ACDMC

Advanced Clinical Data Management Centre

Credible Data & Training

Supported by: PATH-New Delhi, WHO-IVR, WHO-TDR and CMC-Vellore

Introduction

In today's scientific and medical world, various issues in clinical trials and research have permeated every society and every field in medicine. Ethics and in particular the quality of research are two aspects of clinical research. The advances in technology have greatly helped high quality clinical data management. It is therefore of utmost importance to achieve optimum quality in the conduct, analysis and report of a clinical trial.

The need to provide quality data management and training of personnel, has spurned on the creation of an Advanced Clinical Data Management Centre at the Department of Biostatistics, Christian Medical College (CMC), Vellore, India. This facility has great potential to impart world class trainings and data management services for clinical trials.

Goals

- To provide quality service in the conduct of clinical trials data management in compliance with Clinical Data Interchange Standards Consortium (CDISC) standards, International Conference on Harmonization-Good Clinical Practice (ICH-GCP) and Food and Drug Administration (FDA) regulatory requirements and guidelines.
- To conduct training courses in critical aspects of clinical data management such as Electronic Data Capture and Audit Trail software, Serious Adverse Event and Drug Coding using software, Principles of Quality Assurance and Quality Control, and Standard Operating Procedures (SOP) writing for clinical research.
- To provide Bio-statistical services for data analyses and scientific report writing.

Organization Profile

Our Organization:

Christian Medical College was started in 1900 by Dr. Ida Sophia Scudder, a young American missionary. Today, CMC offers 90 recognized training programs in medical, nursing, and paramedical fields. CMC is proud to be become 2234 bed multi-specialty, tertiary care teaching hospital now.

The Department of Biostatistics at CMC was established first of its type in the country in 1964. The department has been actively involved in data management, statistical analysis, scientific writing, and training in collaboration with several institutions. Biostatistics Resource and Training Center (BRTC) was set up in 1998 which works with government and non-government organizations, providing advisory and training services. This resource center also organizes workshops on recent developments in Biostatistics in collaboration with universities from USA and Canada.

IT Services

We have designed our IT systems and associated SOPs to comply with FDA (Food and Drug Administration) "Guidance for Industry – Computerized Systems Used in Clinical Trials" and FDA 21 CFR Part 11 regulations. To ensure the highest level of security and to maintain the functionality of

Functional Expertise

- CDISC dataflow integration
- Case Report Form Design
- Design of Clinical Trial databases in Oracle Clinical or Promasys
- Codeing in MedDRA and WHO DD
- Secured subject accessible platforms for monitor and investigator
- Statistical Programming
- Data Migration and Integration
- Biostatistical Analysis
- Consulting & Training

EDC, we have designed a multi-layered network with multiple firewalls to mirror these activities. This architecture also ensures that only fully authenticated users are able to access our internal LAN. Our security protocols begin with controlled access to the premises, workstations and servers.

Data Management Services

The department of Biostatistics is a large-scale data management office where the prime approach is to provide solutions in clinical data management solutions to potential clients.

- CDISC data repository design optimized for SDTM/ADAM implementation systems
- Paper to Electronic Data Capture (eCRF)
- Accelerated query management
- Changes to Protocol, CRF Template and project specifications
- Data Management Plan
- Database Design
- Data Validation Plan
- Data Entry
- Medical Coding
- Data Validation and Query Management
- Database Lock and Audit
- Database Documentation & Release

Electronic Data Capture (EDC) Services

Our secured and FDA21 CFR Part 11 compliant EDC system with its intuitive user interface is used to host your studies on-line. The services are

- Study set up
- Design user-friendly data entry screens
- Implement on-line data validation
- Produce/customize status reports and data listings
- Database exports and locks
- User support

Design and Protocol Development

We develop new protocols that include safety and efficacy trials, large sample-size registration trials.

The summary of our study design and protocol development services is:

- Study Design
  - Phase I/II safety and dose finding studies
  - Phase II exploratory efficacy trials
  - Randomized controlled phase III trials
  - Phase III and IV trials
  - Bio-equivalence and therapeutic equivalence trials
  - Pharmacovigilance and pharmacoeconomic trials
- Protocol Development
  - Statistical planning (sample size estimation, randomization, and approach in the statistical methods)
  - Complete protocol development
  - Case Report Form design
  - Literature review and meta-analysis
  - CRF completion guidelines

Biostatistics Services

The staffs of the Department of Biostatistics have experience in the design and analyses of clinical trials.

- Study design
- Analysis and reporting of pre-clinical and Phase I-IV clinical trials of various designs to match the objectives of the study
- Randomization – envelops, fax or web
- Unscheduled interim analyses
- Post-hoc and exploratory analyses
- Formal interim and final analyses
- Statistical consulting.

Clinical Study Reports and Manuscripts

To augment our Biostatistics services, we prepare clinical research reports and manuscripts. Our complete study documentation includes the research report with summary tables and graphics, clinical data listings and computer output of statistical analyses. The following is a list of clinical research report and manuscript writing services we offer:

- Clinical research reports:
  - Statistical Reports
- Interim efficacy reports
- Reports on post-hoc/exploratory analyses
- Integrated Summary of Safety and Efficacy Reports.
- Abstracts and Manuscripts:
  - Medical writing

- Editing for publication
- Graphics and visuals

CDM Tools (Softwares)

Oracle Clinical

Oracle provides integrated; complete solution for design, conduct and managing of Paper, EDC and hybrid clinical studies. The solution consists of

- Oracle Clinical, a Clinical Data Management Software for paper CRF, database management, data entry through eCRF, data cleaning, query resolution can be done.
- Remote Data entry for conducting and managing Electronic Data Capture (EDC) trials,
- Proven compliance platform for various regulatory requirements including FDA's 21 CFR part 11, GCP guidelines etc.
- Thesaurus Management System for managing dictionaries required for medical coding during clinical trials

Key benefits of using Oracle clinical are as follows

- Single study definition tool for paper and electronic data collection and support for hybrid studies
- OC provides a Global Library Management that enables enforcement of global data standards like SDTM; using global library facilitates rapid study set-up by re-using standard objects.
- Ease integration with external systems (workflow, imaging, OCR/ICR, Barcode Systems, additional data collection devices)

- Interface for defining complex validation checks, including configurable online checks, without the need for PL/SQL skills
- Handling Unplanned Pages / Visits

Promasys 7.0

Promasys is an integrated clinical data management and EDC system that brings quality and efficiency to your clinical data capture and data management processes. On top of industry standard data management functionality -which is available to the users without having to do any programming- Promasys offers rich reporting and work flow support solutions, like automatic distribution of subject recruitment progress reports, automatic generation of bar-coded sample tube labels, work lists, data listings and SAS data sets, etc.

Some of Promasys' main features include:

- Easy setup of new trials; use templates and recyclable trial design elements
- Paper CRFs, EDC screens, iPad app screens, forms and labels are all generated from the clinical database design
- Build edit checks without programming
- Manual queries and system generated batch queries
- Full audit trail compliant with 21 CFR part 11
- Electronic signatures
- Set & forget access control, dynamic access rights management through the Study Life Cycle

Contact

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