Lisa K. Brooks

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Experience

2007–Present: Founder and Independent Consultant, Iris Statistical Computing, Foster City, CA (http://www.irisstatcomp.com)
Provide technical biometrics project management in support of CDISC data submissions for medical authority licensing applications. Ensure standardized clinical data and documentation (meta-data) are submission ready. Consulting and implementation of sponsor infrastructure remediation including team building, outsourcing, inspection readiness, training matrices, SOPs, and computer system validation (SAS server and electronic document management system).

- **Acelyrin (2021-present):** Supporting the development of Izokibep (a unique antibody mimetic and potent interleukin-17A (IL-17A) inhibitor) for the treatment of Uveitis (orphan drug status), Axial Spondyloarthritis, Hidradenititis Suppurativa, and Psoriatic Arthritis.
- **Arcus Biosciences (2021–present):** Supporting multiple molecules in phase 1-2 development for oncology indications for eSub package evaluation. Help develop biometrics infrastructure by means of SOP development and SAS/R server validation.
- **Zogenix MDS (2019-present):** Formerly Modis and now part of UCB. Supporting doxTM (previously MT1621) submission activities for the treatment of TK2 deficiency (a mitochondrial depletion disorder). doxTM has received Breakthrough Therapy and PRIME designations and is currently in Phase 2 clinical development.
- **Corcept Therapeutics (2016–present):** Supporting multiple compounds in phase 1-3 development for endocrine, metabolic, oncology, addiction, and ophthalmology indications. Help develop biometrics infrastructure by means of SOP development and SAS server validation.
- **Amylyx Pharmaceuticals (2021)**: On November 2, 2021, Amylyx submitted a New Drug Application (NDA) to FDA for AMX0035 (sodium phenylbutyrate and taurursodiol) for the treatment of amyotrophic lateral sclerosis (ALS) and was approved for marketing in the US on September 29, 2022.
- **Horizon Therapeutics (2019–2020):** TEPEZZA™ (teprotumumab-trbw) is the first treatment for thyroid eye disease (TED) and is one of 5 medicines to receive Priority Review, Orphan Drug, Fast Track and Breakthrough Therapy designations from the FDA and was approved for marketing in January 2020.
- **Neurocrine Biosciences (2017–2020):** On April 27, 2020, FDA approved ONGENTYS® (opicapone) for the adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing OFF episodes.
- **Alkermes (2017–2019):** In July 2018, FDA approved ARISTADA INITIO™ (aripiprazole lauroxil) for the treatment of schizophrenia in adults.
- **Portola Pharmaceuticals (2014–2017):** In August 2016, ONDEXXYA® (andexanet alfa) was approved for marketing in Europe and in May 2018, FDA approved for marketing in the US. In December 2016, Bevyxxa® (betrixaban) was approved for marketing in Europe and in June 2017, FDA approved for marketing in the US.
- **PaxVax (2009–2019):** On June 10, 2016, FDA approved Vaxchora™ for US marketing.
- **InterMune (2007–2014):** 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

Experience (continued)

2015–Present: PHUSE, Kent, UK (http://www.phuse.global)
PHUSE is a data science not-for-profit organization run by volunteers with a worldwide membership exceeding 10,000. We are the industry voice to regulatory agencies and standards organizations such as the FDA, EMA & CDISC. We act as a platform for the discussion of topics encompassing the work of data managers, biostatisticians, and data standards professionals.

- **Board of Directors Collaborations Director (2019-present)**
- **Co-Chair Optimizing the Use of Data Standards Working Group (2017-2019)**
- **Co-Chair Foster City Single Day Event (February 22, 2018)**: *Marching at the Double-quick to Successful Submissions with Innovative Automation within the Study Lifecycle*
- **Co-Lead Legacy Data Conversion Plan and Report (2016-2019):** Developed the Legacy Data Conversion Plan & Report (LDCP) within the Clinical Study Data Reviewer's Guide (cSDRG) and Analysis Data Reviewer's Guide (ADRG).
- **Sub-lead Study Data Standardization Plan (2015-2018):** Developed the Study Data Standardization Plan (SDSP) template and examples.

2003–2007: 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.

2001–2003: 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. Trained clinical and site personnel at investigator meetings. 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.

1998–2001: Programmer Analyst, Quintiles Inc., RTP, NC
Lead statistical and data programmer 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. Developed and improved methodologies and technologies. Lead on Visual Basic Process Improvement Team. Member of SAS Y2K remediation team.

Experience (continued)

1998–1999: Part-time Faculty, Durham Tech Community College, Durham, NC
Taught SAS Programming: Taught the fundamentals of programming with the SAS system in lecture and lab. Developed textbook in collaboration with SAS Publishing.
Taught Intro to Microcomputers: Lectured on computer history, hardware, and software. Gave hands on instruction for the Microsoft Office application suite in the microcomputer lab.

1997–1998: 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, University of North Carolina, Chapel Hill, NC, 1996

AA Humanities & Soc Sci, Mercer County Community College, Trenton, NJ, 1994

Publications and Presentations

Brooks, L. (2022) "Thinking Outside of the Box: Real World Data for Ultra-rare Disease Studies", PHUSE US Connect Conference Atlanta..

Brooks, L., Chhatre, D., and Arkala, S. (2021) "Hey, Data Scientist: Are You Following the Rules and Your Conscience?", PHUSE EU Connect Conference London.

Brooks, L., Shiba A. (2019) "Ensuring Consistent and Supported Standards Across Data and Metadata in a Large Regulatory Filing is Tricky Business", PHUSE US Connect Conference. Baltimore. presentation

Hurley, C., Brooks, L. (2018) "Bili's Journey", PHUSE US Connect Conference. poster

Smoak, C., Brooks, L. (2018), "Practical Lessons Learned from Recent NDA and BLA Submissions to FDA", PHUSE EU Connect Conference Frankfurt. 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 Conference* **and** P*roceedings of the Northeast SAS Users 2001 Conference*. Presented at NESUG, 10/2001

Awards

Exceptional Plane Builder Award, PHUSE CSS (2019)

Best in Stream Standards Implementation for **"**Ensuring Consistent and Supported Standards Across Data and Metadata in a Large Regulatory Filing is Tricky Business**"** (2019)

Best in Stream Real World Evidence for "Hey, Data Scientist: Are You Following the Rules and Your Conscience?" (2021)