

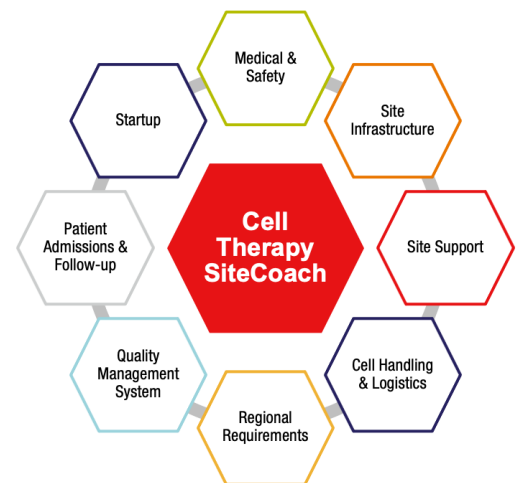
Cell and gene therapy**Cell Therapy SiteCoach™****Training and support for new sites to meet surging demand**

Cell therapy clinical development is experiencing a shortage in the number of qualified clinical sites, with these centers often located in metropolitan areas that are not easily accessible by all patients. Current clinical studies are predominantly managed by understaffed large hospitals and medical research institutions that are already saturated with studies. Meanwhile, regulatory requirements for patient diversity are driving higher demand for targeting underrepresented communities, which frequently lack appropriate infrastructure to support the complexities of a cell therapy trial. Meanwhile, sponsors are increasingly concerned with their ability to onboard sites in a timely manner, recruit patients and meet their milestones.

The PPD™ clinical research business of Thermo Fisher Scientific launches a new pilot Cell Therapy SiteCoach™ training program. 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.

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



FACT-JACIE standards outlines quality and safety standards for cell therapy. While FACT-JACIE accreditation is not required to conduct cell therapy studies, it represents a highly desirable attribute when sponsors select sites. This globally recognized accreditation is managed independently by the Foundation for the Accreditation of Cellular Therapy (FACT) and JACIE, the Joint Accreditation Committee of International Society for Cell and Gene Therapy (ISCT) and the European Society for Blood and Marrow Transplantation (EBMT).

Training curriculum

The Cell Therapy SiteCoach program consists of multiple training modules covering critical components needed to implement a cell therapy trial while adhering to the FACT-JACIE guidelines for immune effector cells. As requirements to conduct cell therapy studies evolve, our team will continue to refresh training material.

This program is designed with optimal flexibility to accommodate clinical staff members in various cross-functional roles, with no pre-requisite courses nor completion of all modules. Modules may be taken in any order and do not require completion at one time. Trainees will have a defined period to access training content. Upon request, we may offer live virtual sessions to provide additional support.

Medical & safety requirements <ul style="list-style-type: none">• Aligned to US FDA guidance (early identification, prevention, and treatment of safety issues)• Toxicities: Short and long term• Replication competent retrovirus (RCR) alert/false positive reporting• Bridging therapies	General startup considerations <ul style="list-style-type: none">• Informed consent process• Re-consent considerations• Institutional Biosafety Committee• CMC-specific requirements impacting on startup
Startup considerations <ul style="list-style-type: none">• Import/export requirements• Regional regulatory requirements• North America, Europe and Asia-Pacific regions	Site infrastructure <ul style="list-style-type: none">• Aligned with regulatory guidance• Operational equipment and facility requirements• Handling simple manipulations of fresh or cryopreserved cell products in bags• Reagent provisions
Patient admissions & follow-up <ul style="list-style-type: none">• Patient screening and consent• Pediatric population• Recruitment and retention strategies for long term follow-up, easing burden on patients and caregivers	Cell handling & logistics <ul style="list-style-type: none">• Cell journey: chain of custody and identity maintenance• Coordination among site, courier, manufacturer, sponsor/ CRO• Just-in-time delivery considerations vs. established cryo-equipment
Quality management system <ul style="list-style-type: none">• Risk-based approach for cell therapies based on FACT-JACIE accreditation checklist	Site support <ul style="list-style-type: none">• Required SOPs• Strategy to accelerate site activation• Additional resources

Site qualification and prerequisites for enrollment

The Cell Therapy SiteCoach program targets existing sites actively conducting clinical studies outside of cell therapy, with an established basic understanding of Good Clinical Practices, or sites conducting investigator-initiated cell therapy studies that are interested in expanding services to include sponsor-initiated cell therapy trials. Sites should either have access to an apheresis center, partner with local blood banks, or have a focus on allogeneic cell therapy trials. There may be investment required to develop appropriate infrastructure. As part of the Cell Therapy SiteCoach program, sites will start with a comprehensive site assessment to identify gaps. This will provide the basis for selecting appropriate training modules.

Program scope may include access to documents, checklists, and pre-recorded lectures. Not included: SOP writing, facilitation of FACT-JACIE audits, funding to onboard new capabilities.

About SiteCoach

The training you need to succeed in conducting cell therapy trials

SiteCoach is a comprehensive training program that offers sharing of best practices, coaching and support to healthcare practitioners who are new to clinical research or new to certain therapeutic modalities (e.g. cell therapy). Our customized training program paves the way for a more successful experience for your patients, enabling you to offer more options to patients who are seeking relief or want to contribute positively to medical research.

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 PPD Cell Therapy Center of Excellence team members
- Opportunity to join the PPD Select site network
- Opportunity for investigators to join the PPD Cell Therapy Investigator Network

Process for joining the Cell Therapy SiteCoach program

Site outreach	Ideal site profile: <ul style="list-style-type: none"> • Currently conducting clinical research • Applying for FACT-JACIE accreditation • Inexperienced to cell therapies or having participated only in investigator-initiated cell therapy studies • Experience in bone marrow transplant
Solicit interest	<ul style="list-style-type: none"> • Schedule introductory meeting
Secure CDA	<ul style="list-style-type: none"> • Set up confidentiality agreement
Curriculum & syllabus	<ul style="list-style-type: none"> • Site receives training curriculum and syllabus
Gap analysis	<ul style="list-style-type: none"> • Site to complete questionnaire assessment survey • Site to confirm commitment to training and desire to obtain FACT-JACIE accreditation within next 24 months
Initiate training	<ul style="list-style-type: none"> • Site to identify Cell Therapy Champion for oversight, Medic-PI representative and QA staff • Schedule follow-up meeting to review training curriculum based on responses from site assessment survey • Receive access to training content
Content updates	<ul style="list-style-type: none"> • Gather feedback on training curriculum to refine training content
Post-training support	<ul style="list-style-type: none"> • Ongoing mentorship throughout FACT-JACIE accreditation journey • Post-training assessment
Join the PPD Cell Therapy Community	<ul style="list-style-type: none"> • Join PPD Select Site Network • Join PPD Cell Therapy Specialized Investigator Network • Site receives PPD completion certificate

The Cell Therapy SiteCoach program promotes excellence in adding qualified sites to meet research demands for new, life-changing therapies.

 Learn more at thermofisher.com/ppd

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