

Worldwide Clinical Trials' Digestive Disease Experience









Broad individual and combined team experience across multiple indications in common and Digestive Diseases

 Ulcerative Colitis, Crohns Disease, NASH, Alcoholic Hepatitis, PSG, Postgastric Bypass



Clinical Trial Technology and other core services for Digestive Diseases

- Central labs and bioanalytical labs (PK/PD, biomarker, and pathology)
- Scale & PRO management, identification, and acquisition
- Management of Imaging Vendors and DSMBs
- Translations management
- Rater experience assessment
- Clinical assessment training



Scientific solutions to support preclinical compound strategy

- This team offers Phase 1 through post-marketing approval services
- Worldwide offers full-service support to Digestive Diseases, starting with our 200-bed Clinical Pharmacology Unit, supported by the bioanalytical lab, and continuing to Phase 1-4 studies and post-marketing
- Pediatric strategic considerations (including preparation and submission of PSPs and PIPs)



Global network

 Our team consists of top investigators and consultants, including KOLs and medical experts in the industry.



Scientific and medical expertise available to support protocol design and development

 Deep insights and advice from our Scientific Solutions Team



Understanding the unique challenges of Digestive Diseases Studies related to:

- Clinical assessments:
 - Protecting the clinical endpoints
 - Reducing screen failures
 - Minimizing placebo effects
- Recruitment and retention



Global and regional regulatory expertise for Digestive Disease Programs

- Planning and operationalizing trials globally with the latest (in-country) regulatory intelligence
- Engagement with regulatory agencies
- Pre-submission meetings with the FDA
- Utilizing expedited pathways and programs

Worldwide Clinical Trials is founded on an unwavering commitment that combines scientific rigor with personalized attention.

Contact us to learn more about our digestive disease solutions.

Meet the Team

Digestive Diseases at Worldwide Clinical Trials



Chris Bell
Executive Director Franchise Lead Inflammatory
Bowel Diseases

- 25 years in the Industry
- Expertise in delivery of global projects in Ulcerative Colitis and Crohns Disease
- Based in United Kingdom



Amy Ali Project Vendor Manager

- 20 years in the Industry, Global UC and Crohn's experience
- Expertise in IBD vendor management
- Based in the UK



Adrian Curtis
Associate Director

- 12 years in Industry
- Expert Global Project Lead with 6 years spearheading major Phase 2 and 3 ulcerative colitis and Crohns disease programs, extensively managing IBD research across all regions Globally
- Dedicated resource for IBD franchise
- Based in the United Kingdom



Agnieszka Baczewska, MD Director Project Management

- 25 years in the Industry
- Expertise in leading global IBD studies
- Medical Doctor, based in Poland



Christian Achten Senior Project Manager

- 13 years in Industry with significant experience in IBD and Liver disease. Clinical Project Manager in Phase III UC study
- Dedicated resource for IBD franchise
- Based in United Kingdom



Michael Murphy, MD, PhD
Chief Medical and Scientific Officer

- 30 years' experience
- Experience in the IND application process, end of Phase 1 and Phase 2, and pre-NDA meetings
- Provides expertise in translational research services, strategic program development, and the facilitation of commercialization



Britt Gales

Associate Director, Project Management

- 18 years in the Industry
- Experience as Clinical Trial Manager in Phase IIB Crohn's Disease trial
- Associate Director/Global Project Lead on global Crohn's Disease Phase II
- Lead Clinical Research Associate (CTM) in GERD Phase IV
- Based in US. East Coast time zone



Ahmed Samad, MD Senior Medical Director

- Over 18+ years in global experience in pharmaceutical R&D with a focus on Rheumatology, Immunology, and Gastroenterology
- Experience with Biologics, Small molecules and Biosimilars including Enbrel®, CIMZIA® and Humira®
- Extensive global development leadership experience in Crohn's disease and Ulcerative colitis
- Assembled and chaired Data and Safety Monitoring Boards (DSMBs), Steering Committees, and Ad boards



Atilla Timar-Peregrin
Executive Medical Director

Executive Medical Director

- 20+ years in Industry, Special focus on digestive diseases and other gastrointestinal disorders
- Lead medical expert in over 40 gastrointestinal/hepatology studies
- Based in Hungary



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.