Kiran Kishore
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Profile:

- Above **eight years** of experience in performing analytic SAS/statistical programming for clinical trials Phase I -III for client companies.
- **Statistical programming** related to the design, programming, implementation, maintenance, and validation of trial information for the submission to the **FDA** during various phases.
- In-depth knowledge of statistical analysis techniques for clinical studies, and excellent experience in analyzing **safety & efficacy data for Phases (I-III) of clinical trials.**
- Excellent work experience in **generating tables, listings, and graphs** by following the Statistical Analysis Plan **(SAP**), Standard Operating Procedures **(SOPs),** and departmental guidelines.
- Utilizing advanced SAS skills, including **Macros** and **SQL** procedures to deliver concise and flexible code; Making efficient usage of SAS functions and procedures, including common statistical procedures.
- Extensive experience in the **eSubmission** of **deliverables** to **FDA**
- Good experience in **storing and managing data in SAS files, merging SAS data sets, SAS Formats, and SAS Informats**.
- Worked with the Clinical Data Reporting in **CDISC SDTM 3.1.1 Format**.
- Extensive experience in Clinical Data Management, data analysis, and to generate **CRT tables**, reports, graphs for FDA submission according to protocol.
- Created **Metadata tables** (**data definition tables** for the CRT's) using **Define. PDF**.
- Familiar with standard dictionaries such as **MEDRA** and **WHO Drug.**
- Accustomed to working in challenging environments under deadlines, excellent analytical, and problem solving skills.

Certification:

- SAS Certified BASE PROGRAMMER for version SAS 9.

Technical Skills:

Operating Systems:	Windows 95/98/NT/2000, UNIX.
SAS Skills:	SAS 9.1 (BASE, ACCESS, MACROS, CONNECT, SHARE, GRAPH).
SAS Procs:	SQL, Report, Means, Univariate, Corr, Reg, Tabulate, Freq, Chart, Sort, Summary, Contents, Format, Import, Export, Append, Transpose, Plot, Mixed, and ANOVA.
Languages:	C, HTML, SQL, and Matlab.
Databases:	MS SQL Server 2K/7.0/6.5, MS Access 2K/97.

Professional Experience:

Pharma Data Associates **Sep 2012 - Current**
Principal Programmer

Responsibilities:

- Generated TLG's and performed statistical analysis on the clinical data.
- Assumed active lead role on a number of projects.
- Provided Statistical analysis and programming to support phase II and III clinical trials for oncology and Rheumatology.
- Extensive experience for generating safety and efficacy tables, listings, and graphs.
- Coordinated extensively with Bio-Statisticians as **Lead Programmer** on various occasions for generating study specific requirements.
- Worked on a variety of Adhoc reports as per client's requirements.
- Developed specifications and programmed Study Data Tabulation Model (SDTM) datasets according to the CDISC v3.1.2 standards.
- Experience using **Open CDISC Validator** Tool to validate SDTM datasets.
- Created Patient profile listings, Transport files (xpt) for e-submissions to NDA for Cara Therapeutics and Tesaro Inc.
- Developed SAS MACROs to create tables, graphs, and listings (TLG's) for inclusion in clinical study reports, and regulatory submissions while maintained existing ones.
- Used Output Delivery System (ODS) facility to write custom ISS and ISE reports directing SAS output to RTF and HTML files.
- Responsible for creating the **module5 deliverables** (clinical study reports) consisting of **define.pdf/xml**, blankcrf.pdf, transport files and patient listing.
- Provided Quality Control (QC) programming support by developing programs for comparing them with source programmer's code.
- Expertise in Integration (Pooling) of datasets from different studies for further analysis for Tesaro Inc.
- Review the protocol, case report forms (CRFs), statistical analysis plan (SAP) for clinical trials.
- Worked in an environment requiring challenging timelines and extreme dedication.

Environment: Oracle9.x, SASV9.1.3, Base/SAS, SAS/Macro, SAS/STAT, SAS/GRAPH, Oracle Clinical,

Myriad Pharmaceuticals, Salt Lake City, **Apr09-Aug12**
Sr. Statistical Programmer

Responsibilities:

- Responsible for **standardizing** the **deliverables** to **FDA eSubmission requirement**.
- Knowledge of CTD/eCTD format and **US regulatory submission requirements.**
- Responsible for creating the **module5 deliverables** (clinical study reports) consisting of **define.pdf/xml**, blankcrf.pdf, transport files and patient listing.
- Responsible for creating the **standalone SAS programs** for the FDA (for deliverables) upon their request.

- Responsible for ensuring that **proper folder structure** has been developed to put the complete package in those folders according to the FDA requirement.
- Responsible for the understanding the **FDA questions** and responding them back with the appropriate results within the given timeline.
- Responsible for all the **3 months safety updates** to be submitted to FDA.
- Excellent knowledge of the **FDA eSubmission ready formats.**
- Create **define.pdf /define.xml** with proper **hyperlinks** to the referred **SAS datasets, CRF pages** or to any **additional derivation specification** mentioned in the comments.
- Used both **SAS macros** as well as **definePDF tool (datafarm inc.)** to create the define.pdf/xml.
- Using **S-Cubed CRT** for the recent projects.
- Extensively used **ISI toolbox** for creating hyperlinks.
- Daily **managemen**t and **coordination** of all E-sub deliverables.
- Direct and timely communication with the PD drug project teams and regulatory to keep all E-sub submissions timelines up to date.
- Responsible for ensuring the E-sub delivery within **negotiated submission timelines.**
- Used a **standard QA review** process to ensure the **accuracy** and **consistency** of the E-sub deliverables, including review of the **data definition document**, the **annotated CRF**, the **SAS transport file**, the **patient list** and **SAS program.**
- Implement new E-sub macros to automate manual QA processes. Follow change control and validation procedures.
- **Validation** of the **Xpt's** to be submitted to FDA to ensure **FDA compliance** and **data error.**
- Provides **SAS programming** support for E-sub macro changes and enhancements working in a **UNIX environment.**
- Provide **SAS programming** support to **create** the **TLG's** for the study..
- Support users to effectively make use of the tools and suggest solution and best practice.
- Responsible for actively contributing to the development and implementation of Regulatory Operations strategy for assigned projects and programs.
- Responsible for **interaction with the regulatory liaisons** with specific product responsibilities within the global R& D organization.
- **Gathers information** from other departments and external resources for contribution to completion of Regulatory filings and compliance.
- Provides **leadership** to the teams to ensure submissions are in accordance with electronic specifications and/or standard industry practice.

Tools used: Proficiency working with **eCTDXPress**, **ISIToolBox**, definePDF, **S-Cubed**.

Alpharma Pharmaceuticals, NJ **Apr 2008-Mar09**
SAS Programmer

Alpharma is a vertically integrated branded pharmaceutical company that develops, manufactures and markets therapies and technologies primarily in specialty-driven markets including neuroscience, hospital and acute care medicines. The study was in Phase II of the clinical trials. As a SAS Programmer my role was in analysis of clinical trials data and generating required reports, listings, summaries and graphs for submission to FDA and other regulatory authorities.

Responsibilities:

- Worked in three phase II and III studies and many Phase I studies.
- Developed programs to generate **analysis datasets** from raw datasets.
- Revised and modified analysis datasets to meet the company – modified **FDA submission** standards.
- Extensively involved in creating and Validating Analysis Datasets, **Tables**, **Listings** and **Graphs**.
- Provided SAS programming and statistical support to Clinical studies.
- Extensive experience with the SAS programming, with various SAS Procedures in Base SAS and thorough knowledge of SAS Macro language. Generated departmental macros for **PATIENT PROFILE LISTING**.
- Generated **PATIENT PROFILE PLOTS** (Used SAS **ANNOTATION MACROS**, **PROC GPLOT**).
- Produced quality customized reports by using PROC TABULATE, PROC REPORT, and PROC SUMMARY and also provided descriptive statistics using PROC MEANS, PROC FREQUENCY.
- Experience in **CDISC** Models like Study Data Tabulation Model (SDTM), Analysis Dataset Model (**ADaM)** for FDA submission. Standardized Analysis datasets according to CDISC ADAM Model. (Maintained **ISO 8601** date formats).
- **Reverse Engineering** to read SAS programs and specifications to figure out the derivations, and to fill into **DEFINE TABLE.**
- Involved in creating CRT by implementing the CDISC standards (**Generated Define. PDF** Tables with variable derivation for ADAM datasets using ISI tool box and created XPT files).
- Knowledge of CRT Dataset creation from clinical trial data, CDISC and MedDRA for regulatory submissions. Generated macros for Standardized **MedDRA Queries.**
- Programmed SMQ's as per the MedDRA terms provided by company specifications for **Adverse Events** datasets.
- Identifying and **mapping** data into specific domains as per the **CDISC** metadata model.
- Generated ad-hoc reports and browser viewable reports using SAS/ODS and proficient in **ODS RTF** output using **PROC TEMPLATE**.
- Creating permanent formatted SAS data sets and developed reports using PROC REPORT, PROC TABULATE and DATA_NULL_ for analysis.
- Involved in Table Programming for Integrated Summaries of Efficacy **(ISE**) and Safety **(ISS).**
- Interacted with Clinical, Regulatory, and Data Management staff to coordinate collection and reporting of clinical trial results.
- Used Output Delivery System **(ODS**) facility to write custom safety and efficacy reports directing SAS output to **PDF** and **HTML** files.

Environment: SAS 9.1, SAS/BASE, SAS/MACROS, SAS/SQL, SAS/GRAPH, SAS/ODS.

Takeda Pharmaceuticals, Deerfield, IL **Aug' 07 to Jan'08**
SAS Programmer

Takeda Pharmaceuticals, Inc. is a new kind of pharmaceutical company, serving patients by providing innovative products that improve their lives with better healthcare. This was a phase 3, multi-center, randomized, parallel group, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of AD-4833-536 in subjects with type 2 diabetes and hypertension. To determine the effects of treatments on diabetes and high blood pressure, hemoglobin A1c (A1C) was measured at designated visits and blood pressure will be measured at all visits.

Responsibilities:

- Developed Efficacy datasets (Lab Efficacy 1 and 2, Nonlab, Demographics) from raw datasets.
- Responsible for **data validation** and **corrections**; uploading/ downloading data from/ to a PC.
- Developed several macros (AUC, CESD, IWQLITE, HOMA2B, HOMA2S) used in the creation of efficacy datasets.
- Proficient in **sorting** and **merging** techniques to get the required report.
- Performed Data analysis, generated reports, statistical analysis, listings, and graphs.
- Involved in the creation of study specific **macros.**
- Created SAS Customized Reports using the **Data _Null_** technique.
- Generated reports using Proc **TABULATE, REPORT**, and **SUMMARY** and also provided descriptive statistics using Proc Means, Frequency, and Univariate.
- Created **tables**, **graphs**, and **listings** for inclusion in Clinical study reports and regulatory submissions.
- Converted existing raw data into **CDISC standards** and reviewed CRFs (Case Report Form) to ensure the consistency and adequacy with the protocol requirements.
- Involved in **mapping**, **pooling** and analysis of clinical study data for safety.
- Formatted **HTML** and **RTF** reports, using SAS - Output Delivery System (**ODS**).
- Performed program documentation on all programs, files, and variables for accurate historical record and for future reference.

Environment: SAS 8.0, SAS/BASE, SAS/MACROS, SAS/SQL, SAS/GRAPH, UNIX, Windows NT, XP, 2000.

Inhibitex Pharmaceuticals Inc., Alpharetta, GA **Jan '07- Jul '07**
SAS Programmer/Analyst

Inhibitex is a clinical-stage biopharmaceutical company dedicated to the development of innovative products that can treat or prevent serious infections. The purpose of this study is to assess the safety and pharmacokinetics of standard antibiotic therapy, plus Aurexis or Placebo for treatment of (SAB). This was a phase 2, randomized, double-blind, multi-center clinical trial comparing safety and pharmacokinetics of standard antibiotic therapy, plus Aurexis or placebo, for treatment of Staphylococcus Aureus Bacteremia (SAB).

Responsibilities:

- Responsible for developing new SAS programs and as well modifying the existing SAS programs.
- Assisted fellow programmers in **validation**, edit checks, and data review listings.
- Developed reports using **PROC REPORT, PROC TABULATE PROC SUMMARY, PROC MEANS**, and **DATA _NULL_** steps.
- Extensively used procedures such as **PROC TRANSPOSE**, **PROC COMPARE**, PROC FORMAT, and **PROC CONTENTS**.
- Extracted data from existing data sources and performed adhoc queries.
- Responsible for designing analysis dataset structures integrating **CDISC submission Data** Standards and **STDM** structures and concepts.

- I even worked by Modifying existing SAS mappings and created new mappings using SAS macro variables to improve **CDISC Mapping**.
- Explained the purpose and functions of complicated SAS programs to non-statistical personnel and was responsible for ensuring the validity and accuracy of data analysis.
- Generated various clinical reports, tables and developed data entry validation programs for Phase **II & III clinical tria**l studies using SAS.
- Prepared clinical data listings and summaries for statistical analysis and analyzed clinical data using SAS.

Environment: SAS Base 6.12, SAS/STAT, SAS/ MACROS, Windows NT, UNIX.