



Biometrics Understanding Data



CHILTERN GLOBAL BIOMETRICS

Working to global SOPs, Chiltern's global Biometrics team provides local communication to our sponsors and shares the benefits of support, knowledge and experience with their colleagues around the world.

DATA MANAGEMENT AND eCLINICAL SOLUTIONS

Our project teams are specialists in eClinical systems; we specify, program and manage eCRF builds, set-up integrations with external data, support ePRO and IVR/IWR implementations, perform EDC site training and manage a high quality data cleaning process culminating in a timely database lock. We are experienced in training using a wide variety of EDC systems and the high standard of our training prevents many problems that sites may otherwise encounter using EDC.

Chiltern's wide knowledge of eClinical systems assists us in the creation of the best fit solution for our clients. We partner with the leading industry's EDC, ePRO, and IVR/IWR vendors:

- Perceptive DataLabs® – EDC/CDMS
- Medidata Rave® and Oracle InForm – EDC
- endpoint Pulse – Integrated IVR/IWR and ePRO
- PHT, invivodata, CRF Health – ePRO

Chiltern has the resources and experience to be flexible with data collection methods by offering EDC and where appropriate, traditional paper CRF or a hybrid of both. We can provide recommendations of systems designed to meet the needs of your study or work with your preferred platform/vendor.

Our database programmers design databases to specifications, including CDASH, to meet our clients' needs as well as specific statistical and regulatory requirements. Chiltern has experience transferring data to our clients in a wide variety of formats to meet client specifications or SDTM.

Accurate and robust eCRF integrations require detailed technical knowledge and consideration of the most appropriate integration methodology (back-end, front-end, frequency, blinding issues). Chiltern has a significant integration experience using a wide variety of EDC, IVR/IWR and ePRO systems, many data sources from central laboratory, bioanalytical laboratory, ECG and E2B compliant data transfers of clinical data for reconciliation of E2B exports from safety databases.



BIostatistics AND STATISTICAL PROGRAMMING CAPABILITIES

The statistician is an integral part of our clients' project team and is involved in all key stages of their clinical trials. We provide full service statistical support including:

- Study design consultation for all phases of development, including primary/secondary endpoint planning
- Adaptive design strategies
- Statistical methodology, analysis plans, sample size estimation/re-estimation
- Implementation of complex randomization plans
- Interim analysis and data monitoring committee support
- Regulatory and advisory meeting support

- Management of data monitoring committees
- Production of integrated summaries (ISS/ISE)
- ADaM and submission datasets

All deliverables are reviewed and verified to ensure the highest quality prior to issue and are structured to meet the varying needs of our clients. SAS® is used for reporting and analysis and WinNonlin for pharmacokinetic parameter estimation. Our experienced biostatistical and SAS programming teams provide value to our clients with their understanding of the complexities of study design, analysis and interpretation required for their projects.

MEDICAL WRITING CAPABILITIES

Using our experience from all clinical phases and a wide variety of therapeutic areas, our medical writing team works closely with statistical and clinical colleagues to write protocols, CSRs and publications. Prior to issue, stringent quality control and proofreading procedures are applied to ensure the highest quality

deliverables ready for client review. Chiltern has experience in using client CSR templates as well as our own CSR template which is compliant with eCTD guidelines. CSRs can be provided as hyperlinked and bookmarked PDF on request. Chiltern has experience with ICH E3, E6, E9, ICH M2 and eCTD guidelines.

KEY ADVANTAGES OF GLOBAL BIOMETRICS

- Global systems and SOPs
- Global integration of Biometrics resources
- Highly experienced project leads
- Rapid, high quality eCRF set-up
- In depth experience in leading EDC systems
- Specialized expertise in eCRF integration services

- Focused EDC site training
- Detailed planning and management for database lock
- Extensive experience in adaptive trial database designs
- High quality statistical and medical writing services for all regulatory requirements

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