MEDPACE

RHEUMATOID ARTHRITIS AND PSORIATIC ARTHRITIS

Medpace's expertise in Rheumatoid Arthritis (RA) and Psoriatic Arthritis (PsA) 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 RA/PsA 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 provide guidance on the complexities often involved in complex research.

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

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

With experience in RA/PsA diseases, Medpace has a thorough understanding of the complex conditions that cause these diseases, as well as the medical complications experienced by patients.

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 RA/PsA 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 RA/PsA**
- **In-depth knowledge working with global regulatory authorities**
- **Deep understanding of the medical complications experienced by patients with RA/PsA**

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**

IN-HOUSE MEDICAL EXPERTISE

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 RA/PsA studies are led by Richard Kay MBChB PhD. Dr. Kay has expertise in RA, 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 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 CT and MRI scans for confirmation of eligibility, safety and efficacy evaluations.

RA/PsA imaging expertise:

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

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 RA/PsA with the ability to rapidly 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.

RA/PsA testing services:

- C-Reactive Protein
- Rheumatoid Factor
- Cyclic Citrullinated Pepties (Anti-CCP)
- Human leukocyte antigen (HLA) typing
- Safety testing

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™