



# **CCEK – NSQF ALIGNED PROGRAM**

## **COURSE SYLLABUS**

### **FOR**

## **Basics of Clinical Data Management**

# CCEK - NATIONAL SKILL DEVELOPMENT TRAINING PROGRAM

## Basics of Clinical Data Management

CCEK – NSDC course package covers the following Qualification Packs and leads to the following NSDC certifications. The students who successfully completed the course programs are entitled to get NSDC certification after undergoing the assessment process of NSDC as per the rules and regulations stipulated by NSDC from time to time.

SL. NO.	QUALIFICATIONS PACK	QUALIFICATIONS PACK CODE	NSQF LEVEL
1	<p><b><u>Basics of Clinical Data Management</u></b></p> <p><b>Brief Job Description:</b></p> <p>The professional with Basics of Clinical Data Management have foundational knowledge and skills in the field of clinical data management (CDM). This includes understanding of the importance of CDM in clinical research, learn key terminology and concepts, explore data sources in clinical trials, delve into the design of case report forms (CRFs), and understand the critical processes of data entry, cleaning, and quality assurance in CDM.</p>	<b>LFS/MCr-0009</b>	<b>5</b>

**COURSE DETAILS****Basics of Clinical Data Management****EXAMINATION DETAILS**

COURSE NAME		COURSE CODE	ELIGIBILITY	DURATION	
Basics of Clinical Data Management		G43	Degree/2-year Diploma (after 12th Class)	30	
SL. NO.	EXAM	EXAM CODE	MAXIMUM MARK	INTERNAL	TOTAL MARK
THEORY PAPERS					
1	The Fundamentals of Clinical Data Management	T001	100	50	150
2	Data Collection and Source Documentation	T002	100	50	150
PRACTICAL PAPERS					
1	Data Cleaning and Validation	L001	100	50	150
TOTAL MARKS					
1	Total Examination Marks (Theory Online + Practical Examination)				300
2	Total Internal Marks				150
3	<b>Total Marks (Total Internal Marks + Total Examination Marks )</b>				<b>450</b>

**Basics of Clinical Data Management****INTERNAL MARK CRITERIA FOR EACH**

<b>SL NO.</b>	<b>MODULE</b>	<b>MODULE CODE</b>	<b>MAXIMUM MARK</b>	<b>INTERNAL MARK</b>	<b>TOTAL MARK</b>
1	The Fundamentals of Clinical Data Management	T001	100	50	150
2	Data Collection and Source Documentation	T002	100	50	150
3	Data Cleaning and Validation	L001	100	50	150
	TOTAL		300	150	450

<b>ATTENDANCE</b>	<b>GENERAL PERFORMANCE</b>	<b>INTERNAL EXAMINATIONS/ PROJECTS/ ASSIGNMENTS</b>	<b>TOTAL MARKS</b>
5	5	40	50

# **COURSE SYLLABUS**

**FOR**

**Basics of Clinical Data Management**

<b>COURSE</b>	Basics of Clinical Data Management	
<b>TOTAL MARKS</b>	Mark: 450	Internal Mark: 150
<b>TOTAL HOURS</b>	30 Hrs	

### DEFENITION OF CREDIT

1 Credit	15Hrs Theory/ 30Hrs Practical
Skill Components	60 – 70 % of Total Credit

### MODULES INCLUDED IN THIS SUBJECT

SL NO	MODULE NAME	CREDIT BREAKUP
1	Module 1: Introduction to Life sciences sector and Clinical Data Management	0.5
2	Module 2: Clinical Data Collection and Source Documentation	
3	Module 3: Clinical Data Entry and Cleaning	
4	Module 4: Clinical Data Quality Assurance	0.5
5	Module 5: Regulatory Guidelines in CDM	
	Total	1

### Training Outcomes

- Comprehensive knowledge of Clinical Data Management.
- Demonstrate proficiency in Clinical Data Management, including data collection, verification, validation, and cleaning, ensuring data accuracy and reliability.
- Understand and apply international regulatory guidelines, such as ICH-GCP, and ensure compliance with data privacy and protection regulations, safeguarding patient data and maintaining ethical standards.
- Understanding the role of data monitoring and audits in maintaining data integrity.
- Understand how regulatory requirements shape CDM practices.
- Ensure data integrity, confidentiality, and compliance with industry standards.

## **MODULES**

### **Module 1: Introduction to Life sciences sector and Clinical Data Management**

#### **THEORY**

- Discuss the Life Sciences industry in Indian and global context.
- Explore the structure and dynamics of the life sciences industry, including pharmaceuticals, biotechnology, and medical devices
- Explain the core role of Clinical Data Management (CDM) in the clinical research process, highlighting its importance in ensuring reliable and high-quality data.
- Describe the data life cycle in clinical research, outlining CDM's involvement at different stages, from data collection to analysis.

### **Module 2: Clinical Data Collection and Source Documentation**

#### **THEORY**

- Explain the various data sources commonly used in clinical trials, including primary sources (e.g., medical records) and secondary sources (e.g., laboratory reports).
- Explain the purpose of Case Report Forms (CRFs) and demonstrate the ability to design
- Develop CRFs that are aligned with the specific needs of a clinical study.
- Define Source Data Verification (SDV) and its role in ensuring the accuracy and reliability of clinical trial data.

#### **PRACTICAL**

- Design a sample CRF for a specific clinical trial, considering data collection requirements, user-friendliness, and data accuracy.

### **Module 3: Clinical Data Entry and Cleaning**

#### **THEORY**

- Describe the processes involved in data entry for clinical trials, and demonstrate an understanding of data entry guidelines, emphasizing the importance of accuracy and consistency.
- Explain the concept of data cleaning in Clinical Data Management (CDM), and understand its role in enhancing data quality and integrity.
- Define query management, and understand the process of generating, tracking, and resolving data queries in clinical trial data sets.

#### **PRACTICAL**

- Develop and implement a data cleaning process specific to clinical data.

### **Module 4: Clinical Data Quality Assurance**

#### **THEORY**

- Understand the principles and methodologies of quality control processes in Clinical Data Management (CDM), emphasizing their role in maintaining data integrity.

- Describe how to assess data quality using various metrics and tools and interpret the results to ensure data accuracy and reliability.
- Discuss emergency preparedness plan for critical situations
- Explain the significance of data monitoring and audits in clinical research, and how they contribute to data quality assurance.

### **PRACTICAL**

- Create a risk management plan to minimize errors and enhance patient safety in a retail pharmacy setting.

## **Module 5: Regulatory Guidelines in CDM**

### **THEORY**

- Explain the principles of ICH-GCP (Good Clinical Practice) related to data management.
- Explain data privacy and protection regulations, such as GDPR and HIPAA, and understand their impact on Clinical Data Management practices.
- Discuss regulatory requirements influence and shape Clinical Data Management practices, with a focus on maintaining data integrity, confidentiality, and compliance.