YOUR TRUSTED PARTNER

FULL SERVICE CRO

- Pre-clinical to Phase 1–4
- Conduct global clinical trials
  - North & South America
  - Europe
  - Africa
  - Asia
  - Oceania
- Comprehensive protocol development services
- Adaptive Design Trials
- Decentralized Clinical Trials
- Independent Data Monitoring Committee Services (IDMC)
- Recognized industry leaders in CDISC SDTM and ADaM
- NDA and BLA Development

FUNCTIONAL SERVICE PROVISION

- Clinical Operations
- Data Management
- Database Programming
- Biostatistics
- Statistical Programming
- Medical Writing
- Pharmacovigilance & Medical Monitoring
- Regulatory Affairs

QUALITY

INTEGRITY

INNOVATION

FOR MORE INFORMATION, VISIT OUR WEBSITE: WWW.PROMETRIKA.COM OR SCAN ME

PROMETRIKA, LLC
100 CambridgePark Dr.
2nd Floor
Cambridge, MA 02140
617.868.2020
prometrika.com

INNOVATIVE CLINICAL DEVELOPMENT SOLUTIONS

GLOBAL FULL-SERVICE CRO

BASED IN CAMBRIDGE, MA SINCE 2003

SUPPORTING BIOPHARMACEUTICAL AND MEDICAL DEVICE INDUSTRIES

PROMETRIKA
A FULL-SERVICE CRO

STRATEGIC CONSULTING SERVICES

- Clinical Development Program Planning
- Statistical Consultation and Study Design
  - Simulations for Trial Designs
  - Complex Adaptive Trial Design
  - Meta Analyses
  - Regulatory Interactions Support
  - Design and Analysis of Natural History Studies
  - Surrogate Endpoints for Accelerated Approval
  - Design and Analysis of Studies with External Control Arms
- Support for Abstracts, Posters, and Manuscripts
- Regulatory Affairs & Operations
- Technology Solutions
- Infrastructure Support

YOUR FULL-SERVICE CLINICAL PARTNER IN ALL STAGES OF YOUR PRODUCT DEVELOPMENT

PRE-IND | IND | PHASE 1–3 | NDA | PHASE 4

A STRONG CLINICAL PROGRAM STARTS WITH STRATEGY AND PLANNING

Our Pre-IND Services include:

- Natural History Study Design and Implementation
- Surrogate Endpoint Development
- Global, Region-Specific Regulatory Authority Meeting Planning
- Review of Regulatory Agency Feedback

Our IND Services include:

- Enabling Activities
  - Clinical Development Planning
  - First-in-Human Study Design
  - Non-clinical Program Development
- Clinical Protocol Development
- Finalization of Non-clinical Reports
- Preparation of IB
- Preparation of IND/CTA

OUR EXPERIENCED CROSS FUNCTIONAL TEAM DELIVERS AN INTEGRATED EFFICIENT SOLUTION

- Study Design & Protocol Writing
- Worldwide Study and Site Feasibility
- Inspection-ready eTMF
- IRB/EC Submissions
- Randomization Plan and List
- IWRS Design & Build
- eCRF Design & Database Build
- Data Management Plan and Case Completion Guidelines Development
- Safety Database Build
- Risk Assessment and Management
- Clinical Trial Monitoring & Data Cleaning
- Adverse Event and Concomitant Medications Coding
- External Data Integration
- Medical Monitoring & Safety Review
- Statistical Analysis Plan (SAP)
- Develop CDISC SDTM, ADaM datasets, and Tables, Listings, and Figures (TLFs)
- Clinical Study Report (CSR)

DOSSIERS PREPARED AND SUBMITTED TO GLOBAL REGULATORY AUTHORITIES

- Specialized statistical analyses of integrated safety data
- Meta-analyses of efficacy data
- Expert medical writing to support optimal strategies in submission materials
- Presented before FDA and advisory committees, including Oncologic Drugs Advisory Committee [ODAC]

More than 20 NDA/MAA:

- Allergy
- Infectious Diseases
- Nephrology
- Neuroscience
- Oncology
- Ophthalmology
- Pulmonology
- Rare Diseases

MEETING THE UNIQUE CHALLENGES OF PHASE 4 TRIALS... SUPPORTING THE FUTURE

- Head-to-head studies with equivalence or non-inferiority endpoints
- Non-randomized observational studies and patient registries
- Special Phase 4 safety studies
- Observational marketing research
- Post-marketing safety update reports for regulatory submission
- Exploratory statistical analyses of data from marketing authorization clinical trials
- Awareness building, medical education and publication support
- Editorial services: abstracts, posters, manuscripts, and scientific meeting presentations
- Post-marketing Pharmacovigilance

PROMETRIKA
A FULL-SERVICE CRO