# KALPANA N

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Willing to relocate: Anywhere

## Work Experience

### Senior SAS Programmer Analyst

Pfizer - Groton, CT
May 2018 to Present

Responsibilities:
· Responsible for providing SAS programming and analysis support for phase III clinical study.
· Involved in e-submissions by creating Annotated CRFs, and Transport datasets in.
XPT format.
· Developed Tables, Listings and Figures using PROC REPORT.
· Perform program documentation on all programs, files, and variables for future reference.
· Interacted with statistician and clinical people for creating reports.
· Experience in providing tables and figures to be incorporated into Clinical
Study Report along with patient data listings and technical statistical details such as derivations, computations, analyses etc., and involved in discussions with medical writers in the preparation of Clinical Study Report.
· Developed specifications for database in CDISC format and involved in programming datasets in CDISC format and managed CDISC database for several studies.
· Experience in creating lab shift tables.
· Created cut off macro for individual analysis as per specification.
· Involved in generating and validating TLGs for Integrated Summaries Safety (ISS) for FDA submission and for other studies.
· Created Specifications for complicated analysis datasets as per SAP.
· Created and validated ADaM datasets from raw data.
· Created and Validated most of the SDTM datasets from raw dataset as per CDISC standards by using e-CRF and specification.
· EX: DM, DS, AE, LB, SV, VS, MH, CM, DM etc.
· Created and validated most of the ADaM datasets from the SDTMs as per specification guidelines.
· Used internal macros to automate statistical table, figure, and listing production
· Worked as a validation programmer and validated various SDTM, ADaM and TLFs.
· Developed programs from the scratch and modified / updated existing programs.
· Used Proc GLM, Proc TTEST, PROC MIXED, PROC LIFTEST, and PROC CORR for Efficacy analysis.
Environment: Base SAS, SAS/STAT, SAS/Graph, SAS/SQL, SAS/Macros, SAS ODS.

### Senior Statistical Programmer / Clinical Data Analyst

AstraZeneca - Wilmington, DE
September 2015 to April 2018

Responsibilities:

· Performed Data analysis, statistical analysis, generated reports, listings, and graphs using SAS/Tools, SAS/Base, SAS/Macro and SAS/Graph, SAS/SQL
· Involved in creation of ADaM standard datasets like ADSL, ADAE, ADLB, ADEX,
ADTTE etc.
· Involved in handling missing results following various imputations technique like LOCF, BOCF, and WOCF etc.
· Involved in handling, Partial dates, incomplete days of various datasets like
ADAE, ADMH, ADLB, ADVS etc.
· Involved in visit windowing for ADLB, ADVS etc., as per SAP.
· Extensively worked on edit check programming and supported Data Management in creating Logic Specs in cleaning data.
· Lead programming activities within the assigned drug development projects and ensured that all programming is executed in a timely manner and to the required high statistical and reporting standards.
· Synced up with statisticians, created analysis and SDTM data set specifications combining various types of internal as well as external data from different sources.
· Mapping and integrating study data to a CDISC-compliant proprietary analysis data system.
· Delivered datasets following the agreed specifications and adhered to stringent deadlines
· Created clinical data tables for Safety Analysis like Adverse Events (AE), Lab tables, Vital Signs tables.
· Worked with statistician and clinical data manager in analyzing the data, generating reports, TLG's as per SAP
· Actively involved in designing annotated CRF with data management group for
Phase I, II and III
· Performed data validation such as checking for missing values, checking for "n" observations per subject and identifying duplicate observations.
· Used company standard smart macros to create outputs and experience in creating outputs by writing own program.
· Used Output Delivery System (ODS) facility to create customized reports directing SAS output to RTF, PDF and HTML files
· Involved in creating data-cut macros to apply data-cut to the raw data for ongoing studies.
· Map source raw data from EDC system like Oracle clinical and created SDTM datasets using industry standard CDISC implementation guidelines.
· Data cleaning to remove incorrect data entered by using edit check programs before data analysis.

### Clinical SAS Programmer

PAREXEL International Pvt Ltd - Hyderabad, Telangana
February 2014 to May 2016

Roles & Responsibilities:
· Extracting the data from the database and creating new Datasets from raw data files.
· Modifying existing datasets using Set, Merge, and Sort, update, Formats,
Functions, Conditional statements, and procedures.
· Creating datasets in SDTM standards from raw datasets as per the Specifications.
· Involved in data mapping from RAW datasets to SDTM Standards.
· Created reports using the PROC REPORT for the submission as per the FDA regulations and company standards
· Creating datasets in SDTM standards from raw datasets as per the Specifications.
· Involved in multiple projects and interacted with other Programmers, statisticians and data managers to analyze data.

· Extraction of data from external databases and developing folder structures as per the standard requirements and facilitating the usage of global macros.
· Developed SAS programs based on SAP with wide usage of SAS/Base to Generate
Listings and Tables.
· Extracted and analyzed data from the database and created SAS datasets.
· Performed Data conversions and Data corrections of the data. Created based on specifications provided by the clients.
· Provided SAS programming for the generation of data Listings, Tables for the clinical trial study.
Clinical SAS Programmer

PAREXEL - Bengaluru, Karnataka
April 2012 to March 2015

Responsibilities:
· Create various SDTM and ADaM datasets according to CDISC.
· Created SDTM datasets and worked on creation of datasets like DM, AE, EX, VS etc. for clinical trials.
· Validated SDTM datasets in accordance with specifications by using procedures like Proc Means, Proc Freq, Proc Compare, and Proc Contents.
· Created and validated ADaM datasets like ADEG, ADMH, ADAE etc.
· Lead programming activities within the assigned drug development projects and ensured that all programming is executed in a timely manner and to the required high statistical and reporting standards.
· Produced data Listings, summary Tables, and Graphs as per SAP (Statistical
Analysis Plan) shells.
· Experience in working with Biostatisticians and representatives from clinical to regulatory, to develop clinical trial reporting systems, tables, patient listings, case report form tabulations, and derived datasets.
· Developed SAS macros to create tables, graphs, and listings for inclusion in
Clinical study reports and regulatory submissions and to maintain existing ones.
· Converted SAS Listings and Tables into PDF, RTF and HTML formats using SAS/ODS.
· Analyzing the data according to the Statistical Analysis Plan (SAP)
Environment: SAS/Base, SAS/Macros, SAS/Stat, SAS/Graph, SAS/ODS, SAS/SQL, java,
SQL*Plus, MS-Excel, UNIX.

## Education

### Master's in computer science
University of Cumberland's

### Bachelor's in pharmacy
Acharya Nagarjuna University

## Skills

- SAS Tools:
- Languages:
- Databases:
- Operating Systems:

- Base SAS
- SAS/MACROS
- SAS/STAT
- SAS/GRAPH
- SAS/ACCESS
- SAS/SQL
- SAS/SQLE
- SAS- Enterprise Guide 5.1
- 6.1
- 7.1.
- C
- C++
- SQL
- PL/SQL
- MySQL
- and HTML
- HL7
- SQL Server
- MS Access
- Oracle 7.x
- Oracle Clinical.
- UNIX
- WINDOWS
- Analysis skills
- Leadership