Clinical Trials Solutions

INTRODUCTION

Tegra works with investigators, administrators, sponsors, and the FDA to design the data and statistical and analytical components of both study protocols and statistical analysis plans. We also manage data collection and create statistical tables, figures, and listings after the trial concludes to deliver a comprehensive FDA submission.

SERVICES AVAILABLE

Study Design
Protocol Development and Review
Statistical Analysis Plan (SAP)
Sample Size Determination
Phases 1, 2, 3, 4
Power Calculation
Randomization, Blinding, and Data Lock
Paper CRF, Paper Source, and eCRF
Data Entry, Validation, and Edit Checks
Tables, Figures, and Listings
Interim Analyses
Controlled and Uncontrolled Trials
Crossover and Parallel Trials
Survival Analysis
Multivariate Analysis
Linear Models
FDA Preparation and Submission
SAS Data, Documentation, and Procedures
CDISC, ADaM, and SDTM datasets

EXPERIENCE

Matthew C. Hutcheson - Founder and Partner
Matt leads the Clinical Trial Solutions Team for Tegra with over 20 years of experience. He is also an adjunct professor at Delaware Valley University and teaches Statistical Data and Research.

Fields of expertise include:
- Pain and Pain Relief
- Anesthesia
- Neurology
- Dentistry and Dental Surgery

DSG eCaseLink:
Tegra works in collaboration with DSG’s eCRF software for electronic data entry that combines CTMS, EDC, IWRS and Safety into a single system compliant with 21 CRF Part 11.

For additional information, visit www.dsg-us.com

REFERENCE

“OraVerse® has been approved in the pediatric setting with no 483s, no supplemental TFLs, and within the review cycle. We had a successful FDA NDA submission with Tegra a few years ago with Articaine and history repeated itself with this OraVerse® study. Once again Tegra provided excellent study design, accurate statistics, and quality data.

Tegra has been an invaluable addition to Novocol’s pharmaceutical clinical study team. Their knowledgeable advice, keen attention to detail and ability to interact with all members of the team from President to lawyers to clinicians has made them an excellent choice as our statistical partners. In addition to the technical skills they brought to the project, their team is courteous, helpful, prompt in meeting deadlines and equally comfortable offering suggestions or incorporating other ideas into the study design. I would not hesitate to recommend the services of Tegra for our next project.”

Novocol Clinical Research Team

PUBLICATIONS


