Clinical development solutions for cell and gene therapy

At Fortrea, we are committed to driving clinical development of cell and gene therapies forward and helping you transform the future of healthcare.

Fortrea

Fortrea's teams bring dedicated cell and gene expertise for emerging target indications. Our multi-disciplinary operational, medical, and regulatory teams provide comprehensive, strategic insights to enable efficient, cost-effective development of your therapeutic and reduce risk across critical milestones.

Fortrea's deep and broad experience with cell and gene therapies and integration of critical services within a single global organization amplifies proven clinical trial approaches, streamlines complex processes, and minimizes risk.

We are committed to helping you transform the future of healthcare by bringing promising cell and gene therapies to more patients.

70+ **Indications of clinical study experience for cell and gene therapies**

No matter where you are or where you intend to go, we're here to provide the global infrastructure you need combined with the personalized experience you deserve throughout your clinical development journey.

Holistic regulatory strategy and services

With comprehensive experience in cell and gene therapy, our global regulatory affairs organization can help you develop an effective program strategy and meet critical regulatory milestones, potentially including expedited program designations. Whether your goals are related to reaching IND/IMPD/CTA or going beyond to achieve BLA/MAA or other submissions, our team can support you with the right expertise.

- Target Product Profile Development
- Comprehensive Clinical Development and Plan Generation
- Regulatory Authority Engagement (e.g., INTERACT Meeting)
- Dossier Assembly, Publishing and Submission
- Scientific Review and Gap Analysis
- Long-Term Follow-Up Strategy
- Global Experience and Expertise

Comprehensive clinical development

Fortrea has a complete range of support from first in human and dose range-finding to long-term follow-up monitoring and testing strategy.

- Cell and gene therapy expertise across oncology, immuno-oncology, rare diseases, and pediatrics
- Cell therapy logistic solution and unique Long-Term Follow-Up operational model
- Patient advocacy group and patient community interactions and insights
- Protocol development, modeling, design, and statistical support
- Project management and oversight
- Medical monitoring and specialized training for AEs
- Clinical monitoring, data management and biometrics

150+ **Clinical studies for cell and gene therapy products involving First-In-Human and registrational studies**

Conducted in the last 8 years, with 16,000+ patients across 1,600 sites across U.S., Europe and Asia (AAV and lentivirus-based vectors, autologous/allogenic cells including iPSCs and gene editing)

Patient-centric clinical trials designed to enable access to your innovative treatment

For cell and gene therapies, the challenges of clinical trial recruitment and retention require a deeper understanding of patients' needs, disease- and indication-specific considerations and individual participation hurdles.

We draw actionable insights from our expansive datasets, including real-world patient data gleaned from our unprecedented patient access to improve recruitment—designing trials that address the specific needs of every patient.

Identification and Recruitment

PATIENT ADVOCACY GROUPS

Collaborating on visibility and enrollment in indication-specific clinical trials, including those for pediatric patients.

Trial Design

VOICE OF PATIENTS AND CAREGIVERS

Providing critical insights on patient preferences, as well as the needs and considerations of their caregivers.

Trial Conduct, Operations and Patient Retention

DECENTRALIZED TRIAL SUPPORT

Using integrated, technology-enabled solutions that reduce patient burden and make participation easier.

FLEXIBLE AND ROBUST LOGISTIC SOLUTIONS FOR CELL THERAPIES

Logistical oversight and management of the product delivery to sites from scheduling a patient visit to processing cells to getting cell therapy product back to the investigative center.

Registrational Trials and Long-term Follow-up

Full-service support for extended long-term follow-up, optimization of availability, long-term safety and value demonstration for your cell and gene therapeutic.

- Early access strategies to support commercialization including ideal site selection, optimal patient recruitment, and more accurate forecasting
- Comprehensive market access strategy
- Decentralized trial solutions to decrease patient burden and optimize engagement

Monitoring patient safety and efficacy through extended long-term follow-up

Cell and gene therapies can have the potential for long-lasting or curative effects. However, the novel nature of these treatments means extended long-term follow-up of up to 15 years may be required. To alleviate the challenges these timelines present, we approach your long-term follow-up with:

Ongoing dialogue with regulators

Developing a well-defined regulatory strategy that focuses on study design to support the success of extended long-term follow-up for cell and gene therapies

Holistic program approach

Collecting data through local physicians, generating disease and product registries and using interventional trials to inform long-term follow-up design

Minimizing patient and sponsor impact to promote engagement

Reducing burden and cost while encouraging compliance with technology (e.g., televisits, mobile clinical services, etc.) and real-world data

Optimizing availability and demonstrating long-term safety and value for your cell or gene therapy

Given the unique nature of cell and gene therapy products, the significant cost of treatment, shifts from prescriber- to patient-driven choices and the need to demonstrate value, it is critical to start developing your market access strategy early in clinical development.

Our Market Access team takes a comprehensive approach to your commercialization strategy with focus on:

- Understanding the market access landscape and recommending strategies to position your product with key stakeholders
- Developing health economic models and assessing disease burden to inform clinical development and market access strategy
- Generating real-world evidence to demonstrate benefit and durability for reimbursement

Exceptional is possible

Harnessing our passion for scientific rigor and decades of clinical trial experience, we're looking to navigate obstacles with agility and ease. We are problem solvers and creative thinkers committed to opening the doors between promising ideas and proven therapies.

LEARN MORE at fortrea.com

Fortrea