Savitribai Phule Pune University
(Formerly University of Pune)

Department of Technology
Board of Studies Chemical & Biotechnology (CB)
STRUCTURE OF ONE YEAR FULL TIME POST GRADUATE DIPLOMA IN
Clinical Data Management and Pharmacovigilance

Semester 1

Sr. No.	Course Code	Course Name	Teaching Scheme			Credits
			L	T	P	
1.	PGCDM101	Clinical Data Management	3	1	0	4
2.	PGCDM102	Query Management	2	1	1	4
3.	PGCDM103	CRF Design and Development	2	1	1	4
4.	PGCDM104	Clinical Data Process	1	2	2	4
5.	PGCDM105	SAE Reconciliation	1	2	2	4
		Total Credits				**20**

Semester 2

Sr. No.	Course Code	Course Name	Teaching Scheme			Credits
			L	T	P	
1.	PGCDM201	Pharmacovigilance	3	1	0	4
2.	PGCDM202	Overview and Navigation	3	1	0	4
3.	PGCDM203	Business Process Workflow	3	1	0	4
4.	PGCDM204	Case Entry and Processing		2	2	4
5.	PGCDM205	Coding Terms and MedDRA Browser		2	2	4
		Total Credits				**20**

Clinical Data Management and Analytics

Introduction to Clinical Data Management

The Working process in Clinical data Management working with a range of computers applications, database system to support collection cleaning and management in clinical trails

Query Management : data correction as per the source documentation, types of query , how to manage a query generated by the data management team, generation of queries (system generated and manual query), identification of query ,audit trail.

CRF design & development -**Case Report From (Paper & Electronic):-** CRF design & development (Paper & electronic), data base build up & testing , how to prepare Sop of CDM

Clinical Data Process (Data Capture ,Data Collection , Data Validation, Lab Data Management ,Query Management) ,:- How to capture the data from the site , data entry in ECR / paper CRF ,Query management process in CDM

Data validation Rules, Testing the validity of **data** in accordance with the protocol specifications as per the clinical trial studies

Prospective **Validation**,Concurrent **Validation**.,Retrospective **Validation**,Revalidation (Periodic and After Change) , Verification of Validation (QA Validation)

SAE Reconciliation (I medidata tool or equivalent):- SAE Reconciliation plan that identifies the variables to be reconciled between the study DB and the Safety DB. SAE reports, CIOMS or MedWatch reports are manually reviewed against the clinical database or SAE listings from the clinical database. Data discrepancies are immediately posted as queries and applied once resolutions are obtained. When studies utilize SCiAN's EDC^{PRO} and SAE^{PRO} systems, Sponsors can be assured that SAE reconciliation is performed quickly and efficiently.

Pharmacovigilance (Training on Argus Safety or equivalent tool)

Preliminary Module : Principles of Pharmacovigilance

important concepts of Pharmacovigilance which are essential to understand to develop preliminary understanding of Pharmacovigilance before taking the Argus Safety tutorials.

Overview and Navigation

learn the process of logging in and Navigating through the Oracle Argus Safety user interface. This chapter shall also cover the various user interface elements of the Oracle Argus Safety application and the functionality of each element.

: Business Process Workflow

In this chapter we shall discuss the business process and workflow of a basic single case within Argus Safety

Case Entry and Processing

In this chapter we shall discuss how to work with cases using the standard workflow of case management within Argus safety. This would include the process of booking in a case, performing case entry, processing the case, performing medical and coding review and printing medical summaries. The process of performing case operations such as closing, copying and revising a case shall also be discussed.

Case Form Features and Worklists

This chapter will cover the various features of the Case Form and their functions. The various tabs of the Case Form and thier utility in the process of management of safety related data shall be discussed.

Coding Terms and MedDRA Browser

This chapter describes the MedDRA (Medical Dictionary for Regulatory Activities) browser and how it is used to encode diseases, symptoms, signs, and so forth. In Argus Safety, using such a dictionary provides consistency when assigning terms for adverse events.

Advanced Conditions

This chapter provides information about Advanced Conditions, a powerful search tool within Oracle Argus Safety, that enables you to build complex queries for retrieving system data.

Dashboard and Utilities

This chapter describes the various types of information available on the dashboard and the utilities functions available that allow the user to view, change or retrieve case related information.

Reporting and Submissions

In this chapter we shall discuss about the regulatory requirement for reporting adverse event cases and the reporting capabilities of the Argus safety suite. We shall also understand the serious adverse event reconciliation process and module as well as the study unblinding process and module.

Course Completion

This course completion module, includes a Final Quiz that you will need to take to complete this course. The marks of the final quiz will be added to the marks of all other graded activities of this course. If your total score in the course is 75% and above, you will be able to see a Course completion certificate which you can then download.

ICSR Case processing, Narrative Writing, Training on Argus/ Aereis software

BOOK FOR CDM

1) **Practical Guide to Clinical Data Management, 3rd Edition**
2) **Clinical Data Management Second Edition**
3) **Handbook of Research on Information Technology Management and Clinical Data Administration in Healthcare Hardcover – Import, 15 June 2009 by Ashish N. Dwivedi (Editor)**

BOOKS FOR PV

1) **An Introduction to Pharmacovigilance Kindle Edition**
2) **Textbook of Pharmacovigilance (India) [Print Replica] Kindle Edition**
3) **Pharmacovigilance: A Practical Approach Kindle Edition**