



Data Operations.

Premier Research's data operations group can help you achieve your study goals by navigating your drug through the development lifecycle quickly and efficiently, providing you with clean scientific data.

Services

- CRF Design and Annotation (Conventional, CDASH, or SDTM Compliance)
- Protocol and CRF Review
- Internal EDC Capabilities using Oracle Clinical RDC Onsite
- CRF Scanning and Tracking Management
- Database Design, Validation, and Maintenance
- Lab Data Management and Conversions to Standard Units (Conventional or SI)
- Query Management
- Medical Coding
- SAE Reconciliation
- Real-Time Data Access/Browsing
- Standard and Custom Reporting
- Database Transfers (Conventional and SDTM formats)
- CDISC (SDTM) Dataset Conversions
- Generation of Define Documents (to describe either Conventional and SDTM) for Regulatory Reporting
- Independent Review/Validation of SDTM Datasets, SDTM Annotated CRFs, and DEFINE.XML Documents
- Complete Data Operations Support for NDA Submissions

Benefits

- Experience includes data management projects in all major therapeutic areas
- Oracle Clinical experience and expertise provides industry leading solution for your study
- EDC, paper, or hybrid data collection designs available
- 24/7/365 internal Oracle Clinical support services and training provided
- Flexibility in data offerings including full-service solutions as well as standalone and functionally-based biometrics services
- Data operations in North America (Atlanta, Boston, Philadelphia, Raleigh) and Europe (Darmstadt, Germany; Wokingham, UK) allow for flexibility in local or global management of data
- Our Parallel Processing Approach™ (PPA) means most aspects of data operations are initiated in unison rather than sequentially, resulting in shorter timelines
- Comprehensive, industry-standard compliant processes ensure the quality, safety, and confidentiality of your trial data
- Use of industry standards for your clinical trial in order to provide efficiencies and cost-savings, including CDASH CRF design conventions, CDISC database naming and structural conventions, and SDTM compliant SAS dataset deliverables
- State-of-the-art security, data replication, server load balancing, back-up, and disaster recovery systems ensure confidence that your data is safe

Case Study: Providing Oracle Clinical Expertise

An emerging biotechnology company invested in Oracle Clinical as their data management system, but lacked an internal data management staff that could fully utilize the robust features of the tool and provide data management support for multiple studies in their pipeline.

Premier Research was able to provide strategic data management services, including development of departmental SOPs and a plan to provide comprehensive data management services when and where they were needed—both on-site and through a secure, remote connection to their Oracle Clinical database. We acted as the client's data management team for well over two years, providing services ranging from CRF design through database lock on numerous studies.

This gave the company the freedom to focus on the important part of clinical research they knew, drug development, rather than on technology and operational support.

Data Operations.

Premier Research's highly experienced data operations group offers a range of options for data collection, cleaning, and reporting using the latest versions of industry leading software.

Expertise: The People

- Each data operations team member is carefully selected and trained in regulatory practices, company policies and processes, department procedures, and study guidelines
- Size and structure of global team is strategically located and adequate to handle and scale for any size of trial
- Experience in all phases of clinical development in a wide variety of indications/therapeutic areas with strengths in Premier Research's core therapeutic areas
- Experience with multiple data platforms and EDC vendors with a focus on Oracle Clinical
- Staff are located in data centers around the world to provide local management to your data processing as well as global reach for the management of your multi-national clinical trials
- Advanced degrees in natural and medical sciences, mathematics, computer sciences, statistics and other related disciplines
- Conversant in SAS, Visual Basic, SQL, Oracle PL-SQL and other data management related programming languages

Technology

Oracle Clinical v4.5.3

Clinical Data Management System (CDMS) platform running from a state-of-the-art data center in Austin, Texas utilized and accessed globally

Oracle Clinical Remote Data Capture Onsite

Internally operated and supported EDC tool

SAS v.9

Supports the production of all data operations deliverables

Adobe Frame Maker 8.0

Utilized for all form related development services including CRFs and diaries

Oracle Discoverer and Integrated Review

Tool for data review, data browsing, and standardized report deployment for client use

Microsoft SharePoint

Version control document repository

Distributed File Sharing

Manages local server storage replication and access across all data operations servers at each of the data centers

ExtraView

Issue and workflow management tool to facilitate the completion of the study activities

Proprietary User Management Applications

Designed to streamline the requesting, approving, processing, and management of EDC users

Training Software Suite

Designed to facilitate the testing, certifying, and storing of certificates and training history for EDC users

Case Study: Employing Electronic Data Capture

A biotech company planned to conduct a two-part dose-ranging/dose-escalation study. The blinded safety data for each cohort in the first part needed to be available in a short period of time for the client to review for critical risk and safety management study decisions. Additionally, two formal interim analyses, which included efficacy analyses, were to be conducted during this phase. These analyses were critical for deciding dosing requirements and other variables needed for part two.

Performing the multiple analyses for these critical decision points required delivery of clean data in one day and locked patient data in less than three days. Premier Research was able to utilize an EDC solution for this project that allowed the sites to directly connect to the database in real-time for processing of eCRF pages. Data managers at Premier Research reviewed and cleaned the data directly within the system through direct query processing with the sites allowing quick delivery of a locked database for client analysis. The time savings was critical to decision making, and as a result, the appropriate patients continued to part two of the study allowing the client a complete evaluation of their new product.



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