**Summary:**

* 13 Yrs. experience in clinical SAS Programming (SAS/Base, SAS/Macros and SAS/STAT).
* End to end experience as a study lead, team building and knowledge sharing.
* Strong experience in SDTM, ADaM(ADSL, ADTTE, BDS, ADTR, ADRS and OCCDS) datasets, Pinnacle validation and TFL Programming.
* Lead Experience of Integrated Summary of Safety (ISS).
* Submission experience (review and writing of ADRG, SDRG, Define, aCRF, XPT file, .txt SAS program files)
* Experience in using SAS statistical procedures LIFTEST, PHREG, GLM & MIXED.
* Lead Experience in Oncology studies of Solid Tumor & Hematology therapeutic, RECIST Criteria, Time to Event Analysis, and Survival Analysis.
* Strong understanding/experience of Efficacy analysis.
* Experience in writing and reviewing specification of ADaMs and SDTM.
* Experience in Vaccine Studies (Reactogenicity and Safety analysis).
* Phase-III Pivotal, Randomized double blind study set-up and lead experience in both restricted and un-restricted areas.
* Experience in Kaplan Meier Tables and Figures.
* Experience in Forest plot, box plot, and dot plot.
* Review of aCRF, SAP, Specification (ADaM & SDTM) document, TFL shell & Other docs.
* Experience in writing standard macros using SAS Macros, Macro Statements, and Macro Functions.
* Writing SAS programs for complex datasets and for complex TFL based on Statistical Analysis Plan (SAP) and TFL shell to generate statistical reports for analysis of clinical data.
* Well understanding of protocol, statistical analysis plan, TFL shell & CRF.
* Validation & Verification of programs to check the consistency of the statistical reports.
* Having knowledge in all aspects of clinical trials from initial study set-up to study completion.
* Full knowledge and understanding of the processes and procedures used within a Statistical Programming environment.
* Self-motivation and ability to work independently.
* Good organizational and communication skills, work in a collaboratively.

**Skills Summary:**

|  |  |
| --- | --- |
| **Domain** | Pharma, CRO’s & HealthCare |
| **SAS Modules** | SAS /BASE, SAS/Macros & SAS/Graphs. |
| **Version** | SAS 9.4 |
| **Other Skills** | Writing specification and creating dataset for ADaM & SDTM, TFL, Pinnacle21, ADRG, SDRG, Leading ISS activities & Study Lead Experience. |
| **Operating System** | Windows 11 |
| **Tools**  | Excel, PPT, Word & PDF Annotation. |

 **EDUCATIONAL QUALIFICATIONS:**

* M.Sc. Applied Statistics, Osmania University, 2008, Hyderabad.
* B.Sc. Statistics, Kakatiya University, 2004, Warangal.

 **PROFESSIONAL EXPERIENCE:**

**Pfizer JUNE 2022 To Present.**

**Senior Statistical Programmer (Contract)**

**Responsibilities:**

* SAS programming and analysis support for phases II & III of Vaccine clinical trials.
* Review & refer the study documents (Protocol, Annotated CRF, SAP, Specification doc, TFL shell & etc.) and send comments and queries to respective stake holders.
* Collaborating and co - ordinating with study team on study issues and updates.
* Writing & reviewing ‘Programming Data Specification’ for CDISC ADaM & SDTM standard datasets.
* Develop SAS Program (or write validation programs for) and document statistical deliverables
(SDTM/ADAM/TLG’s) for statistical analysis.
* Writing SAS program for complex analysis datasets ADCEVD & ADFACEVD (ADaM).
* Working on Vaccine studies for both Reactogenicity & Safety Analysis reports.
* Develop standard SAS macros for SDTM and ADaM datasets, and tables, listings, and figures ( TLFs).
* Annotating Tables and preparing SAS code for eSUB.
* Creating and validating safety and TFL using SAS/BASE, SAS/MACROS, SAS/STAT & SAS/GRAPHS.
* Works with statistical personnel to provide definitions, documentation and review of derived variables needed to produce planned tables, listings, and graphs.
* Develops programs for development & validation of SDTM, ADaM & TFL’s.
* Generating complex ad-hoc ADaMs & reports utilizing SDTM data.
* Delivery of the Clinical Study Report (CSR, CSPD & DMC), Study Data Tabulation Model (SDTM)/Analysis Data Model (ADaM) datasets, Pinnacle validation and Tables, Figures and Listings (TFL) outputs through both internal and external delivery models, following applicable data standards and regulations.
* Development of standard methodology to improve quality, efficiency, and effectiveness.
* Ensure the statistical programming systems, processes and deliverables are aligned with the
relevant project requirements for instance understanding all SOP’s/WI.
* Communicating with project programmer, project lead, biostatistician and with clients.
* Reviewing the final reports and sending comments to the team.

**Novartis 01APR2018 to 10MAY2022**

**Senior Statistical Programmer**

**Responsibilities:**

* SAS programming and analysis support for phases II, III & IV of clinical trials.
* Leading multiple studies, new studies setup, planning timelines, facilitating data for team and assigning work for team members, guiding, suggesting and driving team to deliver outputs with high quality within timeframe.
* Leading Integrated summary of safety analysis (ISS).
* Submission experience (review and writing of ADRG, SDRG, Define, aCRF, XPT file, .txt SAS program files)
* Review & refer the study documents (Protocol, Annotated CRF, SAP, Specification doc, TFL shell & etc.) and send comments and queries to respective stake holders.
* Collaborating and co - ordinating with different stake holders (Stat, DM, Clinical, & etc) on study issues and updates.
* Writing & reviewing ‘Programming Data Specification’ for CDISC ADaM & SDTM standard datasets.
* Develop SAS Program (or write validation programs for) and document statistical deliverables
(SDTM/ADAM/TLG’s) for statistical analysis.
* Writing SAS program for complex analysis datasets.
* Develop standard SAS macros for CDISC SDTM and ADaM standard datasets, and tables, listings, and figures ( TLFs).
* Communicating with responding to internal cross-functional teams for project specifications, status, issues, or inquiries in standard SAS macros.
* Creating and validating efficacy, safety and TFL using SAS/BASE, SAS/MACROS, SAS/STAT & SAS/GRAPHS.
* Works with statistical personnel to provide definitions, documentation and review of derived variables needed to produce planned tables, listings, and graphs.
* Develops programs for development & validation of SDTM, ADaM & TFL’s.
* Generating complex ad-hoc ADaMS & reports utilizing SDTM data.
* Delivery of the Clinical Study Report (CSR, CSPD, DMC & CTSD), Study Data Tabulation Model (SDTM)/Analysis Data Model (ADaM) datasets, Pinnacle validation and Tables, Figures and Listings (TFL) outputs through both internal and external delivery models, following applicable data standards and regulations.
* Development of standard methodology to improve quality, efficiency, and effectiveness.
* Ensure the statistical programming systems, processes and deliverables are aligned with the
relevant project requirements for instance understanding all SOP’s/WI.
* Communicating project programmer, project lead, biostatistician, and vendors.
* Reviewing the final reports and uploading document management system.

**Novartis 21SEP2015 to 31MAR2018**

**Statistical Programmer II**

**Responsibilities:**

* SAS programming and analysis support for phases II, III of clinical trials.
* Leading and supporting multiple studies, planning timelines, and assigning work for team members, guiding, suggesting, and driving teams to deliver outputs with high quality within timeframe.
* Review & refer the study documents (Protocol, Annotated CRF, SAP, Specification doc, TFL shell & etc.) and send comments and queries to respective stake holders.
* Collaborating and co - ordinating with different stake holders (Stat, DM, Clinical, & etc) on study issues and updates.
* Writing & reviewing ‘Programming Data Specification’ for CDISC ADaM & SDTM standard datasets.
* Develop SAS Program (or write validation programs for) and document statistical deliverables
(SDTM/ADAM/TLG’s) for statistical analysis.
* Writing SAS program for complex analysis datasets.
* Communicating with responding to internal cross-functional teams for project specifications, status, issues, or inquiries in standard SAS macros.
* Creating and validating efficacy, safety and TFL using SAS/BASE, SAS/MACROS, SAS/STAT & SAS/GRAPHS.
* Works with statistical personnel to provide definitions, documentation and review of derived variables needed to produce planned tables, listings, and graphs.
* Develops programs for development & validation of SDTM, ADaM & TFL’s.
* Generating complex ad-hoc reports utilizing raw data.
* Delivery of the Clinical Study Report (CSR, CSPD, DMC & CTSD), Study Data Tabulation Model (SDTM)/Analysis Data Model (ADaM) datasets, Pinnacle validation and Tables, Figures and Listings (TFL) outputs through both internal and external delivery models, following applicable data standards and regulations.
* Ensure the statistical programming systems, processes and deliverables are aligned with the
relevant project requirements for instance understanding all SOP’s/WI.
* Communicating with project programmer, project lead, biostatistician, and vendors.
* Reviewing the final reports and uploading document management system.

**ClinAsia Labs 18DEC2013 to 19AUG2015**

**SAS Programmer.**

**Responsibilities:**

* SAS programming and analysis support for phases II & III of clinical trials.
* Leading and supporting single study, planning timelines, and assigning work for team members, guiding, suggesting, and driving team to deliver outputs with high quality within timeframe.
* Review & refer the study documents (Protocol, Annotated CRF, SAP, Specification doc, TFL shell & etc.) and send comments and queries to respective stake holders.
* Collaborating and co - ordinating with different stake holders (Stat, DM, Clinical, & etc) on study issues and updates.
* Writing & reviewing ‘Programming Data Specification’ for CDISC ADaM & SDTM standard datasets.
* Develop SAS Program (or write validation programs for) and document statistical deliverables
(SDTM/ADAM/TLG’s) for statistical analysis.
* Writing SAS program for complex analysis datasets.
* Communicating with responding to internal cross-functional teams and client for project specifications, status, issues, or inquiries in standard SAS macros.
* Creating and validating efficacy, safety and TFL using SAS/BASE, SAS/MACROS, SAS/STAT & SAS/GRAPHS.
* Works with statistical personnel to provide definitions, documentation and review of derived variables needed to produce planned tables, listings, and graphs.
* Develops programs for development & validation of SDTM, ADaM & TFL’s.
* Generating complex ad-hoc reports utilizing raw data.
* Delivery of the Clinical Study Report (CSR, CSPD, DMC & CTSD), Study Data Tabulation Model (SDTM)/Analysis Data Model (ADaM) datasets, Pinnacle validation and Tables, Figures and Listings (TFL) outputs through both internal and external delivery models, following applicable data standards and regulations.
* Ensure the statistical programming systems, processes and deliverables are aligned with the
relevant project requirements for instance understanding all SOP’s/WI.
* Reviewing the final reports and uploading document management system.

**SRISTEK Clinical Research Solutions 01APR2013 To 17DEC2013**

**Lead SAS Programmer**

**Responsibilities:**

* SAS programming and analysis support for phases II & III of clinical trials.
* Leading and supporting single studies, planning timelines, and assigning work for team members, guiding, suggesting, and driving team to deliver outputs with high quality within timeframe.
* Review & refer the study documents (Protocol, Annotated CRF, SAP, Specification doc, TFL shell & etc.) and send comments and queries to respective stake holders.
* Collaborating and co - ordinating with different stake holders (Stat, DM, Clinical, & etc) on study issues and updates.
* Writing ‘Programming Data Specification’ for CDISC ADaM & SDTM standard datasets.
* Develop SAS Program (or write validation programs for) and document statistical deliverables
(SDTM/ADAM/TLG’s) for statistical analysis.
* Creating and validating safety and TFL using SAS/BASE, SAS/MACROS, SAS/STAT & SAS/GRAPHS.
* Works with statistical personnel to provide definitions, documentation and review of derived variables needed to produce planned tables, listings, and graphs.
* Develops programs for development & validation of SDTM, ADaM & TFL’s.
* Delivery of the Clinical Study Report (CSR, DMC & CTSD), Study Data Tabulation Model (SDTM)/Analysis Data Model (ADaM) datasets, Pinnacle validation and Tables, Figures and Listings (TFL) outputs through both internal and external delivery models, following applicable data standards and regulations.
* Ensure the statistical programming systems, processes and deliverables are aligned with the
relevant project requirements for instance understanding all SOP’s/WI.
* Communicating with project manager and clients.
* Reviewing the final reports and uploading document management system.

**SRISTEK Clinical Research Solutions Ltd. 23AUG2010 To 31MAR2013**

**Jr. SAS Programmer**

 **Responsibilities**:

* SAS programming and analysis support for phases II & III of clinical trials.
* Provide statistical programming support for multiple projects.
* Produce datasets, analyses, tabulations, graphs, and listings of project’s data.
* Contribute to on-going quality improvement efforts within the project.
* Refer the study documents (Protocol, Annotated CRF, SAP, Specification doc, TFL shell & etc.).
* Refer SAP and TFL shell, asking queries to study lead.
* Referring ‘Programming Data Specification’ for ADaM analysis datasets.
* Co - ordinating and collaborating with the team members.
* Creating and validating safety ‘TFL’ using SAS/BASE.
* Develops programs, verifies, and validates.
* Communicating with study lead and other programmers.