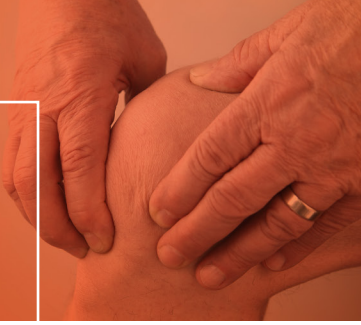
WORLDWIDE
CLINICAL TRIALS

HOW TO TRANSFORM YOUR IMMUNE-MEDIATED INFLAMMATORY DISORDER CLINICAL PROGRAM

Last Update: 24092019

CREATING A CUSTOMIZED APPROACH FOR YOUR SUCCESS



GENERAL MEDICINE PORTFOLIO

- Bullous Pemphigoid
- Familial Mediterranean Fever (FMF)
- Juvenile Rheumatoid Arthritis
- Lambert-Eaton Myasthenic Syndrome (LEMS)
- Lupus
- Lupus nephritis
- Pemphigus Vulgaris
- Psoriasis
- Rheumatoid arthritis
- Ulcerative Colitis

CRO LEADERSHIP AWARDS2019

Capabilities, Compatibility, Expertise, Quality, and Reliability

"Worldwide Clinical Trials opened a site in Germany in record time – fewer than 3 months from the first contract day to the initiation visit. I am very pleased with the expedited work done by Worldwide. Job well done!"

– Worldwide Customer (Global Project Management)

1,700+ Professionals

Real Offices in Emerging Markets for Access to Hard-to-Find Oncology Patients Across

60+ Countries

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WORLDWIDE CLINICAL TRIALS: ON THE FOREFRONT OF IMID RESEARCH

Worldwide Clinical Trials contains the scientific acumen, operational excellence, and project flexibility that your general medicine program demands. 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 your challenges. Those specialists are at Worldwide Clinical Trials.

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 IMIDs presents unique challenges.

ARE YOU WORKING WITH AWARD-WINNING OPERATIONAL TEAMS?

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. Worldwide's award-winning operational professionals, including project managers, clinical research associates, and quality assurance managers, 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 optimal strategic, scientific, and operational solutions.

WE CAN HELP: PROVEN PATIENT RECRUITMENT AND RETENTION RESULTS

Due to exploding trial activity in this therapeutic area, 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. Worldwide's proven solutions to these challenges include:

Thorough site evaluation and selection based on precise metrics

Careful recruitment and screening to confirm eligibility

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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 collaborationa

ISR reports

RATED OVERALL TOP PERFORMER FOR:

- Budget Factors
- Delivery Factors
- Staff Characteristics
- Accessibility
- Services
- Customer Loyalty

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Frequent patient communication and education

Extensive training for 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, Worldwide 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.

RUNNING A GLOBAL TRIAL IN A VAST REGULATORY LANDSCAPE

Worldwide Clinical Trials is a global CRO, with a presence in 60+ countries worldwide. We have built close relationships with patient engagement groups, key opinion leaders and investigator sites, working to bridge science and operational excellence to deliver new solutions. When your program depends on global, regulatory knowledge, trust Worldwide Clinical Trials.

CASE STUDIES: SHOWCASING WORLDWIDE CLINICAL TRIALS’ SUCCESS

Worldwide Offers Scientific Expertise and Strategic Enrollment Plan for Successful Lupus Nephritis Program

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: Worldwide 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. Worldwide 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.

Worldwide Decreases Screen Failure Rate, Regulatory Delays Resulting in the Recruitment Period Ending 2.5 Months Early

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%, Worldwide identified a reliable and well-established network of sites. To avoid regulatory delays, Worldwide 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.

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THERE'S NO SUBSTITUTE FOR UNCOMMON EXPERTISE. MEET YOUR PARTNERS.

Many large CROs offer "off-the-shelf" advice and solutions to their customers. Worldwide delivers tailored and pragmatic advice, regardless of the size or complexity of the project. Our collaborative, customized project teams with phase- and indication-specific expertise develop successful strategies for even the most novel therapies.

Ian Braithwaite, Ph.D

Senior Vice President, Global Project Management, General Medicine

Ian Braithwaite brings deep industry and therapeutic experience to his role overseeing project management and operational delivery for Worldwide Clinical Trial's General Medicine business unit. He has full accountability for strategic development and execution of all projects conducted by these therapeutic areas, ranging from immunology/inflammatory dDiseases (rheumatoid arthritis, lupus, psoriasis, IBD, asthma, COPD, etc.), rare diseases (for e.g., sickle cell disease, IPF, bullous pemphigoid, cutaneous T-cell lymphoma.)

Dr. Braithwaite worked in clinical research for more than 26 years before joining Worldwide in 2015, including serving as Executive Vice President & GM, General Medicine at INC Research, and Global Therapeutic Area Head – General Medicine & Executive Director and Therapeutic Group Head Hematology/Oncology at PPD. Prior to joining the CRO industry, Ian was Director, Clinical Development at AstraZeneca Pharmaceuticals working primarily on Oncology and Immunology/Inflammatory Diseases. He began his career as a clinical research scientist at SmithKline & French after completing his academic studies.

Hazel Gorham, BSc(Hons), Ph.D.

Senior Director, Project Management, General Medicine

Dr. Gorham has over 20 years of clinical research experience in the pharmaceutical and CRO industries across a wide range of roles, including CRA, project management, and developing and implementing clinical development strategies for biosimilars and complex generics. More recently, Dr. Gorham gained in-depth experience in clinical pharmacology, working closely with Phase I units. She has experience in all aspects of biosimilar development, including study design and study execution and interactions with regulatory agencies. In the last few years, she has worked in the developing regions to better understand their expectations for licensing biosimilars and educate potential investigators in the region. She has worked on over 10 biosimilar molecules across a range of products and indications, including monoclonals and insulins, in various capacities, including contributing toward regulatory and clinical strategies, feasibility, and supporting study delivery across all phases of development (Phase I to IV).

Joanna Reeder, MSc

Vice President, Project Management, General Medicine

Joanna Reeder's successful career within the clinical research industry spans more than 30 years. She has directed global project and program teams across all clinical phases and diverse therapeutic areas. Prior to joining Worldwide, Joanna successfully held the positions of Executive Director and Vice President, Clinical Development, with leading CROs, where she focused on managing portfolios of work in the endocrinology and inflammatory therapeutic areas. Joanna has significant experience in autoimmune diseases, rare disease indications, biosimilars, and rheumatology. She joined Worldwide's General Medicine business unit as a key member of the leadership team. Her focus is to achieve optimal customer delivery by ensuring the contracted services of all programs and projects are fully delivered by the project teams in accordance to contracts and customer expectations.