MEDPACE

AUTOIMMUNE DISEASE CLINICAL RESEARCH

Medpace's expertise in autoimmune 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 autoimmune research.

Our cross-specialty experience is key for managing complex autoimmune trials. Our in-house medical experts collaborate across therapeutic areas to create effective and efficient study designs for Sponsors of all sizes. Our expertise and lessons learned to provide guidance on the complexities often involved in complex research.

Indication Experience:

- Amyloidosis
- Ankylosing Spondylitis
- Celiac Disease
- Crohn's Disease
- IgA Nephropathy
- Inflammatory Bowel Disease
- Lupus
- Mellitus
- Meniere's Disease
- Multiple Sclerosis
- Neutropenia
- Pemphigus
- Psoriasis
- Psoriatic Arthritis
- Rheumatoid Arthritis
- Type I Diabetes
- Ulcerative Colitis

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.

MAKING THE COMPLEX

SEAMLESS™

EXPERTS

- **Embedded physician leadership including Clinical Immunologist**
- **Cross-functional teams with scientific, operational, and regulatory expertise**
- **Global staff experienced in autoimmune research including an ongoing training program**
- **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**
- **Experienced in biosimilars, combination therapies, and new approaches for autoimmune diseases**
- **In-depth knowledge working with global regulatory authorities**
- **Deep understanding of the medical complications experienced by patients with autoimmune disease therapies**

EXECUTION

- **Full-service outsourcing model provides cross-collaboration and insights from various medical perspectives**
- **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 for autoimmune disease studies**

IN-HOUSE MEDICAL EXPERTISE

Medpace is unique in its scientifically-driven approach to clinical research. The Medpace model gives Sponsors the advantage of early and ongoing insight and guidance from therapeutic experts throughout trial design and execution. Our highly experienced medical doctors work closely with our regulatory and operations experts to provide strategic direction for study design and planning, train operational staff, work with Investigators, provide medical monitoring, and meet with regulatory agencies. They are embedded throughout every study, providing greater depth and the ability to tackle complex and challenging diseases.

Our Autoimmune studies are led by Richard Kay MBChB PhD. Dr. Kay has expertise in autoimmune diseases, as well as long-standing relationships with KOLs and global Principal Investigators (PIs).

Dr. Kay is a Clinical Immunologist with a background in experimental immunology, molecular biology, and immunogenetics. Before joining Medpace, he worked in Global Medical Director roles at both AstraZeneca and Novartis. He has over 13 years of industrial experience in portfolio management, biomarker development, translational medicine, and later development experience in the inflammatory and respiratory disease areas.

IMAGING CORE LABS

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 to analyze CT and MRI scans for confirmation of eligibility, safety and efficacy evaluations.

GLOBAL CENTRAL LABS

Our wholly-owned central laboratory — with locations in the US, Europe, China and Singapore — offers safety testing as well as a wide range of inflammation and immunology-related biomarker assays and can quickly establish and validate novel assays as needed.

Flexible and highly-customizable ePRO solution that is fully-integrated into ClinTrak®, Medpace's proprietary data management system.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

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

MAKING THE COMPLEX SEAMLESS™