CLINICAL OPERATIONS & PHARMACOVIGILANCE

“PROMETRIKA enhances the success of a trial by working in close collaboration with our sponsors and investigational sites. We always anticipate challenges and manage proactively.”

PROMETRIKA
A FULL-SERVICE CRO

CLINICAL OPERATIONS & PHARMACOVIGILANCE

ACCURATE, CONSISTENT DATA

. . . Positive Site Experience

PROMETRIKA's experienced team provides comprehensive clinical trial management services, from start-up through reporting. PROMETRIKA enhances the success of a trial by working closely and collaboratively with our sponsors and investigational sites, anticipating challenges and managing trials proactively. To maintain operational and financial health, our senior management team regularly evaluates each study.

PROMETRIKA clinical project managers expertly oversee timely initiation of clinical trials, including feasibility assessment, site and vendor selection, risk management planning, subject recruitment and retention strategies, and enrollment projections. Throughout the conduct of trials, we provide real-time reporting metrics to manage enrollment progress and monitor site expectations, activity and performance.

Trials are monitored by clinical research associates (CRAs), based throughout the U.S. and Europe and matched to the protocol requirements in indication and experience. Utilizing regional, seasoned professionals and, if requested, remote monitoring and targeted source document verification, PROMETRIKA maximizes cost efficiency in the conduct of these trials.

FOR CLIENT–FOCUSED CLINICAL DEVELOPMENT SOLUTIONS...

PROMETRIKA's Clinical Operations & Pharmacovigilance Team — A Snapshot

- Average of 10 years of experience
- In-house and regionally-based throughout the United States and Europe
- ACRP-certified CRAs (CCRA)
- Experienced in all major therapeutic areas

OUR SERVICES

- Study Feasibility Assessment
- Investigator Identification & Selection
- Site Contract & Budget Negotiations
- Investigator Payment Administration
- Vendor Selection & Management
- Clinical Monitoring Plan Development
- Informed Consent Form Development
- Trial Master File Creation & Maintenance / Regulatory Document Management
- Central IRB/EC Submissions
- Investigator Meeting Coordination
- Site Instruction Manual Development
- Enrollment Projections & Management
- Subject Accrual & Retention Strategy
- Risk Management
- Comprehensive & Risk-based Monitoring
- Clinical Site & Vendor Audits

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