Post Graduate Diploma in Clinical Data Management and Biostatistics with SAS

Programme Guide

PGDCDM

School of Health Sciences
Indira Gandhi National Open University
WHY THIS PROGRAMME?

The Post Graduate Diploma in Clinical Data Management and Biostatistics with SAS is designed for students to acquire theoretical knowledge and develop practical skills on managing clinical data. This is a focused course of study for individuals seeking to work in clinical research data management in the pharmaceutical trials industry.

The package includes 4 theory and 1 practical course covering Clinical Data Management in Courses 1 and 2, Biostatistics in Course 3 and SAS Programming in Course 4. Course 5 consists entirely of practical work in the form of a project.

This course presents the essential elements of monitoring a clinical trial and upon completion of this course a student should have in depth knowledge of:

- Clinical trial protocol, case report forms
- Database design, lock, SOPs and Audit trails
- Data management and validation plan
- Loading external lab data, generating DCF
- CRF annotation and CFR 11 compliance
- Safety and safety reporting
- SAP, protocol and study design
- SAS Programming

WHAT IS THIS PROGRAMME?

Programme Package
The programme package in distance education mode is developed with the help of available technology commonly known as multi-media package. The package for this programme consists of print material in the form of booklets called blocks and the audio video materials in the form of CDs. Besides these, there is an arrangement for teleconferences and contact session at programme study center and skill development centre level as discussed below.

In IGNOU parlance, the study hours are measured in credit system. **One credit is equivalent to 30 learning hours.** Each theory booklet is called a block, which consists of 3-9 chapters called units. Usually each block represents 1 credit. The block on practical manual is meant for guidance in ‘Hands on training’. Hence, the credit hours represented by it will be as mentioned against the respective courses in Section 2.2.

The duration of the programme is of 1 year duration i.e. July to June of a calendar year. The print material consists of 29 Theory Blocks, 1 Practical logbooks, 16 Assignments and 1 Programme Guide and bound together. You will receive all the print materials in the beginning of the session. The audio/video CDs developed for the programme will be made available at programme study centres.

**Programme Structure**

The PGDCDM consists of 5 courses. These represent broad disciplines of Clinical Data Management. Course 1 covers the Fundamentals of Clinical Research, Course 2 covers Clinical Data Management, Course 3 covers Biostatistics, Course 4 covers SAS and Course 5 is practical project work. The only practical component is in Course 5 given in the Log Book and the courses are designed on the basis of learning hours required by the average student. As mentioned earlier, **one credit represents 30 hours of learning.** The design of the PGDCDM programme in terms of credit distribution of the courses is as per the following pattern:

<table>
<thead>
<tr>
<th>Course Code</th>
<th>Name of the Course</th>
<th>Nature of the Course</th>
<th>No. of Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fundamentals of Clinical Research</td>
<td>Theory</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Clinical Data</td>
<td>Theory</td>
<td>7</td>
</tr>
</tbody>
</table>
**Practical Component**

In this programme, 4 courses are theory course and 1 course is a complete practical course. Every student will take a Project, which is a small research work to enhance your ability to logically pose a question and find answer. Project will be done under a guide. Normally project work should require seven to ten days of effort. Please plan the work you would like to do and approach any of your teachers to guide the work. You may also choose a guide from associated field. Project need to be submitted in the form of hard as well as soft copy to the coordinator of the respective centres.

**HOW WILL YOU BE EVALUATED?**

In IGNOU, every course is considered as an independent unit. Hence, every course will be evaluated separately and for all purposes will be considered as a separate entity.

Evaluation will be made both concurrent (internal assessment) and at the end (end-assessment). Theory and practical components will be evaluated separately. In the theory courses, the weightage of the internal assessment will be 20% and that of the term-end assessment will be 80%. The internal assessment is divided into 4 assignments per course of 5 marks each. For successful completion of the programme, you will have to pass in both components of each of the courses with a minimum score of 50%. For the practical course, 100% evaluation will be based on the projects submitted and a minimum score of 50% will be required to pass.

**Distribution of Marks**
Each course will have 100 full marks.

Course wise Distribution of Marks

<table>
<thead>
<tr>
<th>Course Name</th>
<th>Nature of the Course</th>
<th>Assignment Marks</th>
<th>Term-end Marks</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fundamentals of Clinical Research</td>
<td>Theory</td>
<td>20 (10)</td>
<td>100 (50)</td>
<td>100 (50)</td>
</tr>
<tr>
<td>Clinical Data Management</td>
<td>Theory</td>
<td>20 (10)</td>
<td>100 (50)</td>
<td>100 (50)</td>
</tr>
<tr>
<td>Biostatistics</td>
<td>Theory</td>
<td>20 (10)</td>
<td>100 (50)</td>
<td>100 (50)</td>
</tr>
<tr>
<td>SAS</td>
<td>Theory</td>
<td>20 (10)</td>
<td>100 (50)</td>
<td>100 (50)</td>
</tr>
<tr>
<td>Project Work</td>
<td>Practical</td>
<td>100 (50)</td>
<td>-</td>
<td>100 (50)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td>500 (250)</td>
</tr>
</tbody>
</table>

*Note:* Figures in paranthesis show the pass marks. 80% weightage will be allocated to the term end exam which will comprise of a single paper of 100 marks for each course

**Method of Evaluation of Theory Courses**

**Internal Assignments (Assignments)**

In IGNOU, the internal assessment for theory is carried out by providing you 4 assignments for every course. These assignments are questions that you will answer at your own place by referring to your blocks. For the PGDCDM Programme, you will have to do 4 assignments for each course. You have to secure at least 10 marks to pass. If one fails to secure 10 marks, he/she will have to repeat the assignment (s) in which he/she has scored less than pass mark. The last date of submission of assignments is mentioned in section 6.4

**Term-end Examination**

Term-end examination for theory will be held twice a year ie in the month of June and December. There will be 4 papers of 100 marks each. Each paper will be of 2.5 hrs duration.
You will have to secure at least 50 marks in each of the theory papers for successful completion. Overall you have to score 50% marks in each course for successful completion.

**Method of Evaluation of Practical Courses**

The practical course is broken up into 3 projects comprising of 1 credit each. Each project will be scored equally and the total will add upto 100. There is no term-end exam for the practical course and 100% weightage is assigned to the projects carried out during the term. Overall pass mark is 50%.

**SYLLABUS**

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**Course-wise List of Blocks and Details**

**COURSE I : Fundamentals of Clinical Research**

**Block 1 : Clinical Research; An Overview**

1. Introduction to Clinical Research
2. Global Scenario including US, Europe & Japan
3. The International Conference on Harmonisation and Its Impact
4. Opportunities in India
5. Working with Contract Research Organisations

**Block 2 : Drug Development Process**

6. Overview of Drug Development Process
7. Cost of Drug Development
8. Pre Clinical Drug Development Process
9. Animal Studies in Drug Development
10. CMC Package
11. Regulatory Process in Preclinical Drug Development
12. Pharmacodynamics & Pharmacokinetics
13. Preclinical Toxicity Studies
14. Overview of Clinical Trial Process

Block 3 : Clinical Trial Design

15. Principles in Clinical Research design; Types of study designs
16. Research objective / Hypothesis
17. Clinical Epidemiology
18. Phases of Clinical Trials
19. Clinical Trials in Pharmaceuticals, Biologicals and Vaccines
20. Trial differences for Nutraceuticals, new drugs, medical devices
21. Bioequivalence studies for generics

Block 4 : Good Clinical Practices

22. GCP – Roles and Definitions
23. Roles & Responsibilities of a Sponsor & Regulator
24. Roles & Responsibilities of an Investigator
25. Roles & Responsibilities of a Monitor

COURSE II : Clinical Data Management

Block 1 : Clinical Data Management: An Introduction
1. Data – Definition & Types
2. CRF Design for Clinical Trial
3. Query Resolution
4. Database update, drug safety and database locking
5. EDC System and 21CFR Part 11 compliance
6. Data Privacy: Implications for Clinical Operations
7. Data Management in Epidemiology
8. Data Management in Pharmacoeconomics

**Block 2 : Project Management**

9. Data management plan
10. Project management for the clinical data manager
11. Vendor selection and management
12. Data management standards in clinical research
13. Design and development of data collection
14. Edit check design principles

**Block 3 : Electronic Data Capture and Case Report Forms**

15. Electronic data capture-Concepts and study start up
16. Electronic data capture-Study conduct
17. Electronic data capture-Study close out
18. CRF Completion Guidelines
19. CRF printing and vendor selection

**Block 4 : Validation**
20. Data validation, programming and standards
21. Laboratory data handling
22. External data transfer
23. Patient-reported outcomes
24. CDM presentation at investigator meetings
25. Training
26. Metrics for clinical trials
27. Computer Systems
28. Systems Software Validation Issues – Clinical Trials Database Environment

**Block 5  :  Data Quality & Integrity**

29. Data Quality and Data Integrity
30. Assuring data quality
31. Measuring data quality
32. Data storage
33. Data entry process
34. Medical coding dictionary management and maintenance
35. Safety data management and reporting
36. Serious adverse event data reconciliation
37. Database closure
38. Clinical data archiving

**Block 6  :  Metrics for Electronic Clinical Trials**

39. Objectives & Introduction
40. Clinical Trials Metrics Collection
41. Re-engineering the Clinical Data Management Process

**Block 7 : Quality Audits**

42. Audit – Definition, types & procedures
43. Audit standards
44. Audit trail & its role in authenticity of data
45. Audit plan
46. Audit by regulatory authorities
47. GMP, GDP & logistics
48. Preparing and delivering audit reports
49. What makes a good audit
50. New product development & GxP Regulations

**COURSE III : Medical Writing & Biostatistics**

**Block 1 : Medical Writing / Documentation**

1. Importance of Medical writing in clinical research
2. Medical terminology
3. Understanding disease states for drug trials
4. Ingredients of good medical writing
5. ICH E3 structure & content of clinical study reports
6. Format of paper for publication
7. Standardization of medical terms, MedRA and other coding dictionaries
8. Introduction to Clinical Data Interchange Standards Consortium
Block 2  :  Introduction to Biostatistics

9. Role of biostatistics in clinical trials
10. Hypothesis formulation
11. Common terms in biostatistics
12. Probability theory and power distribution
13. Statistical tests of significance and their uses
14. Statistical aspects of trial design

Block 3  :  Measuring and Protecting Data

15. Introduction
16. Data and Data types
17. Measurement Scales – nominal, ordinal, interval, ratio scales
18. Frequency Tables
19. Graphs

Block 4  :  Measures of Central Tendency and Location

20. Central Tendency
21. Arithmetic Mean, Calculation of Mean
22. Median, Mode
23. Relative Advantages and Disadvantages
24. Decile, quintile, quartile, location of percentiles, deciles

Block 5  :  Measures of Variation and Dispersion

25. Variation
26. Range
27. IQR and Quartile deviation
28. Normal values and normal range
29. Average deviation / mean deviation
30. Variance
31. Standard Deviation
32. Standard error
33. Coefficient of variation

**Block 6 : Defining the Question / Tests of Significance**

34. Defining the question
35. Significance
36. Tests of significance
37. Test statistics, hypothesis testing
38. Levels of significance
39. T-test, chi-square test

**COURSE IV : SAS**

**Block 1 : Introduction to SAS**

1. Getting Started Using SAS Software
2. Getting Your Data into SAS

**Block 2 : SAS Functioning**

3. Working with your data
4. Sorting, Printing and Summarizing your data
**Block 3**: Output Delivery System, Data Sets and Macro Facilities

5. Enhancing your output with ODS
6. Modifying and Combining SAS Data Sets
7. Writing Flexible Code with the SAS Macro Facility

**Block 6**: Statistical and Other Procedures

8. Using Basic Statistical Procedures
9. Exporting Your Data
10. Debugging Your SAS Programs

**Block 7**: The CDISC Standards

11. The CDISC Standards
12. The CDISC Clinical Research Glossary
13. Protocol Representation
14. Clinical Data Acquisition Standard Harmonization – CDASH
15. The Operational Data Model – ODM
16. The Clinical Laboratory Data Model – LAB
17. Submission Data Standards: SDTM, SEND, Trial Design & Define.xml

**COURSE V**: PROJECT

**Block 1**: Project Work

1. Research work project