DIVYA REDDY

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SAS programmer with 5+ years of experience working with SAS emphasizing on Design, Development, Analysis, Validation, and Reporting for Pharmaceuticals and Clinical Research Organizations.

Work Experience

Senior SAS Programmer

Syneos Health
March 2023 to March 2023

• Provided SAS Programming and analysis support for three phases (I-III) of the Clinical Trials in different therapeutics areas.
• Annotated Case Report Form (CRF) for data mapping of raw clinical data to CDISC.
• Created SDTM specifications document based on SDTM implementation guide.
• Developed and validated SDTM and ADaM datasets according to CDISC criteria.
• Developed tables, listings, and graphs according to study-specific Mock shells and SAP.
• Developed Oncology specific domains Tumor Identification (TU), Tumor Results (TR) and Disease Response (RS), ADRS, ADTTE.
• Verified with stats for any revisions to the statistical analysis strategy, mock-ups/shells/templates, etc.
• Contributed to the development of define.xml and assisted in establishment of reviewer's guide (SDRG, ADRG).
• Extensively involved in generating various types of graphs using PROC SGPLOT.
• Generated Kaplan-Meir estimates are using the PROC LIFETEST.
• Estimated the hazard ratio using Cox regression model with PROC PHREG.
• Checked the Compliance of SDTM/ADaM by Pinnacle 21, CDISC, and company customized check list and update SDTM/ADaM correspondingly.
• Used Output Delivery System (ODS) facility to generate safety and efficacy reports in PDF, RTF and HTML formats.
• Involved in generating TLG's for Integrated Summaries of Efficacy (ISE) and Safety (ISS) for FDA submission.
• Involved in creating various SAS Reports satisfying the 21CFR-11 Code for Federal Regulations for electronic data submission.
• Created and edit check programs to find data discrepancies in raw datasets provided by Data Management Group.
• Used MACROS effectively to improve the process of coding and to standardize programs.
• Attended study specific meetings with internal and client team.

Clinical SAS Programmer

Grifols Biologicals - Los Angeles, CA
October 2018 to November 2021

• Understood and followed department's working practice documents and SOPs.
• Extracted data from database and created new Datasets from raw data files.

• Created SDTM datasets like DM, EX, CM, AE, MH, LB, VS, EG, PC, PP etc. based on SDTM mapping specifications and validated them.
• Created ADaM datasets like ADSL, ADEX, ADLB, ADVS, ADDS, ADAE, ADEG, ADVS, ADPC, ADPP and etc.
• Worked on ADaM Dataset derivations like Treatment Emergent Adverse Event, Visit Windowing, Baseline, CTCAE grading, DType (LOCF, WOCF, BOCF) based on SAP.
• Generated tables and listings by using Data step and statistical procedure like PROC MEANS, PROC FREQ, PROC SUMMARY, PROC TRANSPOSE, PROC SEQ and PROC REPORT.
• Calculated p-values using different statistical analysis such as CHISQ, EXACT, Mantel-Haenszel (MH), Cochran-Mantel-Haenszel (CMH) using PROC FREQ.
• Converted various validated SAS datasets into transport files (.XPT) using XPORT engine and PROC COPY.
• Worked on Pinnacle 21 validator to check the compliance of the SDTM and ADaM datasets.
• Generated define.xml and define.pdf as part of CRT for FDA submission.
• Created RTF and PDF reports using SAS ODS output statements.
• Created ad hoc programs to provide information to the project team and/or client, as required.
• Developed Edit checks for different studies and in reporting those issues to the data manager in excel sheet.
• Created Macros at various instances for automating listings and tables of clinical data for analysis.

Development Chemist II

Hologic - San Diego, CA
September 2016 to April 2018

• Coordinated strategy meetings to modify and develop operating procedures, techniques and research protocols for continued success.
• Ordered supplies, inventoried chemicals and materials and summarized and recorded data to meet control and research requirements.
• Monitored packaging and storage of hazardous materials and waste to comply with laboratory, state and federal safety regulations.
• Made decisions and executed changes based on process data, quality checks and test results to keep products at target and within specifications.
• Provide support in production for troubleshooting in validation runs/ production runs.
• Planned and completed group projects, working smoothly with others.
• Provide daily maintenance, calibration, and runs quality control testing on analytical machinery before testing samples for the client.
• Proactively checks and stays current with all training across multiple learning platforms.

Education

Masters in Chemistry And Biochemistry

San Diego State University - San Diego, CA, US
May 2016

Bachelor of Science in Biotechnology And Computer Applications

Osmanity University — Hyderabad - Hyderabad, Telangana
August 2012 to June 2014

Skills

- Statistical Software: SAS (Base SAS, SAS/STAT, SAS/GRAPH, SAS/ODS, SAS/SQL, MACROS), R
- Operating Systems: Windows and UNIX.
- Microsoft Tools: MS office Word, Excel, Access, Project and Power point