbent spot (ELISpot) to measure cellular immunity
- Cytokine ELISA/MSD to detect Cytokine Release Syndrome (CRS)
- qPCR/dPCR for measuring persistence and expansion and for engineered transgene detection

Biomarker Analysis:

- RNA-seq gene expression to assess efficacy
- NanoString nCounter to quantify specific RNA or protein targets
- Ligand binding assays using ELISA (e.g., IL-2 release for PD-1/PD-L1 and CTLA-4; IL-8 release for OX-40)
- Flow cytometric phenotyping of immune cell populations (endogenous and CAR differentiation)
- Evaluation of expression levels of the CAR target protein using quantitative flow cytometry

Cell and gene therapies have demonstrated patient benefits, and the quality of bioassay methods for safety and efficacy assessment plays an important role in ensuring the success of these novel therapies. Regardless of the type of cell or gene therapy under development, our scientists can design detailed protocols for method development, validation, and transfer at multiple phases of the development process, with expertise across multiple specimen types, including PBMC, whole blood, bone marrow, serum, urine, saliva, and nasal swabs.



40 years of Scientific Experience

Trusted Laboratory Partner

CAP Accredited CLIA Licensure

Over 3,000 validated assays

Contact us today to discover how the Eurofins Clinical Trial Solutions team can make the difference in your projects.

Eurofins Viracor BioPharma
18000 West 99th Street
Lenexa, KS 66219 USA
Tel +1 800 305 5198

clinicaltrials@vbp.eurofinsus.com
eurofins-viracorbiopharma.com