Clinical Data Management

ICBio provides full clinical data management services for phase II & III clinical trials supported by oracle® clinical, MedDRA coding and workflow system. Data management services are dedicated to the highest quality, excellence and client satisfaction through project management, communication and execution of studies.

Our team understands the complex gamut of the global regulatory requirements and has expertise to deliver the tailored, cost effective solution that will ensure punctual and cost-effective delivery of clinical trial project.

Our data management services are governed by well-defined SOPs and comply with ICH-GCP, GCDMP and FDA 21 CFR Part 11. Our CDMS is oracle® clinical and TMS based product which is user friendly, fast & effective, comprehensive and generates extensive reports and audit trails.
Prominent features of data management

Overview of Clinical Data Management Services

Study Set-Up

- CRF/eCRF Designing
- Data Managment Plan
- Database Design & Setup
- Import/Export Setup
- Dictionary Setup (eg. Med DRA)
- CRF Tracking Setup

Study Conduct

- Double data entry & Verification
- Data Loading(Central Lab Data, e-patient Dairy, PK Data Loading)
- Data Review & Query Management
- Medical Data Coding
- Project Specific Document Management
- SAE Reconcillation

Review

- QC, Dtabase Audit
- Adverse Events Evaluation of Medical & Scientific Consistency of Data
- Periodic Review for protocol adherence, data recorded & regulatory file maintenance
- Data Quality Control

Study Close Out

- Interim Data Closure
- QC, Data Audit & QA
- Final Database Closure
- Database Lock
- Relevant project closure documentation
- Analysis & Report

Coding dictionary:
MedDRA
WHO DD
Sponsor specfic coding dictionary