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Cell & Gene Therapy Clinical Development Testing

Increased understanding of cancer immunology in recent years has aided the discovery of new therapeutic technologies that work by manipulating the immune response. These immunotherapies have emerged as some of the most promising approaches to treating cancer patients.

However, the complexity of both tumors and the immune system interaction creates many challenges to developing and implementing applicable bioassays for evaluating the distribution, safety, and immunogenicity of these therapies as part of the clinical trial process. In addition, with many unique immuno-oncology therapies in development, there is an increased need for specialty assays; and the requisite scientific expertise to understand how to apply the best technology platforms to develop, validate and implement custom assays for clinical studies.

At Eurofins BioPharma Services, we offer a variety of innovative ligand-binding, genomic and cell-based testing services for immunotherapy trials, combining our expertise with state-of-the-art technology/platforms.

Gene Therapy (oncolytic viral vector)

Oncolytic viruses constitute a new promising therapeutic approach for the treatment of cancer, offering the potential to deliver customized therapy to specific targets, at the cellular level. However, because immunogenicity of oncolytic viral therapy includes both adaptive and innate immune responses (toward the vector delivery system and for the transgene product), their development can involve some unique challenges in assessing interference, and the impact of pre-existing antibodies.

Eurofins BioPharma Services offers a broad portfolio of clinically relevant testing services to aid in development of gene therapy drugs involving viral vectors, including:

- Transgene or target protein expression
- Detection and quantification of the viral genome in serum (or target tissue)
- Assays for measuring anti-drug antibodies (ADA) against the oncolytic virus
- Neutralizing Antibody (NAb) assays to test for neutralizing activity against the gene therapy vector.
- Cell-based assays for immune function and proliferation.
- Quantitative analysis of viral shedding by qPCR for safety testing to assess potential for transmission.

Our scientists also have broad expertise in assay development for the assessment of ADAs and NAbs, as well as viral shedding assays, and other immunogenicity testing for clinical trial studies with validation expertise across multiple specimen types, including serum, urine, saliva, and nasal swabs.

CELL & GENE THERAPY TECHNOLOGIES

Oncolytic Viral Vectors:

These engineered viruses selectively help kill tumor cells without harming normal ones, with the bonus of stimulating the patient's immune response.

CAR T- Cell Therapy / Adoptive Cell Therapy:

Chimeric antigen receptor (CAR) T-cell immunotherapy is a rapidly growing personalized treatment that expands native cellular products ex vivo for re-infusion into patients.

Checkpoint Inhibitors (PD-1 or PD-L1 inhibitors, CTLA-4 inhibitors):

These drugs remove inhibitory signals of T-cell activation, which enables tumor-reactive T cells to overcome regulatory mechanisms and mount an effective anti-tumor response.

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Cellular Therapies / Chimeric antigen receptor (CAR) T-cell therapy

This therapeutic approach turns the immune system's cancer-fighting cells into better defenders by either increasing their fighting ability or their numbers. However, the construct and vector used sometimes necessitate custom assay design for immunogenicity assessment of humoral or cellular-type responses.

The platforms and technologies available to Eurofins BioPharma Services clients include many analytical methods applicable to this category of immunotherapy, such as specific ligand binding, cell-based, and genomic assays, including:

- Immunoassays (ELISA, MSD, Luminex) to measure cytokines and potential ADA
- CAR T-cell detection and quantification by flow cytometry in PBMC (peripheral blood mononuclear cell) samples
- Enzyme-linked Immunospot (ELISPOT) analysis for characterizing specific T- or B-cell responses.
- Measurement of gene expressions performed by quantitative polymerase chain reaction (qPCR, ddPCR, or NGS).
- Multi-color flow cytometry for analysis of intracellular targets and lymphocyte differentiation

Checkpoint Inhibitors

In recent years immune checkpoint inhibitors have garnered attention as being one of the most promising types of immunotherapies on the horizon. Checkpoint inhibitors yield positive clinical responses by targeting key immune checkpoints to restore exhausted T cells, resulting in more effective anti-tumor immune function. As with all immune-therapies and biologics, a thorough immunogenicity assessment is important for managing drug and target interference, understanding and handling the impact of pre-existing antibodies, and interpreting the clinical significance of assay data.

Relevant assays offered by Eurofins BioPharma Services to support clinical development of checkpoint inhibitors include:

- Biomarker ligand binding assays using ELISA (e.g., IL-2 release for PD-1/PD-L1 and CTLA-4; IL-8 release for OX-40).
- Inhibitor efficacy determined by proliferation and cytokine secretion assays via ELISpot technology
- Functional assays, as well as intracellular cytokine staining by 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 immunotherapy under development, our scientists can design detailed protocols for method development, validation, and transfer at multiple phases of the development process. A dedicated project manager will also ensure all parties involved in the project are aligned on project requirements, timelines and budgets.

>35 years of Scientific Experience

Trusted Laboratory Partner

CAP Accredited CLIA Licensure

Over 3,000 validated tests

Contact us today to discover how the Eurofins BioPharma Services team can make the difference in your projects.

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