celerion
Translating Science to Medicine

Data Management and Biometrics

The unique combination of an experienced Data Management and Biometrics team and a complete suite of clinical pharmacology sciences enables Celerion to help our customers accelerate development, deliver on tight timelines, and avoid unnecessary costs.

The Celerion Data Management and Biometrics team is a market leader in adaptive study design, early clinical data management and PK/statistical interpretation/reporting. Our extensive experience and breadth of expertise has historically produced over 5,000 protocols, enabling clients to expedite their drugs to market.

Full service offering

Our end-to-end service offering combined with immediate access to data, enables customers to execute faster go/no go decisions.

- Save time and money by having access to a full complement of early clinical studies including first-in-human and adaptive design protocol development and execution
- In-house clinical research, clinical pharmacology sciences and bioanalytical services enable 48 hour data turnaround thereby eliminating risk, cost and time.
- 24-hour data turnaround from last sample to pharmacokinetic analysis for rapid dose escalation decision making
- ClinQuick® early phase clinical study management system with electronic data acquisition, allow integration across our sites to recruit and run simultaneous studies seamlessly
- Celexus® client portal, directly populated with data from ClinQuick, gives clients visibility and transparency to their early clinical research data in real time, as it is collected in the clinics and laboratories. The viewable data includes screening, recruiting, adverse events, clinical laboratory, pharmacodynamics, pharmacokinetic and bioanalytical data. Celexus' Key Performance Indicator Dashboard provides visual displays of study progression including recruitment, deviations, study milestones, dosing and retention. This enables faster assessment of trends and identification of potential safety signals such as vital signs, dosing, adverse events, ECGs and inclusion/exclusion criteria.

Services

- Modelling and Simulation
- Study Design and Protocol Development
- Clinical Data Sciences
- Biostatistics
- Pharmacokinetics/Pharmacodynamics (PK/PD)
- Medical Report Writing

Experience and expertise

- Over 40 years experience
- 120 specialized scientific staff to supplement your team
- Study designs to optimize outcomes, reduce risk and shorten development time lines
- In-depth understanding of dynamic regulatory environment
- Evaluation of > 400 Phase I and II protocols each year
- Produces over 200 study reports annually

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Global reach

Our Data Management and Biometrics team has global capacity across four sites in North America and Europe. Our global SOPs, procedures and deliverables enable clients to work with the same scientific team regardless of where the clinical portion of their study is executed.

- Lincoln, Nebraska, USA
- Phoenix, Arizona, USA
- Belfast, Northern Ireland, UK
- Zürich, Switzerland

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CLINICAL DATA SCIENCES

Full clinical data management services (eCRFs using ClinQuick and EDC or paper CRFs)

Full use of CDISC data standards including CDASH and SDTM data files

External database imports including reconciliation

Submission-ready data packages

MEDICAL WRITING AND REPORTING

Review coding of AEs, medical history and conmeds

Write safety analysis for clinical study reports

Prepare and format ICH-compliant clinical study reports

eCTD submissions

BIOSTATISTICS

Provide sample size calculations, randomizations, endpoint selection and consultation services

Produce detailed statistical analysis plans

ADaM datasets to facilitate "One PROC away" analysis programs

Produce TFLs including required statistical analyses

STUDY DESIGN AND PROTOCOL DEVELOPMENT

Develop and write study protocols and amendments

Review sponsor-written protocols and provide feedback

Provide consultation services related to study design

Experience with protocols in Phase I and II, covering a variety of dosage forms and therapeutic areas

PK/PD

Provide study design input

Perform PK and PD analyses and interpretation

Provide consultation services on PK/PD topics

MODELING AND SIMULATION

PK/PD modeling

Extrapolate data from discovery and preclinical and/or in vitro to forecast drug action

Determine appropriate dose based on animal or human data