WORLDWIDE CLINICAL TRIALS

YOU HAVE A NASH/NAFLD STUDY. WE HAVE YOUR TEAM

THERE IS NO SUBSTITUTE FOR UNCOMMON EXPERTISE

SCOTT BEASLEY

Executive Director, Project Management, NASH/NAFLD Franchise Area Lead

- 24+ years' industry experience
- Extensive experience in NAFLD/NASH Phase II and several Phase III programs
- Strategic protocol and operational expertise
- Proven leadership, ensuring successful implementation and delivery

JANET COMBS

Director, Project Management, NASH

- 17 years' industry experience
- Proven proactive management success in NAFLD/NASH trials
- Adaptive quality-driven program delivery
- Collaborative and personalized client relationships

RAFAL ZIECINA, MD, PHD

Executive Director, Scientific Solutions

- 22 years' experience
- NAFLD/NASH Scientific Advisor
- Focuses on filing strategies, regulatory & safety strategies, and protocol and drug development plan writing for CVOT

MELANIE MYERS

Lead Clinical Research Associate, Clinical Operations Site Management, NASH – USA

- 22+ years' clinical research experience
- Exceptional clinical leadership in NAFLD/NASH
- Effective methodology and process improvement implementation
- Provided clinical management oversight and successful delivery of numerous Phase I – IIIb programs

YOUR HOLISTIC NASH TEAM

Our dedicated team of experts is ready to meet your full-service needs.

MARK W. TENGOWSKI, DVM, MS, PHD

Scientific Director, MSK & More Medical Affairs

- 21 years' experience
- Imaging experience spans ultrastructural- and light-level microscopic evaluations to non-invasive imaging methods, applying imaging end points to nominate and advance compounds, manage safety findings, and achieve regulatory approval

AMAN KHERA

Global Head of Regulatory Strategy

- 23+ years' experience
- Expertise in providing global strategic direction in regulatory affairs, with an emphasis on developing comprehensive strategies and specific experience in metabolic and NASH/NAFLD regulatory strategies

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

DAKSHA DESAI-KRIEGER, PHD

Senior Director, Head of Bioanalytical Sciences

- 20+ years' experience
- Experience in planning and managing safety and efficacy biomarkers for global NASH clinical trials
- Well-versed in method development, validation, instrument operations, and sample analysis to ensure full compliance and delivery of quality data within defined timelines

WORLDWIDE NASH/NAFLD TEAM EXPERIENCE

30+ countries

5,000 patients

500+ sites

Broad individual and combined team experience across multiple NAFLD, NASH, and related metabolic and liver indications

- Chronic liver diseases, obesity, type 2 diabetes mellitus, hypertension, and dyslipidemia.

Central laboratory services and core imaging labs

- Central labs and Bioanalytical labs (PK/PD, biomarker, and pathology)
- Core Imaging and ECG Laboratory
  - Expertise in liver imaging for:
    - Whole organ volume analysis (liver and spleen volume)
    - Hepatic fat fraction (MRI-PDFF)
    - Liver stiffness (MR elastography)
    - SAT/VAT fat depot segmentation
- Experience integrating vibration controlled transient elastography (VCTE) +/- controlled attenuation parameter (CAP) into NASH/NAFLD clinical trials

Extensive CV outcome and adjudication experience

- Our experience executing outcome trials includes understanding the events, treatment, and outcomes. These studies require event adjudication and working closely with Clinical Events Committees (CECs).

Scientific solutions to support preclinical compound strategy

- This team offers Phase I through post-marketing approval services. Worldwide offers full-service support to NASH/NAFLD, starting with our 180-bed Clinical Pharmacology Unit, supported by the Bioanalytical lab, and continuing on to our Phase I-IV studies and postmarketing.

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 NAFLD/NASH studies related to:

- Clinical assessments:
  - Non-invasive diagnostic measurements
    - Liver imaging modalities
    - Biomarker composite scoring (NAFLD fibrosis score, FIB-4, APRI, Fibrosure/Fibrotest, ELF
  - Pathology (including liver biopsy collection, processing, and reads)
- Recruitment and retention

Global and regional regulatory expertise for NAFLD/NASH programs

- Planning and operationalizing NASH and NAFLD trials globally with the latest (in-country) regulatory intelligence
- Engagement with regulatory agencies
- Pre-submission meetings with the FDA
- Utilizing expedited pathways and programs
- Assistance with biomarker qualification programs
- Guidance for critical path innovation meeting (CPIM)
- Pediatric strategic considerations (including preparation and submission of PSPs and PIPs)