Worldwide Clinical Trials' Biosimilar Experience

25+ Countries

4,400+ Patients

550+ Sites

Broad individual and combined team experience across multiple indications

- Recent experience in many indications including Psoriasis, Oncology, Rheumatoid Arthritis, Osteoporosis and Inflammatory Bowel Disease
- Many of our Global project leads in Biosimilars also hold MDs leading to more successful relationships with our sites
- Cost effective strategies for successful delivery
- Flexible approach to get you first to market

Clinical Trial Technology and other core services for biosimilars

- Central labs and bioanalytical labs (PK/PD, biomarker, and pathology)
- Clinical Assessment Technologies (CAT) group for advice and acquisition of COA/PROs, Rater training and expert advice on minimizing placebo effects
- Development of electronic COA and PRO solutions

Scientific solutions to support preclinical compound strategy

- Scientific & Regulatory support from Phase I through post- marketing approval services.
- Expert consultancy service at no cost to sponsors
- Team consists of Medical, Scientific & Regulatory experts, as well as a team of Research Fellows

Scientific and medical expertise available to support protocol design and development

- Therapeutic and Biosimilar Medical Experts
- Thoughtful advice on how study design impacts operations. Reducing time and cost.
- Biosimilar protocol and medical writing

Global network of top investigators and consultants, including KOLs, and medical experts in the industry

- Global Site Networks
- Proven, high enrolling sites in Biosimilar Studies
- Offers full-service support to biosimilars, starting with our 180-bed Clinical Pharmacology Unit, supported by the bioanalytical lab
- Partnerships with other CRUs in UK, Poland & South Africa

Significant global operational experience with enhanced awareness of assessments and challenges unique to biosimilar studies related to:

- Understanding the unique challenges of Biosimilar Studies
- Protecting the clinical endpoints
- Reducing Screen Failures
- Proven record in Recruitment and retention

Global and regional regulatory expertise for biosimilar programs

- Planning and operationalizing trials globally with the latest (in-country) regulatory intelligence
- Engagement with regulatory agencies
- Pre-submission meetings with the FDA, EMA and other agencies
- Utilizing our biosimilar knowledge to ensure expedited pathways and programs
- Driving regulatory excellence

To learn more about how Worldwide can support your next biosimilar trial, **contact us.**

worldwide.com

Meet the Team
Biosimilars at Worldwide Clinical Trials

Chris Bell
Executive Director, Project Management, Franchise Area Lead
- 25+ years' industry experience
- 15+ years Biosimilar experience
- Expertise in delivery of global projects in Biosimilars in multiple indications including Psoriasis, Rheumatoid Arthritis, Oncology, and IBD
- Strategic protocol and operational expertise
- Proven leadership and delivery of Biosimilar Programmes for multiple sponsors

Jan Kenny RN
Executive Director, Project Management, Franchise Area Lead
- 28+ years in Pharma and CRO
- Expertise in global delivery of Biosimilars in multiple indications including Psoriasis, Rheumatoid Arthritis, Osteoporosis and Oncology
- Extensive experience in Phase I and Phase III
- Strategic operational expertise
- Proven leadership, ensuring successful implementation and delivery

Zlata Gotshkova, MD, PhD
Director Project Management
- 18+ years in industry
- Experise in delivery of global Biosimilar Programmes
- Proven leadership ensuring successful delivery
- Medical doctor

Adrian Curtis
Associate Director, Project Management
- Biosimilars Global Project Lead
- 9+ years in Project Management
- Specialism in Inflammatory Bowel Disease
- Proven track record in Biosimilar project delivery

Kalpesh Vispute
Senior Project Manager, Project Management
- 18+ years in the Industry
- Proven track record in Global Biosimiar Study delivery
- Regulatory expertise in India and APAC
- Medical Doctor, based in India

Ahmed Samad, MD
Senior Medical Director
- Over 18+ years in global experience in pharmaceutical R&D with a focus on Rheumatology, Immunology, Gastroenterology, and Dermatology.
- Extensive experience with Biologics, Small molecules and Biosimilars.
- Involved in the launch of Humira® biosimilars across the European regions.
- Global development leadership expertise

Agnieszka Bieniek
Associate Director, Project Management
- 24 years of clinical research experience in the pharmaceutical research industry
- 16 years in Project Leadership
- Global Project Lead with successful track record of delivering large Phase I and Phase III biosimilar programmes

Anamarie Costache
Director, Site Activation Therapeutic Lead
- 20+ years in the industry
- Expertise in global startup and regulatory across multiple therapeutic areas and biosimilars
- Startup delivery driven by metrics in a complex environment, including portfolios
- In depth knowledge in biosimilars, rare diseases, UC, IMID

Agnieszka Baczewska, MD
Director, Project Management
- 25+ years in the Industry
- Global Biosimilar trial expertise
- Successful track record of delivering large clinical programmes
- Medical Doctor, based in Poland

Ariela Knallevsky, MD
Executive Medical Director and Scientific Advisor
- 25 years in global Phase I to IV clinical research as a medical advisor, medical
- Director, and sub-investigator for CROs and medical centers
- Expertise in biosimilar clinical development and safety monitoring
- Provides global leadership roles in regulatory filing, with an emphasis on developing comprehensive strategies on clinical development and safety
- Significant experience in protocol, clinical development plan development, and study
- Expert in design of biosimilar studies
- Facilitation of commercialization

Aman Khera
Global Head of Regulatory Strategy
- 23+ years' experience
- Expertise in providing global strategic direction in regulatory affairs, with an emphasis on developing comprehensive strategies and specific experience in autoimmune and inflammatory disease regulatory strategies

Michael Murphy, MD, PhD
Chief Medical and Scientific Officer
- 30+ years' experience
- Expert advice on protocol and study design
- In depth analysis and advice on operational feasibility of protocols
- Provides expertise in translational research services, strategic program development, and the facilitation of product commercialization

Worldwide Clinical Trials

Worldwide Clinical Trials (Worldwide) is a leading full-service global contract research organization (CRO) that works in partnership with biotechnology and pharmaceutical companies to create customized solutions that advance new medications – from discovery to reality.
For more information on Worldwide, visit www.worldwide.com or connect with us on LinkedIn.

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