

Shannon Labout CCDM performs international online and classroom training in clinical data management and standards topics. Her more than thirty years in business includes sixteen years in the field of health care. For the past thirteen years she has worked in pharmaceutical and CRO organizations. Shannon's experience includes eight years managing clinical data management organizations at two different pharmaceutical companies, developing and leading the people and the processes.

Shannon has clinical data management experience in all phases of clinical trials in multiple therapeutic and diagnostic areas. She has worked on global clinical programs for submissions in all three ICH regions. Shannon has been a Certified Clinical Data Manager since 2004, and is a primary contributor to both the Society for Clinical Data Management (SCDM) Certification Examination and to the Good Clinical Data Management Practices (GCDMP) document published by SCDM.

Shannon has been on the Clinical Data Interchange Standards Consortium (CDISC) Clinical Data Acquisition Standards Harmonization (CDASH) Core Team since its inception, is a primary contributor to the published CDASH standard, and is currently co-leading the CDASH Core Team. She has been a member of the Submission Data Standards (SDS) Team and an authorized CDISC trainer since 2007. She has been involved in implementing and maintaining CDISC standards at two pharmaceutical companies and one contract research organization. Shannon is currently the Director of Education for CDISC.

# Shannon Labout, CCDM

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- Summary of qualifications**
- Diverse, international organizational leadership experience
  - Strong working knowledge of ICH region clinical development processes
  - Expertise in implementation of industry standards, GCDMP and cGCP
  - Leadership on industry standards development teams (CDISC, SCDM)
- Certification**
- Certified Clinical Data Manager (SCDM 2004, 2007)
- Recent work experience**
- February 2010 – Present**                      **CDISC**                      **Austin, TX, USA**
- Director Education**
- Provide technical and organizational leadership for CDISC education programs and activities
  - Oversee the selection, training and development of internal and external training staff
  - Facilitate and deliver education courses, presentation and webinars
  - Facilitate the development and maintenance of standards, including CDASH
  - Facilitate communications between FDA and CDISC development teams
- 2009 – 2010**                      **Independent Consultant**                      **St. Louis, MO, USA**
- Principal Consultant**
- Built a profitable training and data management consultancy leveraging expertise in:
    - Standards development and leadership
    - Drug development process and ICH Good Clinical Practice (GCP)
    - Mentoring and training clinical data management (CDM) professionals
    - Standard Operating Procedures development
- 2008 – 2009**                      **Astellas Pharma B.V.**                      **Leiderdorp, The Netherlands**
- Manager Clinical Data Management**
- Recruited for this position to provide FDA knowledge to European organization
  - Provided strong leadership to the local CDM team, improving overall department metrics
  - Initiated and led cross functional process improvement, and cost reduction measures
- 2007 – 2008**                      **PPD/CSS Informatics**                      **Cambridge, MA, USA**
- Senior Consultant**
- Primary responsibility for training business development and services
  - Provided strong project management skills and process knowledge
  - Involved in business development and customer relationship management
- 1997 – 2008**                      **Tyco Healthcare / Mallinckrodt**                      **St. Louis, MO, USA**
- Manager, Clinical Data Management (June 2004 – January 2007)**
- Provided strategic and tactical direction to clinical data management staff
  - Built effective partnerships with clinical operations and other R&D organizations
  - Initiated and led process improvement activities, and implementation of ICH GCP and industry standards
- Senior Data Management Associate / CDM Supervisor (October 2000 – June 2004)**
- Provided strong leadership to the data management organization through a period of transition following a merger
  - Initiated cross-training activities to efficiently utilize resources following staff reductions

**Clinical Database Associate (November 1999 – October 2000)**

**Clinical Database Assistant (July 1998 - November 1999)**

- Learned all clinical data management processes from CRF design through database lock, including database programming, data cleaning, coding and SAE reconciliation
- Supervised, trained, and mentored junior staff

**Administrative Coordinator (March 1997 - July 1998)**

- Responsible for clinical data management regulated records management
- Implemented newsletter and website initiatives to improve inter -and intra-department communications

**1994 – 1997**

**BNSF Railroad**

**Fort Worth, TX, USA**

**Medical Analyst**

- Program and data management for health and wellness programs, for an employee population of several thousand
- Worked with department management to integrate medical departments during merger with Santa Fe, contributing staff utilization and technology improvement ideas that were implemented to support merger activities
- Administrative review of DOT/FRA physical exams, lab reports, and other medical records
- Administration of department payroll, accounts payable and \$12 million budget
- Functional supervision of temporary clerical staff

**Education**

**Maryville University**

**St. Louis, MO, USA**

**B.A. Organizational Leadership** (emphases in psychology and information systems),  
*summa cum laude*

- Member Delta Epsilon Sigma national honor society
- Coursework completed in biology, statistics, research methods and health sciences

**Professional activities**

- Society for Clinical Data Management (SCDM)
  - Co-Chair of Products and Services Committee (2010)
  - Subject Matter Expert (SME) for GCDMP chapter authoring and review (2007-present)
  - SCDM publication contributor (2008-2009)
  - Member of SCDM Certification Taskforce (2007- present)
  - Item Writing Sub-Taskforce co-lead (2009), and SME Item Writer (2007)
- Clinical Data Interchange Standards Consortium (CDISC) work groups
  - Core Team member and Stream Lead for Clinical Data Acquisition Standards Harmonization (CDASH) (2006-present), co-lead of CDASH project (2009-present)
  - Participating member of CDISC / SDS Team (2007 – present)
- Invited SME for Research Triangle Institute's survey of clinical data management professionals on behalf of the Department of Labor (2008)
- Frequent international presenter of CDISC and CDM topics at industry conferences and webinars.