Syllabus for Clinical Programmer

Become a Clinical Programmer in 8 weeks

Why choose COE Pharma for your training needs?

- COE Pharma will prepare a comprehensive (end-to-end) training for programming in Clinical Trials in which you will gain the necessary skills to:
    - create specifications for domains and datasets
    - produce and validate SDTM* domains
- 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.

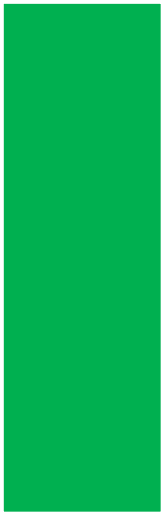
What will you know at the end of the course?

- 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 Data Listings, Subject Profiles, Edit Checks 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 Clinical Programmer in the pharmaceutical industry?



Clinical Programmer

Median Pay (Salary.com, Clinical Programmer I San Francisco):

$89,404

Data edit checks

External data transfer agreement (DTA) and acceptance check

External data conversion

Patient profile creation

Data snapshot creation/documentation

Regular uploads of data visualization data

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 (Mon, Wed, Fri) Monday: 1 pm – 3 pm PST Wednesday: 10 am – 12 pm PST Friday: 1 pm – 2 pm PST	10 hours per week

1,2,3	Team introduction
	Clinical Trials Introduction
	Introduction of the Study
	SDTM* specifications
		• Introductions (trainer and trainees)
		• Trainer will act as Statistician/Gate Keeper/Project Manager
		• Introduction to Good Clinical Practice
		• Types of Clinical Trials
		• Concepts:
		  ○ Source programmer and validator
		  ○ CDISC* standards
		  ○ Pinnacle 21*
		• SAS*/SQL* introduction:
		  ○ Methods for merging data
		  ○ Sorting and functions
		  ○ Macros
		• CRF* pages
		• Clinical Data Management Reports
		• Introduction of the Study (Protocol, SAP*)
		• Introduction to SDTM*
		• Create specifications for SDTM*:
		  ○ TA*, TE*, TI*, TV* (prepare specifications with trainer)
		  ○ IE* (specifications available)
		  ○ DM* (specifications available)
		  ○ AE* (specifications available)
		  ○ CM* (student to prepare specifications)
		  ○ MH* (student to prepare specifications)
		  ○ EX* (prepare specifications with trainer)
		  ○ FA* (prepare specifications with trainer)
		  ○ DS* (student to prepare specifications)
		  ○ SV* (prepare specifications with trainer)
		  ○ Efficacy domain (prepare specifications with trainer)
		  ○ VS* (student to prepare specifications)	

4,5	SDTM* assignments Program SDTM* source Program SDTM* validation	• Assess workload and negotiate timeline • Program SDTM* source • Program SDTM* validation • Communicate (source and validator) to pass quality control on SDTM*	
6,7	SDRG* MedDRA*	• SDRG* to be created by each student • Discuss MedDRA* and WHODrug* dictionaries	

Week	Task	Active (Live Sessions) Training (Expected: 40 hours)	Student Learning/Hands-on (Expected: 80 hours)
	WHODrug* Pinnacle 21* Define.xml for SDTM*	• Use of Pinnacle 21* for data issues and Define.xml* for SDTM* • Define.xml* for SDTM* to be created by each student	
8	Presentations End of training	• Implementation of Hard-coding • Data issues at the end of study • Overall comments	
	Assessment for Certification "COE Pharma"	• Students must **pass** a multiple-choice exam to receive Certification • Minimum passing grade is 80%. • Assessment can be taken multiple times in a period of 1 week.	

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

Acronyms:

AE	Adverse Events
CDISC	Clinical Data Interchange Standards Consortium
CM	Concomitant Medications
CRF	Case Report Form
Define.xml	File that describes any tabular dataset structure. When used with the CDISC Foundational Standards, it provides the metadata
DS	Disposition
EX	Exposure
FA	Findings About
FDA	Food and Drug Administration
IE	Inclusion/Exclusion Criteria Not Met
LB	Laboratory Test Results
MedDRA	Medical Dictionary for Regulatory Activities
MH	Medical History
Pinnacle 21	Also previously known as OpenCDISC Validator, provides great compliance checks against CDISC outputs like SDTM and Define.xml.
R	The R Project for Statistical Computing
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SDRG	Study Data Reviewer's Guide
SDTM	Study Data Tabulation Model
SV	Subject Visits
TA	Trial Arms
TE	Trial Elements
TI	Trial Inclusion/Exclusion Criteria
TV	Trial Visits
WHODrug	WHO Drug Dictionary