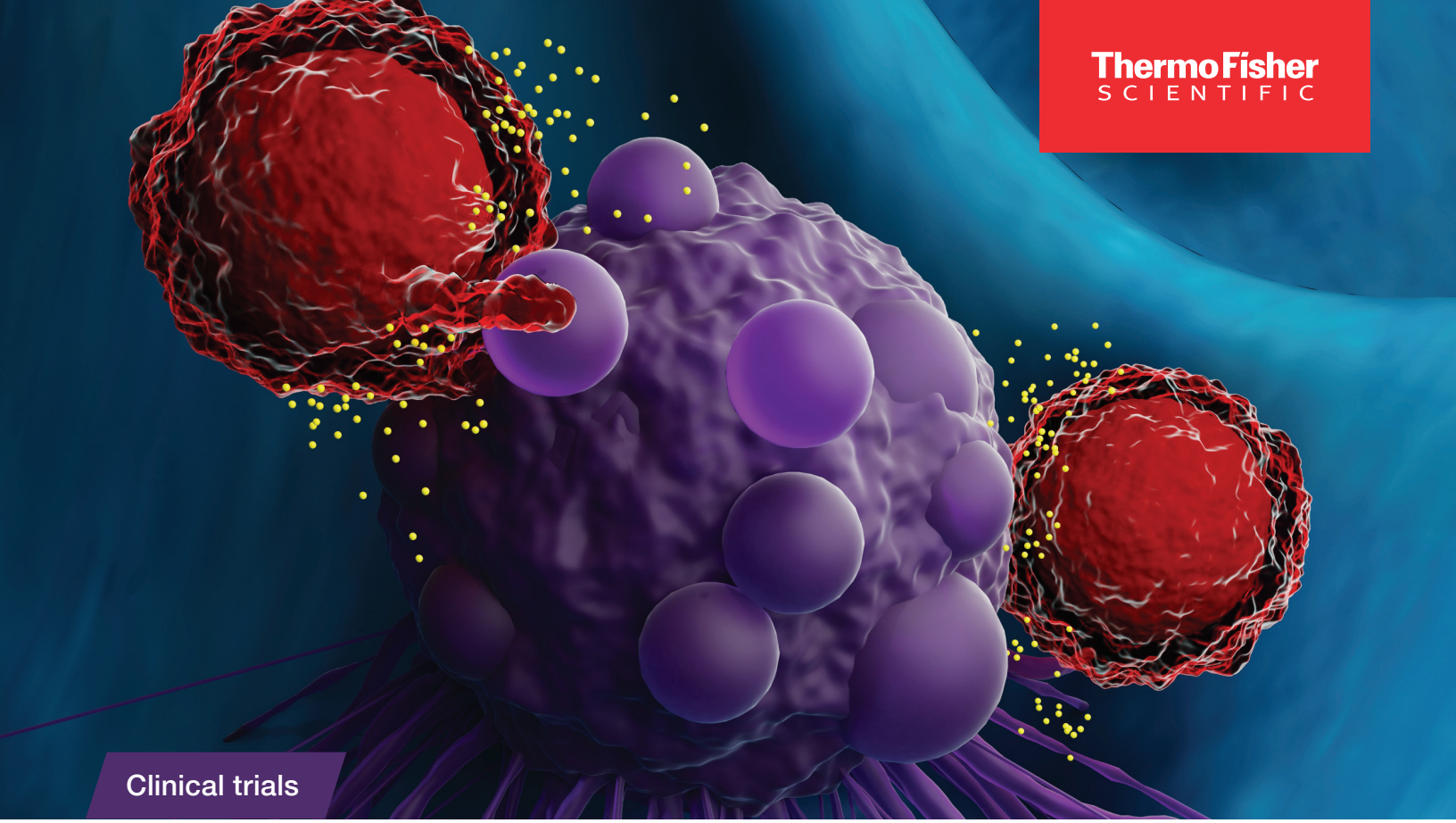


Innovating the future of medicine through cell therapy clinical development

ppd

Redefining what's possible in cell therapy

Cellular immuno-oncology is the development and use of living immune cell therapies — often collected from a patient or donor, expanded and/or genetically engineered outside the body, and then infused back — to recognize and eliminate cancer cells. Chimeric antigen receptor T-cell (CAR-T) therapy is the best-known example. First developed for hematological diseases, where it showed dramatic clinical success, the field is now expanding into solid tumors as advances in cell engineering, target selection, and strategies to overcome immunosuppressive tumor environments improve effectiveness. These same technologies are also being applied to autoimmune diseases, where engineered cell therapies have the potential to restore immune balance rather than simply suppress symptoms.

At the PPD™ clinical research business of Thermo Fisher Scientific, we believe in the promise of cell therapies to treat unmet medical needs. Our multi-disciplinary team of experts has deep insights into the sophistication required to develop and execute a cell therapy study to the highest standards. Our full spectrum of services is designed to support sponsors at every stage of their clinical development journey, including both *ex vivo* approaches (cells collected and modified outside the body before reinfusion) and emerging *in vivo* strategies that engineer or direct immune cells within the patient.

Advancing cell therapy programs with more than a decade of real-world experience

By pairing deep CGT insight with proven clinical execution, we enable you to navigate complexity and bring your therapies closer to patients.

In the past five years, our team have supported:

75+ Cell therapy trials across both autologous and allogeneic cell types, including T cell infiltrating lymphocytes (TILs), CAR/TCR-T, CAR-NK, B cells, dendritic cells, and stem/progenitor cells

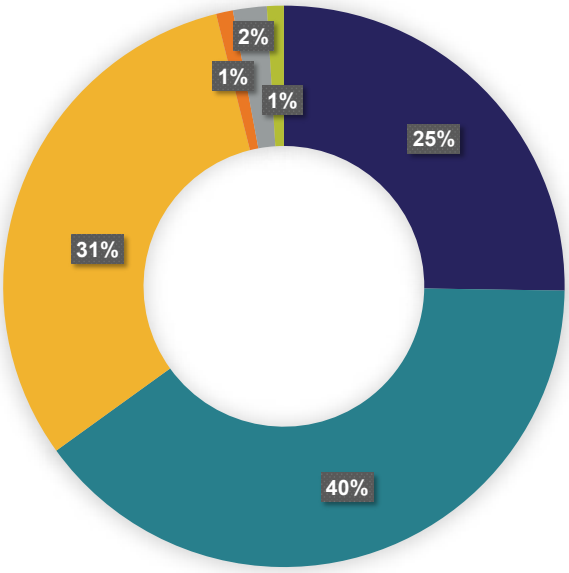
155+ Cell and gene therapy (CGT) clinical trials spanning therapeutic areas that include hematology, rare disease, oncology, immunology, urology, neurology, cardiovascular and more

75+ Gene therapy trials across adenoviral, adeno-associated viral (AAV), lentiviral and gamma retroviral vector delivery platforms

300+ Projects in CGT value demonstration, market access and commercial strategies

*# of studies listed here is from our full-service offering and does not include functional services or consultative offerings.

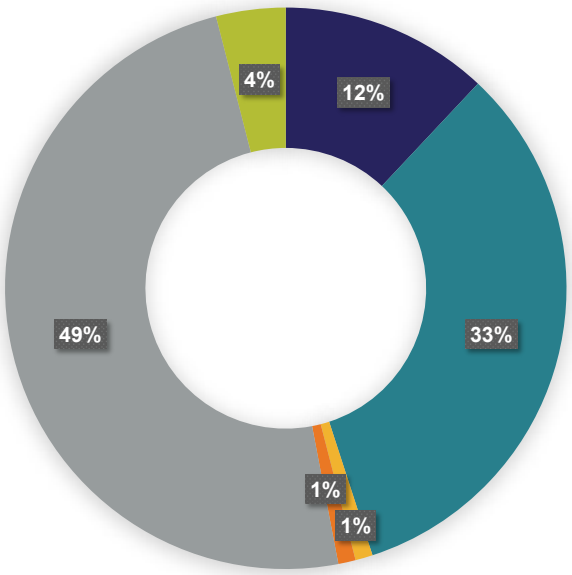
Experience leading CGT studies across different therapeutic areas



155+

CGT studies in the past five years across six therapy areas

Cell therapy clinical experience in different primary and immune cell types



75+

CT studies in the past five years across all cell types

Unmatched expertise in hematology/oncology

When managing complex studies such as cell therapy trials, it's critical to partner with a CRO that brings deep expertise and proven execution. We've spent decades supporting the strategic development and operational management of CGT programs — from identifying and activating highly qualified sites and aligning start-up activities across regions, to safeguarding chain of custody and chain of identity across all collections and shipments. Our teams coordinate time-sensitive scheduling and logistics, enable robust vendor and lab oversight, and maintain clear end-to-end visibility to help reduce risk and variability. We also deliver patient-centric solutions — education, travel and reimbursement support, and concierge-style coordination — to improve enrollment, retention, and overall trial experience, while maintaining rigorous quality and compliance standards throughout.

530+ Oncology studies

240+ Phase I oncology studies

400+ Oncology/hematology patients treated with cell therapies

70+ Oncology/hematology cell therapies sites

80,000+ Oncology patients

23,000+ Sites

60+ CGT studies in hematology/oncology

1 approved oncology autologous cell therapy product

Through the complexities of cell therapy trials, we stand with you at every step

Conducting cell therapy clinical trials involves a different set of challenges than conventional drug studies, with specialized requirements that need close coordination across clinical sites, labs, and logistics partners. Common issues include time-sensitive scheduling, variability in site readiness, complex chain of custody/identity processes, and data capture complexity, which can contribute to delays, slower recruitment, data quality gaps, and budget pressure. A structured approach can help reduce these risks. For each program, we align staffing and functional expertise to the protocol and operational model, develop tailored execution plans, and focus on consistent oversight and communication from start-up through closeout. A key element is close collaboration with sponsors and maintaining agility — using frequent touchpoints and clear decision pathways to surface issues early and pivot as protocols, sites, timelines, or business needs evolve.

As an industry leader in cell therapy clinical research, we leverage our extensive experience and industry-leading capabilities to address these challenges and support your cell therapy clinical trials.

Complex monitoring

We support the design and implementation of a comprehensive data monitoring plan to ensure quick detection of safety concerns and enable protocol modifications as needed.

Chain of identity and custody

We implement a comprehensive set of chain of identity and custody protocols to safeguard the traceability and quality of each shipment.

Long-term follow-up

We assist our partners in developing long-term follow-up (LTFU) protocols that prioritize the needs of patients and caregivers.

Site competition

We provide a hub-and-spoke site network model that centralizes expertise and resources, ensure high-quality cell handling and reduces data variability.

Limited qualified trial sites

Through our innovative Cell Therapy SiteCoach™ training program, we enable sponsors the option to broadening their study to new sites, including community clinics.

Cold chain logistics

Our dedicated cell therapy team of clinical logistics monitors use real-time monitoring and tracking systems to maintain precise temperature controls and manage risks proactively.

Stringent regulatory requirements

Our team of regulatory experts offer strategic guidance specific to your asset and business objectives.

Cell Therapy SiteCoach™

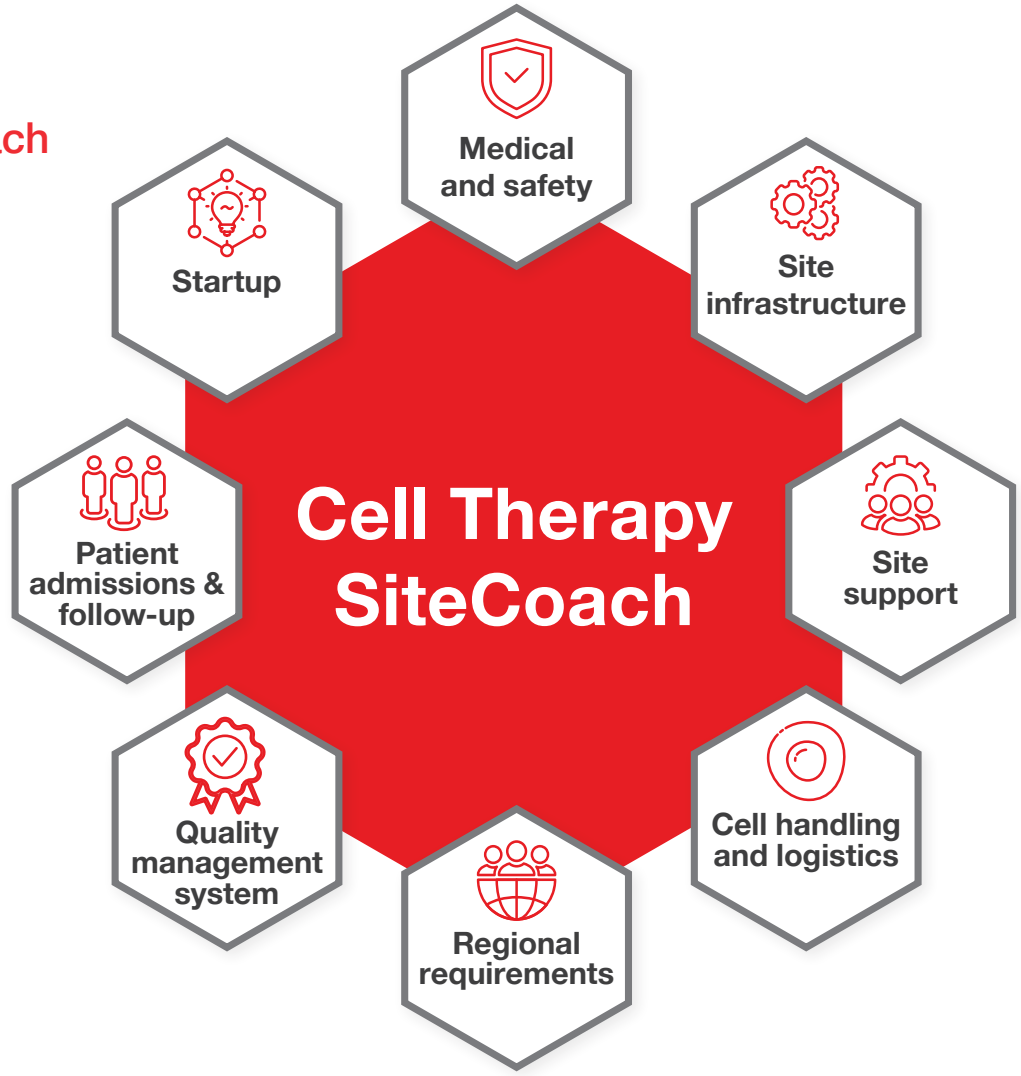
Training and support for new sites to meet surging demand

As cell therapies expand beyond major academic centers and into community clinics, specialized training becomes an important prerequisite to ensure teams are prepared to deliver these complex modalities safely and consistently. Anticipating this need, we developed Cell Therapy SiteCoach, a comprehensive training program that shares best practices and offers coaching and support to health care practitioners who are new to clinical research or new to cell therapy. This customized training program enables a more successful experience for patients and supports sites in offering additional options to individuals seeking relief or interested in contributing to medical research.

Cell Therapy SiteCoach training overview

Preparing sites to help deliver successful cell therapy trials

- Taught by our experienced, multi-disciplinary team of clinical development experts
- Training modules offered in a real-time, virtual class and/or pre-recorded sessions
- Intended for principal investigator (PI), co-PI, sub-PI, study coordinator, and key operations staff



Through SiteCoach, sites receive:

- Comprehensive training and tools at each stage of the clinical trial process
- Optimally timed training before, during and after the study to ensure continuity of support
- Virtual, in-person or hybrid training approach to meet your specific needs
- A user-friendly online interface
- Access to our Cell Therapy Center of Excellence team members
- Opportunity to join the PPD™ Select site network
- Opportunity for investigators to join the our Cell Therapy Investigator Network

Through this innovative site education solution, clinical sites interested in establishing or enhancing their cell therapy capabilities will be enabled with comprehensive training materials following FACT-JACIE* international standards for immune effector cells. This will enable our sponsors the option of broadening their study to new sites and reach more patients.

*Foundation for the Accreditation of Cellular Therapy-Joint Accreditation Committee, ISCT (International Society of Cellular Therapy), European Society for Blood and Marrow Transplantation

FACT and JACIE are independent organizations. PPD™ clinical research business of Thermo Fisher Scientific has no affiliation with, endorsement from, or partnership with FACT or JACIE.

A CRO partner that is flexible to your needs

We enable you to conduct efficient, compliant, and scientifically robust cell therapy clinical trials, bringing innovative therapies to patients faster and more effectively.

How we partner

For emerging biotech companies

Start-up and mid-sized biotech organizations need to deliver timely and high-quality results to satisfy their investors, especially when venturing into the cell therapy market for the first time. We understand these pressures and forge partnerships with a shared biotech mindset. You maintain hands-on oversight of your study and full stewardship of your asset, with clear visibility into every stage of execution. Our empowered cell therapy teams operate with end-to-end accountability, giving you transparency into our processes, reliable financial forecasting, and the agility to adapt quickly as your program evolves — even when priorities change.

For established biopharma companies

As an experienced partner to global biopharma organizations, we are built to operate at the scale and complexity your programs demand. We align closely with your enterprise priorities, governance models, and development strategies — ensuring execution that supports your broader portfolio and commercial objectives. Our teams understand what it takes to advance a safe, effective cell therapy from late-stage development through commercialization in a highly regulated environment.

You engage with seasoned teams who collaborate seamlessly across trial design, program execution and market access strategy. With integrated cell therapy manufacturing and clinical research capabilities, we bring a unified perspective that enables informed decision-making, operational continuity and efficient execution across the development lifecycle.

Reach your next clinical milestone with our cell therapy expertise.

Learn more at **ppd.com**

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