



## Specialists at the Forefront of IMID Research

A valuable CRO offers experiential wisdom along with forward thinking and flexibility. When medicine advances and long-held concepts evolve, you want to be working with specialists who are versed in the new approaches and already meeting fresh, related challenges. Those specialists are at **Worldwide Clinical Trials (WCT)**.

Traditionally viewed as organ-specific with an inflammatory component, seemingly unrelated inflammatory disorders are now known to share common pathways of immune mediation. While the exact identity of the inflammatory stimulus is often unknown, genetic linkages across indications continue to emerge. Treatment is no longer based on the physical site of disease, but rather targets underlying mechanisms. For you, this major paradigm shift means opportunities for therapeutic advances across multiple indications, including new classes of drugs that target inflammation through novel mechanisms as well as expanded market share and new markets. Of course, each of the immune-mediated inflammatory disorders (IMIDs) presents unique challenges.

## You Need Solutions

IMIDs are a core specialty for WCT. Our team combines knowledge about inflammatory processes, clinical manifestations, and therapeutic targets with deep operational expertise in the challenges associated with advanced clinical research in this complex and crowded field.

WCT professionals are attuned to the heterogeneous nature of IMIDs and able to deep-dive individual disease areas, while also sharing experiential wisdom and best practices across trials. Further, because IMID drugs have potential clinical applications extending across different therapeutic areas, we collaborate with our other core therapeutic specialty divisions to provide you optimal strategic, scientific, and operational solutions.

## We Can Help

Due to exploding trial activity in this arena, competition for subjects has increased, particularly for those with unique clinical characteristics. Patient retention can be difficult in long-term studies. Sizeable placebo response rates have been observed in psoriasis, rheumatoid arthritis (RA), and ulcerative colitis (UC) trials. Patient-reported outcomes (PROs) are receiving broader attention across IMIDs. For example, the FDA is focusing more on PROs for inflammatory bowel disease, and there is growing interest in PROs in rheumatology. WCT's proven solutions to these challenges include thorough site evaluation and selection based on precise metrics; careful recruitment and screening to confirm eligibility; frequent patient communication and education; intensive training of site personnel; and, if appropriate, electronic PROs using measures that are appropriate to specific disease entities.

Our IMID team has helped develop several biological therapies and also offers biosimilar experience. Over years of successful collaboration, WCT specialists have maintained close relationships with key opinion leaders, major academic institutions, and seasoned practitioners. These relationships plus extensive investigator networks in the optimal countries for IMID therapy development ensure highly effective, "made to measure" strategies.

## IMID PORTFOLIO

- Ankylosing spondylitis
- Asthma
- Chronic obstructive pulmonary disease
- Crohn's disease
- Juvenile idiopathic arthritis
- Lupus nephritis
- Psoriasis
- Psoriatic arthritis
- Rheumatoid arthritis
- Systemic lupus erythematosus

## INTEGRATED TECHNOLOGY

- Clinical Trial Management System
- Electronic Data Capture
- Interactive Voice Response System
- Interactive Web Response System



WCT's Supply Management and Randomization Technology (SMaRT) offers a cost-effective solution for centralized randomization, drug inventory management, and controlled code-break capabilities. We also develop bespoke solutions for sponsors. With the capability to integrate complex needs into sponsor data systems, we can reduce costs while enhancing both quality and efficiency.

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## Science + Service + Solutions = Success

Resources for you include:

- Consultation in clinical program development
- Access to prominent advisory boards for medical, scientific, and operational perspectives
- Well-established, global relationships with experienced investigative sites:
  - Located in countries that produce high-quality data and large subject pools
  - Proficient with all international criteria and disease staging methods
  - Meet most widely used standards of site performance (i.e., high recruitment and low screen-failure rates)
- Recruitment strategies tailored to each study and site
  - Knowledge of geographic influences on standards of care
  - Insight about local factors that can affect recruitment rates
- In-depth risk assessment and early implementation of mitigation strategies
- Extensive knowledge of local practices and regulations, including standard of care and reimbursement conventions
- Proactive management of regulatory body expectations

Benefits for you include:

- Fast decision making and captured opportunities
- Optimized site selection, reliable performance, and preemptive study management
- Successful delivery of patient populations consistent with study design
- Meeting or exceeding recruitment targets within timelines

## Delivering Impeccable, Reliable Data—On Time

Case studies illustrate the WCT approach.

### I. Lupus Nephritis

A Phase II, multicenter, randomized, double-blind, placebo-controlled study to evaluate safety, tolerability, and clinical efficacy of an investigational immunomodulator in adults with active lupus nephritis (LN). **Challenges:** complicated, narrow therapeutic indication, limited patient population, and strict inclusion/exclusion criteria. **Solutions:** WCT assessed feasibility and, based on our knowledge of the healthcare system and patient flow in study areas, selected sites with broad referral nets. Because an inclusion criterion was kidney biopsy within 6 months prior to baseline, and renal biopsy is routinely performed at nephrology sites in the country where the study was executed but not at rheumatology and internal medicine sites, we selected mostly nephrology sites. WCT actively participated in protocol amendment discussions and provided timely feedback from investigators, critical for achieving enrollment target with the protocol amendment. With our proactive approaches, the enrollment goal was exceeded.

### II. Rheumatoid Arthritis

A Phase II, double-blind, placebo-controlled, randomized study to evaluate clinical efficacy of an investigational medicinal product with methotrexate (MTX) in adults with moderate to severe RA despite MTX. This study was performed in 11 countries spanning Central/Eastern Europe, the former Commonwealth of Independent States, and the Middle East and North Africa (MENA) region to facilitate regulatory approval. **Challenge:** protocol required 140 enrollees with CRP >10 mg/L. **Solution:** To overcome a relatively high (correctly predicted) screen-failure rate of >50%, WCT identified a reliable and well-established network of sites. To avoid regulatory delays, WCT created two back-up strategies: sponsor approval of 7 additional sites as replacements, if needed; and possible extension to 5 sites in Russia. With our experience, the recruitment period ended 2.5 months early.



Immune-Mediated  
Inflammatory Disorders

## KEY SERVICES

- Biostatistical analysis
- Clinical monitoring
- Data management
- Data and Safety Monitoring Board charters and management
- Drug depot services
- Endpoint adjudication
- Feasibility assessments
- Global project management
- Investigator meetings
- Medical monitoring
- Medical writing
- Project management
- Protocol design
- Pharmacokinetics
- Pharmacovigilance
- Quality assurance
- Regulatory affairs (includes consultancy)
- Safety monitoring
- Scientific consultancy
- Site identification, recruitment, and management
- Supply management and randomization
- Third-party collaboration<sup>a</sup>

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**WORLDWIDE CLINICAL TRIALS**  
SCIENTIFICALLY MINDED · MEDICALLY DRIVEN

<sup>a</sup> WCT partners with a range of specialized service providers, including centralized clinical and imaging laboratories, drug procurement and management specialists, and logistics support for transfer of temperature-controlled pharmacokinetic samples, etc.