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.**

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

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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