CompleWare provides eClinical and CRO services for many of the largest pharmaceutical companies in the world. With a staff comprised of knowledgeable and experienced professionals, CompleWare consistently demonstrates the ability to provide leadership in the design, implementation, and conduct of clinical trials, and the analysis of clinical trial data.

Our expertise, combined with our proprietary software, CompleClinical®, simplifies the management of clinical trials and results in high-quality data. Through prompt and accurate data capture, validation, and reporting, the information needed to guide development decisions is readily available. We are committed to providing the most efficient, user-friendly, and cost-effective solution for every study.

CompleWare Contract Research Organization Services

Contracts and Budgets

- Legal Document Development
- Confidential Disclosure Agreements (CDAs)
- Contract and Budget Development and Negotiations

Protocol and Clinical Trial Design

- Key Opinion Leaders (KOLs) Input and Research
- Clinical Study Protocol (CSP) Development, Review, Implementation
- Regulatory Submissions [New Drug Application (NDA), Investigational New Drug (IND), Bio-IND, Institutional Review Board (IRB)]
- Regulatory Document Processing
- Drug Retains and Randomization Scheme Development

Project Management

- Study Initiation
- Site Selection (Management, Payments)
- Investigator Meeting (Planning, Coordination)
- Training for Sponsor, Monitors, Sites (Includes Document Development, Printing, Deployment)
- IRB Documents (Development, Review, Document Handling)
- Investigational Site or Site Network Oversight (Recruitment, Evaluation, Support)
- Monitoring (Qualification Visits, Initiation Visits, Routine Visits, Closeout Visits, 100% and Risk-Based Approach)
- Monitoring Reports (Generation, Review, Submission)
- Essential Document Management [electronic Trial Master File (eTMF), Archiving]
- Central Laboratory Services (Selection, Supervision)
- Drug Accountability
- Equipment Sourcing and Logistics
- Interactive Web Response System (IWRS)
- 24/7 Live, In-house Help Desk Support
- Translations [eDiaries, electronic Case Report Forms (eCRFs), Informed Consent Forms (ICFs)]

Data Management

- Data Acquisition, Review, and Verification (Includes Edit Checks, Batch Procedures)
- Query Generation, Resolution
- Data Clarification
- Data Transmission
- Collection and Central Review of:
  - Spirometry
  - Spirometry Challenges (Exercise, Methacholine, Allergen)
  - Electrocardiogram (ECG) and Holter
  - Fractional Exhaled Nitric Oxide (FeNO)
  - Electronic Patient-Reported Outcomes (ePRO)
- Pulmonary Diagnostics, Pulse Oximetry (SpO2)
- Image Analysis (Radiology)
- Clinical Laboratory Data (Integration)
- Data Validation

Biostatistics and Clinical Study Report (CSR)

- Statistical Analysis Plan (SAP) (Development, Review, Implementation)
- Biostatistical Analyses (Including Interim Analyses, Listings, Meta-Analyses, Reporting)
- Writing, Review of CSR
- Evaluation and Integration of Safety, Efficacy Data
- Pharmacoeconomic Analyses
- Pharmacokinetic Analyses
- Serious Adverse Event (SAE) Reporting
- Protocol Variance Handling
- MedDRA Coding
- Disposition Coding
- Drug Coding
- Data Submission (ClinicalTrials.gov posting)

Quality Assurance and Auditing

- Pre-study and Post-study Audits
- Monitor Audits
- Site Audits
- Subcontractor Audits
- Good Clinical Practice (GCP) and Compliance Training

For more information about CompleWare software and services, email businessdevelopment@compleware.com.
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