VERISTAT

CRO of Choice for Cell and Gene Therapies

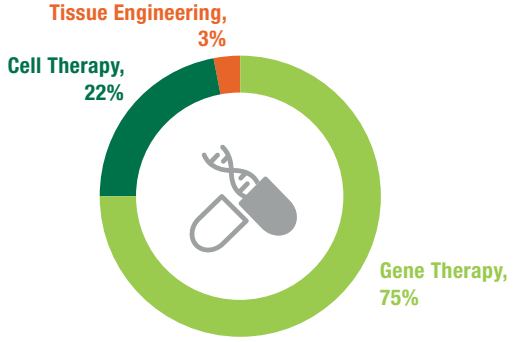
Tailored Strategies and Expert Insights to Accelerate Your Cell and Gene Therapy to Market

Nothing is standard about study design, trial conduct or regulatory process in this specialized area. Veristat has assembled a scientific team of experts who are adept at strategy and execution across the clinical development journey. Whatever the study's unique considerations – patients, products, process, follow-up, regulatory – Veristat can successfully get you through it.

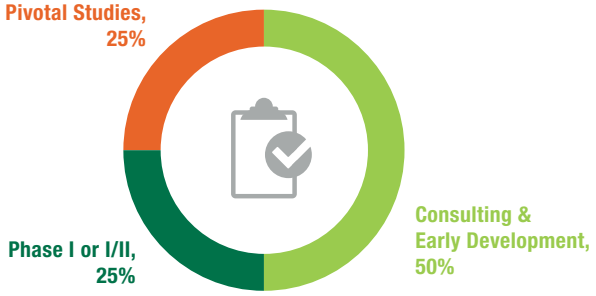
110+
cell and gene therapy programs in the last 5 years

Executed trials for the **first gene therapy approved in Europe**

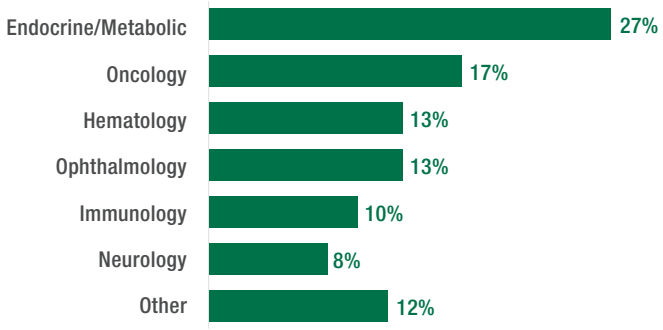
EXPERIENCE BY TYPE



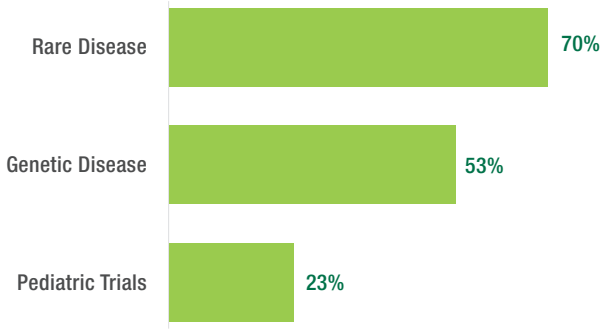
TRIALS BY PHASE



TRIALS BY THERAPEUTIC AREA



TRIALS BY CATEGORY



Delivering Results Across a Complex Clinical Development Pathway

Veristat offers tailored solutions from early stage through submissions and post-marketing approval. We're here to help you get your cell or gene therapy to market faster and positively impact patients around the world.

- World-class regulatory and clinical insights
- Proven track record with accelerated paths/ special designations
- Centralized site model/ remote monitoring
- Direct-to-patient capabilities
- Expertise in logistics/ handling genetic material
- Experience across all major therapeutic areas

Advanced Therapies Require Special Regulatory Focus

Maintaining strong relationships and interactions with key global regulatory agencies is critical. Our team has deep expertise in all accelerated pathways to approval, and in applying for and retaining special designations. Through ongoing regulatory engagement, we keep up with the constantly changing landscape for advanced cell and gene therapy products.

25+ cell and gene submissions completed

3 Marketing Application approvals including BLA and MAA

VERISTAT

CASE STUDY

Guiding a Complex Gene Therapy Trial to BLA Submission

A Game-Changing Central Site Model Paves the Way

Situation: A clinical-stage biotechnology start-up asked Veristat to run complex international trials of their gene therapy for a rare pediatric indication. Veristat brought invaluable global capabilities and expertise to a small client team tackling their first clinical stage program.

Solution: Confronted with various hurdles and regulatory issues, Veristat's global cell and gene therapy team created new agile processes to help the sponsor reach the application stage. A new model was set up allowing patients to receive the gene therapy treatment at central sites, then have follow-ups with their local doctors.

Impact: Now prepared to submit for BLA, the sponsor has assigned Veristat to handle European regulatory affairs on this program and undertake further work, continuing with the same experienced gene therapy project teams.

Contact Veristat Today

Learn more about Veristat and how we can assist you with your cell or gene therapy trial development, execution, and regulatory submission preparation.

www.veristat.com

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