SERVICES

BIOMETRICS

“ Team is avid believer in data sciences concepts, and expert in providing data related services for Global project

Our Biometrics team understands and apply the study specific attributes including scientific principles, attributes of data, purpose of investigation and therapeutic indication knowledge to optimize future studies in your drug’s development.

We do it all: study design consulting, modeling, data collection, data cleaning, analysis, and reporting - and our data flow process is streamlined and transparent so that you can view the results in real time.

Data Management

Start-up:

Data management plan
- Case report form design (electronic/paper CRF)
- Database designing, Programming & validation check
- User acceptance testing

Close-out:

Database finalization and extraction

Conduct:

- Real time data review, data Validation and data reconciliation
- Medical coding
- Study Metrics and tracking
- Quality Control to ensure validity and integrity of the data
- Identification of data trends

Support:

- Follows standards like CDISC- CDASH/ SDTM
- Design and set-up of patient recorded data (paper or electronic (e-diary)
- Data Consolidation, migration and Conversion

Biostatistics

Clinical Design:

- Special approaches like adaptive design
- Sample Size Calculations
- Randomization plan

Statistical Analysis:

- SAP- Statistical Analysis Plan Preparation
- SAS Programming
- TLF generation
- PK/PD Analysis
- CDISC conversion and/or Deliverables (SDTM, ADaM, Define)
- Statistical Reports development

Contribution:

- Protocol Development
- Data Safety meeting/update
- Clinical Study Report

Support:

Regulatory query resolutions

COD BIOMETRICS

Why COD Biometrics?

PEOPLE

Data Management

- Lead DM has 11+ years of rich & extensive experience, worked for >50 clinical studies.
- Team with hands on experience on various EDC systems like, Medidata RAVE, TrialKit, Oracle Clinical, OC-RDC, ClinCapture, PheedIt, Clinion, OctalSoft, Acceliant, EDC2Go, Protocol First, Medrio, Symetric, CRFweb, ARS EDC etc.

Biostatistics

- Lead biostatistician has 18+ years of rich & extensive experience, worked for >250 clinical studies
- SAS certified, seasoned advance SAS Programmer team lead with 11+ years of experience in GCT environment

CAPABILITIES

- Handled of multiple GCTs and handling largest project for up to 20000+ study subjects.
- Worked on major therapeutics area of Drug, Biosimilar, Vaccines and medical device trio
- Providing standalone biometrics service support through FSP model
- Shorter lead time for study Go-Live

PLATFORM

EDC/RTSM/eCOA/ePRO

- We are channel partner with Medidata RAVE
- We are Business Partner with TrialKit
- Other Systems based on Study and/or Client's requirements
- Seamless integrations with other clinical software/ technologies
- In-house SAS V 9.4 software for statistical analysis

COD® RESEARCH

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