Michael Burak

Biostatistician and SAS Programmer Consultant

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Summary

I have worked for over 9 years in the pharmaceutical industry as both a statistician and a statistical SAS programmer. I started my consulting company, MPB Biostats Inc., in March 2014 where I work for CRO's, other independent consultants, and biotech/pharma companies. Before that I worked 4 years for 2 different biotech companies as a statistical SAS programmer (including successful NDA and BLA eCTD submissions). I also have 3.5 years of experience working for a CRO (over a year of management experience). The main areas I've worked with include pharmacokinetics, dermatology, obesity, gastrointestinal, and immunology. I am a highly skilled SAS programmer in creating various types of tables, figures, and listings (TFLs) for efficacy, safety, and demographic analyses. I have been creating and working with CDISC SDTM & ADaM datasets and Define.xml for over 8.5 years.

Experience

CEO/Founder - Biostatistician and SAS Programmer Consultant at MPB Biostats Inc.
March 2014 - Present (2 years 4 months)

- Consulting work with CRO's, independent consultants, and biotech clients
- Create and review CDISC SDTM and ADaM datasets for past and ongoing clinical trials
- Provide ad hoc and planned CSR Tables, Figures, and Listings (TFLs)
- Able to provide many statistical and SAS® programming services depending on the client's needs

Sr. Statistical Programmer at Santarus, Inc. (Acquired by Salix Pharmaceuticals, Inc. in January 2014)
May 2011 - March 2014 (2 years 11 months)

- Worked onsite in the San Diego office for 1 year and for almost 2 years I worked as a remote full-time SAS® programmer from my home in Minnesota
- Worked on a successful Biologics License Application (BLA) eCTD submission for Ruconest® (drug is currently being reviewed by the FDA)
- Worked on a successful New Drug Application (NDA) eCTD submission for Uceris® (drug was later approved by the FDA)
- I combined pooled Phase III study data for Uceris® to create sponsor-defined SAS® analysis datasets and tables for the Integrated Summary of Efficacy (ISE)
- I combined pooled Phase I, II, and III study data for Uceris® to create sponsor-defined SAS® analysis datasets and tables for the Integrated Summary of Safety (ISS)
- Provided many analyses for FDA questions regarding Uceris® and Ruconest®

- Provided many post hoc analyses in preparation for potential FDA Advisory Committee Meetings for Uceris® and Ruconest® (meeting for Uceris® never took place)
- 1 week of Electronic Common Technical Document (eCTD) training which helped with NDA and BLA submissions
- Provided ad and post hoc Tables, Figures, and Listings (TFLs) for various types of efficacy, safety and demographic analyses for 4 different therapeutic compounds used in posters, publications, manuscripts, safety reviews, etc.
- Created draft post hoc TFL mock shells for Statisticians and other teams to review
- Created over 150 TFLs for a Uceris® Signal Detection project for Pharmacovigilance team
- Write/Update SOPs, WIs, and Forms
- QC TFLs and SAS® datasets provided from CROs
- Write & modify various types of template SAS® programs/macros
- Assign and monitor work with SAS® programming contractors
- Determine edit checks and provide queries prior to locking databases
- Review and provide comments for Statistical Analysis Plans (SAPs)

Senior Analyst, Statistical Programming at Orexigen Therapeutics

April 2010 - February 2011 (11 months)

- Participated and provided many post hoc analyses in preparation for FDA Advisory Committee Meeting for Contrave® (majority of FDA panel's results were positive)
- Created post hoc Tables, Figures, and Listings (TFLs) for various types of efficacy, safety and demographic analyses (primarily Phase III ISS, ISE, and individual studies)
- Modify ADaM SAS® datasets from other ADaM, CDISC SDTM, or raw eDC datasets
- Created primary output and QC of TFLs and SAS® datasets
- Write & modify various types of template SAS® programs/macros
- Developed SAS® programs/macros that produced Patient Graphical Profiles for AEs, Con Meds, and PK/PD parameters. Outputs ranged from 4-16 unique figures per page and 1 page per patient
- Helped developed a process for tracking the company’s various ad and post hoc requests
- Developed a SAS® program to output post hoc TOC spreadsheet with hyperlinks for TFLs
- Worked closely with the Statisticians to help them develop mock TFLs shells and explain analysis/data related issues to them
- Developed SAS® programs for narrative listings for SAEs and reasons for discontinuation
- Write/Update SOPs, WIs, and Forms
- Initiated a process that would convert raw eDC data – CDISC SDTM – ADaM datasets

Clinical (SAS) Programming Team Leader at Cetero Research

January 2009 - April 2010 (1 year 4 months)

- Oversee and manage the Clinical Programming team (SAS® Programming)
- 4 workers directly reported to me

- Participated in a 3-month in-house management training course
- I also continued working as a Statistician
- Worked closely with the Data Management, Statistics, Medical Writing, Protocol Writing, Publishing, Clinical, IT, Finance, Operations, and Validation departments within Cetero Research
- Worked closely with Sponsors, Vendors, and Contractors to provide them their needs
- Write & validate various types of template SAS® programs/macros for Clinical Programming, Statistics, and Data Management within Cetero Research
- Write/Update SOPs, WIs, and Forms
- Create TFLs for various types of demographic and safety data (AEs, Vital Signs, ECGs, Labs, Physical Examinations, Medication History, Concomitant Meds, etc.) for the CSR
- Create in-text and post-text TFLs for various types of analyses within the CSR
- Provide CDISC SDTM, ADaM, and sponsor-defined SAS® datasets
- Create define.xml or other sponsor-defined SAS® dataset definition documents
- QC most of my team's tasks (SAS® datasets, TFLs, SAS® programs, etc.)
- Review annotated Case Report Forms (aCRFs)
- Write Statistical Analysis Plans (SAPs) and help Statisticians with complex projects
- Assisted Data Managers with building eDC databases

Statistician at Cetero Research (formerly PRACS Institute Ltd.)
September 2006 - December 2008 (2 years 4 months)

- Write & validate various types of template SAS® programs/macros for the Statistics team
- Analyzed many different types of pivotal & pilot BA/BE study designs
- Pharmacokinetic designs for Phase I clinical trials
- Developed SAS® programs/macros that calculated over 40 PK parameters so that it would replace the need of WinNonlin for PK pivotal & pilot BA/BE study designs
- Analyzed many different types of Dermatology Adhesion and Irritation study designs
- Analyzed many in-vivo vasoconstrictor study designs (dose ranging, multiple treatment comparisons, BE pivotal, and potency ranking)
- Generate various types of randomization schemes
- Sample size calculations
- Writing Statistical Analysis Plans (SAP)
- Write/Update SOPs, WIs, and Forms
- Write/Review Statistical sections of CSR and stand alone Statistical reports
- Write/Review Statistical sections of protocols

Skills & Expertise

CDISC
Clinical Trials
SAS

EDC
SAS programming
CRO
Data Management
SDTM
ADaM
SAP
NDA
BLA
ISS
ISE
Biostatistics
Validation
QC
Randomization
Legacy Conversion
FDA
eCTD
Pharmaceutical Industry
Biotechnology Industry
Therapeutic Areas
Protocol
SOP development
WinNonlin
Pharmacokinetics
Dermatology
Clinical Data Management

Education

North Dakota State University
Master’s Degree, Applied Statistics

University of Minnesota-Crookston
Bachelor's Degree, Sport and Recreation Management

Languages

English

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2 person has recommended Michael

"Mike is an extremely efficient and highly-skilled SAS programmer with a strong statistics background. I have enjoyed working with Mike since 2010 on several different projects for a couple of different companies. Mike's superior attention to quality and integrity, accompanied by his warm personality make it an easy decision to welcome working with him again."

— Rob Howard, worked directly with Michael at Santarus, Inc. (Acquired by Salix Pharmaceuticals, Inc. in January 2014)

"Out of all the qualities that Mike possesses, I truly appreciate his forward-thinking, analytical and fast-paced programming skills which I believe played a major role in the NDA approval of Uceris and in the ongoing submission of the BLA for Ruconest which is on track for approval. His statistical knowledge, attention to detail and communication skills are tremendous assets to any company wishing to have an experienced programmer in their ranks."

— Anish Vora, worked directly with Michael at Santarus, Inc. (Acquired by Salix Pharmaceuticals, Inc. in January 2014)

Contact Michael on LinkedIn