

# 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**

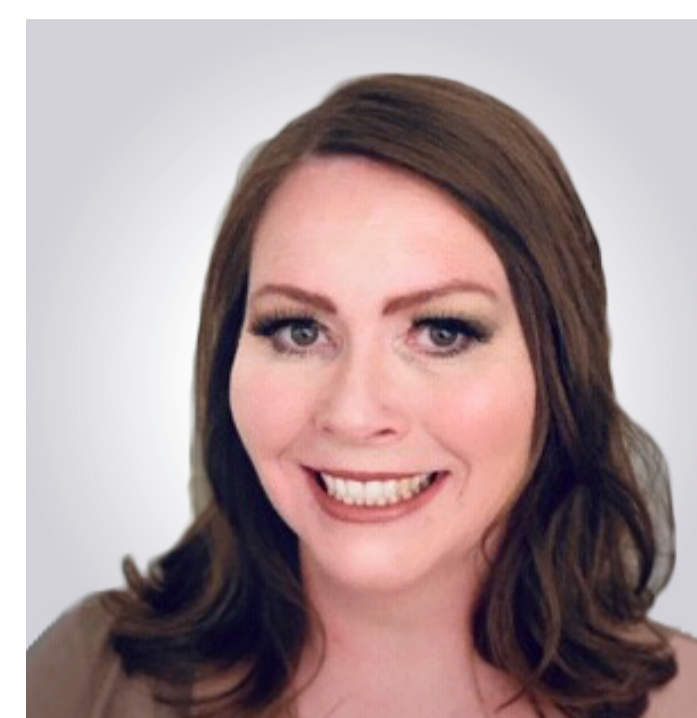
- 17 years' industry experience
- Proven proactive management success in NAFLD/NASH trials
- Adaptive quality-driven program delivery
- Collaborative and personalized client relationships



## 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.



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



**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



**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



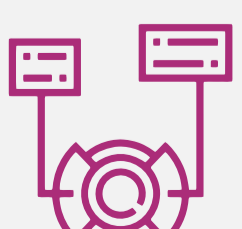
**Extensive CV outcome and adjudication experience**

- 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).



**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)



**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.