cliantha research

Convenient Compliant Competent

CDISC Solutions

CDISC Deliverables

SDTM

- Domain XPTs
- Reviewer guide - SDRG
- Annotated CRF
- Define.xml
- Define.pdf
- CDISC validation report

ADaM

- Inputs from biostatistician
- Domain XPTs
- Reviewer guide - ADRG
- CDISC validation report
- Define.xml
- Define.pdf

Facts since FDA required CDISCs submissions:

- Cliantha Research is a CDISC gold member
- Successfully completed more than 350 Bio equivalence studies - CDISC submissions.

Expertise

Dedicated & experienced team

- Team of 30 professionals to provide CDASH & CDISC submission package
- Technical review team to ensure accurate interpretation of SDTM / ADaM is applied in the package.

On-time

Whether it is a First-to-File, First-to-Market or a standard study, we commit to the timeline & meet it.

Delivers high quality & compliant services, cost-effectively

324 Successfully completed Bioequivalence and Clinical Trial CDISC submission