Thermo Fisher SCIENTIFIC

Autoimmune disease

Cell therapy in autoimmune disease

Beyond oncology: Cell therapy is opening a new frontier in rheumatology

Cellular therapies, including autologous CAR-T cells and emerging allogeneic and in vivo approaches, are being investigated for rheumatic and other autoimmune diseases such as systemic lupus erythematosus and multiple sclerosis. These strategies aim to reshape immune responses by targeting disease-associated cells. Early-phase and Phase II studies report feasibility and preliminary clinical activity in selected patients. Despite substantial progress in the past five years, use remains investigational, with no FDA-approved cell therapies for autoimmune disease. Broader adoption will depend on stronger evidence of durable benefit, more scalable and standardized manufacturing, manageable cost, reliable safety monitoring and the clinical infrastructure to deliver these complex treatments.

Oncology cell therapy experience. Immunology expertise. Study-specific execution.

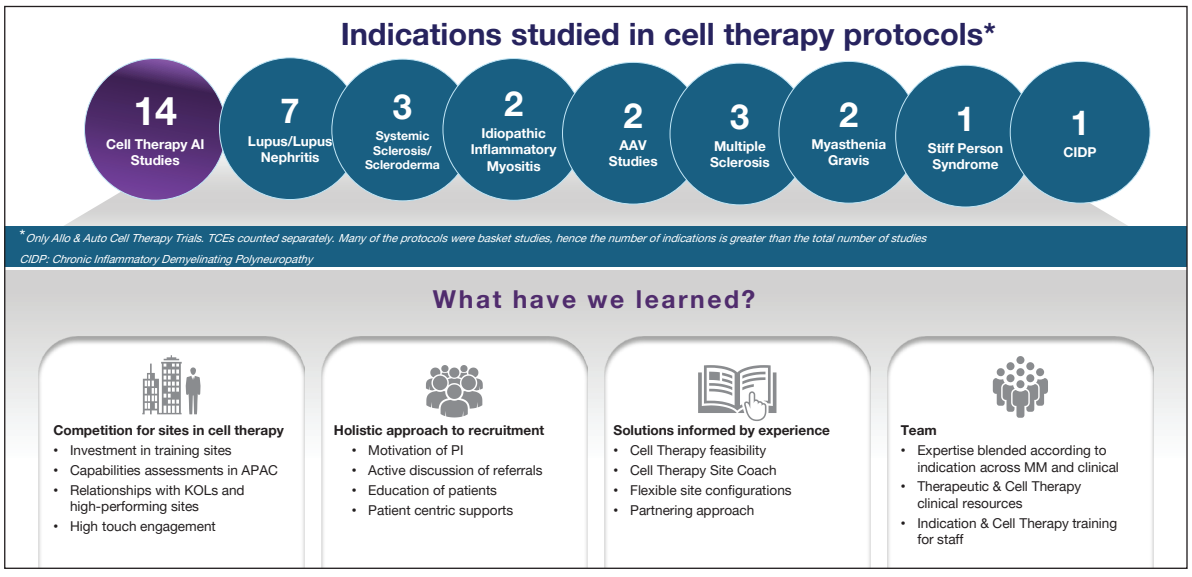
The PPD™ clinical research business of Thermo Fisher Scientific combines oncology cell therapy experience with immunology and rheumatology expertise to enable sponsors to reduce development risk, operationalize this emerging treatment paradigm and execute autoimmune cell therapy programs with confidence. Our dedicated operational strategies support complex manufacturing coordination, multidisciplinary site engagement and patient-centered trial delivery from feasibility through follow-up.

Connected immunology and rheumatology capabilities

Over the past three years, we have supported 14 cell therapy studies in autoimmunity, including 11 CART-T and four CAR-NK studies. Additionally, our experience also includes eight T-cell Engagers studies, basket studies as well as Phase I–II and pivotal experience.

Our cross-functional, cross-therapeutic teams apply this experience to operationalize planned studies through tailored feasibility, site planning, early investigator engagement and recruitment support. Established investigator and patient-group relationships, protocol-aligned staff training and resourcing matched to site and study needs help build an operating model around the investigational product and target population. Where the protocol allows, decentralized and home-health options support participant access. We also bring clinical science, data review and disease registry capabilities to address program-specific evidence needs and collaborate with researchers on emerging considerations in cell therapy beyond oncology.

Experience over the last three years



ppd

How we enable sponsors to operationalize a planned study

What we bring to your next study

- **Therapeutic insight:** A global immunology team; operational subject matter experts in cell therapy autoimmunity, lupus, rare immunology and arthritis; and a global group of seven globally distributed board-certified rheumatologists. Medical monitoring, clinical science liaisons and specialist data reviewers support study delivery and evidence review.
- **Cell therapy execution:** Experience across autologous and allogeneic approaches, informed by oncology cell therapy operations and adapted to autoimmune protocols. Teams can plan study-specific manufacturing handoffs, chain of identity and custody, time-sensitive logistics, safety oversight and long-term follow-up.
- **Sites and participants:** Global relationships with investigators, key opinion leaders, site networks and patient organizations. Feasibility and site planning can consider capability, referral pathways, recruitment, patient burden and the training required by the protocol.

From feasibility to site-ready execution

A coordinated delivery approach turns cell therapy complexity into a study-specific operating plan.

We align feasibility, site selection, staffing, training, vendors, patient pathways and governance to the investigational product and protocol. The operating model can evolve with the program, with clear responsibilities, escalation routes and communication across sponsor, sites, manufacturers, laboratories and logistics partners.

What this experience means for sponsors

- **Find and prepare sites:** Address competition for cell therapy sites through site feasibility, investment in training, APAC capability assessments, relationships with KOLs and high-performing sites and flexible site configurations. Cell Therapy SiteCoach™ supports study-specific site training; sponsor qualification and activation requirements remain in force.
- **Build a recruitment and engagement plan:** Use a holistic approach to recruitment, principal investigator motivation, patient-centered tactics and an expanded footprint, informed by site and patient needs and by the protocol.
- **Bring the right expertise to the team:** Plan for global medical monitor coverage in rheumatology and oncology, immunology and cell therapy clinical resources and indication-specific and cell therapy training for staff.
- **Partner around the program:** Use cell therapy feasibility, SiteCoach, a flexible partnering approach and solutions informed by experience to align the operating model with sponsor priorities and study needs.

Providing an integrated operational approach to cell therapy trials

Cell therapy trial requirements go beyond conventional drug studies. Time-sensitive product schedules, site readiness, chain-of-identity and chain-of-custody processes, specialized logistics and complex data capture call for close coordination among sponsors, sites, manufacturers, laboratories and other partners. Gaps in these areas can affect timelines, recruitment, data quality and budgets.

We build a cross-functional operating approach around each study's protocol, product and participant population. Support may include:

- **Cross-functional study teams and sponsor coordination:** Align staffing and functional expertise to the study model, with regular touchpoints, clear decision pathways and escalation routes. Teams can adjust as protocols, sites, timelines or sponsor priorities evolve.
- **Hub-and-spoke site and referral strategy:** Assess site capabilities and patient access and consider hub-and-spoke configurations to connect specialized expertise with appropriate referral pathways. Cell Therapy SiteCoach™ training prepares site staff for study-specific processes; site qualification and activation remain subject to sponsor and protocol requirements.
- **Manufacturing coordination and specialized logistics:** Coordinate time-sensitive handoffs among collection sites, manufacturers, laboratories and couriers. Plan product-specific handling, shipment tracking, temperature monitoring and chain-of-identity and chain-of-custody processes.
- **Safety, data and long-term follow-up:** Develop monitoring and data oversight plans aligned with the protocol and investigational product. Plan participant follow-up around study objectives, applicable requirements and the needs of patients and caregivers.
- **Patient-centered support:** Coordinate practical participant needs, including concierge support where included in the study scope.

By combining cell therapy operational experience with autoimmune expertise, we help sponsors build the sites, referral pathways and study processes needed to advance their clinical programs.

Move your cell therapy in autoimmune disease clinical development program forward.

Learn more at **ppd.com/therapeutic-expertise/immunology/**

© 2026 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. 10.2026