WORLDWIDE
CLINICAL TRIALS

BE THE FIRST TO MARKET WITH YOUR BIOSIMILAR

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WORLDWIDE CLINICAL TRIALS

AWARD-WINNING CRO

Our award-winning biosimilars team delivers uncommon value by providing the flexibility and attention to detail necessary to bring your biologic to market.

CRO LEADERSHIP AWARDS 2019

Data Quality, Meeting Overall Project Timelines, Technology for Real-Time Access to Data, Operational Excellence, Responsiveness

UNCOMMON GLOBAL SITE AND INVESTIGATOR NETWORKS FOR FASTER PATIENT RECRUITMENT

With Worldwide, you get the best of both worlds: a global CRO that is also agile. What does this mean for you? Access to global resources without the hefty price tag and cookie-cutter approach you get from large, consolidating CROs.

Biological medicines have changed the treatment pathway for many debilitating conditions, but the high price tag is a barrier, and many patients are denied access to these life-changing and life-saving medicines. This, combined with the increasing prevalence of chronic diseases has led to higher demand for available, affordable drugs that can improve health and utalization.

ADDRESSING DEVELOPER CHALLENGES

Increased interest in biosimilars is leading to increased development as companies can see the positive outlook for return on investment. There are 13 (EU) and 16 (US) unique biosimilars in development at various stages ranging from pre-clinical to late phase, but challenges for successful development and commercialization of biosimilars are growing, despite years of practice. Such challenges include:

- New regulations in the developing regions that add to divergence
- Companies that want to go “global” with one program for maximum return on investment
- Advances in technology that are changing regulatory expectations
- Orphan drug biosimilars that are challenging the core biosimilar development pathway
- Competition for recruitment
- Availability of biologic-naïve populations
- Lower-cost biosimilars that impact incentives for patients to take part in a biosimilar study
- Availability and cost of comparable products
- Racing against the clock to deliver a biosimilar before the patent expires

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THERAPEUTIC EXPERTISE

- Central Nervous System
- Cardiovascular
- Endocrine & Metabolic
- General Medicine
- Rare & Orphan Disease
- Oncology & Hematology
- Biosimilars

YOUR CRO PARTNER CAN SIGNIFICANTLY IMPACT THE SUCCESS OR FAILURE OF YOUR BIOLOGIC

Bigger isn't better. You read that correctly. A partner who tells you they have an infinite amount of resources may not be the best approach for biosimilar developers. No one can be everything to everyone. When deadlines are fast approaching, resources are limited, and teams are small, turn to a partner that can act quickly alongside you.

Choosing a CRO partner who understands the challenges and offers solutions is key to your success. Worldwide Clinical Trials has the knowledge and experience to deliver your program to the global market. We offer:

Regulatory insight
Navigating through the labyrinth of the global regulatory landscape and keeping up to date with the evolving guidance for biosimilar development through a vast
network of regulators on a global scale.

Personalized approach
Utilizing the stepwise approach in biosimilar development, each company and each molecule is unique. One strategy does not fit all.

Strategic solutions
The best strategy that meets company objectives and regulatory expectations.

Collaboration
Collaboration has no hierarchy; access to leaders within
the organization is the "norm."

Life cycle management
From phase I through post-marketing: device studies, switching studies, real-world evidence, post marketing
safety studies – all under one leadership team.

Operational excellence
Recruitment is key. With the growing number of biosimilar studies as well as competition with novel drugs, the CIS region is getting saturated. Country and site relationships with global reach in regions ripe for biosimilar opportunities provide populations with unmet need and ones that are biologic naïve, making them ideal candidates for biosimilar studies.

Nimble, flexible, and adaptable leadership
Move forward together and success takes care of itself!

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

Ian Braithwaite, Ph.D.

Senior Vice President, Global Project Management

Ian Braithwaite brings deep industry and therapeutic experience to his role overseeing project management and operational delivery for Worldwide Clinical Trial's General Medicine, Rare diseases and Oncology business unit. He has full accountability for strategic development and execution of all projects conducted by these therapeutic areas, ranging from immunology/inflammatory diseases (rheumatoid arthritis, lupus, psoriasis, IBD, asthma, COPD, etc.) and 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 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

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).

Jan Kenny, RN

Director, Project Management

Jan Kenny is a Registered Nurse with more than 30 years' experience in the pharmaceutical and CRO industry, including 15 years in hematology/oncology managing and coordinating large-scale global clinical trials across the US/Canada, Asia Pacific, Latin America, South Africa, Europe, and CIS. She has been responsible for the oversight and management of a multitude of trials ranging from global Phase I-II (cohort management/dose finding studies) to large global Phase III-IV trials. Jan has worked in a wide variety of therapeutic areas and tumor types and has considerable experience in other oncology areas, namely, hematology, prostate cancer, liver, lymphoma, solid tumors, NSCLC, myeloma, leukemia and gastroenterology. In addition, Jan has experience in overseeing studies in gastroenterology involving endoscopy for DU, reflux oesophagitis and Crohn's disease. Jan is also experienced in bioequivalence studies supporting registration.

Aman Khera

Global Head of Regulatory Strategy

Aman is the Global Head of Regulatory Strategy at Worldwide. She is an accomplished leader and expert in regulatory affairs, with a 22-year track record of success within the CRO environment in providing global strategic direction in regulatory affairs. She has led regulatory strategy and development services on a wide variety of regulatory projects for a variety of client sponsor companies, ranging from virtual companies to large companies in many therapeutic indications. In 2017, Aman was shortlisted for an industrywide Regulatory Excellence award in the Inspiration category. Aman is passionate about developing comprehensive strategies. Her career has been built on helping clients achieve their end-to-end regulatory strategies – from study submission to commercialization.

Joanna Reeder, MSc

Vice President, Project Management

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.