**Anitha D**

**SAS Programmer  
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**PROFESSIONAL SUMMARY:**

* Having **7 years** of experience as **SAS Programmer** **Analyst** in **Pharmaceutical** / **CRO** industry.
* Developed **SAS Programs** to produce and validate analysis datasets, listings, graphs and summary tables of safety and efficacy data for Phase I-III clinical trials.
* Strong working knowledge in **clinical trial data analysis**, generating reports and summary tables, listings and graphs as per Statistical Analysis Plan **SAP** and **protocol** specifications.
* Excellent experience in **SAS** programming using **BASE SAS, SAS/ACCESS, SAS/GRAPH**, **SAS/MACRO, SAS/SQL, SAS/ STAT**.
* Strong skills in working with various **SAS** versionsand **BASE SAS, SAS/MACRO, SAS/STAT, SAS/SQL,** **SAS/GRAPH, SAS/ODS, SAS/ACCESS**.
* Extensive programming experience with **PROC SQL, PROC REPORT, PROC ACCESS, PROC** **GPLOT, PROC SORT, PROC GCHART, PROC FORMAT, PROC TRANSPOSE, PROC PRINT, PROC** **COMPARE, PROC APPEND, PROC IMPORT/EXPORT**.
* Hands on experience in implementing **CDISC** standards **SDTM** and **ADaM**.
* Modified existing SAS programs and created new programs using **SAS MACROS** to improve ease and speed of modifications as well as consistency of results.
* Experienced in analysing the clinical trials and generating reports, tables, listings and graphs for internal purpose and for **FDA** according to the **21 CFR Part 11.**
* Experienced with **CDISC** defined **SDTM, ADaM** data model standard for transforming and creating analysis dataset for generating **TFL’s**.
* Experienced on working with legacy data to convert them to **CDISC** requirements.
* Experienced in creating non-standard ad-hoc requests as per statisticians demand.
* Good understanding of complex SAS concepts like **macros**, **SAS arrays** and Proc sql.
* Knowledge of generating electronic deliverables submissions**.**
* Familiar with **IND** and **NDA** submissions, **Clinical Terminology** and Regulatory Guidelines for **FDA** submissions.
* Worked on **Open** **CDISC** validator to ensure data is compliant with **CDISC** standards.
* Generated several permanent outputs in **RTF** format per client's requirement using **SAS**/ **ODS** and Proc report.
* Experienced on creating efficacy datasets and efficacy tables using statistical procedures.
* Exceptional problem solving skills for delivering useful and prudent solutions.
* A quick learner with an eye for detail and excellent analytical and quantitative skills.

**TECHNICAL SKILLS:**

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| **Operating System** | Unix, MS-DOS, Windows 98, XP, Vista, Windows 7 |
| **SAS** | SAS/BASE, SAS/PROCs, SAS/MACROS, SAS/ACCESS, SAS/GRAPH, SAS/SQL, SAS/ODS, SAS/REPORT, SAS/STAT, SAS/CONNECT, TRANSPOSE, CONTENTS, IMPORT, EXPORT,  SAS/TABULATE SAS PLOT SAS/MEANS |
| **Databases** | RDBMS, Oracle 11i/10g, SQL, MS ACCESS |
| **Programming Languages** | SAS 9.2, SQL, C, Object Oriented Programming OOP , HTML |
| **Office Tools** | MS-Office 97/2000/03/07/10, MS-Excel, MS-Power Point, MS-Word, MS-Paint, MS-Access, MS-Outlooks, MS-Communicator |

**PROFESSIONAL EXPERIENCE:**

**Benuvia Therapeutics Inc, Chandler, AZ May 2022 – Till date**

**SAS Programmer**

**Description**: Benuvia Therapeutics Inc. is focused on financing and developing low-risk assets with high clinical value to improve the quality of life for patients with rare and underserved diseases. We have a broad pipeline of clinical stage product candidates targeting rare and underserved diseases. Our pipeline is based on nearly a decade of clinical research across a dozen clinical studies. We seek partners to support the future development of these candidate assets through the 505(b) 2 pathway.

**Responsibilities**:

* Responsible for **SAS** programming (**SAS/BASE, SAS/ MACROS, SAS/SQL, SAS/ODS, SAS/ stat**, **SAS/ Graph**) and validation of **SDTM, ADaM** datasets following specifications and **TLFs** as per **TLF** Shells.
* Highly efficient in handling various **SDTM** domain classes like special-purpose, interventions, events, findings, findings about, Trial design models.
* Created specifications and involved in programming/validation of **ADaM** datasets from **SDTM** datasets, **ADSL, ADAE, ADMH, ADCM, ADLB, ADDV, ADEX, ADVS, ADEG, ADTTE** and analysis Questionnaire datasets etc.
* Running Open **CDISC** **Validator/Pinnacle 21** and addressing the errors and warnings on multiple studies and helping/guiding the teams.
* Worked as Validator on multiple studies, provided quality outputs to the client. And created an internal checklist for thorough validation process for **SDTM**, **ADaM** and **TLFs** for programmer’s reference.
* Created standard macros and applications to improve the working efficiency of the department.
* Involved in creating various **SAS** Reports satisfying the **21CFR-11** Code for Federal Regulations for electronic data submission.
* Provided input into planning documents such as validation plan, statistical analysis plan, and **TFL** templates as per **AdaM** Standards.
* Extensively used internal macro tools in creating mapping specifications documents, creating common header variables across all extracted datasets, handling global appending/merging, checking attributes conformance with **SDTM/ADaM** and Tables production and validation.
* Expertise in handling Analysis of the data, performing **CTCAE** grading, Missing data imputation using **LOCF/BOCF/WOCF**, Visit windowing etc.

**Vertex Pharmaceuticals, Boston MA Mar 2021 – Apr 2022**

**SAS Programmer**

**Description:** Vertex is a global biotechnology company that invests in scientific innovation to create transformative medicines for people with serious and life-threatening diseases. We discovered and developed the first medicines to treat the underlying cause of cystic fibrosis (CF), a rare, life-threatening genetic disease. In addition to clinical development programs in CF, Vertex has more than a dozen on-going research programs focused on the underlying mechanisms of other serious diseases.

**Responsibilities**:

* Extracted datasets from database using **SAS/ACCESS, LIBNAME** Statement and other Import methods.
* Verified accuracy and integrity of **Clinical** data by performing validation checks written in SAS and data cleaning by investigating data related errors and missing values.
* Reviewed clinical study protocols, case report forms and statistical analysis plans for clinical trials.
* Worked with various **SAS** products **SAS/BASE, SAS/STAT**, **SAS/GRAPH**, and **SAS MACROS** to develop required solutions.
* Successfully designed and implemented statistical reporting processes for regular data collection and clinical data analysis.
* Used **PROC SORT, SET, UPDATE** and **MERGE** statements for creating, updating and merging various SAS datasets.
* Validated data is processed based on the business rules. Used SORT, MERGE, SET statements and created final datasets for analysis.
* Provides load balancing for all **SAS** servers to improve output put and response time of all **SAS** clients.
* Analysed **Phase** **II** and **III** **Clinical Trials**.
* Developed and maintained programs in **SAS** using **SAS** tools for Windows and **UNIX** in a user support environment.
* Extensively used **Base** **SAS MEANS, FREQ**, and **REPORT** for summarization, cross-tabulations and statistical analysis purposes and **SAS/GRAPH** procedures like **PROC GPLOT** and **PROC** **GCHART** to generate reports.
* Conducted documenting and reporting computer validation inspections in compliance with **21** **Code** of Federal Regulations **21CFR** and other regulatory compliance
* Wrote programs using base **SAS** and **SAS/Macros** to extract data from oracle tables.
* Extracted raw data from warehouse and created **SAS** data sets that are required for the project analysis.
* Knowledge of **CTMS**, drug discovery and development, bioinformatics, **ICH-GCP**, drug protocol development, **clinical trials**, **CDISC, SDTM, ADaM**, clinical data management, **CRF** **Design**, **EDC** and **Pharma covigilance**.
* Involved in creating **SAS** datasets from flat files and **EXCEL** data as per requirement.
* Developed Edit check programs to clean invalid data from database.
* Generated tables, listings and graphs including patient’s demography and characteristics, adverse events, laboratory etc.
* Extensively used different **SAS** **procedures** such as **PROC MEANS, PROC SORT, PROC FREQ**, **PROC COMPARE, PROC REPORT, PROC SQL, PROC GPLOT** and Data NULL step and other statistical procedures.
* Collaborated with **clinical researchers** in the design of clinical trial selection of clinical endpoints, sample size requirements, protocol development, and Research and the Case Report Form design.
* Participated in writing of clinical trial reports and presenting of the trial results.

**Environment**: SAS/BASE, SAS STATS, SAS/BI, SAS/MACROS, SAS/MERGE, SAS Enterprise Guide, SAS/ODS.

**Medpace, Cincinnati, OH May 2019 – Feb 2021  
SAS Programmer**

**Description:** Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace’s mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

**Responsibilities**:

* Involved in creating specifications documents for **SDTM** and **ADAM** using annotated **CRFs**, SAP, mock-shells and Implementation guide.
* Created several domains in **CDISC** i.e., both **SDTM** and **ADAM** datasets on production side as well as validation side using specification.
* Good understanding of **CDISC** concepts and control terminology for **SDTM IG 3.1.1** and **3.1.2** and **ADAM IG 1.0** and **2.0**.
* Worked as both production programmer and validation programmer in the process of creating Tables, Listings and Graphs.
* Used **SAS/ACCESS** to extract data from Oracle and other relational databases for analysis.
* Prepared new datasets from raw sets files using Import Techniques and modified existing datasets using Set, Merge, Sort, Update, Formats, and Functions.
* Developed and customized reports using **PROC REPORT, PROC SORT, PROC FREQ** and **PROC** **MEANS** and **DATA** **NULL**.
* Created new datasets from existing data-sets by using concatenation, merging, interleaving and using conditional statements.
* Defining, Manipulation, Controlling and Reporting/Storage Query Language of Clinical Data by using **PROC SQL**.
* Created edit-check program and created clinical review listing for clinical team to review for data consistency.
* Involved in developing Kaplan-Maier Survival curves for comparison of event free survival rates using Proc Life test and **Proc Gplot**.
* Created ad hoc programs to provide information to the project team and/or client, as required.
* Imported data in the form of **SAS** datasets from flat files of various formats like tab delimited, .**CSV**, .**XPT** etc.
* Developed Macros to generate ad hoc reports weekly, monthly or on a specified cut date.
* Created various study specific macros by implementing debugging options.
* Created data quality listings to ensure data correctness and clinical review for clinical team.

**Environment:** SAS/BASE, SAS/MACRO, SAS/ACCESS, SAS/SQL, SAS/STAT, SAS/GRAPH, SAS/ODS, SDTM, CDISC, MS WINDOWS 2000 and UNIX.

**Advanced Clinical, Deerfield IL Jun 2015 –Apr 2019   
SAS Programmer**

**Description:** Advanced Clinical is a clinical development and strategic resourcing organization committed to providing a better clinical experience across the drug development journey. Our goal is to improve the lives of all those touched by clinical research – approaching each opportunity with foresight, character, resilience and innovation.

**Responsibilities:**

* Analysed three phases (I-III) of the Clinical Trials in different therapeutics areas.
* Developed **SAS** programs using **SAS/BASE, SAS/SQL, SAS/MACROS, SAS/STAT** and **SAS/GRAPH** and for statistical analysis and data displays.
* Experience with creating all files, documents, and analyses necessary to support an electronic submissions in **eCTD** format.
* Contributed to on-going preparation of **SAS** datasets for statistical analyses and demonstrations.
* Created complex and reusable Macros and extensively used existing macros and developed **SAS** Programs for Data Cleaning, Validation, Analysis and Report generation. Tested and debugged existing macros.
* In-depth knowledge of programming and reporting with Base **SAS, SAS/STAT, SAS** Language, **SAS/ODS** and Graph.
* Macros were written at various instances for automating listings and graphing of clinical data for analysis.
* Participated in edit check program development, testing and implementation when required by in house data management system.
* Generate reports either in **HTML**, **PDF** or **RTF** formats according to the client specifications.

**Environment**: SAS/BASE, SAS/MACROS, SAS/STAT, SAS/GRAPH, Oracle, Windows.

**EDUCATION**:

* Masters in Microbiology from Osmania University 2001