Todd Colbeth

Todd can be reached through
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EDUCATION

University of St. Thomas, St. Paul, Minnesota
Bachelor of Arts

EMPLOYMENT

Libra Medical, Inc.
Aug 2007 to Present
Clinical Data Analyst
Responsible for all data management activities from database setup to lock. Specified database design and validated all objects and programs used to record and clean clinical data. Contributed to interim reports and provided summary statistics for studies. Managed legacy data and migration of datasets to common database.

- Designed and reviewed Case Report Forms
- Database development using Clindex (Sybase)
- QC/QA audit of database to Case Report Forms
- co-Monitored clinical site for study conducted in India

American Medical Systems
Jan 2006 to May 2008
Clinical Data Analyst

Drawing upon previous experience and knowledge of clinical studies and database programming, communicated clinical needs in terms of database function. Created the specifications for new databases, performed validation, and supported data collection for reports, publications, and physician requests.

- Designed and reviewed Case Report Forms
- Created Data Management Plans
- Specified database requirements and edit checks
- Validated clinical study databases and edit check programs
- Validated database changes

Orphan Medical Incorporated
Sep 2002 to Dec 2005
Clinical Data Manager

Coordinated all data management activities between Sponsor and Contract Research Organization for as many as 5 multi-centered, multi-national sleep studies at various phases and operation. Assigned data management obligations; timelines and milestones for deliverables and set quality standards against which those deliverables would be evaluated. Created database structure, programming, queries and reports for 2 retrospective, oncology studies using Microsoft Access. Data Cleaning performed using SAS. Wrote 4 Annual Safety Summaries for submission to FDA.

3M Pharmaceuticals
Dec 1999 to Feb 2002
Senior Clinical Data Analyst

Implemented standard operating procedures to ensure that all data collected and entered into databases from clinical trials is timely, accurate and complete. Ensured that data will meet rigorous data quality audits, performed by 3M and/or regulatory auditors. Assisted in giving work direction, procedures, and guidance to other members of the Clinical Data Management section.

Selected new and modified protocol-specific automated consistency checks expressed as "English" summaries. Programmed Oracle SQL code of specified checks and validated using test data to ensure that only true data failures are reported. Supervised a team of five DBA's.

Maintained standard database objects: code lists, variables, tables, pages, dictionaries, and programs. Loaded blinded randomization for clinical trials. Integrated electronic data from external sources through batch loading process into clinical database. Used eRT *eDataManagement*™ software. Contributed to writing company and department SOP's and work guidelines.

G. D. Searle
Jan 1997 to June 1999
Data Management Associate

Managed the processing, coding and cleaning of clinical databases for arthritis clinical study trials in an accurate and timely manner to reflect the data collected on Case Report Forms for clinical trials, in accordance with Clinical Data Management and Clinical Research Procedures and Guidelines.

Responsible for coordinating all data management activities between Searle and Contract Research Organization for as many as 17 clinical studies at various phases and operation. Assigned data management obligations; timelines and milestones for deliverables; quality standards against which those deliverables would be evaluated; and the manner of interaction between Searle and the external provider.

Validated the programming being used to populate the batch load tables to ensure clinical data was being loaded properly into DLB Recorder (now called *eDataManagement*™ from eResearchTechnology. The verification that the data was accurately mapped and loaded to the correct data items in Oracle tables was tested in pivotal phase III clinical trials.

Lorex Pharmaceuticals
Feb 1995 to Jan 1997
Senior Data Base Processor

Data entry - original and verification - for clinical trial data; trained data processors; coordinated work distribution; processed Case Report Forms prior to data entry; back up support for logic changes and Clin-Trials (oracle) study set-up.

For assigned studies: tracked, reviewed, edited and coded clinical trial data; maintained working copy files of Case Report Forms; resolved all missing and questionable items and reconciled conflicting data; reviewed and approved final data entry; maintained consistency and accuracy in data base; input all changes/corrections to data base.

Relevant Training

Member Society for Clinical Data Management (SCDM), 2010
NIH web-based training course: "*Protecting Human Research Participant,s*" 2010
CITI web-based training course: "*Health Information Privacy and Security*," 2010
Clindex Developer I, 2008
Clindex Monitoring Development, 2008
21 CFR Part 11 Workshop (DIA), 2001
SAS Fundamentals (SAS Institute), 1999
ICD-9 CM Coding (AHIMA), 1998
Effective Outsourcing and Managing CRO's (PERI), 1998
Statistics for Non-Statisticians (PERI), 1998
Interpreting Clinical Laboratory Tests (PERI) 1998
Good Clinical Practice Workshop (PERI), 1996
Oracle SQL+, 1996