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Education:

MA. Molecular Biology, Wayne State University

Non-Degree MBA. Information Systems (Micro Masters Equivalent)

BSc., MSc. Genetics, Osmania University

Training and Certifications:

- Python – IBM - Cognitive AI courses - 2019
- Data Science A-Z – Udemy – 2023
- Statistics – Freecodecamp.org – 2023, 2024
- Project Management Professional Certificate – University of California, Irvine – 2017, 2018
- Data Science - R Programming Training – Coursera-Johns Hopkins University – 2017
- Linked Data Engineering – Open.hpi.de – 2017
- Certified Advanced Programmer for SAS9 – 2009, 2017
- Data Analyst Training – 2016, 2017
- MBA curriculum (Information Systems, Operations Mgmt., Org Behaviour, Marketing, Finance, Accounting, Computer Architecture, Operating Systems) School of Business – Wayne State University – 2002

CDISC Experience:

Over 14 years of CDISC standards experience including CDASH, SDTM, ADaM and Define.xml. Supported, developed, and maintained SAS Macros for CDISC compliance and utility. Utilized SDTM and ADaM standards extensively to review and map standards compliant clinical data.

Summary:

- Over 20 years of experience in biotech and pharmaceutical industries as a Research Analyst
- Over 14 years of CDISC standards and governance experience: CDASH, SDTM, ADaM and Define.xml
- CRO oversight on CDISC datasets (SDTM, ADaM), derivations, TFL and submission packages (CDISC transport files, SDRG, ISS/ISE datasets)
- SAS Macro development for programming efficiency
- Experience in Pain, Neurology & Oncology Tx areas and ability to work in any therapeutic area.
- Advanced Programming expertise in Statistical Analysis Software (SAS), SQL, R and related software applications used in the conduct and analysis of clinical trials data.
- Familiar with semantic web tools and working with linked data applications (Protégé/Topbraid).
- Familiar with Clinical trials related EDC/CTMS tools such as Medidata, Inform, and Oracle Clinical etc. Used Medidata Rave to review study data.
- Good understanding of FDA and other relevant guidelines applicable to clinical trials.
- Participated in industry user group and contributed towards data traceability white paper.

Work Experience:

Pro Unlimited Inc., (Genentech) – South San Francisco, CA
Consultant, Clinical Programmer

Mar 2020 – June 2022

- Worked with Genentech Clinical Programmers, study management team members to process raw data for visualization tasks within Spotfire software.
- Develop and review the data quality check specifications, generate programs using SAS or Spotfire to check the data quality and flag data issues for both non-CRF and CRF data.
- Generate visualization report for data quality checks and for medical data review.
- Assist in other housekeeping activities like managing and scheduling jobs on server.
- Assisted in other ad hoc programming tasks like generating patient profiles and process laboratory data.

Apex Systems, (Juno Therapeutics) - Seattle, WA
Consultant, Clinical Programmer

May 2018 – Oct 2019

- Participated in SDTM / ADAM, Tables, Listings and Figures validation.
- Supported operational activities for ISS and other Pivotal study submission deliverables.
- Supported validation of cell therapy manufacturing related analysis data and reports
- Manage reporting activities for projects including finance and operations.
- Manage study data acquisition for multiple studies from multiple vendor sites and sources.
- Prepare generic SAS programs to import or export data from source and generating SAS datasets.
- Manage data on internal study repository for sharing data across teams within organization.
- Create SAS and R programs to transform and schedule clinical data upload to internal repository.
- Work with IT knowledge management teams on using new IT tools to schedule jobs on servers using Linux and other OS tools.
- Work with internal teams to create and manage UATs during study builds and, deployment.
- Provide ad-hoc programming support to import efficacy, safety, protocol deviations data.

Bioforce LLC (Biogen), Cambridge, MA
Clinical Data Analyst (Consultant)

Mar 2014 – Oct 2015

- Utilized technical experience managing clinical data using the CDISC SDTM standard to fulfill the role of the Metadata Analyst.
- Applied study specific metadata for loading clinical data into, and creation of, analysis data from Clinical Data Repository.
- Utilized experience with the SDTM model, specifically reviewing and mapping clinical data to ensure SDTM compliance.
- Worked with other roles in the organization focused on clinical data standards and metadata operations to promote efficiency in the loading and exchange of data.
- Participated in drafting and performing user acceptance testing (UAT) of the repository tool.
- Participated in review of trial design data for pivotal studies.
- Worked on the ODM-SDM trial design model.
- Extracted trial summary and inclusion/exclusion information from protocols to fit the SDM model.
- Worked with semantic web tools used to create and visualize linked clinical data.

Purdue Pharma, Stamford, CT
Clinical Data Analyst

Aug 2008 – Mar 2014

- Supported Developed and maintained SAS Macros for CDISC compliance and utility.
- Supported development and review Study Data Reviewer's Guide (SDRG)
- Developed and validated Tables and Listings using PROC REPORT, TEMPLATE and ODS
- Provided CDISC compliance checks using company specific SAS Macros based on OpenCDISC.
- Worked as an Analyst within the Process Management group overseeing submission related activities in all areas including Operations, Data Management, and Statistical Programming and Regulatory submissions.
- Conducted data traceability analysis for pivotal phase II and III studies which included programming selected sample SDTM and ADAM data as well as output tables and listings.
- Reviewed SDTM/ADAM deliverables from CROs as part of Data Traceability reviews to check conformance to standards and specifications.
- Worked with CRO teams to resolve issues related to Mapping and Conversion of raw or legacy data to CDISC standard SDTM data.
- Worked with several FSP / CRO's and provided direct oversight and support in all areas of the Clinical Trials including TMF / Regulatory documentation, Data Mgmt., Statistical programming.
- Used Medidata Rave tool to review Subject eCRFs.
- Assisted with and provided solutions for creating annotated CRFs (aCRFs) during SDTM conversion / mapping process and for FDA submission.
- Reviewed Data Management plans (DMPs), Statistical Analysis Plans (SAPs).
- Participated in reviewing other critical documentation such as eCRF specifications, eCRF completion guidelines, annotated CRFs, edit check specifications.

- Managed Medicare / HIPAA reporting requirements via third party
- Developed PGx (Pharmacogenomics) process flow including operations, sample management and data transfer specifications.

Independent Consultant, Somerset, NJ

2007 – 2008

Research Analyst

- Participated in developing project specific CRA and SAS training programs.

Medco Health Solutions, Blue Bell, PA

2007

Business Analyst (Consultant)

- Worked as campaign management specialist for one of the largest Pharma Benefits Manager.
- Designed and developed campaigns that process millions of patients claims records from Teradata warehouse environment.
- Managed projects using Unica-CRM software. Created SQL code with OLAP functions for clinical data processing and reporting.
- Performed extensive fine tuning of SQL queries by optimizing joins, sub-queries for faster data processing and incorporating code to collect statistics on tables / columns.
- Helped translate business requirements documents and functional requirement documents into program/code design and development.
- Performed file encryptions, cksum computations for data integrity and FTP transfer of files via secure server to outside vendors.
- Used OLAP functions in raw SQL code for data partition into percentiles / quantiles for ranking.

Lexicon Genetics Inc., Woodlands, TX

2002 – 2007

Sr. Research Associate

- Worked on over a hundred mouse knockout projects utilizing the Sequence analysis software, Molecular Biology research protocols like Long-Range PCR technology / southern hybridization.
- Maintained the Lambda KOS library.
- Initiated projects and managed projects independently & maintained extensive documentation related to the project initiations for approval.
- Work also involved utilizing DNA sequence analysis software in making / identifying recombinant DNA molecules and ES cells respectively to produce mutant knockout mice.
- Conducted yeast two hybrid experiments.
- Performed Data mining and analysis using various internal resources, public databases, and publications.