Lisa K. Brooks

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Clinical Trials Experience

Biometrics Project Manager: 10 NDA CDISC, 2 BLA CDISC, 3 MAA and many Phase I-III.
Programming Manager: 2 Phase III and 3 Phase II vaccine trials.
Statistical Programming Lead: 3 Phase III trials, 1 Phase II trial, and 2 Phase I trials.
Support Programmer: 3 NDAs, 1 Phase IV and 10 Phase III trials.
Project Manager & IVRS Systems Designer: 2 Phase IV and 6 Phase III trials.

Career Highlights

2/07–Present: Independent Consultant, Iris Statistical Computing, Foster City, CA

- **Neurocrine Biosciences, Inc (2017-present):** Act as CDISC Technical Advisor consulting for their clinical programs. Provide biometrics outsourcing support, including writing RFPs, vendor selection, management, and quality control of deliverables. Evaluate CDISC data packages for submission readiness.
- **Alkermes Plc (2017-present):** Act as NDA Technical Advisor and provide CDISC consulting for Phase 1 through NDA for clinical programs. Develop a workshop for Biometrics NDA readiness and prepare a checklist for quality data and meta-data deliverables. Provide biometrics outsourcing support, including writing RFPs, vendor selection, management, and quality control of internal and vendor deliverables. Evaluate individual study and NDA data packages for submission readiness.
- **Portola Pharmaceuticals, Inc. (2014-2017):** Provide CDISC consulting for Phase 1 through BLA/NDA for their andexanet alfa and betrixaban programs. Provide biostatistics outsourcing support, including writing RFPs, vendor selection, management, and quality control of vendor deliverables. Evaluate individual study and BLA/NDA data packages for submission readiness. The andexanet alfa BLA received an FDA complete response letter in August 2016 primarily regarding manufacturing and the MAA was validated by the EMA in August 2016. In December 2016 the EMA validated the MAA for betrixiban. June 23, 2017, FDA approved Bevyxxa® (betrixaban) for marketing in the US.
- **PaxVax, Inc. BLA CDISC Submission and Phase I-III support (2009-present):** Provide strategic consulting and support for Phase 1 through BLA Cholera Vaccine trials. Evaluate BLA data package for submission readiness. Draft and review Biostatistics SOPs. In collaboration with a regulatory auditor, completed vendor audit of Clinical Research Organization for DM and Biostatistics. On June 10, 2016, FDA approved Vaxchora™ for marketing in the US.
- **Zogenix NDA CDISC Submission and Phase I/II support (2010-2016):** Evaluate Biometrics deliverables to ensure submission readiness. Provide strategic consulting in support of NDA CDISC data submission for a single compound, extended release, opioid drug candidate. Support outsourcing activities, including vendor selection, management, and oversight. Evaluate vendor deliverables to ensure submission readiness. In October 2013 FDA approved Zohydro™ for marketing in the US.
- **InterMune NDA CDISC Submission (2007-2014):** Provide outsourcing support, including vendor selection, vendor audit, management, and oversight. As Biometrics Project Manager, prepare project plans, facilitate communication, attend to project details, and contribute to the successful implementation of NDA strategic planning. In collaboration with IT, completed SAS programming environment validation. Supported Biostatistics and DM in Pre-Approval Inspection preparation. On March 3, 2011, Esbriet® was approved for marketing in Europe and on October 1, 2012 in Canada. On October 15, 2014, FDA approved Esbriet® for marketing in the US.

SAS Certified Professional™ Version 6

SAS Certified Professional™ Data Management V6

10/03 – 2/07: Associate Director of Statistical Programming, Vaxgen, Inc., SSF, CA

- Hired, trained, motivated and evaluated a staff of 5 programmers and several consultants.
- Evaluated, negotiated, and provided input into consultant, CRO and Central Lab proposals, scope of work, budgets, and agreements. Developed departmental and project budgets.
- Independently set up methods and processes for development, production and validation of statistical output for FDA submission. Documented processes in guidelines and SOPs.
- Evaluated, presented, implemented and validated to GCP standards all aspects of statistical computing environment including: platform (Linux), operating system (Red Hat Enterprise), upgrade to SAS V9.1.3 and statistical reporting software.
- Sat on IT Steering Committee. Presented, evaluated and approved large IT systems and implementation strategies.
- Provided programming and GxP validation guidance (using the Software Development Life Cycle-SDLC) for implementing computer systems for assays performed in QA/QC, Analytical Development, R&D, and Clinical Immunoassay groups.

9/01 – 10/03: Project Manager and IVRS System Designer, PPD Inc., RTP, NC

Served as technical project manager, designer, and validation plan developer for interactive voice response (IVR) systems for clinical trial randomization and drug distribution. Managed project timelines and budgets. Gave training presentations at investigator meetings to clinical and site personnel. Gathered user requirements and wrote technical specifications for IVR systems and reports. Programmed and validated database transfers from Oracle using SAS/Access, Base SAS, and SAS Macro. Loaded and maintained study drug management and randomization databases with MS Access and SQL.

12/98 – 9/01: Programmer Analyst, Quintiles Inc., RTP, NC

Provided lead statistical and data programming support for clinical trials. Constructed analysis files and databases. Produced statistical tables and appendix listings for statistical reports. Specified checking to be done by quality control. Developed timelines, assessed resources and attended client meetings. Processed external computerized files. Assisted department members with technical problems. Developed and improved methodologies and technologies. Lead on Visual Basic Process Improvement Team. Member of SAS Y2K remediation team.

5/98 - 12/99: Part-time Faculty, Durham Tech Community College, Durham, NC

Courses Taught:

SAS Programming: Taught the fundamentals of programming with the SAS system in lecture and lab. Developed text book in collaboration with SAS Publishing.

Introduction to Microcomputers: Lectured on computer history, hardware and software. Gave hands on instruction for the Microsoft Office application suite in the microcomputer lab.

2/97- 12/98: Applications Programmer, UNC-FPG Design and Statistical Computing Unit, Chapel Hill, NC

Primary database manager and team programmer on a Phase II clinical trial and social science studies. Consulted directly with clinicians during DM tasks. Developed SAS applications and programs for data entry and programmed analysis files, tables and listings. Developed the CRF and web site for the Comprehensive Sickle Cell Program, a multi-site collaborative study.

Education

Postgraduate classes in Comp Sci & Biostatistics, University of NC, Chapel Hill, NC, 1997
BA Psychology, Univ of North Carolina, Chapel Hill, NC, 1996
AA Humanities & Soc Sci, Mercer County Community College, Trenton, NJ, 1994

Certification

SAS Certified Professional and SAS Certified DM, V6 Credential, SAS Institute, 1999

Professional Training

From the Laboratory to Leadership, The Leadership Edge, 2005
New Features in Version 8 of the SAS System, SAS Institute, 2000
SQL Processing with the SAS System, SAS Institute, 1999

Publications and Presentation

Collins, L., Brooks, L., Rea, M. and Hopkins, A. (2006), "Have it Both Ways: Macros that Produce Publication-Quality Tables and Stand-alone Code", *Proceedings of the Western Users of SAS Software 2006 Conference.*

Litzsinger, M. and Brooks, L. (2001), "A Modular Approach to Portable Programming", *Proceedings of the Southern SAS Users 2001 Conferenc*e **and** P*roceedings of the Northeast SAS Users 2001 Conference*. Presented at NESUG, 10/2001

Volunteerism

10/2017 – Present: PhUSE Co-Lead Optimizing the Use of Data Standards Working Group
I work with a great group of people to develop tools and processes for improving efficient delivery of data and standards to support drug product and device submissions as well as the review process. We identify specific gaps that prevent FDA and industry from optimizing the use of data standards. Our goal is to fill gaps and address issues and challenges in the interpretation and use of data standards. In this role, I help in the organization and planning of the PhUSE Computational Science Symposium in Silver Springs, Maryland (http://www.phuse.eu/css18).

10/2017 – Present: PhUSE Co-Chair Foster City Single Day Event February 22, 2018
This year's theme is: *Marching at the Double-quick to Successful Submissions with Innovative Automation within the Study Lifecycle*

5/2016 – Present: PhUSE Project Member Legacy Data Conversion Plan and Report
The team works on the development of a Legacy Data Conversion Plan & Report (LDCP) within the Study Data Reviewer's Guide (SDRG). The goals of the team are to provide a template, instruction, and examples that may be utilized by sponsors to develop the LDCP.

3/2015 – 2/2018: PhUSE Sub-lead Study Data Standardization Plan
The team worked on the development of a Study Data Standardization Plan (SDSP) template and examples. The SDSP supports the Clinical and Non-Clinical development plans, as well as the Target Product Profile for a compound or device. The team met its goals to publish a template, instruction, and examples to be utilized by sponsors to develop the SDSP.