MEDPACE

RHEUMATOLOGY CLINICAL DEVELOPMENT

Medpace's expertise in rheumatology studies and consistent track record of success as a full-service CRO across a variety of therapeutic areas ensures the flexibility required for the unique needs of rheumatology research. Our cross-specialty experience is key for managing complex trials across systemic lupus erythematosus, rheumatoid arthritis, spondyloarthropathies, and more.

Our in-house board-certified adult and pediatric rheumatologists have a thorough understanding of the complex conditions that cause these diseases, as well as the medical complications experienced by patients. Experts collaborate across therapeutic areas to create effective and efficient study designs for Sponsors of all sizes. A clear example of this collaboration is the tandem work of our rheumatologists and hematologists hand in hand, providing medical expertise in rheumatological indications trials in which advanced therapies such as CAR-T are applied. Our expertise and lessons learned provide guidance for navigating the complexities of rheumatology research.

Medpace is experienced in supporting biosimilars, combination therapies, and new approaches such as:

- CAR-T therapies
- Genetically altered cell therapies
- Immunomodulatory biologics
- Gene transfer-mediated immunotherapies
- Monoclonal microbial immunomodulation
- Selective Kinase Inhibitors

Our scientifically driven and therapeutically-focused operational model gives Sponsors cross-collaboration and insights from various medical perspectives. As a full-service CRO, Medpace trials are supported by our in-house Imaging Core Lab and our global central laboratory providing safety testing and biomarker support.

EXPERTS

- Embedded physician leadership, working in multi-specialty collaboration based on the indication, including rheumatologists, immunologists, dermatologists, allergists, gastroenterologists, and hematologists
- Cross-functional teams of medical, operational, and regulatory experts that are actively involved throughout the lifecycle of the project
- Global staff experienced in rheumatology research and cell-based therapies, including an ongoing training program for CRAs
- Integrated experts from wholly-owned core imaging and global central labs

EXPERIENCE

- Conducted global Phase I-IV trials covering countries and regions with high incidences of disease
- Successfully conducted Phase III registration trials leading to marketing authorization of products for systemic autoimmune rheumatic diseases and inflammatory arthropathies
- Experienced in biosimilars, combination therapies, and advanced therapies in rheumatology
- In-depth knowledge working with global regulatory authorities
- Deep understanding of the medical complications experienced by patients with rheumatologic diseases

EXECUTION

- A full-service, single-vendor outsourcing strategy build efficiencies and streamlines communication and study management
- Strong relationships with investigative sites and key opinion leaders (KOLs)
- Global central lab with safety and biomarker validation and analysis
- Imaging Core Lab brings expertise to support endpoints and classification of disease state
- Flexible and highly customizable ePRO solution that is fully-integrated into ClinTrak®, Medpace's proprietary data management system.

IN-HOUSE EXPERTISE

The Medpace model gives Sponsors the advantage of early and ongoing insight and guidance from therapeutic experts from early planning through close-out. Our highly experienced medical experts bring the unique combined expertise of clinical practice, knowledge of current therapeutic paradigms and the experience in the clinical development industry that they have acquired in their roles as global medical monitors in a CRO. They work closely with our regulatory and operational experts to provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies. Embedded throughout every study, medical experts provide greater depth and the ability to tackle complex and challenging diseases.

Additionally, our operational teams, including clinical trial managers and program coordinators, are therapeutically aligned to facilitate specialized training to sites and help mitigate challenges.

Key Indications:

- Systemic Lupus Erythematosus & Lupus Nephritis
- Rheumatoid Arthritis
- Psoriatic Arthritis
- Scleroderma / Systemic Sclerosis / Raynaud
- Spondyloarthropathies – Non-radiographic and radiographic axial spondyloarthritis
- ANCA-Associated Vasculitis
- Inflammatory Myositis – Dermatomyositis, Polymyositis
- Sjögren's Syndrome
- Osteoarthritis
- Hyperuricemia & Gout
- Osteoporosis
- Polymyalgia Rheumatica
- Giant Cell Arteritis

INTEGRATED IMAGING CORE LAB

CRO and imaging integration—imaging expertise and clinical trial experience ensures that imaging components are seamlessly integrated into the complex structure of the overall trial. Notably, we use a web-based image management system used to analyze MRI scans for confirmation of eligibility, safety and efficacy evaluations.

Rheumatology Imaging Expertise:

- Qualitative visualization
- Serial measurement
- Response/outcome measures in rheumatology clinical trials (OMERACT)
- RA magnetic resonance imaging (RAMRIS) System

WHOLLY-OWNED GLOBAL CENTRAL LABS

Our wholly-owned central laboratory—with locations in the US, Europe, China, and Singapore—offers a menu of validated biomarkers associated with rheumatology with the ability to rapidly establish and validate novel assays as needed.

Rheumatology Testing Services:

- C-Reactive Protein
- Autoantibodies > ANA, Rheumatoid Factor, Cyclic Citrullinated Pepties (Anti-CCP), anti-ENAs, myositis related/specific
- Human leukocyte antigen (HLA) typing
- Safety testing

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.

MAKING THE COMPLEX SEAMLESS®