Immunology

Accelerate your clinical trial with our immunology expertise

Advancing immunology and rheumatology: Expertise in disease mechanisms and resilient networks

Immunology studies face specific challenges, such as rapidly changing standards of care and clinical strategies; supply of complex materials to global sites and complex testing of clinical samples; and high data volume and collection requirements. To maximize success, sponsors often turn to an experienced contract research organization (CRO) that can help them navigate inherent complexities.

Our commitment to excellence

Sponsors partner with the PPD™ clinical research business of Thermo Fisher Scientific to advance their immunology and rheumatology development through our:

- **Therapeutic expertise**
  - In the past five years, we have conducted 166 immunology and rheumatology clinical trials globally.
  - Our operational subject matter experts span cell therapy in autoimmunity, lupus, rare immunology and arthritis.
  - A team of programmers and specialist data reviewers are available to perform targeted eligibility reviews and real time review of efficacy data.
  - Our expert team includes a global group of seven board certified rheumatologists.
  - We deploy clinical science liaisons to optimize trial delivery.
- **Investigational sites network**
  - We build and maintain strong relationships with key opinion leaders and investigators.
  - Our global site network partnership program focuses on building holistic, trusted, site-centric, and mutually beneficial relationships with 42 networks across 27 countries and 108 traditional partnerships across 41 countries.
- **Patient-centric solutions**
  - We offer digital solutions to decentralize clinical trials away from the trial site, including at-home administration options or home nursing.
  - Our expanding relationships with community networks and patient advisory groups to increase patient engagement by incorporate the patient voice
  - We optimize trial design to remove barriers to patient participation and reduce patient burden – supporting recruitment of diverse patient cohorts

Clinical disease registry network

- We offer more than 25 years of embedding regulatory-grade data collection in real-world settings.
- Our longitudinal clinical disease registries track patient health status, care pathways and treatment outcomes in:
  - Rheumatoid Arthritis (RA)
  - Psoriatic arthritis/Spondyloarthritis
  - Systemic lupus erythematosus
  - Our network boasts scientific advisors and pre-eminent experts in their fields.

Integrated clinical trial services: Expert advice and support at every stage of the process

We provide clients with a fully integrated approach to the development of immunology and rheumatology therapies.

Our experience encompasses strategic consultancy from pre-clinical, analytical, regulatory, and clinical development to MAA/NDA/BLA submission for sponsors worldwide, as well as execution of various phases of clinical trials.

Our experience:

166 Immunology studies

Across **3,721** sites around the world

Involving **13,983** patients

As a leader in key immunology and rheumatology indications, sponsors benefit from our many years of immunology and rheumatology experience, spanning all clinical trial phases and a broad spectrum of different indications.

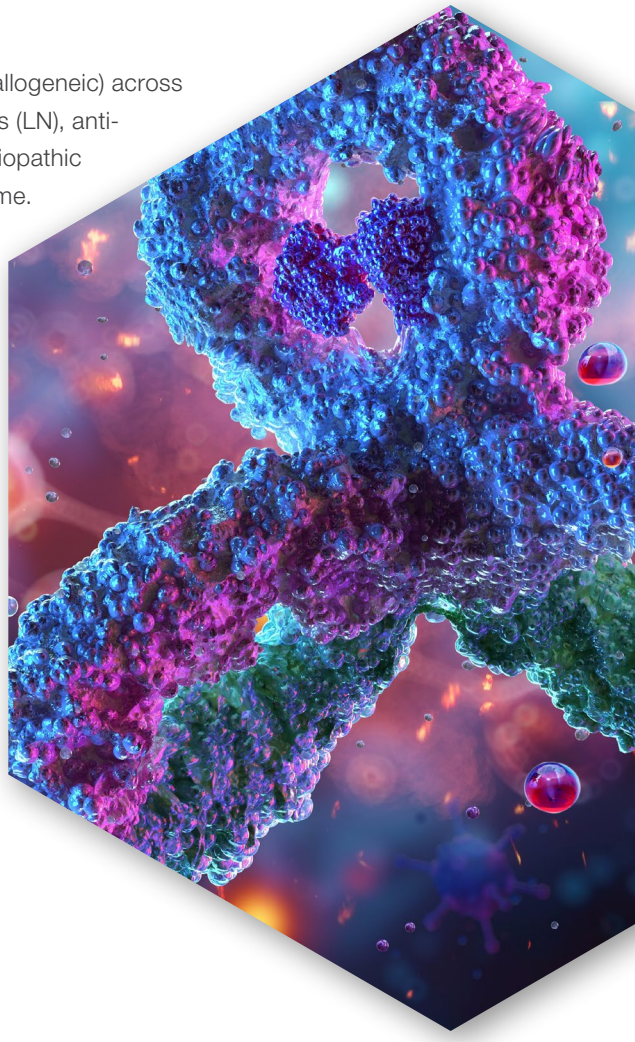
Our experience over the past 5 years encompasses:

Indications	No. of protocols	No. of sites	No. of patients
Rare Immunology	54	368	2,049
Lupus (all types)	29	1,157	3,669
Arthritis (rheum and psoriatic)	23	828	4,550
System sclerosis	13	409	845
Immunodeficiency (all types)	12	14	280
Gout	10	52	276
Psoriasis	9	11	506
Hereditary angioedema	8	268	887
Sjögren'ssyndrome	6	563	851
Giant cell arteritis (GCA)	2	50	70
Total	166	3,721	13,983

What our experience means to you:

- Relationships with experienced sites, networks, and investigators, including access to metrics on site performance and capabilities, empowers us to identify the best sites for your study.
- Proven recruitment strategies enable you to enroll study specific patient populations in a highly evolving research space.
- Sound understanding of operational nuances in autoimmune studies, including our understanding of the current treatment, regulatory and competitive landscapes.
- Proven, strategic operational capabilities and leadership from our immunology therapeutic experts and thought leaders.
- Therapeutic insights to support streamlining the protocol criteria and study design elements, keeping in mind your larger objectives and data-oriented needs.
- Strong relationships with patient advocacy groups in immunology
- Regulatory-grade datasets at your fingertips to fill evidence gaps, support regulatory obligations and inform decision-making

Our experience in cell therapy: Autoimmunity



In the past 3 years, we have worked on 16 cell therapy studies (12 autologous/four allogeneic) across a variety of indications including systemic lupus erythematosus (SLE), lupus nephritis (LN), anti-neutrophil cytoplasmic antibody (ANCA) associated vasculitis, systemic sclerosis, idiopathic inflammatory myositis, myasthenia gravis, multiple sclerosis and stiff person syndrome.

Our interdisciplinary teams support the onboarding of cell therapy studies. Combining experience from the oncology and immunology units, our cross-functional operational teams have the complementary experience necessary to operationalize these trials.

Based on this experience, we have developed a differentiated delivery strategy that leverages the progressive application of lessons learned from other cell therapy trials to offer sponsors:

a. Customized cell therapy feasibility approach
b. Innovative approaches to creating study sites with appropriate technical expertise and access to the required patient population
c. In-house site support functions that drive early site engagement and recruitment

As part of our ongoing commitment to developing our operating model for cell therapy trials in autoimmunity, we:

1. Proactively upskill staff to deliver cell therapy trials in AI
2. Flex our resourcing models to match the needs of the sites and studies
3. Collaborate with leader researchers to produce thought leadership
   - Key Considerations for Cell Therapy Trials beyond Oncology
   - CAR T-cell Therapy for Autoimmunity On-Demand Webinar | PPD

An experienced team that keeps immunology and rheumatology development on track

Dedicated immunology expertise

Our global immunology team is comprised of more than 8,300 experienced professionals. These professionals include a team of more than 1,300 project management experts serving as your key point of contact and responsible for overall project delivery and quality. We also provide medical monitoring by board-certified physicians, as well as dedicated data management and statistics team members with far-reaching immunology study experience. With a retention rate of 95 percent over the past three years, our experts are well-positioned to work together to execute successful immunology trials.

Trialmed provides comprehensive clinical pharmacology services across all phases of clinical development. With more than **250 global study sites** and access to a database with **20 million patients**, Trialmed ensures flexible locations for optimal patient engagement. Their network design offers comprehensive solutions for trial design, patient recruitment, data management, and regulatory compliance, simplifying the study conduct process for pharmaceutical companies and research institutions. Trialmed's integrated global clinical site network offers robust solutions for early development service needs, connecting businesses with the resources necessary for successful clinical trials. Additionally, their Home Trial Services (HTS) solution supports decentralized trial enrollment, making clinical trials more accessible and removes patient burden.

Trialmed creates holistic experiences that put the patient first through welcoming clinics, user-friendly digital technology, and a relentless focus on total quality delivery. With a patient-first approach, Trialmed is the clinical research destination of choice for patients and healthy volunteers.

With **extensive access to patients in multiple geographies,** Trialmed ensures reliable enrollment outcomes. Trialmed offers extensive **early phase solutions** with a dedicated team, and a large suite of offerings.

Flexible clinical trial solutions scale to the sponsor's needs and budget, offering a best-in-class site network from **Phase I to Phase IV.**

Home trial services offer the ultimate in-patient flexibility – conducting clinical trial visits where the patient prefers, such as the patient's home, office, or school.

Trialmed has extensive experience in immunology and musculoskeletal/rheumatology clinical trials, having randomized over **15,900** patients across various indications and delivered more than **137 Phase I–IV trials**. They possess deep expertise in engaging patients with immunologic/rheumatoid conditions in their preferred ways, supported by a robust proprietary database that provides insights on patients most likely to randomize. This database includes millions of households reporting immunologic/rheumatoid conditions.

Key advantages of working with Trialmed include:

- Accelerated enrollment rates and recruitment timelines.
- Access to a large, pre-screened patient population, enhancing the efficiency of patient recruitment.
- Expert clinical staff and experienced research site teams, ensuring high-quality trial execution.
- Support for over 300 sites, providing extensive reach and flexibility for clinical trials.

Accelerator™ Drug Development | 360° CDMO and CRO solutions

The manufacturing process in immunology drug development is fundamental to the success of the product. It ensures the final product meets the necessary regulatory standards and provides the required evidence that the biosimilar is comparable to the reference biologic in terms of quality, safety and efficacy. The key areas in the biosimilar manufacturing process include the following:

- Consistency and quality
- Comparability to the reference product
- Regulatory approval
- Scalability and reproducibility

Gain an advantage by partnering with a CRO that also has CDMO expertise with drug manufacturing process.

As a leading global provider of a full suite of innovative CDMO (contract development manufacturing organization) and CRO services as core offerings, partnering with us at any point in your unique drug development journey can accelerate your goal of getting treatments to patients faster.

We deliver:

Speed – Work with one partner, instead of multiple vendors, eliminates timeline gaps and regulatory challenges and proactively mitigates risks.

Operational flexibility – Meet your unique program development and research requirements, both locally and globally, with our innovative solutions and scalable manufacturing and clinical research solutions.

Collaborative partnership – Get the integrated expertise you need across all phases of your drug development journey.

More than **120** biotech and biopharma companies are currently accelerating their time to market by partnering with Thermo Fisher Scientific across our CDMO and CRO services on more than **350** protocols.

Accelerator drug development

Partner with us starting at **any point**, in **any phase**

Preclinical, IND, Phase I

Benefits:

- De-risk early-phase development
- Gain speed to IND and Phase I trials
- Scientific and regulatory expertise

Phase II-III, NDA

Benefits:

- Speed to market
- Cost efficiency
- Streamlined supply chain and labs
- Patient recruitment and retention
- Global reach and expertise

Commercialization and post-approval studies

Benefits:

- Maximize an asset's market potential
- Manufacturing capacity
- Post-approval studies
- Real-world data (RWD) and real-world evidence (RWE)

Accelerating your unique **drug development journey** with **innovative 360° CDMO and CRO solutions**, supporting your aspiration to get treatments to patients faster

Every drug development journey is unique. That is why you can partner with Thermo Fisher Scientific at any point, in any phase of your drug development and gain benefits by using combinations of our global expert CDMO, CRO, clinical supplies, labs, regulatory and consulting services.

If you are in pre-clinical development, we can provide you with speed to IND by manufacturing your investigational medical product, using our GMP labs for testing, and leveraging our expert CMC and regulatory consulting services for your IND application and Phase I trial planning.

We can provide benefits for Phase II and III trials if you partner with us for your clinical research, clinical trial supplies, and central lab services by using our integrated trial supply and demand forecasting systems.

Your greatest time savings and your highest return on investment can be achieved by starting your drug development journey with us. We understand that every customer has different immediate needs and business objectives. We have a comprehensive array of services that can meet your needs including a combination of our drug substance and drug product services, our clinical research services, and our GMP and central lab services.

Regardless of where you are in your journey – we can enable you to achieve the ultimate goal of getting your treatments to patients, faster.

Patient first digital solutions in immunology and rheumatology trials

Our patient first digital solutions are dedicated to supporting patient recruitment and retention through digitally enabled diverse and sustainable clinical trials. We break down traditional barriers and infuse innovation to expedite drug development for our clients.

Our exclusive collaboration with our immunology team sets us apart. This partnership enhances our digital and decentralized solutions with unique immunology expertise, providing a distinct edge in the industry.

39+

Overall studies with DIM: Demonstrating extensive experience and expertise

101+

Unique scales managed: Delivering precision and excellence in every measurement

52+

Studies with a digital and decentralized solution on (eConsent, eCOA, televisits, wearables, Direct to/from patient shipments, home health care and Patient Navigator)

Support all phases of your pipeline with PPD™ CorEvitas Clinical Registries

CorEvitas Psoriatic Arthritis/ Spondyloarthritis Registry

CorEvitas Rheumatoid Arthritis (RA) Registry

CorEvitas System Lupus Erythematosus (SLE) Registry

More than 25 years of embedding regulatory-grade data collection in real-world care settings to assess:

- Comparative effectiveness (per protocol, active assessments of validated clinical instruments)
- Correlation of clinical outcomes with PROs
- Patterns of care and reasons for treatment start/stop/switch
- Long-term safety to fulfill regulatory commitments

Our purpose-built longitudinal registries deliver robust data to answer critical research questions in rheumatic conditions.

R&D

- **Demonstrate natural history, unmet need** and burden of disease with current therapies
- **External comparator arm (ECA) to contextualize**
  a. clinical trial safety for regulators
  b. clinical trial efficacy (either for single arm trials or smaller control arms)

Drug Safety

- **Post approval real-world safety** across an array of safety endpoints with event validation against primary source medical records
- **Post approval comparative safety studies** for regulatory commitments (e.g., FDA, EMA, MHRA)
- **Identifying risk factors and subpopulations for AEs of interest** on individual drugs or drug classes

Medical Affairs

- **Demonstrate real-world effectiveness and PRO improvements** using validated RCT endpoints
- **Comparative effectiveness** studies of client drug versus other drug classes
- Examine **reasons for starting, switching and discontinuing** client and comparator drug(s)

HEOR

- **Examine real-world persistency on drug** and comparative persistency
- Publish on improvements in validated clinical outcomes as well as **disease-specific PROs**
- Demonstrate for payors improvements in **work productivity and quality of life for patients on client drug(s)**

ThermoFisher SCIENTIFIC

Contact us today at ppd.com/therapeutic-expertise/immunology/ or scan the QR code below to discover how we can support your journey to groundbreaking immunology and rheumatology drug development.

Scan to learn more

Learn more at **ppd.com**

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