

OVERVIEW

Worldwide Clinical Trials' team of experts combines medical expertise within the clinical practice of chronic inflammatory diseases with vast experience in the operational challenges associated with advanced clinical research activities in complex inflammatory disorders. Our therapeutic leadership has led the development and launch of several biological therapies in the chronic inflammatory area that are currently available on the market.

- *Through many years of successful collaboration, we maintain close relationships with opinion leaders, academic institutions and practitioners in rheumatology, dermatology and gastroenterology, consistently reaching study milestones and delivering impeccable data.*

SCIENCE. SERVICE. SOLUTIONS.

- Advisory services in clinical and protocol development allow our clients fast decision making and captured opportunities
- Access to recognized advisory boards
- Well-established relationships and access to experienced investigative sites globally
- Investigative sites highly experienced in using all international criteria and scoring methods
- Customized qualitative feasibility leading to optimized site selection, reliable performance and preemptive study management
- Development of recruitment strategies tailored to each study and site
- A track record of successful delivery of patient populations, meeting or exceeding recruitment targets within timelines
- In-depth risk assessment and early implementation of mitigation strategies
- Extensive knowledge of local practices and regulations, including standard of care and reimbursement conventions
- Pro-active management of regulatory body expectations

CASE STUDIES

Rheumatology

- **Rheumatoid Arthritis**
 - ***A Phase I drug-drug interaction study in subjects with rheumatoid arthritis, this study was conducted in Central Eastern Europe completing recruitment in four weeks.*** Despite the complexity of the PK design, the study achieved the exceptional rate of 100% patient compliance.
 - ***A Phase II placebo-controlled, double-blind, randomized, parallel-group, dose regimen-finding study to evaluate the safety and efficacy of a study drug in subjects with active seropositive rheumatoid arthritis on a stable dose of DMARD.*** The study drug was an innovative IV biologic compound. With a

INDICATIONS

Rheumatoid Arthritis

Juvenile Idiopathic Arthritis

Ankylosing Spondylitis

Systemic Lupus Erythematosus and Lupus Nephritis

Psoriatic Arthritis

Psoriasis

Crohn's Disease

Ulcerative Colitis

CORE VALUES

Bringing together science and flawless operational execution, we have developed a platform providing our clients with services supporting continuity from early clinical development to late phase studies.

Continued on Back >



Continued >

recruitment rate of 1.4 patients/site/month, Serbia, managed by Worldwide Clinical Trials, was rated as the number one recruiter in Europe for the study.

- **Lupus Nephritis**

- ***A Phase II, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of an immunomodulating agent in subjects with active lupus nephritis, in combination with standard of care therapy (corticosteroids and Mycophenolate Mofetil).*** Study medication was administered orally over a period of 24 weeks. The main study challenges consisted of highly selective eligibility criteria and scarce patient population. Thorough country and site evaluation was driven by detailed validation of local standard of care and practices of renal biopsy required for the eligibility of the patient population. Based on its qualitative site selection, Worldwide Clinical Trials was able to select highly experienced sites in Europe delivering the target recruitment of SLE patients in renal flare at an enrollment rate of 0.4 patients/site/month.

- **Systemic Juvenile Idiopathic Arthritis**

- ***A Phase II, open-label clinical trial to investigate safety and efficacy of a study drug in patients with active systemic onset juvenile idiopathic arthritis (SOJIA) who had an inadequate response or intolerance to standard therapy with oral corticosteroids and methotrexate.*** The investigated medication was an immunomodulating agent administered orally for a period of 12 weeks. Challenges of recruiting pediatric patients in this study were exacerbated by the fact that SOJIA is a rare disease (accounting only for 10-20% of the children with juvenile idiopathic arthritis) and by eligibility criteria requiring active disease refractory to standard of care therapy. Through careful site selection, tailored recruitment strategy and close oversight by Worldwide Clinical Trials, all patients were recruited by three sites in Central Eastern Europe two months ahead of target.

Gastroenterology

- **Crohn's Disease**

- ***A Phase II randomized, double-blind, placebo-controlled study to evaluate the effect of an investigational drug on mucosal healing in patients with moderate to severe Crohn's disease.*** The study drug was an orally active compound administered twice daily over eight weeks. The study was conducted in Central and Eastern Europe and, through the support of a dedicated Worldwide Clinical Trials team, the projected recruitment rate was surpassed by 35%. Importantly, the top recruiting site was successfully inspected, highlighting the quality of data collected, in addition to the accelerated patient enrollment.

Dermatology

- **Psoriatic Arthritis**

- ***A Phase IV randomized, double-blind, two-period inflammatory study evaluated the safety and efficacy of the investigational drug (immunosuppressant) on skin and joint disease in psoriatic arthritis subjects.*** In this global study, 2.4 patients/site/month were successfully recruited, leading to the enrollment target being reached ahead of time.

KEY SERVICES

Feasibility Assessments

Protocol Design

Site Identification

Site Management

Clinical Monitoring

Medical Monitoring/Pharmacovigilance

IVRS/IWRS for Randomization

IVRS/IWRS for Study
Supply Management

Clinical Trial Management System

Electronic Data Capture

Global Project Management Services

Biostatistical Services

Medical Writing Services

Quality Assurance

As part of our unique set of services, Worldwide Clinical Trials also provides in-house analytical and pharmacokinetic capabilities.

Americas
+1 610 964 2000

WORLDWIDE CLINICAL TRIALS



www.wctrials.com

International
+44 (0) 207 121 61 61