Worldwide's Rheumatic and Musculoskeletal Team Experience

30+ Countries

2,600+ Patients

740+ Sites

Broad individual and combined team experience across multiple indications: rheumatoid arthritis, systemic lupus erythematosus (SLE) including lupus nephritis, osteoarthritis, osteoporosis, gout

Clinical Trial Technology and other core services for Rheumatic and Musculoskeletal studies

- Central labs and Bioanalytical labs (PK/PD, biomarker, and pathology)
- Clinical Assessment Training and Surveillance (CATS Team) for Scale & PRO Management:
  - Identification and acquisition
  - Translations management
  - Clinical and operational quality control checks
  - Rater experience assessment
  - Clinical assessment training
- Adjudication of Scales

Study Start Up Team to support quick and efficient study start up strategy

- This team offers unique start up expertise using risk identification as strategy to monitor and safeguard site activation planning
- Keen focus on metrics driven start-up performance for global clinical trials across various regions: North America, Europe, Commonwealth of Independent States, Middle East and North Africa, Latin America, Asia Pacific

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

Scientific and medical expertise available to support protocol design and development

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

- Clinical assessments:
  - Securing the primary endpoints
    - Availability of validated Scales and Questionnaires in all languages of interest
    - Investigator and Subject assessment
  - Pathology (including sample collection, processing, and reporting)
- Deep understanding of eligibility review process prior to randomisation
- Central Reading and Imaging Solutions - Set up, documentation, training and logistics management

Global and regional regulatory expertise for Rheumatic and Musculoskeletal studies

- 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
- Pediatric strategic considerations (including preparation and submission of PSPs and PIPs)

To learn more about how Worldwide can support your next Rheumatic and Musculoskeletal Disease trial, contact us.

Meet our Rheumatic and Musculoskeletal Disease Team

Nathalie Spinnewyn

Executive Director, Project Management, Franchise Area Lead

- 29+ years' industry experience
- Extensive experience in Phase I/II to Phase IV Studies
- Wide experience in various therapeutic areas including autoimmune diseases like rheumatoid arthritis and lupus
- Proven leadership, ensuring successful implementation and delivery

Jan Kenny

Executive Director, Project Management, Franchise Area Lead

- 30+ years' industry experience
- Extensive experience in Phase I to IV studies
- Wide experience of managing studies utilising biologics and in particular biosimilars in psoriasis, rheumatoid arthritis, and osteoarthritis
- Successful leadership in delivering large Global studies

Ahmed Samad, MD

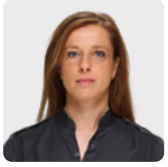
Senior Medical Director, Medical Affairs Adult and Pediatric Rheumatologist

- 18+ years of global experience in R&D with focus on many therapeutic areas including internal medicine, immunology rheumatology and biosimilars
- Experienced with biologics, biosimilars and small molecules
- Experience with adult and paediatric trials
- Steered medical monitoring and clinical investigation for clinical trials (Phase I-IV)
- Assembled and chaired Data and Safety Monitoring Boards (DSMB), Steering Committees, and Ad Boards

Prof. Nemanja Damjanov

Consultant Therapeutic Advisor

- 40+ years of Rheumatology experience with 16 years as Director of Institute of Rheumatology Belgrade, Serbia
- European Alliance of Association for Rheumatology (EULAR) Honorary member, former General Secretary of EULAR and Chair of EULAR Standing Committee on Education and Training
- Author of numerous papers related to rheumatoid arthritis management and well connected with rheumatoid arthritis key opinion leaders and investigators globally



Anamaria Costache

Director, Site Activation Therapeutic Lead

- 21+ years' experience
- 13+ years in-depth knowledge of global regulatory affairs landscape including gene therapy studies and cross border enrollment
- 10+ years' experience leading diverse start -up teams in multiple therapeutic areas including rheumatoid arthritis, osteoarthritis pain, lupus nephritis, multiple sclerosis

Eteri Tsetskhladze, MD, PhD

Vice President, Medical Affairs, Therapeutic Advisor

- Board-certified physician with 26+ years of clinical practice in a university hospital
- 20+ years of clinical research experience in Phase I - IV drug development
- Therapeutic and clinical research experience in various immune-mediated diseases as a Medical Director and as a Therapeutic Advisor
- Experience in connective tissue disorder, including but not limited to rheumatoid arthritis and systemic lupus erythematosus
- Experienced with biosimilars, monoclonal antibodies, small molecules, and ATMPs development
- Was involved in the development of uric acid lowering therapies in chronic treatment-refractory gout
- Credited with more than 50 published articles and monographs

Ariela Knallevsky, MD

Executive Medical Director & Scientific Advisor

- 25 + years in global Phase 1 to 4 clinical research as a medical advisor, medical director, and sub-investigator for CROs and medical centers within the immunology field
- Providing 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 design in immune-mediated inflammatory diseases
- Holds Master's degrees in Osteology and Mineral Metabolism plus Pharmacological and Clinical Research

Michael F Murphy, MD, PhD

Cofounder, Chief Medical and Scientific Officer

- Past President, CRO Division of United Health Group
- Founder, and Research & Development Editor for American Health & Drug Benefits™
- Lecturer within the Clinical and Translational (C/T) Research Academy, Harvard Medical School, the Harvard Clinical and Translational Science Center
- Recipient of the Clinical Research & Excellence (CARE) Lifetime Achievement and PharmaVoice 100 Most Inspiring People in the life-sciences industry
- Responsible for translational medicine consultation including technical and scientific regulatory services within Worldwide for small molecules, biologics, and advanced therapeutic medicinal products
- Program and protocol design consultation in diverse immunological disorders: neuromuscular (e.g. myasthenia gravis), connective tissue (e.g., Sjogren's syndrome, systemic sclerosis, systemic lupus erythematosus), renal (e.g. acute kidney injury, lupus nephritis, chronic kidney disease), and joint (e.g., rheumatoid arthritis)