



## Worldwide's Rheumatic and Musculoskeletal Team Experience



**30<sup>+</sup>**  
Countries



**2,600<sup>+</sup>**  
Patients



**740<sup>+</sup>**  
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)
- Clinician Assessment Technologies (CAT 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

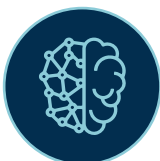


### **Study Start Up Team to support quick and efficient study start up strategy**

- 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

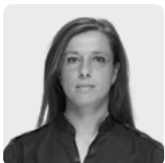
- 18+ years of global experience in R&D with focus on many therapeutic areas including internal medicine, immunology rheumatology and biosimilars
- Experienced with biologics, biosimilars and small molecules
- Experience with adult and paediatric trials
- Steered medical monitoring and clinical investigation 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 Tsetsckhladze, 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

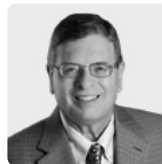
- 25 + years in global Phase 1 to 4 clinical research as a medical advisor, medical director, and sub-investigator for CROs and medical centers within the immunology field
- Providing global leadership roles in regulatory filing, with an emphasis on developing comprehensive strategies on clinical development 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



## **Dele Odulana**

Executive Director, Project Management,  
Franchise Area Lead

- 26+ years' experience
- Extensive experience in managing Phase I to IV studies
- Wide experience in various therapeutic areas including rheumatoid arthritis
- Team leadership ensuring successful implementation of study strategy and delivery



## **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 and PharmaVoice 100 Most Inspiring People in the life-sciences industry
- 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)