Pharma Center of Excellence

# Syllabus for Statistical Programming

## Become a Statistical Programmer in 8 Weeks

**Why choose Center of Excellence (CoE) Pharma for your training needs?**

- CoE Pharma will prepare a comprehensive (end-to-end) training for Statistical Programming in Clinical Trials in which you will gain the necessary skills to:
  - create specifications for ADaM* datasets
  - produce and validate ADaM* datasets
  - produce simple and complex tables, listings and figures
- You will work in a collaborative environment and hone communication and negotiation skills in your role as source programmer or validator.
- It is expected that you will meet the deadline of the project and will produce output with good quality.
- At the end of the training program, you will have your own Portfolio (with codes/output) to present at job interviews and you will have a better understanding of the clinical research process.
- You will be mentored to ace the interview through the mock-up interview sessions.

**What will you know at the end of the course?**

- Be able to provide data analysis support, develop programs using SAS or other data analysis programming tools to generate and validate datasets.
- Be able to generate reports such as tables, listings and figures for clinical project reports and medical research using PROC Report, Data Null, SAS arrays, PROC SQL and Macros.
- Be able to implement CDISC* standards for data mapping and analysis in Clinical Trials.
- Be able to communicate effectively with data management, statisticians and other cross-functional teams to ensure data quality and consistency.
- Ability to assess workload and negotiate timelines.

**Pre-requisite:**

- BS. in Bioinformatics, Biotechnology, Biostatistics, Data Science or any analytical background.
- Minimum knowledge about SAS or R programming and willingness to put effort into learning new skills.

## What can you do as Statistical Programmer in Clinical Trials?

**Statistical Programmer**

**Range Pay*: $114,537 to $140,563**

Responsible for editing and validating programs using SAS macros to generate domains and datasets CDISC* compliant

Generate efficacy and safety reports using PROC Report, Data Null, SAS arrays, PROC SQL and SAS Macro

Maintain programming team documents as requested

Perform analysis in response to data requests in collaboration with designated statistician

At the end of this document is a list of acronyms used in the following table.

Note: CDISC* standards are an industry-wide methods for submitting data to regulatory authorities like the FDA*. Learning about CDISC* standards is important to a career in the pharmaceutical industry.

| Week | Task | Active (Live Sessions) Training (Expected: 40 hours) | Student Learning/Hands-on (Expected: 80 hours) |
|---|---|---|---|
| | | 5 hours per week | 10 hours per week |
| 1, 2 | Team introduction<br>ADaM* specifications | • Introductions (trainer and trainees)<br>• Create specifications for ADaM*:<br>○ ADSL* (prepare specifications with trainer)<br>○ ADAE* (specifications available)<br>○ ADCM* (student to prepare specifications)<br>○ ADEFF* (prepare specifications with trainer) | |
| 3, 4 | ADaM* assignments<br>Program ADaM* source<br>Program ADaM* validation | • Assess workload and negotiate timeline<br>• Program ADaM* source<br>• Program ADaM* validation<br>• Communicate (source and validator) to pass quality control on ADaM* | |
| 5 | TLFs* assignments<br>TLFs* specifications | • Present specifications for TLFs (Tables, Listings, and Figures)<br>• Safety specifications (specifications available) | |

| Week | Task | Active (Live Sessions) Training (Expected: 40 hours) | Student Learning/Hands-on (Expected: 80 hours) |
|---|---|---|---|
| | | • Efficacy specifications (student to prepare with trainer)<br>• Assess workload and negotiate timeline | |
| 6, 7 | Program TLF* source<br>Program TLF* validation | • Program TLFs* source<br>• Program TLFs* validation<br>Communicate (source and validator) to pass quality control on TLFs* | |
| 8 | Presentations<br>End of training | • Implementation of Hard-coding<br>• Data issues at the end of study<br>• Dry Run* results<br>• Overall comments | |
| | Assessment for Certification "COE Pharma" | • Students must **pass** a multiple-choice exam to receive Certification<br>• Minimum passing grade is 80%.<br>• Assessment can be taken multiple times in a period of 1 week. | |

**Contact us for more details at: contact@coepharma.com**

**Acronyms:**

| | |
|---|---|
| ADAE | Adverse Event Analysis Dataset |
| ADaM | Analysis Data Model |
| ADCM | Concomitant Medications Analysis Dataset |
| ADEFF | Efficacy Parameters Analysis Dataset |
| ADSL | Subject Level Analysis Dataset |
| CDISC | Clinical Data Interchange Standards Consortium |
| Dry Run | Also called Blind Delivery Review is conducted to allow the evaluation of the reporting datasets (SDTM/ADaM) and statistical output tables, listings, and figures (TLFs) prior to database lock, to ensure that all outputs are prepared as expected as per agreement |
| FDA | Food and Drug Administration |
| R | The R Project for Statistical Computing |
| SAS | Statistical Analysis System |
| SDTM | Study Data Tabulation Model |
| TLFs | Tables, Listings, Figures |