Name: Umadevi Koduru
US Permanent Resident (EB1A - 'Alien of Extraordinary Ability')
Skills: SAS Clinical Programmer
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SUMMARY:

- Over five years of experience in SAS programming with good knowledge of advanced statistical methodologies applied in Pharmaceutical and Biotech industries.
- Expertise in analyzing and reporting various phases (Phase I-IV) of Clinical Trials using tools like Base SAS, SAS/STAT, SAS/GRAPH, SAS/SQL, SAS/MACRO, SAS/ACCESS and SAS/OD.
- Experience in debugging and testing SAS programs to check and process data, generate graphs, tables and listings in analysis system.
- Individually capable of developing new SAS Programs and/or enhancing existing SAS programs from protocols and SAP's.
- Experience in Data manipulation and producing reports employing various SAS procedures like PROC SQL, PROC REPORT, PROC TABULATE, PROC FREQ, PROC MEANS, PROC UNIVARIATE, PROC SUMMARY, and PROC CONTENTS.
- Experienced in data analysis, data manipulation, data reporting using SAS and relational databases.
- Developing SAS macros for reusable applications used in generating datasets and different reports as per the requirement.
- Hands on experience in SAS programming for importing and exporting huge data sets from Flat files, Excel spreadsheets and external RDBMS (ORACLE)tables using LIBNAME and SQL PASSTHRU facility.
- Working knowledge of medical terminology in clinical trials, clinical trial methodologies, and software systems development.
- Well- versed with ICH GCP, CDISC, SDTM3.1.2 format implementations and 21CFR Part 11 and GCDMP guidelines and regulations.
- Experience in data mapping from non-CDISC to SDTM datasets using annotated CRF, and creating ADAM datasets (ADSL and BDS) and TLF.
- Validating statistical programs, review of CRF's and perform edit checks
- Exposure to CDISC Standards,21 CFR Part 11, GxP guidelines, Bioethics, IRB guidelines, HIPAA guidelines and Regulatory Submissions (CSR, BLA, NDA, including ISE and ISS).
- Efficient in maintaining working relationships with clients and internal project members, including data managers, research scientists, and other statistical programmers.
- Experience in developing and maintaining statistical documentation, including description of statistical methods, SAS programs, results and discussion.
- Documented, summarized and recorded data as per standard operating procedures (SOPs)and FDA regulations.
- Possess a strong ability to adapt and learn new technologies and new business lines rapidly.
- Effective team player with strong communication & interpersonal skills.
- Areas of research are in Genetics, Microbiology, Molecular Biology and Microbial Biotechnology
- Led (as a PI) over ten research projects with funding from Netherlands, Germany (DAAD, DFG) and Indian Governments (CSIR, DST, DBT MoES, UGC)

- Served as both a consultant and collaborator in multiple research projects with private corporations and government entities
- Excellent customized figures using python.

TECHNICAL SKILLS:

- Operating systems: WINDOWS XP/2000/98
- SAS Tools SAS/Base, SAS/Stat, SAS/Graph, SAS/SQL, SAS/Access, SAS/ODS, SAS/Report, Proc SQL, Macros
- Database: Oracle Clinical, SQL Server 2000, PL/SQL and MS Access
- Python for data visualization (statistical analysis and Graphs).
- Statistical modelling linear and nonlinear models.
- Sound background in Biostatistics having taught this subject for over two decades to post graduate students in life sciences at a university and used several statistical designs and statistical procedures to analyze my research data as a Research Professor
- MS Office: Word, Excel, PowerPoint, Access and Outlook
- Statistical tools: SAS v 9.x/8.x/6.x, SPSS
- Conversant with Bioinformatic tools (BLAST MEGA etc.) and in-silico drug discovery.

PROFESSIONAL EXPERIENCE

Client: LabCorp September 2021 to present
Role: Clinical SAS programmer

- Responsible for providing Clinical SAS programming and analysis support for clinical studies across multiple protocols for the submissions like CSR and Safety.
- Generated Tables, Listings and provide QC check, validation of outputs for Oncology clinical trials.
- Generated customized graphs using python.
- Responsible for Developing reports for Safety and efficacy as per study requirements.
- Involved in Developing, Debugging, and validating the project-specific SAS programs to generate derived SAS datasets, summary tables, and data listings according to departmental standards.
- Used Sorting and Merging techniques on the raw data sets for value added data preparation, to get the required Reports or Analysis data sets.
- 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.
- Extensively used Proc SQL to retrieve, update and report on information from SAS data sets and other database products.
- Modification of existing SAS programs and creation of new programs using SAS Macros.
- Built Macros and create macro variables using %LET, CALL SYMPUT, and DATA _NULL_ to help generate analysis data sets and create specified structure of TLFs.
- Ability to quickly debug SAS compiling errors, to review SAS code and quickly identify areas of concern.
- Worked with Statisticians and Clinical Data Managers to provide SAS programming in analyzing the Clinical Trials and generating Reports.

- Created analysis datasets based on the guidelines provided in the Data Definition Tables (DDT) and following the CDISC standard. Used SDTM model (v3.2)/ ADAM for domain creation and CDISC compliant analysis datasets.
- Used Proc CDISC for verifying compliance of datasets with CDISC standards and electronic submissions.
- Helped in drafting ISS and creating define.xml docs for FDA submission.
- Worked on multiple protocols and/or drug compounds at a time.

Environment: SAS 9.x/8.x, SAS/BASE, SAS/MACROS, SAS/STAT, SAS/GRAPH, Windows

Client: Bristol Myers Squibb New York October 2017 – August 2021
Role: Clinical SAS programmer

Bristol Myers Squibb New York specializes in designing customized solutions to aid the pharmaceutical, biotechnology, medical devices and diagnostics industry by establishing the safety, efficacy and value of health technologies. Primary areas of research include registries and late-phase clinical trial studies as well as market research and strategies.

Therapeutic area: Oncology/Hematology

- Provided SAS Programming and analysis support for phase III (oncology) clinical trials
- Co-worked with Statisticians as a primary SAS programmer to analyze initial data sets and create tables, listings and figures (TLFs) for clinical trials.
- Created tables, graph (using python) to generate clinical study reports for the collected requirement from the statisticians referring to the Statistical Analysis Plan (SAP).
- Extracted data from ORACLE database and involved in cleaning the data (data cleansing) using various edit check techniques.
- Used procedures like PROC TRANSPOSE, PROC SORT, etc. in Data transformation and Manipulation processes.
- Extensively used Proc SQL, Proc Transpose, Proc Format, Proc Means, Proc Univariate, Proc Freq, Proc Printto and Proc Compare for checking the assumptions and conducting Statistical Analysis.
- Effectively developed SAS code for modeling data and implemented SAS/STAT procedures such as Proc Lifetest, Proc lifereg, Proc Phreg, proc reg and Proc Glm for Survival analysis, logistic regression analysis and other statistical analyses.
- Produced Ad hoc reports of various kinds like Listings, Tables, and Figures (TLGs/TLFs) using Proc Report, Proc Tabulate, Data _Null_ technique, Proc Gplot etc.
- Used SAS ODS to report outputs in different formats like RTF, PDF, and HTML
- Validated analysis data sets and SAS outputs with other programmers' outputs and mockups in SAP using PROC COMPARE, PROC CONTENTS, and PROC FREQ. Created formats for the coded data and used PROC SQL for data validation.
- SAS macros were successfully used to create new programs and modified existing SAS programs to make them portable as well as for consistency of results.
- Documented, summarized and recorded data as per standard operating procedures (SOPs) and FDA regulations.
- Majorly worked with the data management team and was involved in handling documentation and submission processes (under managers' assistance).
  Environment: Windows XP, Oracle 9i, SASV9.1.3, Base/SAS, SAS/Access, SAS/Macro, SAS/STAT

- Andhra University, Visakhapatnam, India Upto 2017
  Research Professor (Life Sciences)

Research in front line topics in life sciences that involved extensive statistical analysis of data. Collaborated with several research groups from research institutes in India UK, Germany and the US. Published research extensively in high impact journals. Several sabbatical research visits to research labs in the UK and Germany.

EDUCATION

❖ PhD, 1982 Area: Genetics; Andhra University. Andhra University (AU , India)
❖ MSc , 1977 Plant sciences, AU, India
❖ BSc 1975 Chemistry Zoology and Botany
Distinction all through Academic career.

REFERENCES

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