

## Jack Shostak

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### Computer Skills:

- **Software/Languages:** SAS, R, SQL, Java, Perl, C, FORTRAN, Pascal, BASIC, DCL, MS Excel, Word, Powerpoint, Project.
- **Hardware/Environments:** Microsoft OSs, \*NIX (UNIX, Solaris, Linux), OpenVMS, IBM MVS

### Professional Experience:

#### 10/98 to present: **Duke Clinical Research Institute**, Durham, NC

(Academic Research Organization)

*ASSOCIATE DIRECTOR OF STATISTICS*

*MANAGER STATISTICAL PROGRAMMING*

- Supervise and train Statistical Programming staff.
- Assess, plan, allocate, and assign work. Organize and schedule workload in accordance with project priorities and staff availability.
- Coordinate with Managers of Statistics to ensure sufficient resources to support these groups.
- Report to Director, Statistics on staffing needs, workload, etc.
- Interact with Information Technology, Informatics, and Data Integration Groups to develop and facilitate methodology for efficient data organization and flow in the organization.
- Directs Statistical Programming activities such as the creation and validation of SAS programming for tables, graphics, and listings.
- Interact with partner sites to ensure compatibility of data bases, programming tools, and methods for data storage and sharing.
- Reviews and assesses staff performance individually and as an operational group.
- Writes and reviews functional group SOPs primarily as they relate to statistical programming functions.
- Serve as a regulatory and CDISC data submission resource.

#### 05/07 to present: **Clinical Data Interchange Standards Consortium**, Austin, TX

(Standards Organization)

*ADaM INSTRUCTOR*

- Certified ADaM instructor teaching the FDA, NIH, sponsor companies, and CROs about the CDISC ADaM standard..
- Serve as ADaM training team leader and ADaM alternate leadership team.

#### 9/89 to 9/98: **PRA International**, Charlottesville, VA

(Contract Research Organization)

*BUSINESS SYSTEMS ANALYST*

(6/97 to 9/98)

- Integrate and oversee all corporate business software systems.

- Implement a beta-software rollout worldwide of the Lawson software system, with oversight of 15 internal implementation staff and five external consultants.
- Implementation tasks including: scheduling of training, system validation and production transition processes.
- Consolidate legacy accounting, financial and human resources software systems.

*SENIOR PROGRAMMER/ANALYST* (10/92 to 6/97)

- Coordinated and oversaw several clinical programmers on multiple projects.
- Acted as project lead on three NDA submissions.
- Ensured the quality of all reports and electronic medium sent to clients.
- Developed internal standards to guarantee the quality of all report materials to meet changing FDA regulations.
- Designed generic program code to meet FDA and client needs.
- Acted as company-wide SAS consultant and SAS Institute liaison.
- Special Project: from 10/92 to 12/94, handled the set-up, administration, and maintenance of company computer hardware, software and telecommunications systems. Utilized DEC VAX, IBM PC and AT&T PBX systems.

*PROGRAMMER/ANALYST* (10/91 to 10/92)

- Acted as project team representative for up to six clinical projects, supporting company-wide SAS training and overseeing the work of other programmers.
- Assisted in the European office development at PRA, BV, including generation of EC compliant reports, overseeing and training new programmers and working as operation assistant in the operation of a VAX 3110.

*PROGRAMMER* (9/89 to 10/91)

- Supported statisticians in statistical analysis using SAS software.
- Performed analysis, table, listing and graphic presentation of clinical trials data for client and FDA submissions.
- Estimated time requirements and timelines.
- Acted as project team representative, ensuring the quality of client work.

**6/89 to 9/89**

**A.H. Robins**, Richmond, VA  
(Pharmaceutical Manufacturer)  
*PROGRAMMER*

- Supported statisticians in statistical analysis using SAS software.
- Performed analysis, table, listing and graphic presentation of clinical trials data.

**Education:**

**James Madison University**, Harrisonburg, VA  
Masters of Business Administration, 1997

**Virginia Tech**, Blacksburg, VA

Bachelor of Science in Statistics, 1989

**Certification:** SAS Certified Clinical Trials Programmer Using SAS 9

**Associations:** Pharmaceutical SAS Users Group  
SAS Users Group International  
RTP SAS User's Group  
RTP CDISC User's Network  
Clinical Data Interchange Standards Consortium

**Publications:** Shostak, Holland 2012. Implementing CDISC Using SAS: An End-to-End Guide, Cary, NC: SAS Institute.

Freimark, Kenny, Shostak, Troxell, 2012. "Common Misunderstandings about ADaM Implementation" in PharmaSUG 2012 Proceedings.

Shostak, Walker 2010. Common Statistical Methods for Clinical Research with SAS Examples, Third Edition. Cary, NC: SAS Institute.

Shostak, 2006. "De-Identification of Clinical Trials Data Demystified" in PharmaSUG 2006 Proceedings.

Shostak, Jack 2005. SAS Programming in the Pharmaceutical Industry. Cary, NC: SAS Institute.

Shostak, 2005. "Implementation of the CDISC SDTM at the Duke Clinical Research Institute" in PharmaSUG 2005 Proceedings.

Shostak, Jack 1994. "Reporting and SAS Tool Selection" in Reporting from the Field: SAS Software Experts Present Real-World Report-Writing Applications. Cary, NC: SAS Institute., PP 217-235 inclusive.

Shostak, Sun, Lago, Handlesman 1996. "Macros Developed for Statistical Summary and Tabulation of Clinical Data" in Proceedings of the Ninth Annual Northeast SAS Users Group Conference. PP 316-325 inclusive.