Certified Base Programmer for SAS 9

Geetha.S

Lead Clinical SAS Programmer

geethasivanandam11@gmail.com

EXPERIENCE:

LEAD CLINICAL SAS PROGRAMMER

Confidential

September 2021 – Present

Responsibilities:

- Collaborated with the data management team in reviewing the protocol, and **CRF**, and generated edit check listing.
- Converting large datasets into **SDTM** datasets (according to **CDISC** requirements)
- Created **ADaM** datasets based on the **ADaM** Implementation guide.
- Reviewed clinical study protocol, and case report form (**CRF**), annotated the **CRF** and provided comments.
- Validated the edit check program and the reports for the quality control process.
- Reviewed statistical analysis plan, mock-ups/shells/templates, and provided comments as needed.
- Referring to the statistical analysis plan (**SAP**), analysis dataset specification was developed, and developed analysis dataset programs.
- Validated and maintained the status of quality control documents for the team, validation has been performed as specified in the **QC** tracking sheet.
- Created reporting procedures like **PROC REPORT**, and graphical procedures like **PROC GPLOT** and **PROC LIFETEST** for survival analysis.
- Generated safety, efficacy, and graphs as mentioned in the template and validated as per the **QC** tracking sheet, used **SAS** Output Delivery System (**ODS**) for generating reports in specific output formats like **RTF, PDF,** and **HTML**.
- Efficiently utilized macros to eliminate repetitive **SAS** codes.
- Generated tables, listings, and graphs as mentioned in the template using **PROC** report, and **PROC** tabulate.
- Validated the generated **TLG**s according to the **QC** tracking sheet.
- Generated Ad-hoc reports for several important datasets as per the senior programmer's request.
- Used and customized company/therapy/study level macros for generating tables, listings, and graphs.
- Familiar with different classes and several domains related to **CDISC SDTM** standards.
- Prepared data for **FDA submission** as per **CDISC** submission standards and guidelines.
- Utilized **PROC COMPARE** to conduct quality control checks on datasets, tables, and listings.
- Involved and worked with **ADRS, ADTTE,** and **ADTR** datasets and created tables

PROFILE SUMMARY

More than 8 years of experience in clinical data analysis. Worked with Statisticians to provide SAS programming in analyzing the Clinical Trial Data including Phase I, II, and III, generate and validate analysis datasets, tables, listings and graphs with respect to Statistical Analysis Plan (**SAP**), Standard Operating Procedures (**SOP**s) and departmental guidelines. Experience in **Oncology, Immuno Oncology** and **Neurology** therapeutic areas.

PROFESSIONAL SKILLS

- Good Communication skill
- Time management
- Computer proficiency
- Work ethic
- Attention to details
- Team work

TECHNICAL SKILLS

Statistical Software:

SAS/BASE, SAS/MACRO, SAS/GRAPH, SAS/REPORT, SAS/SQL, SAS/Access, SAS/STAT, SAS/ODS

Statistical Tools:

SAS, SPSS

Database:

on progression-free survival, complete response overall response based **RECIST** document

SR. CLINICAL SAS PROGRAMMER

Confidential

September 2018 - August 2021

Responsibilities:

- Involved in the creation and validation of **CDISC**, **SDTM, and ADAM** datasets.
- Worked on **SDTM** domains which include **EG, FA, IE, LB, QS, VS, CM, EX, TU, TR, and RS**. as per **SDTMIG** V 3.2
- **Annotated CRF's** as per the sponsor requirements
- Generated **ADaM** Datasets with derived variables and flags required for creating **TLF**s (**ADSL, ADLB, ADVS,** etc.,) and performed statistical analysis on data as per the requirements in the **SAP** and Protocol Planned and exploratory statistical analysis of clinical trial data.
- Generated **tables and listings** with the help of **SAS/BASE and SAS/SQL** in the Windows environment.
- Produced Safety reports in **RTF** format.
- Created **Listings** for Demographics, **ECG**, Medical History Vital Signs, Laboratory Findings, and various other domains as per the protocol.
- Provided descriptive statistical analysis using tools **like PROC FREQ, PROC MEANS,** and **PROC UNIVARIATE.**
- Validated the derived datasets that are created.
- Individual studies were pooled for an integrated database in **CDISC/SDTM** format and checked for inconsistencies between the studies before pooling to determine if there are any issues.
- Created integrated analysis datasets for **ISS and ISE** reporting.
- Worked on Table Programming for Integrated Summary of Efficacy (**ISE**) and Safety (**ISS**).
- Created data quality listings to ensure data correctness and clinical review for the clinical team.
- Created and validated **ad-hoc reports**.
- Developed and documented programs to create analysis datasets summarizing key clinical trial data.
- Performed data manipulation by merging several datasets and extracting information.
- Red data from **MS Excel** and flat files into **SAS** software.
- Macros were written in various instances to automate listings and graph clinical data for analysis.
- Created the **analysis data sets**, **tables, and listings**.
- Involved in Edit Checks for cleaning up the data in data management.
- Extensive experience with core SAS reporting technologies and procedures, including **SAS/Base, SAS ODS, the SAS Macro Language, Proc Report, and Proc Tabulate**.
- Prepared new datasets from raw data files using Import Techniques and modified existing datasets using Set, Merge, Sort, and Update, Formats, Functions, and conditional statements.
- Created complex and reusable macros, extensively used existing macros, and developed **SAS** Programs for Data Cleaning, Validation, Analysis, and Report generation. Tested and debugged existing macros.
- Generated Tables and Listings for inclusion in Clinical study reports and

Oracle, MS Access, Hadoop

EDUCATION:

The University of Georgia,
Georgia, USA
Master of Science in Foods and Nutrition
2012 - 2014

Bharathiar University,
Tamil Nadu, India
Master of Science in Microbial Biotechnology
2005 - 2007

Bharathiar University,
Tamil Nadu, India
Bachelor of Science in Plant Biology and Plant Biotechnology
2002 - 2005

regulatory submissions.

- Involved in writing the **SAS** code to help in the process of Quality control by implementing various **statistical procedures** like **Proc Freq, Proc Means, Proc Univariate,** and other procedures like **Proc Summary, Proc Transpose, Proc SQL,** and **Proc Print**.
- Participated in the development and review of study-specific procedures and clinical project team meetings as required

CLINICAL SAS PROGRAMMER II

Confidential

January 2016 - August 2018

Responsibilities:

- Generated tables, and listings using **SAS/BASE, SAS/SQL, SAS/STAT,** and **SAS/GRAPH** in a Windows environment.
- Generate safety (Adverse Events, Safety Adverse Events, Treatment-Emergent Adverse Events, Demographics, Vital Signs, and Laboratory Findings) and efficacy tables using Proc Report.
- Involved in producing and **QC** analysis plans, **TLF** mock-shell development, derived dataset specifications, programming specifications, and other process-supporting documents.
- Generated analysis datasets with derived variables and performed statistical analysis on data as per the requirements in the SAP and Protocol.
- Performed Statistical programming and validation of Analysis Datasets and Tables, Listings, and Graphs (**TLG**'S) for Phase **II** clinical trials by using specifications.
- Worked on **Pinnacle 21** compliance tool (Open **CDISC**)
- Communicated and worked with the data management group on data locks
- Worked as the validation programmer for tables, listings for many **CSR** outputs and ad-hoc requests
- Involved in **ISS** by pooling various studies for **NDA submissions**.
- Involved in generating Adhoc's depending on the requirements of biostatisticians and clients.
- Attended weekly meetings with Manager and Biostatistician to discuss work progress and queries regarding the project.
- Performed **QC** of raw data using edit checks programming.
- Worked on creating analysis datasets, defined variables of interest, study populations, visit windows, and baseline observations.

SAS PROGRAMMER

Confidential

August 2014 - December 2015

Responsibilities:

- Created analysis datasets, tables, listings, and figures using program specifications.
- Performed efficacy and safety analysis for the clinical trials. Created **SDTM** datasets using **SDTM IG** and program specifications.
- Created **ADAM** datasets like **ADSL, ADAE, ADDS, ADLB, ADEX**, etc.,
- Used **SAS** procedures like **PROC FREQ, PROC, PROC MIXED, PROC CORR, PROC REPORT, PROC, PROC SQL, PROC MEANS, PROC UNIVARIATE,** etc.,
- Extensive experience in merging, transposing, appending, concatenating, and

sorting datasets as per the requirement.

- Developed **SAS** Programs/Macros to analyze the data.
- Debugged **SAS** programs of other programmers following **SAP** and **SOP** and developed reports by using **PROC TABULATE, PROC REPORT, PROC SUMMARY, PROC SQL,** and provided descriptive statistics.
- Prepared **SDTM** datasets from different sources of raw datasets.