BIOCLINICA®
eCLINICAL SOLUTIONS

SAS PROGRAMMING SERVICES

Bioclinica's PASSION for statistics and innovative spirit has given us the following significant benefits:

- ✓ Final validated SDTM domains may be available within two business days of final database lock.
- ✓ Initial domains are typically available six to eight weeks after a good representative sample of data is collected in Express.
- ✓ We are able to provide an annotated CRF for SDTM transformations after the CRF has been approved and before the study is live, allowing a shortened timeline to your initial set of SDTM domains.

Bioclinica offers fast, reliable, and cost-effective statistical services that support your Express EDC study. The Bioclinica SAS programming team works in conjunction with the electronic data capture and data management teams to provide you with comprehensive, quality support that can scale to your study and your own team's needs.

- › eCRF annotations - Creation and validation of SDTM annotations on eCRFs following the FDA submission guidelines
- › SDTM transformations – Development of mapping specification; programming and validation of fully compliant SDTM domains; and preparation of QC documentation (including Open CDISC Validator Report)
- › ADaM datasets – Development of mapping specification; programming and validation of analysis datasets (via parallel programming); and preparation of QC documentation
- › Routine generation and validation of SDTM, ADaM and TLFs – SDTM domains can be delivered with as little as one day notice for mid-study analysis
- › Creation of Define.xml following the FDA submission guidelines
- › Development and validation of tables, listings and figures (unique and non-unique)