Mominul Islam

3rd

Sr. Principal Statistical Programmer at Novartis Pharmaceuticals Corporation

East Hanover, New Jersey | Pharmaceuticals

Current	Novartis Pharmaceutical Company
Previous	Vertex Pharmaceuticals, i3 Statprobe, Eli Lilly and Company
Education	The University of Texas at Dallas

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212 connections

https://www.linkedin.com/in/mominul-islam-37b50733

Background

Summary

Extensive (9+ years) pharmaceutical industry experience in leading Phase I-IV clinical trial data analysis and reporting including data manipulation, data convert and transformation and TFLs creation for Oncology, Hepatitis C Virus (HCV), Neuroscience, Diabetes, Cardiovascular and Endocrinology /Metabolism therapeutics.

Experience in implementing CDISC SDTM Implementation Guide Version 3.1.2 and CDISC ADaM Implementation Guide Version 1.0 in the generation of study specific SDTM and ADaM specs and data.

Experience on preparing eSub for sNDA submission to FDA.

Strong SAS macro development, advanced statistical analysis and graphing skills. Wrote several macros to automate the reports generation which in turns reduced the cycle time more than 50% in report generation.

Experience of ISS/CSS and ISE/CSE with capabilities to integrate data and conduct meta-analysis.

Excellent knowledge on Bayesian analysis, Generalized Linear Modeling, Mixed Modeling, Survival Analysis and Adaptive Design Clinical Trials.

Led multiple projects utilizing project management skills and resolve complicated issues as a team member, independently and team lead.

Excellent written and verbal communication skills. Working knowledge of SAS software: Base, Stat, Macro, SQL, Graph and other popular software like WinBUGS, R, S-PLUS, SAS Drug Development (SDD), FACTS and operating systems like UNIX, WINDOWS and MVS.

Experience

Sr. Principal Statistical Programmer

Novartis Pharmaceutical Company

August 2013 – Present (3 years 5 months) | East Hanover, New Jersey

Support SPS team in terms of writing macros to automate the report generation of standard reports.

Work on development of tools to automate CDISC SDTM, ADaM and Define.xml generation and prepare for eSUB to regulatory agencies.

Principal Statistical Programmer

Vertex Pharmaceuticals

March 2013 – July 2013 (5 months) | Cambridge, MA

Work as a Study Statistical Program Lead (SSPL) for VX950 (INCIVEK) studies and provide Statistical Programming technical leadership and support team members for Hepatitis C Virus (HCV) therapeutic. Work with cross functional team to achieve consistency in statistical programming across VX950 studies and to deliver high quality deliverables within reasonable time frame.

Work extensively on various SDTM domains such Special Purpose Domains like Demographics (DM), Subject Visits (SV), Comments (CO), Interventions – Exposure (EX), Concomitant Medications (CM),

People Also Viewed

Sharon Tu
Principal Statistical Programmer at Novartis Oncology; Toastmasters International District 83 Chief Judge, DTM

Naoko Stearns
Bilingual | Senior SAS Clinical Programmer | Pharma & Biotech | Currently Seeking Opportunities

priya balla
Senior Statistical Programmer at PAREXEL

Richard Senecal
Senior Principal Programmer at Novartis

Fan Lin
Principle Statistical Programmer at Chiltern

Murali Kajur
Principal Statistical Programmer at Shionogi Inc.

Rama Empati
Sr. Statistical Programmer at The Medicines Company

Vikas Dudhe
Sr. Statistical Programmer at Amgen

Weizhi Shi
Statistical Programmer at Boehringer Ingelheim

Alak Kondapally
Sr. Statistical Programmer at Novartis

How You're Connected

You

Ailsa Wang

Ailsa can introduce you to someone who knows Mominul ›

Events - Adverse Events (AE), Medical History (MH), Disposition (DS), Findings – ECG Test Results (EG), Laboratory Test Results (LB), Inclusion/Exclusion Criteria Not Met (IE), Vital Signs (VS), Physical Examination (PE), Viral Sequencing (SQ), Subject Characteristics (SC) and their SUPPQUAL datasets in terms of writing specs and SAS programs to generate data.

Work extensively on ADaM data sets like ADSL, ADAE, ADEG, ADVS, ADSQ, ADEX, ADMH, ADLB, ADHI, ADHC in terms of writing specs and SAS programs to generate data.

Work with a team on development of SDTM and ADaM tools (SAS macros and programs) to generate study specific specification and data. The tools are capable to generate metadata for the attributes of data (both SDTM and ADaM) from the spec, check and generate reports for any changes from previous version of the spec, check consistency aligned with CDISC Implementation Guidelines.

Prepare eSUB for sNDA submission to FDA.

Work on managing a pool of statistical programmers in terms of project management, work assignment and resource planning.

Work on automation of TFL generation by developing macros called ae_reporting (for Adverse Events), summarybyvisit_reporting (for any kind of by visit summary analysis) and nonsafety_reporting (for Medical History, Disposition, Exposure, Compliance and Baseline Characteristics related analysis) in order to optimize submission readiness.

Sr. Statistical Programmer

Vertex Pharmaceuticals Inc.

August 2011 – March 2013 (1 year 8 months) | Cambridge, MA

Work with a team on development of SDTM and ADaM tools (SAS macros and programs) to generate study specific specification and data. The tools are capable to generate metadata for the attributes of data (both SDTM and ADaM) from the spec, check and generate reports for any changes from previous version of the spec, check consistency aligned with CDISC Implementation Guidelines.

Senior Statistical Programmer

i3 Statprobe

October 2010 – July 2011 (10 months)

Worked as Oncology Therapeutic Lead by providing technical support in resolving issues and quality review of the deliverables (ADS and TFLs).

Worked as a lead programmer with junior and other programmers by writing efficient SAS programs and macros aligned with Protocols and SAPs to create and quality review of analysis reports (both safety and efficacy) and data sets for Eli Lilly and Company (Lilly) sponsored clinical trials for different indications.

Wrote programs and macros to generate reports for Annual Reporting (AR), Clinical Investigator Brochure (CIB), CTR Registry and Trial Level Safety Review (TLSR). The macros reduced the report generation time more than 50% compare to the stand alone programs.

Wrote SAS macros to automate the creation of the metadata for Analysis Data Set (ADS) requirements development. The macro reduced the study specific ADS requirements writing time significantly.

Reviewed and provided input on eCRF, annotated eCRF and non-CRF data collection so that data was being collected as per Lilly data standards to standardized and automate both safety and efficacy analysis.

Health outcomes analysis to analyze the benefits of study medication compare to best supportive care.

Coached and mentored i3 peers and external partners to make them up to the speed to work on effectively.

Associate Consultant Statistician

Eli Lilly and Company

August 2005 – October 2010 (5 years 3 months)

Worked as a lead statistical analyst for Oncology clinical trials studies as well as led and managed a pool of programmers from CRO in resolving and answering the technical questions related to ADS and TFLs.

Produced ADS, TFLs for CSRs and ISS/ISEs. Created analysis ready datasets and programs (ARD/ARP). Generated reports for DMC, Pharmacogenomics (PGx), PK data, ad hoc requests and publications.

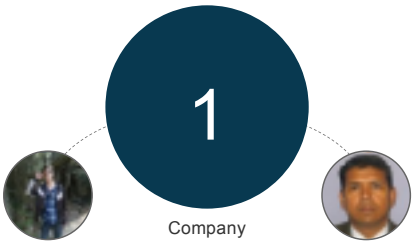
Wrote SAS macros known as Broad Use Modules (BUMs) for Adverse Events (AE), LABS, ECG and VITALS analysis as per Analysis & Reporting (A&R) Conventions adopted by Lilly. The collected metrics showed that the BUMs reduced the cycle time of report generation 83% compare to stand alone programs.

Wrote BUMs for calculating p-values for both categorical and continuous data. These BUMs produce the reports with quality and reduced the report generation time significantly.

Led several projects in the development of standard Trial Level Safety Review (TLSR) process,

Mominul Islam

In Common with Mominul



Aggregate Data Review process for Investigator Brochure (IB), standardizing and automating the Annual Reporting (AR) for all the therapeutics supported by Lilly. The process includes standardizing the TFL requirements and developed the SAS macros and user guide to automate reports creation.

Worked as a lead statistical analyst for several Neuroscience studies for FDA submission.

Wrote SAS programs and macros to generate reports for Zyprexa Depot Submission to FDA.

Worked on Pro-Chain Enterprise (PCE) in critical chain study build to ensure timely delivery of planned work.

Worked as a Subject Matter Expert (SME) for code validation SOPs, ADS/TFL SOPs. Also worked as SAS Drug Development (SDD) power user to resolve SDD work related issues to the peers and external partners.

Statistical Analyst

MedFocus

September 2003 – July 2005 (1 year 11 months) | Indianapolis, Indiana Area

Produced ADS, TFLs for CSRs and ISS/ISEs. Created analysis ready datasets and programs (ARD/ARP). Generated reports for DMC, ad hoc requests and publications.

Languages

Bengali

Skills

Top Skills

Mominul also knows about...

7 Statistical Programming | 6 Data Analysis | 5 SAS programming | 4 Data Management | 4 SDTM | 3 FDA | 1 Strong Command on SAS... | 1 Strong Macro Language... | 1 Bayesian Analysis,...

Education

The University of Texas at Dallas

Masters, Statistics

2002 – 2006

Queens college of the city university of Newyork

MS, Computer science

1999 – 2002

Dhaka University
MS, Statistics
1987 – 1994

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