Meet the Team
Dermatology at Worldwide Clinical Trials

Chris Bell
Executive Director, Project Management, Franchise Area Lead

- 25+ years' industry experience
- Extensive experience in Phase I to Phase IV programs in dermatology
- Strategic protocol and operational expertise
- Proven leadership, ensuring successful implementation and delivery

Brenda Rolfe
Executive Director, Project Management

- Rare Dermatology Functional Area Lead
- 20+ years in CROs managing Phase I-IV studies for common and rare dermatology indications

Enrico Fragasso
Director, Project Management, Dermatology Operational Advisor

- 17+ years' industry experience
- Proven proactive management success in dermatology trials
- R&D lead for clinical development of three NCEs in dermatology
- Experience in NDA submission/management
- EU/US/APAC KOLs network and AD
- Proven strategic and scientific oversight on clinical trial development in common and rare skin diseases

Jean-Luc Burgaud
Director, Project Management

- 20+ years' clinical research experience
- Proven expertise and leadership in clinical development and registration of products in dermatology
- Adaptive, quality-driven program delivery
- Collaborative and personalized client relationships

Jimena Ochoa, MD
Senior Medical Director, Scientific Solutions

- 20+ years of experience in clinical trials and the pharmaceutical industry, and 8 years performing medical monitoring and medical oversight
- Experience in Phase I-IV studies with biologics and biosimilars, for immunologic and skin diseases

Kathryn Adamson
Senior Site Activation Manager, Head of Bioanalytical Sciences

- 20+ years' experience
- Global startup lead experience in multiple therapeutic areas including dermatology
- Experienced in dermatology studies in CRO and Institution

Ariela Knallevsky, MD
Executive Medical Director and Scientific Advisor

- Almost 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 skin disease clinical development and safety monitoring
- 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 rare skin diseases

Ahmed Samad, MD
Senior Medical Director

- Over 18+ years in global experience in pharmaceutical R&D with a focus on Internal Medicine, Immunology, and Dermatology
- Extensive global development leadership experience in both adult and pediatric Phase II-IV immunology programs, including Psoriasis
- Led Submission of Pediatric Investigational Plans (PIPs)
- Assembled and chaired Data and Safety Monitoring Boards (DSMBs), Steering Committees, and Ad boards

Sherilyn Adcock, PhD
Executive Vice President, Scientific Solutions, Early Phase

- More than 30 years clinical research experience, primarily in Phase I-II drug development
- With Worldwide since 2001
- Responsibilities include evaluating scientific, clinical, design, and logistical expertise for early clinical development projects
- Served as Principal or Sub-Investigator on more than 200 clinical trials

Michael Murphy, MD, PhD
Chief Medical and Scientific Officer

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

Worldwide Dermatology Experience

30+ Countries

3,500+ Patients

300+ Sites

Broad individual and combined team experience across multiple indications in common and rare skin disorders

- Acne, alopecia, atopic dermatitis, bullous pemphigoid, erythromelalgia, melanoma, pemphigus vulgaris, necrobiosis lipoidica, psoriasis, rosacea, warts

Clinical Trial Technology and other core services for dermatology

- Central labs and bioanalytical labs (PK/PD, biomarker, and pathology)
- Photographic and other skin imaging solutions
- Scale & PRO management, identification, and acquisition
- Clinical and operational quality control checks
- 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 dermatology, starting with our 180-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 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 dermatology studies related to:

- Clinical assessments:
  - Non-invasive diagnostic measurements
    - Skin imaging modalities
    - Scale and investigator assessment
  - Pathology (including skin biopsy collection, processing, and reads)
- Recruitment and retention

Global and regional regulatory expertise for dermatology 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

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