Phil Guo

Scientist, Stat. Programming at MSD

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Summary

Develop mock-up shells, ADS, AD, and TLF programming and corresponding QC tasks (Mainly Phase II – III).
Coordinate internally and externally as the stats programmer leader for various programming issues.
Coaching and mentoring to new and junior members.

Experience

Scientist, Stat. Programming at MSD
November 2015 - Present (8 months)

Stat programmer II at Covance
April 2014 - November 2015 (1 year 8 months)

- Develop and review SAS specifications, programs and output for the creation of ADaM and client-defined analysis datasets, tables, listings and graphs in support of Statistical Analysis Plans
- Interact with project team members in related disciplines e.g. Clinical Data Management, Clinical and Biostatistics.
- Assume team member responsibilities, including representing Statistical Programming at internal project team meetings and with support from senior Statistical Programming staff at client meetings.
- Demonstrate good problem solving skills, a proactive approach and a willingness to make decisions, seeking advice from senior Statistical Programming staff to confirm decisions when necessary.
- With sufficient experience assume the role of a Lead Programmer for assigned projects.
- Understand scope of project in order to advise Senior Statistical Programming staff of changes in scope of projects to enable the timely development of change orders.
- Assist with training, mentoring of Statistical Programmers under the supervision of senior Statistical Programming staff.
- Participate in the Statistical Programming review of Case Report Forms (CRFs), annotated CRFs, database structures and study related documentation
- Review draft and final production runs for projects to ensure quality and consistency.
- Ensure the filing of study documentation is maintained to the standard required according to processes and acceptable for audit.
- Prioritize personal workload to meet specified completion dates.
- Carry out all activities according to Covance SOPs working within the framework of the Quality Management System and to Good Clinical Practice (GCP).
- Perform other duties as assigned by senior Statistical Programming staff.

Stat programmer II at PAREXEL

November 2013 - April 2014 (6 months)

Responsibilities include:

- Providing technical expertise for the conduct of clinical trials, and works with minimal supervision to support various programming activities related to the analysis and reporting of clinical study data;
- Assisting in the coordination of project start-up activities, including Unix/PMED project area set-up, tracking spreadsheets, and required documentation;
- Interacting with sponsor as the key contact with regard to statistical programming issues for 6 projects(3 of them are UCB studies according UCB-PRA-PXL SPI standard);
- Producing TLF Mock up Shells and ADaM Datasets Specifications per Statistical Analysis Plan, providing inputs on CRF design, review, database setup, data validation;
- Ensuring quality control (QC) on all process and technical activities related to derived dataset, table, listing, and figure programming in accordance with corporate quality standards, WSOPs/Guidelines, ICH-GCP and/or other international regulatory requirements are performed;
- Maintaining all supporting documentation for studies in accordance with WSOPs/Guidelines to ensure traceability and regulatory compliance;
- Providing relevant training and mentorship to 2 new staffs and project teams as appropriate;
- Assisting project teams in the resolution of problems encountered in the conduct of their daily work.

Stat programmer I at PAREXEL

July 2012 - October 2013 (1 year 4 months)

Responsibilities include:

- Providing technical expertise for the conduct of clinical trials, and works with minimal supervision to support various programming activities related to the analysis and reporting of clinical study data;
- Interacting with sponsor as the key contact with regard to statistical programming issues for 6 projects(3 of them are UCB studies according UCB-PRA-PXL SPI standard);
- Producing TLF Mock up Shells and ADaM Datasets Specifications per Statistical Analysis Plan, providing inputs on CRF design, review, database setup, data validation;
- Ensuring quality control (QC) on all process and technical activities related to derived dataset, table, listing, and figure programming in accordance with corporate quality standards, WSOPs/Guidelines, ICH-GCP and/or other international regulatory requirements are performed;
- Maintaining all supporting documentation for studies in accordance with WSOPs/Guidelines to ensure traceability and regulatory compliance;
- Providing relevant training and mentorship to 2 new staffs and project teams as appropriate;
- Assisting project teams in the resolution of problems encountered in the conduct of their daily work.

Stat programmer Intern at PAREXEL

March 2012 - June 2012 (4 months)

Responsibilities include:

- Working with close supervision to support various programming activities related to the analysis and reporting of clinical study data;
- Maintaining all supporting documentation for studies in accordance with WSOPs/Guidelines to ensure traceability and regulatory compliance;
- Using efficient programming techniques to produce low-medium complexity analysis datasets, tables, figures and data listings.

Skills & Expertise

Epidemiology
Medicine
SAS
Clinical Research
Clinical Data Management
Statistical Programming

Education

Sichuan University
Master's degree, Health Statistics, 2009 - 2012

Sichuan University
Bachelor's degree, Preventive Medicine, 2004 - 2009

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