

**Divya K**

**Sr. SAS Programmer**

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**TECHNICAL SUMMARY**

* **Sr. SAS Programmer** with up to **9** years of experience in analysis, design, development, testing and implementation of SAS programs in Pharmaceutical & CRO industry.
* Expertise in **BASE SAS, SAS/MACROS, SAS/STAT, SAS/GRAPH, SAS/SQL and SAS/ODS** in Windows and UNIX environments.
* Acted as primary point of contact (**POC**) for many studies.
* Thorough experience in analysis of Clinical Trial data and in creation of **SDTM**, **ADAM datasets**, **Tables, Listings, Graphs**, Reports and Summaries as per requests of clients, according to **Protocol** and **Statistical Analysis Plans**.
* Experience with Clinical study methodologies, exposure to **phase I/II and III** of Clinical Trials and submissions in various therapeutic areas.
* Experience in working on **SDTM** using **IG 3.1**, **3.1.3 and 3.2.**
* Experience in **ADaM** using **IG 1.0, 1.1 and 1.2.**
* **Created** and **Validated** Analysis datasets and **TLGs.**
* ~~Thorough experience in Programming Validation -~~ **~~white box validation~~** ~~for non-critical outputs and~~ **~~double programming~~** ~~method for critical outputs.~~
* Strong experience in **Oncology**, and worked on multiple therapeutic areas including **~~Neurology, Pediatric, Cardiovascular, COPD, Gastroenterology and Dermatology etc.~~**
* ~~Worked on deliverables likes CSR, DMC, IA request, PSUR and DSUR etc.~~
* Worked on **ISS** and **ISE.**
* Experienced in producing RTF, HTML and PDF formatted files using SAS.
* Experienced in providing **Ad-hoc** reports under tight timelines.
* Proven ability to work effectively on multiple tasks simultaneously and meet project deadlines.
* Excellent analytical, problem solving, communication and interpersonal skills, with ability to interact with individuals at all levels. Ability to work effectively both as an individual and as part of a team.
* Willing to take on extra responsibilities to get the work done. Enthusiastic, innovative and challenge oriented.

**TECHNICAL EXPERTISE**

Statistical Analysis Using SAS® (SAS® STAT, SQL, MACROS, PROC’S, ~~V8/V9~~ and GRAPH)

Database/Software: UNIX, ORACLE, RAVE, PINNACLE 21, CDISC Validator, WINDOWS.

Packages: MS Word, MS Excel, MS Power point, MS Visio, MS Project Management.

**PROFESSIONAL EXPERIENCE**

**Veristat LLC, MA (Remote)**

**Sr. SAS Programmer**

**June 2017 – Till date**

* Generate 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.
* ~~Worked on creating the individual Patient Profiles based on Client requests.~~
* 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.
* ~~Provided Statistical and SAS programming support and training to new hires and clinical Data management group.~~

**Environment:** SAS 9.2/9.3/9.4, Windows 10, SAS/BASE, SAS/MACRO, SAS/SQL, SAS/ACCESS, SAS/ODS, SAS/STAT, PDF, MS Office

**Astellas Pharma, IL (Remote)**

**Sr. Statistical Programmer**

**Jan 2016 – May 2017**

* 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 through the use of 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.

**Environment**: SAS 9.1/9.2, Windows 10, MS Excel, SAS/BASE, SAS/ODS, SAS/MACRO, SAS/ACCESS. SAS/GRAPH and SAS/STAT

**PPD, TX**

**Sr. SAS Programmer**

**Oct 2014 - Dec 2015**

* Programmed and analyzed Phase I – phase II clinical trials involving Gastroenterology, Oncology and Dermatology.
* Created analyzed 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.

**Environment:** SAS 9.2, Windows NT, MS Office, SAS/BASE, SAS/ODS, SAS/ACCESS, SAS/SQL, SAS/STAT, ORABLE CLINICAL and UNIX

**Ariad Pharmaceuticals, MA**

**SAS Programmer-II**

**Oct 2011 - Sep 2014**

* Provided statistical programming support for Phase II and III clinical studies in different therapeutic areas including COPD, Immunology, Hematology and Oncology.
* Used SAS/Access to extract data into SAS and created the datasets and analyzed data based on the Demographic Information.
* Created reports in different formats like RTF, PDF and HTML using SAS output delivery system (ODS).
* Generated SDTM and ADaM datasets following IG and CDISC standards. Created tables, listings and graphs, including Patient Demography Adverse Events, Vitals, Con Meds and Laboratory etc.
* Generated Summary Reports for ISS and ISE analyses of clinical study for FDA regulatory submissions.
* Checked CDISC SDTM compliance on datasets using Pinnacle 21 and Open CDISC Validator.
* Interacted with Biostatisticians on regular basis for programming and validation of clinical data in analysis data sets.
* Wrote Edit Check programs for data validation before final analysis.
* Experienced with Adhoc programming and reporting.
* Investigated missing data and data anomalies in SAS data sets.
* Generated reports using PROC TABULATE, DATA \_NULL\_, PROC REPORT and found out descriptive statistics using PROC MEANS, PROC FREQ, PROC SUMMARY, PROC SQL and PROC UNIVARIATE.
* Extensively performed Data manipulation on SAS datasets using various techniques such as Interleaving, Merging, Appending, Concatenating and Sorting.
* Participated in regular group meetings consisting of Statistician, Development members and Clinical research team to analyze the results.

**Environment:** SAS 9.1/9.2 Windows NT/7, SAS/BASE, SAS/MACRO, SAS/ACCESS, SAS/CONNECT, SAS/SQL, SAS/ODS, SAS/STAT and SAS/GRAPH

**EDUCATION**

Master of Science (M.Sc.) in Genetics, India.