**Srinivas Nomula**

**Sr. Statistical Programmer**

**Mobile: +1 (512) 942-7154**

**Email:srinivasnomula453@gmail.com**

### SUMMARY

* Over 9+ years of end-to-end experience in **SAS** programming on **all phases** of clinical trials.
* SAS experience includes detailed knowledge of statistical analysis and in the production of reports, tables, graphs, and listing.
* Experience in analyzing Clinical Trials data in design, development, testing, and implementation of various projects for Pharmaceutical, Biotech, and CRO industries.
* Involved in **FDA submissions** by supporting **eSub** contents **define.xml, SDRG, and ADRG**
* Experience in using and writing **utility Macros.**
* Develop **SAS** **MACROS** for generic coding and reusable modules
* Experience in producing reports in various file types such as **HTML**, **PDF**, **RTF**, and **EXCEL** using **SAS**/**ODS**
* Thorough knowledge in handling missing data values using tools such as **LOCF**, **WOCF and BOCF**
* Experience working on **ad-hoc reports** from regulatory Authorities like **FDA and PMDA**.
* Working experience in **Safety Narratives**
* Excellent knowledge of working with oncologyclinical trial data
* Experience in working with oncology domains such as **TU, TR, RS, and ADTTE**
* Expertise in **RECIST** Criteria.
* Performed high-level **QA** and acceptance checks for CRO deliverables.
* Develop, test, and implement **Proc** **SQL** data queries and analysis.
* Generate reports in Excel, word, PDF, automated the same using SAS macros and Proc Report.
* Good experience in validating **SDTM** with various techniques.
* Good understanding of standards specific to clinical trials such as **CDISC**, **SDTM**, **ADaM**, **WHO** Drug and **MedDRA**.
* Comfortable working in challenging environments under deadlines, excellent analytical and problem-solving skills.
* Hands on experience with SAS procedures like **PROC** **FREQ**, **PROC** **MEANS**, **PROC** **REPORT**, **PROC** **Lifetest** etc.
* Worked on creation and validation of **Define.XML.**
* Created as well as validated generalized macros for clinical studies for process improvement.
* Good working experience with Clinical Trial Data like Demographic Data, Adverse Event Data (**AE**), Laboratory Data, Physical Examination, Vital Sign Data, Concomitant Medication and Medical History data.
* Experience in Working on different therapeutic areas like **Immunology**, **CVS, Diabetic, Hematology, Rare Diseases and Oncology, etc.**
* Worked as a Co-Lead and Lead Quality Validator (LQV) for various studies and followed company specific plan in production and validation of Datasets and TLFs for various deliverables like DMC, CSR etc.
* Experience in identifying data issues by developing study specific Edit Checks, generating patient profiles and reviewing annotated CRF.
* Generate and maintain programs to meet external and internal clients' needs.
* Experience in taking ownership and distributing work across team members to assure timely delivery of the highest quality outputs.
* Excellent analytical, problem solving, verbal and written communication and interpersonal skills. Proactive, flexible and well organized.
* Flexible and versatile to adapt to any new environment with a strong desire to keep pace with latest technologies. Ability to work in a team as well as independently to accomplish team goals.

### TECHNICAL EXPERTISE

|  |  |
| --- | --- |
| Operating System | Windows, Unix |
| Clinical Database | Rave, Oracle Clinical |
| SAS Tools | BASE SAS (MACROS, ODS, SQL), SAS/ACCESS, SAS/GRAPH, SAS/STAT, SAS/CONNECT |
| Application Software | MS Office - Outlook, Excel, Power Point and Word |
| Statistical Software | SAS 9.4, SAS 9.3, SAS 9.2 |

### PROFESSIONAL EXPERIENCE

**Otsuka Pharmaceutical (Contract) Nov 2021 – Present**

**Sr. Statistical Programmer**

* Review Annotated CRFs as per MSG guidelines.
* Review specifications files for both SDTM and ADaM.
* Review Trial design datasets: TA, TE, TS, TI, and TV.
* Cross-collaborate with the internal team, Data management team, Statisticians as well as Vendor CRO.
* Review the SAP and mock shells.
* Good understanding of RECIST criteria and Efficacy datasets.
* QC SDTM datasets by parallel programming using SDTM aCRF, Specification file and SDTM IG 3.2
* Run P21 on Vendor delivered SDTM and ADaM datasets and make sure they are CDISC compliant.
* Log all the QC issues in the Vendor issue log and follow up with Vendor until the issues are resolved.
* Enter raw data issue in log and collaborate with Data Management team to make sure data issues are queried, resolved before interim and final database lock.
* Work on Adhoc reports as per the request from submission agencies.
* Work on creating various transport files (.XPT files) for FDA submissions.
* Review the submission packages to the FDA for both SDTM and ADaM.
* Conduct CDISC SDTM programming activities for clinical research projects from study start-up through submission to regulatory agencies such as FDA.
* Serve as an SDTM point of contact as needed within a project.
* Perform Gap Analysis on studies requiring migration to CDISC standards to ensure all documentation and datasets necessary to perform the migration activities are present and without issues.
* Annotate Case Report Forms (CRFs) according to the CDISC Implementation Guideline for migration to SDTM & Created Trial design datasets.
* Follow standardized SDTM migration programming procedures to create quality Standard Data Tabulation Model (SDTM) compliant SAS datasets and Define.XML documents.
* Perform data reconciliation whenever it is required by Data management team
* Ensure review of applicable project deliverables (e.g., Protocol, Case report forms, Data base structure, Reviewers guide, Define.xml file) for consistency with data standards.
* Perform Manual QC on SDTM datasets to check whether all the raw data is migrated to SDTM.

**Takeda (PPD) May 2019 – Nov 2021**

**Sr. Statistical Programmer II**

* Primarily worked with Statistical programmers on ongoing Phase I, Phase II and Phase III clinical trials to ensure results are consistent with expectations, and quality control procedures are followed.
* Worked in the Oncology therapeutic area.
* Produced and support systems that extract data from the clinical database; and building analysis databases composed of **SAS** datasets.
* Assisted in establishing standardized programming procedures and work instructions; ensure that regulatory requirements are met through validation/compliance activities; and develop and maintain clinical processing workflow systems.
* Extensively worked on Oncology listings, Summary tables, figures and Oncology endpoints like Progression-free survival methods, Time to Progression, Duration of Complete response and Partial response, Overall survival.
* Involved in creation and validation of **CDISC** **SDTM**, **ADaM** datasets and generated **TLF’s**.
* Helped the programming activities for a trial, early phase project, indication, or publication activities.
* Develop and support statistical programming computer systems that are used in the production of statistical analysis plan (**SAP**) planned tables, **data** **listings**, and **graphs**.
* Perform **gap analysis** before SDTM CRF annotation and SDTM specs creation.
* Experience in annotating **CRF** following SDTM implementation guide
* Experience in writing SDTM specs using CRF, SDTM controlled terminology and SDTM implementation guide.
* Developed and validated SDTM datasets using CRF, and SDTM specs
* Review **SAP** and shells, annotate shells for writing ADaM specifications following ADaM implementation guide.
* Generate **ADaM** datasets and validate them by parallel programming.
* Review **cSDRG** and **Define.xml**
* Validated SDTM and ADaM datasets using **P21 software** and provided comments for the P21 issues.

**Veristat, Southborough, MA Aug 2016 – May 2019**

**Statistical Programmer**

* Worked extensively on **Phase-1** and early phase clinical trials.
* Created SDTM datasets from the raw data sets into in accordance with **SDTM I.G** (using SDTM Specification file and SOPs.
* Created SDTM Specification File for Mapping the Raw Datasets into SDTM datasets, and Qc ed the SDTM specification file.
* Annotated **CRF** according to CDISC standards as per SDTM IG 3.2 and 3.1.2.
* Created Trial Design Domains: Trial Arms (**TA**), Trial Elements (**TE**), Trial Inclusion (**TI**), Trial Summary (**TS**) and Trial Visits (**TV**) domains based on the Protocol, Study design and Schedule of Assessments.
* Created **Custom Domains** as per the requirement based on the CRF and Raw data that do not fit into standard SDTM Domains.
* Validated the SDTM datasets and reported the data discrepancies.
* Performed Various **SAS Edit Check**s for checking and clearing the data issues.
* Developed ADCM, ADAE, ADMH datasets.
* Produced reports in PDF, RTF using SAS/ODS and created various transport files (. XPT files) for FDA submissions.
* Generated and validated summary tables.
* Clear understanding of **Open CDISC** Validation and performed the CDISC Validation using (Pinnacle 21) process.
* Create and use macros to automate the SAS processes**.**

**PRA Health Sciences Sep 2014 – Aug 2016**

**Statistical Programmer**

* Annotated CRF and creation of SDTM, ADaM specifications following SDTM IG 3.2, ADaM IG 1.1 respectively.
* Created SDTM events datasets (AE, MH, HO, DV, DS), Intervention’s datasets (CM, PR, SU, EX,) and finding’s datasets (LB, VS, EG) and special purpose domains like DM, SV, SE.
* Reviewed clinical study protocol, SAP, mock shells.
* Created analysis data sets like ADCM, ADMH, ADAE.
* Generated reports like Demographic tables, Disposition tables, Summary of Adverse Events tables, Conmed tables, Important Protocol deviations tables etc using Proc Report.
* Converted existing raw data into CDISC standards and reviewed CRFs to ensure consistency and adequacy in data to meet the objectives defined in protocol.
* Provided technical support to the clinical study teams.
* Produced quality customized reports by using TABULATE, REPORT and SUMMARY and provided descriptive statistics using MEANS, FREQ.
* Created electronic SAS datasets, such as SAS transport files.
* Formatted HTML and RTF reports, using SAS - output delivery system ODS.
* Generated Tables, Figures (Box plots) and Listings for inclusion in Clinical study reports and regulatory submission.
* Performed QC (Quality Check) extensively on tasks performed by other team members and involved in data validation and data cleaning in all phases of Clinical studies.

### Education

* Bachelors in Computer Science engineering.