



# **QTECH-SOL PROFESSIONAL DEVELOPMENT CENTER LLC**

Somerset New Jersey USA  
Private Vocational School



## **CLINICAL DATA ORIENTED TRAINING (CDOT)**

**SAS Functional  
Clinical Trials:  
Phase I - Phase IV**



***For SAS programmers looking for career opportunities in clinical domain***

If you are SAS certified professional, have strong SAS skills, and are interested in supporting the clinical trial drug projects? You should consider joining the training program that will prepare you for daily tasks completion required from clinical SAS programmers. The QPDC offers Clinical Data Oriented (SAS) Training which emphasizes on clinical trial data reporting and regulatory submissions using statistical analysis software, SAS.

### **The Mission of QPDC**

Our mission is to provide the best-in-class job oriented career development Elearning training courses and programs in clinical research, SAS data management and business analysis for students and professionals requiring a skills refresh - or the development of new skills and experience for job entry, advancement, and placement

# OVERVIEW OF THE TRAINING AGENDA

Designed by highly experienced SAS programmers for students and young professionals interested in pursuing further career as clinical SAS programmers

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The training program provides in depth knowledge of the business, and roles and responsibilities of Clinical SAS Programmers

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The program's teaching methodology is based on real time scenario projects while students are exposed to the entire process of data handling from protocol, testing, data capture, analysis to reporting and final submission.

## LIST OF CHAPTERS

### *Knowledge of the clinical domain*

1. Elementary SAS Concepts
2. SAS Efficiency Programming
3. Introduction to Clinical Trials
4. Types and Data in Clinical Trials
5. Clinical Trial Protocol Development
6. Elements of CRF Design
7. Electronic Data Capture (EDC)
8. Good Clinical Practices
9. Good Documentation Practices
10. Work Flow Instruction Request
11. Documentation Templates
12. Introduction to Data Validation
13. Data Based Validation
14. Protocol Based Validation
15. Basic of Statistics
16. Statistical Analysis Planning
17. Elements of Hypothesis Testing
18. Basic of Efficiency
19. Integrated Summary of Effectiveness (ISE)
20. Integrated Summary of Safety (ISS)
21. Clinical Data Interchange Standards Consortium
22. Preparing Analysis Data sets
23. Creating Tables Listing and Graphs (TLG)
24. Understanding Various Therapeutics Areas
25. Data Based Therapy
26. Introduction to Phase I Studies
27. Oncology Project
28. Introduction to Phase II Studies
29. Ophthalmology Project
30. Introduction to Phase III Studies
31. Cardiology Project
32. Introduction to Phase IV Studies
33. Central Nervous Systems (CNS) Project
34. Introduction to Pharmacovigilance
35. Pharmacovigilance Reporting
36. Aggregate Reporting Process (periodic Safety Update Reporting: PSUR, PUR, ADR, Signaling, etc.)
37. PSUR

## LIST OF EXERCISES

### *Exposure to daily roles and responsibilities*

#### **Data Analysis and Reporting and Therapeutic Areas**

1. PROJECT 1: Data Based Validation
2. PROJECT 2: Protocol Based Validation
3. PROJECT 3: Elements of Hypothesis Testing (Pk, Pd and Dose)
4. PROJECT 4: Preparing Analysis Datasets and CDISC
5. PROJECT 5: Therapeutic Areas: Oncology Project
6. PROJECT 6: Therapeutic Areas: Ophthalmology Project
7. PROJECT 7: Therapeutic Areas: Cardiology Project
8. PROJECT 8: Therapeutic Areas: Central Nervous System (CNS) Project
9. PROJECT 9: Aggregate Reporting Process
10. PROJECT 10: SAS Efficiency Programming
11. Open CDISC Validator



**Are you pursuing Clinical SAS Programmer entry level position?  
Do you know about Current Hiring Trends...?**

**Hiring Clinical SAS Programmers:**

99% of the employers choose candidates with **biostatistics** degree  
80% of the employers choose candidates with **bioinformatics** degree  
75% of the employers choose candidates with **biotechnology** degree  
75% of the employers choose candidates with **public health** degree

**Do you want to know more about current industry trends and statistics?**



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