# Lisa K. Brooks

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## Clinical Trials Experience

**Biometrics Project Manager:** 9 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

- **Alkermes Plc (2017-present):** Act as NDA Technical Advisor and provide CDISC consulting for Phase 1 through NDA for their 5461, 9072, 3831, and 8700 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.
- **Sunesis Pharmaceuticals, Inc. (2016-present):** Provide biometrics project management services. Develop data standard and programming SOPs. Provide quality control of vendor and in-house deliverables including statistical output and CDISC data submission packages.
- **Corcept Therapeutics, Inc. (2016-present):** Provide Data Management (DM) and biostatistics consulting services. Provide quality control of vendor deliverables including CRF design, EDC UAT, statistical output, and CDISC data submission packages.
- **Eiger Biopharmaceuticals, Inc. (2015-present):** Provide DM and biostatistics outsourcing support, including writing RFPs, vendor selection, management, and quality control of vendor deliverables. Act as EDC Build Project Manager for their ubenimex drug candidate for pulmonary arterial hypertension and lymphedema therapeutic areas.
- **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 DM and statistical programming support for Phase 1 Oral Flu Vaccine trial. Provide strategic consulting and support for Phase 1 through BLA Cholera Vaccine trials. Provide DM and biostatistics outsourcing support, including vendor selection, management, and quality control of vendor deliverables. 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):** Provide consulting in support of Phase 1 and 2 data submissions for relday, Zohydro, and Fenfluramine products. Support DM and biostatistics outsourcing activities, including vendor selection and management. Review and approve DM documents and participate in EDC UAT. 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):** Consult with management and staff to support strategic focus and clarity in planning. 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. Collaborated with team to establish departmental processes and documented them in 18 SOPs and Work Instructions.
  Supported Biostatistics and DM in Pre-Approval Inspection preparation. Submitted NDA in November 2009 and MAA in March 2010. 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.
- **Abbott Vascular (2007):** Assist in building Biostatistics team through developing job descriptions, technically screening candidates, on-boarding and training new hires. Develop training program. Provide consultation on departmental methods and processes. Document in-house macros by writing validation plan, user requirements and validation summary report.
- **VaxGen, Inc. (2007):** Provide statistical programming support for R&D Immunoassay Group and Clinical for their Phase II Anthrax and Phase II Smallpox trials.
- **Hygia Biostat (2007):** Executed Validation Protocol for APT Report Writing Tools Ver. 5.1.

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

- Hired, trained, motivated and evaluated a staff of 5 programmers, plus consultants.
- Using a hands-on approach, assured timely delivery of Tables, Listings and Figures. Set department objectives, developed timelines, assigned day-to-day programming tasks and tracked progress. Resolved issues relating to clinical trials analysis.
- 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.
- Ensured seamless data flow between Statistical Programming, DM, Clinical and Immunoassay groups.
- 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.
- Interacted across all functional groups and staff levels, including routine interactions with executives.

### 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. Coordinated the efforts of IVR developers, QC and support staff. Served as the primary liaison with clinical project management team and clients. Gave training presentations at investigator meetings to clinical and site personnel. Gathered user requirements and wrote technical specifications for IVR systems and reports. Defined interaction of IVR data with other databases at PPD and vendors. 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.

**9/94 - 2/97: Lab Technician, UNC-Experimental Psychology Dept., Chapel Hill, NC**
Maintained lab databases for research and lab management purposes. Developed a data collection apparatus and application using LabVIEW software. Carried out experimental protocol and performed general lab duties. Conducted behavioral research with rats and mice.

**8/91- 9/94: Customer Service Representative, Caliper Human Strategies, Princeton, NJ**
Caliper Human Strategies is a psychological testing and consulting firm. Responsible for scoring psychological tests, instructing clients on test administration and distributing computer generated profiles of subjects.

**6/87 – 8/91: Equifax Services, Portland, OR**
**Regional Sales Representative:** Generated revenue in the Pacific NW for the Insurance Services Division by developing a Continuing Education Course for insurance sales licensing.
**Sales Support:** Provided clerical support to sales representatives in regional office.
**Data Entry/Consumer and Customer Service:** Updated consumer credit reports, processed computer generated reports for credit applications, assisted consumers in getting a copy of their report and communicated reports to corporate clients.

## Job Skills

**Programming**: SAS Base, SAS Stat, SAS Macro, SAS Graph, SAS/ODS, SAS Connect, SAS FSP, PROC SQL, SAS Access - Oracle, SAS implicit/explicit SQL Pass-through and VBA.
**Applications**: MS Project, Word, Visio, Excel, Access, Power Point, and Corel Graphics Suite.
**Platforms**: LINUX (Red Hat Enterprise), UNIX (Solaris), Windows NT/XP and OpenVMS.

## Education

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

## Certification

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

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*.

## Conference Presentations

Presented "A Modular Approach to Portable Programming" at NESUG, 10/ 2001.

## Volunteerism

**5/2016 – Present: Project Member Legacy Data Conversion Plan and Report, PhUSE**
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 (to be added to the SDRG), instruction, and some examples that may be utilized by sponsors to develop the LDCP. It is expected that the LDCP will be created when legacy data is converted to standard data (e.g. CDISC, SDTM, SEND, and ADaM).

**3/2015 – Present: Sub-lead Study Data Standardization Plan Template and Example, PhUSE**
The team works on the development of a Study Data Standardization Plan (SDSP). 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 provide a template, instruction, and examples to be utilized by sponsors to develop the SDSP. The deliverables for this project were received by FDA on March 31, 2016 and has completed public review.

**5/2017 – Present: Board of Directors, President, San Mateo High School Music Boosters**
**5/2015 – 5/2017: Board of Directors, Secretary, San Mateo High School Music Boosters**
Supports the arts in education by volunteering and sitting on the Board of Directors.