# Shiva Kumar Bhimreddy

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## SUMMARY:


- **Certified Advanced & Base Programmer for SAS 9** with over **11+ years** of professional experience in SAS programming with emphasis on clinical data analysis, data validation and statistical report generation.
- Extensive experience with clinical trials, randomization process, statistical analysis, data cleaning, data management and reporting.
- Expert in the process of generating Tables and Listings for **Integrated Summary of Efficacy (ISE)** and **Integrated Summary of Safety (ISS)** for **FDA Submissions.**
- Experience working in all the phases **(Phase I to IV)** of clinical trials in pharmaceutical industry.
- Experience in creating **Case Report Tabulations (CRT's)** using **CDISC standards** and performing **E-Submission** to FDA.
- Proficient in producing **Excel, RTF, HTML** and **PDF** formatted files using **SAS ODS** to produce ad hoc reports for presentation and further analysis.
- Expert in creating metadata deliverables like **Define.pdf** and **Define.xml** and completing the required comment sections.
- Involved in clinical data analysis and creating **ADaM** and **SDTM** datasets, reports, tables, listings, summaries and graphs according to **Statistical Analysis Plan (SAP)** and departmental guidelines in **Standard Operating Procedures (SOP)**.
- Closely worked with **Statistical Programmers** and **Bio-Statisticians** to discuss various SAP and SOP related issues and made presentations to make possible changes to improve efficiency.
- Working knowledge in the **CDISC, WHO** and **MedDRA** regulated environment.
- Excellent knowledge of statistical SAS procedures like **FREQ, UNIVARIATE, MEANS, GLM, SUMMARY, REG** and **ANOVA** & reporting procedures like **REPORT, PRINT** and **TABULATE.**
- Expert in using the **SAS Annotate facility** and SAS procedures like **GPLOT** and **GCHART** to produce customized plots and graphs.
- Proficient in generating **Standardized MedDRA Queries (SMQ)** reports and using **Dynamic Data Exchange (DDE)** for importing Excel data into SAS.
- Conducting, documenting and reporting computer validation inspections in compliance with **Title 21 CFR Part 11.**
- Excellent analytical, problem solving, communication and interpersonal skills, with ability to interact with individuals at all levels.
- Extensive knowledge of edit checks, data cleaning, data validation and other Data Management departmental requests.

## PROFESSIONAL EXPERIENCE:

**Pharma Data Associates, Piscataway, NJ** **Apr 12 – Current**

**Manager, Statistical Programming**

**Responsibilities:**

- **Managed multiple projects** simultaneously and provided extensive programming support for programming deliverables.
- **Lead Programmer** for oncology studies and responsible for all the programming activities from the developing the programming specs to finalizing the CSR.
- Responsible for the **resource management** and **timeline forecasting & estimation** for programming deliverables like SDTM Datasets, ADaM Datasets and TLFs.
- Assigned programming tasks to the team members and monitored the Programming progress on a regular basis along with the documentation of the resolution of validation issues.
- Maintained programming tracking sheets for various projects and ensured timely completion of programming deliverables.
- Proficient in developing specifications for the SDTM and ADaM datasets using **SDTM IG v3.1.2** and **ADaM IG v1.0** standards.
- Used **OpenCDISC** Validator Tool to evaluate the compliance of SDTM and ADaM Datasets as per the CDISC standards.
- Developed and validated **Tables, Listings and Figures (TLF's)** according to the shells and specifications provided in the Statistical Analysis Plan (SAP).
- Generated **ad hoc reports** and **exploratory analysis tables** as requested by the Statistician.
- Pooled the clinical data of cancer studies and generated **Integrated Summary of Efficacy (ISE)** and **Integrated Summary of Safety (ISS)** reports.
- Provided programming support for FDA response related statistical analysis and reports.
- Responsible for conducting regular meetings with the clients regarding programming related issues and complex efficacy derivations.
- Developed **Utility Macros** at which can be customized for individual studies as per the need.
- Generated complex **Forest plots** and **Kaplan-Meier survival plots** with annotation as requested by the Statisticians.
- Developed customized **Patient Profile Listings/Hybrid Narratives** as per the requirements provided by the Medical Writer/Clinicians.
- Performed **CRF-Annotation** with respect to various study protocol designs.
- Generated the metadata **Define.xml** documents and confirmed the hyperlinks for the Analysis Datasets using the departmental macros.

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**Environment:** SAS 9.3, SAS/GRAPH, SAS/STAT, Excel/Access 2000, Windows XP

**Shionogi Inc., Florham Park, NJ** **Jan 11 – Apr 12**

**Senior Statistical Programmer**

**Responsibilities:**

- Provided extensive SAS programming support to the Biometrics department for **adhoc** statistical programming**.**
- Generated **Tables, Listings and Figures (TLF's)** according to the shells and specifications provided in the Statistical Analysis Plan (SAP) for clinical studies.
- Developed validation plan and performed validation of CSR deliverables for clinical studies.
- Worked on creating complex survival-failure graphs for statistical analysis and publications.
- Participated in the evaluation of statistical software like SAS JMP Clinical, SAS CDI and Spotfire.
- Generated special tables for **additional/exploratory analysis** for clinical studies as requested by statisticians and the clinical team.
- Created complex **Patient Profile Plots** and graphs by using the **SAS annotate facility** and SAS/GRAPH procedures like Proc Gplot.
- Worked together with statisticians to resolve programming and statistical issues for the CSR deliverables.
- Developed **Metadata** (Study Level Metadata, Dataset Level Metadata, Variable Level Metadata, Value Level Metadata and Code List Metadata) information for clinical studies.
- Worked with **MedDRA** coded clinical data for creating **Standardized MedDRA Queries (SMQ)** reports and special ad hoc adverse event tables.
- Created **Define.pdf** and **Define.xml** for SDTM and ADaM projects.
- Responsible for maintaining Standard SAS Macros for the department.
- Prepared/reviewed SDTM specifications for constipation based studies.
- Generated customized **Patient Profile Listings** using Proc Report and Proc Template for Kapvay studies.
- Resolved programming/data issues by working closely with Data Managers and Statisticians.
- Proficient use of SAS statistical procedures like **Proc Lifetest** to validate the statistics of Kaplan-Meier survival estimates and probability
- Maintained adequate documentation to track the progress of the CSR deliverables.
- Involved in reviewing the company SOPs and in developing standards in accordance with the CDISC SDTM standards.
- Developed and maintained department level work instructions.

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**Environment:** SAS 9.2, Spotfire, SAS/GRAPH, SAS/STAT, Excel/Access 2000, Windows XP

**BioClinica Inc., Audubon, PA** **Jan 10 – Jan 11**

**Clinical Programmer Analyst**

**Responsibilities:**

- Developed mapping specifications and programmed **Study Data Tabulation Model (SDTM)** data sets according to the **CDISC v3.1.2 standards** for clinical studies.
- Provided extensive SAS programming support to the Data Management department for **data cleaning, edit checks** and **data validation**.
- Developed mapping specifications for certain special **ADaM** datasets for **PK analysis**.
- Generated **Tables, Listings and Figures (TLF's)** according to the shells and specifications provided in the Statistical Analysis Plan (SAP).
- Proficient use of **SAS Annotate facility** to create customized graphs and plots.
- Developed and maintained departmental **SOPs** for SAS programming.
- Performed validation of TLFs and SDTM data sets for clinical studies and created **validation documentation** with detailed explanation of the QC issues.
- Responsible for creating and maintaining the programming tracking sheet for clinical studies to track the progress/status of SAS Programming tasks.
- Developed programs for reconciliation process of Laboratory and Pharmacokinetic data.
- Extensive use of **Import/Export** procedures to convert SAS data into CSV and Excel data and to convert Excel data into SAS data.
- Performed **CRF-Annotation** with respect to various study protocol designs.
- Produced edit check reports in various formatted files such as Excel sheets, RTF and PDF using **SAS ODS**.
- Developed **Metadata** (Study Level Metadata, Dataset Level Metadata, Variable Level Metadata, Value Level Metadata and Code List Metadata) information for clinical studies.
- Created **Define.pdf** and **Define.xml** for SDTM and ADaM projects.
- Responsible for populating the comments sections of Define.pdf and Define.xml and also completing the hyper linking within these metadata documents.
- Developed standard macros and program templates for departmental use.
- Created **adhoc requests** by the Data Management to produce customized reports on data issues.
- Worked closely with Data Managers and Statisticians to resolve programming issues of TLFs and AdaM datasets.
- Used **Open CDISC Validator Tool** to validate SDTM datasets.
- Proficient use of Data _null_ and Proc Template to create customized reports.
- Performed **SAS transformations** of clinical data according to the client specifications.
- Extensively worked on back end checks and created customized reports.

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**Environment:** SAS 9.1, SAS/GRAPH, SAS/STAT, Excel/Access 2000, Windows XP

**Sanofi-Aventis, Bridgewater, NJ** **Apr 09 – Dec 09**

**Sr. Statistical Programmer**

**Responsibilities:**

- Extensive experience in the report generation and the validation of the CSR of various **oncology** and **diabetes** based clinical studies.
- Expert in the validation **on Key Results Memo (KRM) TLGs** of various cancer drug therapies related clinical studies.
- Developed, validated and delivered the **CSR deliverables** as per the **Data Monitoring Committee (DMC)** specifications.
- Enrolled and certified at training sessions of the company's in-built macro applications for CSR reporting, Analysis Data Set (ADS) creation and metadata handling for generating **define.pdf** and other e-sub deliverables.
- Worked closely with the Statistician to resolve data issues and programming logic issues for the CSR deliverables.
- Extensively used SAS statistical procedures like **Proc Phreg** and **Proc Lifetest** to validate the statistics of Kaplan-Meier survival estimates and probability.
- Created validation documentation for QC comments/ QC issues and maintained the programming tracking sheet for the clinical studies.
- Developed program templates and macros at project level that can be used in studies for the same compound.
- Performed extensive validation of the **Analysis data sets (ADS)** and optimized the generation of **SDTM (SDS)** from these Analysis Data Sets in accordance with the CDISC v3.1.2 standards.
- Created annotated survival plots by using the **SAS Annotate facility** and GPLOT as per the specifications provided by the Biostatistician.
- Developed and maintained validation plans for the ADS and CSR at study level with the help of Biostatistician and Programming manager.
- Pooled the clinical data of cancer studies and generated **Integrated Summary of Efficacy (ISE)** and **Integrated Summary of Safety (ISS)** reports.
- Created adhoc statistical tables and listings on the request of Biostatistician and the Clinical Data Review team.
- Proficient use of Import/Export procedures to read CSV and Excel data into SAS and SAS ODS to create CSV and Excel data from SAS data.
- Contributed in developing the company's validation SOP for the CSR deliverables.
- Created **Standardized MedDRA Queries (SMQ)** reports and special ad hoc adverse event tables as per the specifications provided by the Biostatistician.

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**Environment:** SAS 8.2/9.1, SAS/GRAPH, SAS/STAT, Excel/Access 2000, Windows XP

**Alpharma Pharmaceuticals LLC, Piscataway NJ** **Apr 08 – Mar 09**

**Clinical SAS Programmer**

**Responsibilities:**

- Extensively used Base SAS, SAS/STAT, SAS/GRAPH and SAS MACROS to generate reports and graphs on **Osteoarthritis - Pain Medication** based clinical studies.
- Worked as a part of **E-Submission team** and contributed towards the final **FDA re-submission** of **NDA** of the KADIAN NT drug.
- Hands on experience on **CDISC v3.1.2 standards** in creating **Study Data Tabulation Model (SDTM)** data sets.
- Contributed in developing the company's **SOP** for SAS Programming and Documentation.
- Performed extensive QC programming for validating ISS data reports.
- Worked with **MedDRA** coded clinical data for creating **Standardized MedDRA Queries (SMQ)** reports and special ad hoc adverse event tables.
- Involved in designing and implementing the company's **Biostatistics Directory Structure**.
- Developed routine **SAS macros** to create tables and listings for inclusion in clinical study reports and regulatory submissions.
- Created **Data Definition Tables (DDT)/ Metadata Table** for clinical studies using **DefinePDF v2.0.**
- Completed the **define.pdf** document with the study related metadata information and documented the derivation of complex analysis variables.
- Used **ISI Toolbox** to create hyperlinks in the define.pdf document.
- Programmed the Analysis Dataset Model (ADaM) datasets according to study protocol specifications with the help of biostatistician to meet future needs.
- Created outputs in PDF, RTF and HTML formats by using **SAS ODS**.
- Created **Patient Profile Plots** and graphs by using the **SAS annotate facility** and SAS/GRAPH procedures like Proc Gplot.
- Generated customized **Patient Profile Listings** using Proc Report and Proc Template.
- Produced data listings, summary tables and graphics for interim and final statistical analysis and publications.
- Used statistical SAS procedures like Proc Means, Proc Freq and Proc Univariate for tabulation counts, correlations, data validations, edit checks and SQL Queries to check data for different conditions like duplicate values and missing values.
- Involved in creating **Transport-files** for electronic submissions to FDA.
- Performed statistical analysis on the clinical data and generated statistical tables and reports according to the specifications provided by the Biostatistician.
- Extensively used **Proc Template** with Proc Report and Data Null technique for producing customized reports.
- Created data sets from Excel data using **Proc Import** for statistical analysis and created Excel data from the analyzed clinical data sets using **Proc Export** and **ODS**.

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**Environment:** SAS 9.1, SAS/GRAPH, SAS/STAT, DefinePDF V2.0, Excel/Access 2000, Windows XP

**Elan Pharmaceuticals Inc., South San Francisco CA** **Jan 07 – Mar 08**

**Statistical Programmer**

**Responsibilities:**

- Generated Tables, Listings and Graphs using various SAS techniques such as SAS Macros and SAS/STAT for statistical analysis of **neuroscience-based clinical studies**.
- Worked on **Phase II** and **Phase III** Clinical Trials.
- Experience working in Quality Control (QC) of analysis datasets, Tables and Listings.
- Created **SDTM** datasets referring to the specifications provided by the **CDISC v3.1 standards**.
- Produced Excel, RTF, HTML and PDF formatted files using SAS ODS to produce ad hoc reports for further analysis.
- Created the **define.pdf** document for clinical studies and created hyperlinks in the metadata table.
- Generated **Standardized MedDRA Queries (SMQ)** reports according to the specifications provided by the Biostatistician.
- Created appendix for all the **Efficacy** and **Safety tables** for all the studies.
- Maintained program documentation on SAS programs, files and variables for accurate historical record and for future reference.
- Excellent knowledge of **SAS Annotate facility** to produce plots and graphs using SAS GRAPH procedures like Gplot and Gchart.
- Created SAS datasets from Microsoft Excel files using **Proc Import** / **Import Wizard**.
- Developed **SAS Macro** programs to replace repetitive codes and generated similar tables with varying parameters.
- Generated customized tables and reports using Proc Report and Data _null_.
- Involved in summarizing the p-values along with the Biostatistician using statistical procedures like Proc GLM and Proc Mixed.
- Performed Data Validation and Data Cleaning.
- Experienced in cleaning and resolving data issues as well as merging data from different sources into a single integrated dataset.
- Created **Transport-files** of data sets for electronic submissions to FDA.
- Wrote **SQL queries** and **edit check** programs for data validation and to check data for conditions like missing and duplicate values.
- Knowledge of **CRF-Annotation** with respect to various study protocol designs.
- Produced quality customized **ad-hoc reports** by using Proc Tabulate, Proc Report and Proc Template.
- Provided descriptive statistics using Proc Means, Proc Frequency and Proc Univariate.
- Maintained appropriate clinical study documentation.

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**Environment:** SAS 8.2, SAS/STAT, SAS/CONNECT, SAS/ACCESS, SAS/SHARE, Excel/Access 2000, Windows XP

**I3 Statprobe, Ann Arbor MI** **Oct 05 – Dec 06**

**Clinical SAS Programmer**

**Responsibilities:**

- Involved in generating the Tables, Listings and Graphs using Base SAS and SAS/STAT.
- Participated in creating **ISS** and **ISE** by integrating **Phase II, Phase III** and **safety studies** for submission to FDA.
- Developed efficient, well-documented, readily comprehensible and modifiable SAS code using Base SAS and SAS Macro facility.
- Responsible for creating and completing the **define.pdf** document for clinical studies.
- Developed permanent **SAS formats** and **templates** for the customized outputs.
- Wrote various data cleaning SAS codes for Data Management Group.
- Documented the pre-written macros and SAS programs.
- Produced output in various formatted files such as Excel sheets, RTF, PDF and HTML using **SAS ODS**.
- Wrote Edit Check Programs for data validation before using for final analysis
- Created transport files for electronic submission to FDA.
- Created **Study Data Tabulation Model (SDTM)** data sets in accordance with the CDISC Standards.
- Extensively used **Dynamic Data Exchange (DDE)** for importing data in Microsoft Excel sheets into SAS.
- Created Patient Profile Listings using Proc Report and customized the output using Proc Template.
- Created customized reports using Data _null_ and Proc Template.
- Experience in calculating the p-values and CI limit for clinical data
- Validated the results obtained by other programmers by using various statistical procedures like Proc Univariate, Proc Freq and Proc Compare.
- Conducted and generated reports on the Regression, Correlation studies and Analysis of Variance (ANOVA) using statistical SAS procedures with the help of Biostatistician.
- Produced accurate, precise tables and graphs for Clinical Study Reports by conducting, documenting and reporting computer validation inspections in compliance with **21 Code of Federal Regulations (21CFR) Part 11.**
- Knowledge of extracting Oracle tables by using Oracle Clinical and PL/SQL.
- Generated ad hoc reports in RTF, PDF and HTML formatted files using SAS ODS for statistical analysis of the clinical data.
- Performed quality control (QC) operations on SAS programs and documented all project data flows and programs.
- Ran monthly and weekly reports using **SAS macros**.

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**Environment:** SAS 8.2, SAS/STAT, SAS/CONNECT, SAS/ACCESS, SAS/GRAPH, Excel/Access 2000, Oracle Clinical 4.0, Window NT/2000 and UNIX.

**Access Pharmaceuticals, Dallas, TX** **Jan 04 – Sep 05**

**SAS Programmer/Analyst**

**Responsibilities:**

- Extensively used Base SAS, SAS MACROS and SAS/STAT to generate Tables, Listings and Graphs (TLG's) according to the specifications provided in the **Statistical Analysis Plan (SAP)**.
- Created **Study Data Tabulation Model (SDTM)** data sets in accordance with the CDISC Standards.
- Produced output in various formatted files such as Excel sheets, RTF, PDF and HTML using SAS ODS.
- Excellent Knowledge of **SAS Annotate facility** for creating customized graphs and plots.
- Documented the pre-written macros and SAS programs.
- Created **define.pdf** document with metadata information for clinical studies.
- Wrote Edit Check Programs for data validation and various data cleaning SAS codes.
- Created special Adverse Event tables and **Standardized MedDRA Queries (SMQ)** reports according to the specifications provided by the Biostatistician.
- Created customized templates and permanent SAS formats for quality customized outputs of the clinical data.
- Extensively used Proc Import to create SAS data sets from Microsoft Excel sheets and also used Proc Export to create Excel sheet reports from the analyzed SAS data sets.
- Contributed to the development of the company's **Standard Operating Procedures (SOP)** for SAS Programming.
- Experience in calculating the p-values and CI limit for clinical data.
- Created Analysis Dataset Model (ADaM) data sets according to the specifications provided by the Biostatistician.
- Performed Data Cleaning and Data validation of the datasets as per the CDISC standards.
- Validated the results for statistical reports by using procedures like Proc Univariate, Proc Freq and Proc Compare.
- Generated customized reports using Proc Template with Proc Report and Data Null Technique.
- Extensively used SAS Statistical procedures like **Univariate**, **Freq, Summary** and **Means** for generating statistical and adhoc reports.
- Extensively used SAS ODS to produce ad hoc reports for presentation and further analysis.
- Ran monthly and weekly reports using SAS macros.
- Performed Validation and quality control (QC) operations on SAS programs written by other statistical programmers.

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**Environment:** SAS 8.2, SAS/STAT, SAS/CONNECT, SAS/GRAPH, Excel/Access 2000, Window NT/2000.

## EDUCATIONAL QUALIFICATIONS:

**Master of Science** in Biomedical Engineering
Drexel University, Philadelphia, PA, USA **GPA = 3. 9**
Awardee of ***Drexel Dean's Fellowship*** for excellent academic credentials

**Bachelor of Science** in Biomedical Engineering
Jawaharlal Nehru Technological University (JNTU), Hyderabad, India **GPA = 4. 0**
Awardee of the ***University Topper*** *and* ***Gold Medalist*** for outstanding academic credentials

## TECHNICAL SKILLS:

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| **SAS Tools:** | *SAS 8.2/9.3, SAS/STAT, SAS/GRAPH, SAS/CONNECT, SAS/ACCESS, SAS/SHARE, SAS MACROS, SAS ODS* |
| **Database Packages:** | *Oracle 7/8, SQL, Oracle Clinical, 4.0, MS Access 98/2000* |
| **Operating Systems:** | *Windows XP / 2000 / NT / 98, UNIX* |
| **Office tools:** | *MS Office 97/2000, WordPerfect, Excel 97/2000* |