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|  | Shreya Rachuri | [**shreyaranga96@gmail.com**](mailto:shreyaranga96@gmail.com)**;** [**shreya.sumana1649@gmail.com**](mailto:shreya.sumana1649@gmail.com)**;**  **(414) 949-3199; 3975 N Cramer St, Apt 205, Shorewood, WI 53211** |

**TECHNICAL SUMMARY:**

* **Clinical SAS Programmer** with up to 7 years of experience in the analysis, design, development, testing, and implementation of SAS® programs in the healthcare, hospital, and CRO industry.
* Skilled in data analytics and database management in using, **SAS®, Python, and SQL** in the Windows environment.
* Experienced in clinical study methodologies, with exposure to **phase I/II and III** of clinical trials and submissions in various therapeutic areas.
* Strong experience in \_\_\_\_\_\_\_\_\_\_\_\_\_ studies and worked on multiple therapeutic studies including \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.
* Acted as the primary point of contact (**POC**) for various clinical studies.
* Created and validated analysis datasets and **TLGs** with experience in **SDTM** using **IG 3.1, 3.1.3, and 3.2** and **ADaM** using **IG 1.0, 1,1, and 1.2**.
* Prepared tables, listings, graphs, reports, and summaries in RTF, HTML, and PDF formats using **SAS® ODS**, according to the **Protocol** and **Statistical Analysis Plans (SAPs)** as per the request of the clients.
* Worked on **ISS** and **ISE**.
* Provided **Ad-hoc** reports under tight timelines.
* Excellent analytical, problem solving, and interpersonal skills with ability to work individually as well as a part of a team. Actively seeking full-time positions in clinical statistician operations and healthcare data analytics.

**TECHNICAL EXPERTISE:**

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| **Certifications:** | SAS Certified Specialist: Base Programming Using SAS 9.4,  Python – Programming for Everybody, MySQL – From MySQL Beginner to Expert.  CPR First-aid, and BLS for Healthcare providers by the AHA. |
| **Computational Tools:** | Statistical analysis using SAS® (Base SAS®, SAS Studio® University Edition, SAS/Access, SAS/GRAPH®, ODS, SQL, MACROs).  Big data processing with Apache Spark, data mining and analytics, natural language processing using Python and Anaconda. |
| **Database/Software:** | CDISC Validator, Pinnacle 21, Oracle, Rave, OpenEMR, Protégé, MySQL, SQLite, PyCharm, Jupyter Notebook, Atom, and Microsoft Office: Word, PowerPoint, Excel, Access. |

**PROFESSIONAL EXPERIENCE:**

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| **Clinical SAS Programmer** | **Company** | **(Duration)** |

* Generated the datasets and TLF's for DMC, CSR, and exploratory analysis for regulatory submission.
* Created Programs to validate datasets CDISC SDTM compliance.
* Worked on Phase II and III trials in Dermatology, Inflammation, Cardiovascular and Oncology studies.
* Used Output Delivery System (ODS) to produce HTML, PDF, and RTF reports.
* Worked on analysis data definition document and transport files for FDA submissions.
* Created and reviewed Analysis dataset specifications based on the mock shells.
* Created and Validated Analysis datasets based on the raw datasets.
* Created and Validated TLGs.
* Reviewed CRTs and Created XPT Transport files for e-submissions.
* Designed, modified, and validated new and existing programs and macros depending on the requirements.
* Programmed and reviewed new programs having a substantial statistical component and standard macros.
* Extracted data from Oracle tables to create SAS files for statistical analysis.
* Developed Edit check programs to clean invalid data from the database.
* Used SAS macros for frequently used programs.
* Validated and verified tables and listings.
* Developed programs for producing reports from analysis datasets according to Statistical Analysis Plan (SAP).
* Developed summary reports for safety.
* Used various SAS procedures such as PROC SQL, PROC FREQ, PROC MEANS, PROC SORT, PROC REPORT, PROC UNIVARIATE, PROC CONTENTS and PROC COMPARE.
* Involved in preparing clinical trials data for FDA submissions according to 21 CFR Part 11 and involved in listing, summary tables for NDA submission.
* Collaborated with clinical researchers in the design of clinical trial selection of clinical endpoints, sample size requirements, protocol development, and Research and the Case Report Form design.
* Analyzed data according to Statistical Analysis Plan (SAP) in accordance with Protocol and CRF (Case Report Form).
* Good Knowledge in debugging Macros with options such as MLOGIC, MPRINT, MERROR, and SYMBOLGEN.
* Involved in periodic meetings focusing on statistical aspects of on-going clinical trials for selection of appropriate methodology, protocol review, interim statistical analysis, and reporting.

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| **Clinical SAS Programmer** | **Company** | **(Duration)** |

* Created Analysis datasets referring to the specifications provided according to CDISC standards.
* Experienced on phase II and III clinical trials in different therapeutic areas including Pediatric, Infectious diseases, Oncology and Neurology.
* Produced data listings, summary tables and graphs for analysis.
* Provided data in SAS transport files, and other appropriate deliverables and documentation for regulatory submissions.
* Created and maintained libraries of SAS application programs, formats, and macros.
* Performed validation on clinical trial data.
* Created annotated case report form using CDISC-SDTM mapping.
* Created CRT’s (Case Report Tabulations) using CDISC standards for submissions to the FDA.
* Good understanding and working knowledge on of SOPs, GCP and FDA guidelines.
* Experienced in running OpenCDISC Validator and creating Define.XML and Study Data Reviewers Guide (SDRG) and Analysis Data Reviewer’s Guide (ADRG).
* Developed permanent SAS formats and Macros following departmental specifications.
* Used Infile statement options to control processing when reading raw data files in SAS.
* Generated Listings and Tables using PROC REPORT.
* Extensive use of PROC FREQ, PROC MEANS, PROC UNIVARIATE, PROC TRANSPOSE, PROC MIXED, PROC REPORT, PROC TABULATE, Data \_Null\_, and Chart procedures.
* Created graphs by using various SAS procedures like PROC GCHART, PROC GPLOT, PROC LIFETEST and PROC UNIVARIATE.
* Produced RTF, and HTML formatted files using SAS/ODS to produce ADHOC reports for future reference.
* Enhanced reports using labels, SAS formats, user-defined formats, titles, footnotes and SAS System reporting options.
* Developed MACROs to replace repetitive codes for generating descriptive statistics.
* Debugged SAS programs using PUT, Data \_NULL\_ statements in code reviews and testing.

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| **Clinical SAS Programmer** | **Company** | **(Duration)** |

**Statistical programming and data analysis of phase I & phase II clinical trials involving Gastroenterology, Oncology and Dermatology.**

* Created analysis datasets from raw data files and modified existing datasets using Set, Merge, Sort, and Formats, Functions, and conditional statements.
* Followed Statistical Analysis plan for generating reports and tabulations.
* Developed macros to map the SDTM and ADaM datasets to use across the study following CDISC standards as per Protocol and SAP.
* Participated in Clinical Data Management by developing simple SAS programs for checking data and ensuring accuracy.
* Extracted, validated, and generated SAS data sets from Oracle using ‘SQL Pass through Facility’.
* Worked on SAS/GRAPH to present results in BAR CHARTS, BOX PLOT, ODDS RATIO ESTIMATES and SCATTER PLOTS.
* Used SAS Macros in creation of new programs as well as modification of existing programs to improve results.
* Handled data about missing and clinical trial dropouts using traditional approach of generating Last-Observation-Carried-Forward (LOCF) data on Visit-wise data.
* Used PROC SQL, PROC FREQ and PROC MEANS for data analysis and generating report using PROC REPORT.
* Used SAS ODS for generating reports in specific output formats like RTF, PDF, and HTML etc.
* Created SAS reports using the Data \_Null\_ technique and Proc Report for NDA submission as per FDA regulations and company standards.

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| **Clinical SAS Programmer** | **Company** | **(Duration)** |

**Statistical programming support for phase II & phase III clinical trials in the therapeutic areas; Diabetes Mellitus and Hodgkin’s Lymphoma.**

* Used SAS/ACCESS® to import clinical trial data into SAS® and generated SDTM and ADaM datasets by applying IG and following CDISC standards.
* Checked CDISC SDTM compliance on the datasets using Pinnacle 21 and Open CDISC Validator.
* Investigated missing values and data anomalies and performed data manipulation on SAS® Datasets using interleaving, merging, appending, concatenating, and sorting.
* Utilized MACROs to perform data analysis and created tables, listings and graphs including patient demography, adverse events, vitals, con meds, laboratory etc.
* Interacted with biostatisticians regularly for programming and validation of clinical data.
* Generated reports in html, pdf, and rtf formats using SAS® output delivery system (ODS).

**EDUCATION:**

**Master’s in Healthcare Informatics** College of Health Sciences, University of Wisconsin – Milwaukee

**Bachelor’s in Dental Surgery** Government Dental College and Hospitals, Hyderabad, India