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Training Parameters

Sector	Life Sciences
Sub-Sector	Contract Research
Occupation	Clinical Trials
Country	India
NSQF Level	5.5
Aligned to NCO/ISCO/ISIC Code	NCO 2015/3512.0601
Minimum Educational Qualification and Experience	Completed 3rd year of 3-year/ 4-years UG in Biology, Nursing, Medical Lab Technician, Life Sciences, Biotechnology OR Completed 3rd year of B.E/ B. tech. Biotech Or Completed 3rd year B. Pharma OR BAMS/ BDS/ BUMS/ BHMS/ MBBS
Pre-Requisite License or Training	NIL
Minimum Job Entry Age	18 Years
Last Reviewed On	08 April 2025
Next Review Date	08 April 2028
NSQC Approval Date	08 April 2025
QP Version	3.0
Model Curriculum Creation Date	08 April 2025
Model Curriculum Valid Up to Date	08 April 2028
Model Curriculum Version	1.0
Minimum Duration of the Course	Compulsory Notional Hours Theory=60 Hours Practical= 30 Hours Employability Skills= 90 Hours Total Compulsory Notional Hours=180 Hours

	<p>4 Electives = 390 Hours each Total Notional Hours with one elective=570 Hours Total Notional Hours with all 4 elective=1740 Hours</p> <p>with recommended apprenticeship of 6 months</p>
Maximum Duration of the Course	<p>Compulsory Notional Hours Theory=60 Hours Practical= 30 Hours Employability Skills= 90 Hours Total Compulsory Notional Hours=180 Hours</p> <p>4 Electives = 390 Hours each Total Notional Hours with one elective=570 Hours Total Notional Hours with all 4 elective=1740 Hours</p> <p>with recommended apprenticeship of 6 months</p>

Program Overview

This section summarizes the end objectives of the program along with its duration.

Training Outcomes

At the end of the program, the learner should have acquired the listed knowledge and skills.

- Discuss performance of Associate-Clinical Research Management in compliance with Good Manufacturing Practices (GMP) and GCP (Good Clinical Practices) and other environmental regulatory guidelines.
- Demonstrate how to conduct clinical trial monitoring and site coordination.
- Demonstrate good documentation practice (GDP) and data integrity while reporting and documentation as per standard operating procedures (SOP), good laboratory practices (GLP), and Good Manufacturing Practices (GMP).
- Demonstrate how to coordinate with supervisor, colleagues and respond to audit queries during GMP/ regulatory audits.
- Demonstrate sensitivity towards genders, cultures and specially-abled persons.

Compulsory Modules

The table lists the modules and their duration corresponding to the Compulsory NOS of the QP.

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
LFS/N3507: Introduction to life sciences industry and clinical trial occupation	30:00	00:00	00:00	00:00	30:00
Module 1: Introduction to Life Sciences industry and the job role	30:00	00:00	00:00	00:00	30:00
LFS/N3506: Carry out management activities related for clinical trial NOS Version No. 1.0 NSQF Level-5.5	15:00	15:00	00:00	00:00	30:00
Module 2: Managing Clinical Trial	15:00	15:00	00:00	00:00	30:00
LFS/N0119: Ensure environment sustainability and sensitivity towards all genders and people with disability NOS Version No. 3.0 NSQF Level-5.5	15:00	15:00	00:00	00:00	30:00
Module 3: Managing environmental sustainability	10:00	10:00	00:00	00:00	20:00
Module 4: Display sensitivity towards all genders and people with disability	05:00	05:00	00:00	00:00	10:00
DGT/VSQ/N0103: Employability Skills (90 Hours) NOS Version No. 1					
Module 5: Employability Skills					
Introduction to Employability Skills	01:30	01:30	00:00	00:00	03:00
Constitutional values – Citizenship	01:00	00:30	00:00	00:00	01:30
Becoming a Professional in the 21st Century	02:30	02:30	00:00	00:00	05:00
Basic English Skills	05:00	05:00	00:00	00:00	10:00
Career Development & Goal Setting	02:00	02:00	00:00	00:00	04:00

Associate-Clinical Research Management (Pharma, Biologics and Medical devices)

Communication Skills	05:00	05:00	00:00	00:00	10:00
Diversity and Inclusion	01:30	01:00	00:00	00:00	02:30
Financial and Legal Literacy	05:00	05:00	00:00	00:00	10:00
Essential Digital Skills	10:00	10:00	00:00	00:00	20:00
Entrepreneurship	04:00	03:00	00:00	00:00	07:00
Customer Service	04:00	05:00	00:00	00:00	09:00
Getting ready for apprenticeship & Jobs	04:00	04:00	00:00	00:00	08:00
On the Job Training	00:00	00:00	990:00	00:00	990:00
Total Duration	150:00	30:00	990:00	00:00	0:00

Elective 1: Site Management

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
LFS/N3503: Manage CRA activities at the site NOS Version No. 3 NSQF Level-5.5	60:00	150:00	00:00	00:00	210:00
Module 6: Clinical trial site coordination	60:00	150:00	00:00	00:00	210:00
LFS/N3504: Carry out reporting and documentation for site coordination activities as per regulatory standards NOS Version No. 3 NSQF Level-5.5	60:00	120:00	00:00	00:00	180:00
Module 7: Reporting and documentation for site coordination	60:00	120:00	00:00	00:00	180:00
Total Duration	120:00	270:00	00:00	00:00	390:00

Elective 2: Study Monitoring

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
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Associate-Clinical Research Management (Pharma, Biologics and Medical devices)

LFS/N3501: Monitor the clinical trial site to ensure that ICH GCP guidelines, study protocol and applicable regulations are followed NOS Version No. 3.0 NSQF Level-5.5	60:00	150:00	00:00	00:00	210:00
Module 8: Clinical trial monitoring	60:00	150:00	00:00	00:00	210:00
LFS/N3502: Carry out reporting and documentation for site monitoring activities as per regulatory standards NOS Version No. 3 NSQF Level-5.5	60:00	120:00	00:00	00:00	180:00
Module 9: Reporting and documentation for site monitoring	60:00	120:00	00:00	00:00	180:00
Total Duration	120:00	270:00	00:00	00:00	390:00

Elective 3: Data management

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
LFS/N3505: Provide support for clinical data management activities NOS Version No. 3 NSQF Level-5.5	120:00	270:00	00:00	00:00	390:00
Module 10: Clinical data management	120:00	270:00	00:00	00:00	390:00
Total Duration	120:00	270:00	00:00	00:00	390:00

Elective 4: Biostatistics

NOS and Module Details	Theory Duration	Practical Duration	On-the-Job Training Duration (Mandatory)	On-the-Job Training Duration (Recommended)	Total Duration
LFS/N3508: Provide data support for Biostatistical analysis NOS Version No. 3.0	30:00	90:00	00:00	00:00	120:00

Associate-Clinical Research Management (Pharma, Biologics and Medical devices)

NSQF Level-5.5					
Module 11: Data support for Biostatistical Analysis	30:00	90:00	00:00	00:00	120:00
LFS/N3509: Provide support in PK & PD through Biostatistics analysis NOS Version No. 3 NSQF Level-5.5	30:00	90:00	00:00	00:00	120:00
Module 12: PK – PD Statistical analysis	30:00	90:00	00:00	00:00	120:00
LFS/N3510: Provide algorithm support for Biostatistics activities NOS Version No. 1 NSQF Level-5.5	45:00	75:00	00:00	00:00	120:00
Module 13: Algorithm for Biostatistical analysis	45:00	75:00	00:00	00:00	120:00
LFS/N3511: Apply AI/ML Models in biostatistical analysis NOS Version No. 1 NSQF Level-5.5	15:00	15:00	00:00	00:00	30:00
Module 14: AI/ML Applications in biostatistical analysis	15:00	15:00	00:00	00:00	30:00
Total Duration	120:00	270:00	00:00	00:00	390:00

Module Details

Module 1: Introduction to Life Sciences industry and the job role

Mapped to LFS/N3507, v1

Terminal Outcomes:

- Explain the overview of the Life Sciences industry in regulation applicable to clinical trial.
- Discuss the importance of a skilled individual in clinical trial.

Duration: 30:00	Duration: 00:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Discuss the Life Sciences industry in Indian and global context. ● Discuss the regulations, legislation, and good practices to be followed in Clinical Research occupation in a life sciences facility. ● Explain the basic skills required to perform the job in Clinical trial occupation. ● Explain the importance of a skilled Clinical Research individual for efficient clinical trial and patient safety. 	
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Scanner, Computer speakers, Pencil	
Tools, Equipment and Other Requirements	
N/A	

Module 2: Managing Clinical Trial

Mapped to LFS/N3506, v1

Terminal Outcomes:

- Discuss the importance of environmental sustainability.
- Demonstrate the adoption of environmental sustainability methods at work for minimizing pollution, water wastage, and maximizing energy conservation.

Duration: 15:00	Duration: 15:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Explain the end-to-end lifecycle of clinical trials, including key phases, regulatory requirements, and compliance standards. ● Discuss the essential components, design considerations, and regulatory standards required for developing robust clinical study protocols ● Explain the concept of assessing and selecting appropriate clinical trial sites based on feasibility, infrastructure, and regulatory compliance. ● Explain the basics of budgeting, financial planning, cost management, and resource allocation in clinical trial operations. ● Explain various guidelines to be followed for accurate data collection, management, validation, and adherence to quality assurance standards. ● Explain the ethical guidelines, patient confidentiality protocols, and Good Clinical Practice (GCP) standards governing clinical trials. ● Discuss about various communication practice need to be followed for trial-specific issues to various stakeholders 	<ul style="list-style-type: none"> ● Demonstrate the process of developing and implementing detailed clinical trial plans to align with project goals and timelines. ● Demonstrate how to use monitoring tools to track trial progress, including making necessary adjustments to meet milestones and deadlines ● Show the process of creation and refinement of study protocols, ensuring clarity, methodology, and adherence to standards ● Demonstrate how to identify and evaluate potential clinical trial sites based on patient demographics, facilities, and regulatory compliance ● Prepare a checklist to ensure site readiness, including assessment of recruitment capacity and adherence to protocols. ● Demonstrate how to Implement various ways to prevent data discrepancies and maintain data quality throughout the trial. ● Demonstrate how to communicate trial-specific issues and trial deliverables to various stakeholders
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Computer speakers, Pencil	
Tools, Equipment and Other Requirements	
color-coded waste bin bag, color-coded waste container	

Module 3: Managing environmental sustainability

Mapped to LFS/N0119, v3

Terminal Outcomes:

- Discuss the importance of environmental sustainability.
- Demonstrate the adoption of environmental sustainability methods at work for minimizing pollution, water wastage, and maximizing energy conservation.

Duration: 10:00	Duration: 10:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Explain the concept and importance of energy conservation. ● Describe the possible actions to optimize energy consumption and minimize energy wastage. ● Explain the concept of environmental pollution and its impact on the health of self, community, and planet. ● Describe the possible actions to be taken to minimize environmental pollution at work. ● Explain various guidelines to be followed for hazardous waste management and disposal of waste. 	<ul style="list-style-type: none"> ● Create a checklist of energy conservation practices during and post-work. ● Classify waste into recyclable, non-recyclable, and hazardous. ● Demonstrate the sustainable waste disposal- process.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector/ screen, Computer speakers, Pencil	
Tools, Equipment and Other Requirements	
color-coded waste bin bag, color-coded waste container	

Module 4: Display sensitivity towards all genders and people with disability

Mapped to LFS/N0119, v3

Terminal Outcomes:

- Describe the Prevention of Sexual harassment (POSH) Act at the workplace.
- Demonstrate how to respect all genders and cultures.
- Explain the importance of sensitivity towards people with disability.

Duration: 05:00	Duration: 05:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Discuss the rules laid by the Sexual Harassment of Women at Workplace (Prevention, Prohibition, and Redressal) Act and the provided penalties for violation. ● Explain the importance of gender sensitive behaviour. ● Explain the procedure to report inappropriate behaviour e.g. sexual harassment. ● Describe the importance of an equal opportunity work culture. ● Discuss the importance of respecting other’s cultures, religion, and caste. ● Explain the need for sensitivity towards people with disabilities. ● Explain the correct ways of communication and collaboration with people with disabilities in compliance with the legal framework. ● Identify stereotypes and prejudices associated with people with disabilities and the negative consequences of prejudice and stereotypes. 	<ul style="list-style-type: none"> ● Demonstrate appropriate verbal and nonverbal communication that is respectful of gender, religion, disability, etc. ● Prepare a list of gender neutral communication terms.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speakers, flip charts	
Tools, Equipment and Other Requirements	
N/A	

Module 5: Employability Skills (90 Hours)

Mapped to DGT/VSQ/N0103- v1.0

Introduction to Employability Skills

After completing this programme, participants will be able to:

- PC1. Outline the importance of Employability Skills for the current job market and future of work
- PC2. List different learning and employability related GOI and private portals and their usage
- PC3. Research and prepare a note on different industries, trends, required skills and the available opportunities

Constitutional values - Citizenship

- PC4. Explain the constitutional values, including civic rights and duties, citizenship, responsibility towards society and personal values and ethics such as honesty, integrity, caring and respecting others that are required to become a responsible citizen
- PC5. Demonstrate how to practice different environmentally sustainable practices

Becoming a Professional in the 21st Century

- PC6. Discuss relevant 21st century skills required for employment
- PC7. Highlight the importance of practicing 21st century skills like Self-Awareness, Behavior Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn etc. in personal or professional life
- PC8. Create a pathway for adopting a continuous learning mindset for personal and professional development

Basic English Skills

- PC9. Show how to use basic English sentences for everyday conversation in different contexts, in person and over the telephone
- PC10. Read and understand text written in basic English
- PC11. Write a short note/paragraph / letter/e -mail using correct basic English

Career Development & Goal Setting

- PC12. Create a career development plan
- PC13. Identify well-defined short- and long-term goals

Communication Skills

- PC14. Demonstrate how to communicate effectively using verbal and nonverbal communication etiquette
- PC15. Write a brief note/paragraph on a familiar topic
- PC16. Explain the importance of communication etiquette including active listening for effective communication
- PC17. Role play a situation on how to work collaboratively with others in a team

Diversity and Inclusion

- PC18. Demonstrate how to behave, communicate, and conduct appropriately with all genders and PwD
- PC19. Discuss the significance of escalating sexual harassment issues as per POSH act

Financial and Legal Literacy

- PC20. Discuss various financial institutions, products, and services
- PC21. Demonstrate how to conduct offline and online financial transactions, safely and securely and check passbook/statement

Associate-Clinical Research Management (Pharma, Biologics and Medical devices)

- PC22. Explain the common components of salary such as Basic, PF, Allowances (HRA, TA, DA, etc.), tax deductions
- PC23. Calculate income and expenditure for budgeting
- PC24. Discuss the legal rights, laws, and aids

Essential Digital Skills

- PC25. Describe the role of digital technology in day-to-day life and the workplace
- PC26. Demonstrate how to operate digital devices and use the associated applications and features, safely and securely
- PC27. Demonstrate how to connect devices securely to internet using different means
- PC28. Follow the dos and don'ts of cyber security to protect against cyber crimes
- PC29. Discuss the significance of displaying responsible online behavior while using various social media platforms
- PC30. Create an e-mail id and follow e-mail etiquette to exchange e-mails
- PC31. Show how to create documents, spreadsheets and presentations using appropriate applications
- PC32. utilize virtual collaboration tools to work effectively

Entrepreneurship

- PC33. Explain the types of entrepreneurship and enterprises
- PC34. Discuss how to identify opportunities for potential business, sources of funding and associated financial and legal risks with its mitigation plan
- PC35. Describe the 4Ps of Marketing-Product, Price, Place and Promotion and apply them as per requirement
- PC36. Create a sample business plan, for the selected business opportunity

Customer Service

- PC37. Classify different types of customers
- PC38. Demonstrate how to identify customer needs and respond to them in a professional manner
- PC39. Discuss various tools used to collect customer feedback
- PC40. Discuss the significance of maintaining hygiene and dressing appropriately

Getting ready for apprenticeship & Jobs

- PC41. Draft a professional Curriculum Vitae (CV)
- PC42. Use various offline and online job search sources to find and apply for jobs
- PC43. Discuss the significance of maintaining hygiene and dressing appropriately for an interview
- PC44. Role play a mock interview
- PC45. List the steps for searching and registering for apprenticeship opportunities

Module 6: Clinical trial site coordination

Mapped to LFS/N3503, v3

Terminal Outcomes:

- Describe various scenarios at work that demand coordination and collaboration with the manager, team, and cross-functional stakeholders.
- Demonstrate the effective coordination and collaboration with manager, cross-functional teams.
- Demonstrate how to participate in audit interviews.

Duration: 60:00	Duration: 150:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Discuss roles and responsibilities of sponsors, CRO (Clinical Research Organizations) and SMO (Site Management Organizations) ● List the functional and cross-functional stakeholders in site management/coordination for Associate-Clinical Research Management. ● Explain the best strategies of collaborating with cross functional teams and vendors involved in clinical trials / BA-BE Study. ● Explain steps for corrective actions/ follow up actions at site in case of an event/adverse event/ serious adverse event/ serious adverse reaction in a clinical trial / BA-BE Study to ensure patient/ volunteer safety and Good Clinical Practices (GCP) compliance ● Explain efficient and clear communication methods for reporting events/ deviations in clinical trial / BA-BE Study to principle investigator or co-investigator and CRO/sponsor to ensure patient/ volunteer safety and Good Clinical Practices (GCP) compliance ● Explain the importance and role of a protocol and its training to all site team before execution of a clinical research project at site ● Explain the process of a site monitoring and role of a site coordinator in the same ● Explain the process of site inspection by regulatory agency or by ethics committee ● Explain the techniques for gaining emotional stability. ● Discuss various ways for conflict resolution. 	<ul style="list-style-type: none"> ● Perform documented shift handovers to the next person in the shift at site. ● Demonstrate how to effectively communicate and collaborate with various stakeholders (e.g. cross functional teams, principle investigator or co-investigator and CRO/sponsor etc.) in a simulated environment for multiple scenarios. ● Demonstrate how to manage corrective actions/ follow up actions at site (in a mock environment) in case of an event/adverse event/ serious adverse event/ serious adverse reaction in a clinical trial / BA-BE Study to ensure patient/ volunteer safety and Good Clinical Practices (GCP) compliance ● Demonstrate activities of a site coordinator during a mock site monitoring visit ● Respond to regulatory audit questions in a mock audit situation. ● Demonstrate how to resolve conflict in multiple scenarios.

- Describe the problem-solving techniques for routine work-related issues.

Classroom Aids:

Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil

Tools, Equipment and Other Requirements

N/A

Module 7: Reporting and documentation for site coordination

Mapped to LFS/N3504, v3

Terminal Outcomes:

- Explain the methods of reporting and documentation as per ALCOA+.
- Discuss how to perform documentation for site coordination/ site management in compliance with Good Documentation Practices(GDP) and Good Clinical Practices (GCP) and other regulatory guidelines.

Duration: 60:00	Duration: 120:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Describe the types of documentation at a clinical trial site and the importance of maintaining the records. ● Explain the method of reporting and documentation for clinical research site management as per Good Documentation Practices(GDP), Good Clinical Practices (GCP) and other regulatory guidelines. ● Describe the Attributable, Legible, Contemporaneous, Original, and Accurate Plus (ALCOA +) principle and its importance. ● Discuss the use of eCRF and eConsent Form and other digital tools in site related documentation during a Clinical Trial or BA/BE study. ● Discuss the importance of generic data like employment record, qualification certificates, training records, signature logs and attendance/ access control records in meeting compliance with GCP and GDP. ● Discuss the use of AI and Cloud computing softwares for enrolment, selection and tracking of volunteers/ patients during and after the clinical trial or BA/BE Study. ● Discuss the importance of ethics committee and regulatory body’s communication and approvals before starting the clinical trial or BA/BE Study. ● Explain the steps for generating an internal audit report and audit response to sponsor/ regulatory audit observations 	<ul style="list-style-type: none"> ● Demonstrate mock reporting and documentation for various site coordination / management activities and scenarios in compliance with study protocol, GCP and regulatory guidelines. ● Demonstrate the steps to prepare audit reports as per internal audit performed in a simulated environment ● Demonstrate the steps to prepare an audit observation response for a dummy audit report
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	

Associate-Clinical Research Management (Pharma, Biologics and Medical devices)



Tools, Equipment and Other Requirements

ICH-GCP guideline book, Sample of Formats used at a Clinical Research Site, Opensource software for Clinical Trial documentation

Module 8: Clinical trial monitoring

Mapped to LFS/N3501, v3

Terminal Outcomes:

- Discuss the clinical trial monitoring protocols.
- Demonstrate site monitoring for a clinical trial site / BA/BE study site.
- Explain and demonstrate importance of clinical trial site monitoring for patient/ volunteer safety

Duration: 60:00	Duration: 150:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Explain concepts of disease physiology and reason of disease condition. ● Discuss licensing requirements for drug import and biological sample exports. ● Explain different phases of the clinical trial. ● Explain the site activation process ● Explain the site monitoring process during a site visit ● Discuss drug related safety events and adverse events. 	<ul style="list-style-type: none"> ● Perform source data verification for evaluating the participant’s eligibility and protection of participant’s rights in a mock setting. ● Demonstrate how to conduct clinical site monitoring and audits. ● Demonstrate how to report drug related adverse events to all concerned stakeholders and ethics committee. ● Demonstrate how to review case report forms (CRFs).
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
ICH GCP guidelines books, Sample participant consent forms , Sample case report forms, case study reports, Sample audit reports, Opensource software for Clinical Trial documentation	

Module 9: Reporting and documentation for site monitoring

Mapped to LFS/N3502, v3

Terminal Outcomes:

- Discuss and demonstrate how to perform documentation during a Clinical Trial Site initiation and activation
- Discuss and demonstrate how to perform Clinical Trial Site monitoring reporting
- Explain and demonstrate how to write and report clinical trial progress at a site

Duration: 60:00	Duration: 120:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Explain WHO regulations and ICH- Good Clinical Practices (GCP) guidelines for documentation. ● Explain purpose and methodology of clinical trial reporting. ● Explain the steps of drafting a site initiation/ activation report. ● Discuss the format and steps of writing site monitoring visit reports and Clinical trial progress report ● Discuss the reports required to be developed for any serious adverse event/ serious adverse reaction ● Discuss the operating procedure of eCRFs and e-reporting in an open source clinical research management software ● Discuss various communication requirement with ethics committee and regulatory body by CROs before and during the clinical trial / BA-BE study 	<ul style="list-style-type: none"> ● Demonstrate how to develop, draft, and write the trial protocols. ● Perform reporting and documentation for each stage of clinical site monitoring in compliance with regulatory guidelines. ● Demonstrate how to prepare site monitoring visit reports. ● Demonstrate the steps to write the reports for any serious adverse event/ serious adverse reaction ● Demonstrate the operating steps for reviewing eCRFs and submission of e-reports in an open source clinical research management software
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
ICH-GCP guideline book, Sample of Formats used at a Clinical Research Site, Opensource software for Clinical Trial documentation	

Module 10: Clinical data management

Mapped to LFS/N3505, v3

Terminal Outcomes:

- Explain the importance and need of Clinical Data Management in a Clinical Trial/ BA-BE Study
- Discuss various methods and processes in clinical data management
- Demonstrate operating procedures of various softwares used in clinical data management

Duration: 120:00	Duration: 270:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Explain characteristics of the investigational drug in the clinical study. ● Explain the concepts of medical coding. ● Discuss medical, clinical research, and Data Management process and terminology. ● Discuss clinical data management (CDM) Process and methods to collect, store, and disseminate clinical trial data. ● Discuss the method of eCRF design and basics of Database design ● Discuss the concepts of edit check design and edit check ● Discuss the steps for data validation and data cleaning ● Discuss the processes for locking the databases and freezing the data extraction ● Discuss the methods and strategies for discrepancy management in CDM ● Discuss the operating steps of a clinical data management software 	<ul style="list-style-type: none"> ● Demonstrate how to design and develop the eCRF. ● Demonstrate how to fill the data in 2 sample CRF(s) for database testing. ● Demonstrate how to create eCRFs using any of the EDC tools. ● Demonstrate the steps for Data Validation and data cleaning ● Demonstrate the steps for database lock and freezing data extraction ● Demonstrate how to coordinate with Clinical Trial team for any discrepancy or coordination for clinical data management
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
Opensource Clinical Data Management Software / EDC tool for Clinical Trials, Opensource Clinical Database	

Module 11: Biostatistical analysis

Mapped to LFS/N3508, v1

Terminal Outcomes:

- Define, structure, and preprocess clinical/research datasets, ensuring data integrity, compliance with statistical assumptions, and adherence to regulatory requirements.
- gain proficiency in handling missing data, transforming datasets, and applying statistical diagnostics to optimize data quality for accurate hypothesis testing and modeling.
- Demonstrate meaningful data visualizations, generate structured reports, and present statistical findings using standardized techniques for regulatory, research, and industry applications.

Duration: 30:00	Duration: 90:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Define the format, structure, and statistical specifications of research/clinical datasets to ensure compatibility with analytical methods. ● Identify and differentiate continuous, categorical, and ordinal data for appropriate statistical treatment. ● Explain mean/mode imputation, regression, and multiple imputation methods. ● Discuss normalization, standardization, and log transformation for statistical modeling. ● Explain techniques for detecting incorrect data types, redundant data, and outliers. ● Identify key goals such as trend analysis, hypothesis testing, and predictive modeling. ● Discuss principles of structured reports, standard templates, and clear narratives. ● Explain when and how to use histograms, box plots, Kaplan-Meier curves, and forest plots. 	<ul style="list-style-type: none"> ● Demonstrate how to structure datasets with indexing strategies for efficient statistical computation. ● Demonstrate how to apply statistical methods to handle missing data. ● Demonstrate how to modify incorrect formats to ensure compatibility with analytical models. ● Demonstrate the steps to Create meaningful subsets for hypothesis testing and subgroup analysis. ● Demonstrate the steps for Implement normalization, standardization, and log transformation. ● Demonstrate how to Use statistical diagnostics such as descriptive statistics and outlier detection. ● Demonstrate how to create appropriate charts and graphs using statistical software. ● Demonstrate how to Summarize key findings using clear, standardized templates. ● Demonstrate how to Cross-check visual outputs with statistical analyses and stakeholder feedback. ● Demonstrate how to Export and disseminate reports and visualizations across research and regulatory platforms.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
Opensource Clinical Data Management Software / EDC tool for Clinical Trials, Opensource Clinical Database	

Module 12: PK – PD Statistical analysis

Mapped to LFS/N3509, v1

Terminal Outcomes:

- Apply unbiased study design methods, determine sample size, and conduct interim analysis for clinical trials.
- Performing pharmacokinetic and pharmacodynamic calculations, data imputation, and statistical modeling.
- Demonstrate how to generate high-quality tables, listings, and figures using automated, reproducible programming practices for regulatory and research purposes.

Duration: 30:00	Duration: 90:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Explain the significance of pharmacokinetics (PK) and pharmacodynamics (PD) in clinical research. ● Discuss randomization, allocation concealment, and blinding to minimize bias in trials. ● Understand the impact of sample size and effect size on study reliability. ● Describe stopping rules for safety and efficacy oversight in clinical trials. ● Explain how statistical methodologies are applied in manuscripts and regulatory submissions. ● Explain methods for handling missing data and the role of Statistical Analysis Plans (SAP). ● Explain the significance of parameters like Cmax and AUC in PK/PD analysis. ● Explain the principles of generating clear, concise, and standardized tables, listings, and figures (TLFs) 	<ul style="list-style-type: none"> ● Demonstrate how to apply unbiased randomization and allocation concealment methods. ● Demonstrate how to use statistical tools to determine optimal sample size based on clinical relevance. ● Demonstrate how to plan safety and efficacy monitoring with clear stopping rules. ● Demonstrate the steps to contribute to manuscripts and reports with validated statistical methodologies. ● Demonstrate the steps to compute key pharmacokinetic and pharmacodynamic parameters such as Cmax and AUC. ● Demonstrate how to Verify completeness and clarity of study reports and diaries. ● Demonstrate how to Justify imputation methods and ensure appropriate handling of missing data. ● Demonstrate how to perform PK/PD analysis using tools like Vinolin and Phoenix. ● Demonstrate how to ensure models align with study design, verifying assumptions and justifications. ● Demonstrate how to implement reproducible programming techniques to minimize errors in statistical reporting.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
Opensource Clinical Data Management Software / EDC tool for Clinical Trials, Opensource Clinical Database	

Module 13: algorithm for Biostatistical analysis

Mapped to LFS/N3510, v1

Terminal Outcomes:

- create, refine, and optimize statistical algorithms for research/clinical data challenges.
- Perform SAS, R, and Python for research/clinical data analysis.
- Demonstrate how to validate and refine statistical models, ensuring adherence to research/clinical protocols and regulatory standards

Duration: 45:00	Duration: 75:00
<p>Theory – Key Learning Outcomes</p> <ul style="list-style-type: none"> ● Explain key statistical principles and mathematical models for research/clinical data analysis. ● Discuss the development of statistical algorithms for adaptive research designs, missing data imputation, and longitudinal data analysis. ● Explain how AI/ML models enhance predictive analytics, patient stratification, and biomarker discovery. ● Describe methods like parallel processing, cloud computing, and memory-efficient data handling. ● Explain benchmarking techniques to ensure accuracy, reproducibility, and regulatory adherence in research/clinical studies. ● Discuss the role of SAS, R, and Python in research/clinical data analysis and modeling. ● Explain key techniques such as survival analysis, mixed-effects models, and propensity score matching. ● Discuss compliance with research/clinical guidelines such as ICH E9, FDA, and EMA. 	<p>Practical – Key Learning Outcomes</p> <ul style="list-style-type: none"> ● Demonstrate how to Design custom algorithms to address research/clinical data analysis challenges. ● Demonstrate how to Develop predictive analytics and biomarker discovery models for research/clinical applications. ● Demonstrate how to Apply parallel processing and cloud-based computing techniques to enhance algorithm efficiency. ● Demonstrate the steps to Test algorithm accuracy and reproducibility using real-world research/clinical datasets. ● Perform analysis using survival models, mixed-effects models, and propensity score matching. ● Demonstrate how to Develop scripts in SAS, R, or Python for research/clinical data analysis. ● Demonstrate how to Modify existing statistical methodologies to meet research/clinical data analysis requirements. ● Demonstrate how to Ensure robustness and reliability of statistical models. ● Demonstrate how to Present algorithmic results in research/clinical-compliant formats. ● Demonstrate how to Collaborate with teams and regulatory stakeholders to ensure compliance with research/clinical protocols.
<p>Classroom Aids:</p> <p>Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil</p>	
<p>Tools, Equipment and Other Requirements</p> <p>Opensource Clinical Data Management Software / EDC tool for Clinical Trials, Opensource Clinical Database</p>	

Module 14: AI/ML Applications in biostatistical analysis

Mapped to LFS/N3511, v1

Terminal Outcomes:

- Perform feature selection and dimensionality reduction (e.g., PCA, LASSO) to identify potential biomarkers.

Duration: 15:00	Duration: 15:00
Theory – Key Learning Outcomes	Practical – Key Learning Outcomes
<ul style="list-style-type: none"> ● Explain the role of AI/ML models in enhancing predictive analytics within clinical research settings. ● Describe patient stratification techniques enabled by machine learning for improving targeted therapies and personalized medicine ● Explain Techniques for clustering patients into subgroups using omics, clinical, and biomarker data. ● Explain how AI/ML accelerates biomarker discovery from large-scale omics and clinical datasets. ● Discuss common ML algorithms (e.g., logistic regression, random forest, clustering) used in clinical predictive models. ● Identify ethical, regulatory, and data privacy considerations when applying AI/ML models in life sciences. 	<ul style="list-style-type: none"> ● Develop and validate a predictive ML model to forecast disease risk or treatment outcomes using sample patient data. ● Apply clustering algorithms (e.g., K-means) to stratify patient groups based on clinical or genomic profiles. ● Perform feature selection and dimensionality reduction (e.g., PCA, LASSO) to identify potential biomarkers. ● Evaluate model performance using appropriate metrics such as accuracy, precision, recall, and ROC-AUC. ● Use explainable AI tools (e.g., SHAP, LIME) to interpret model predictions and ensure transparency.
Classroom Aids:	
Whiteboard, Marker Pen, Computer or Laptop attached to LCD projector, Scanner, Computer speaker, Pencil	
Tools, Equipment and Other Requirements	
Opensource Clinical Data Management Software / EDC tool for Clinical Trials, Opensource Clinical Database	

Module 15: Apprenticeship Training

Mapped to Associate-Clinical Research Management

Mandatory Duration: 00:00	Recommended Duration: 990:00
Module Name: On the Job Training	
Location: On-Site	
Terminal Outcomes	
<ul style="list-style-type: none">● Ensure environment sustainability and sensitivity towards all genders and people with disability.● Monitor the clinical trial site to ensure that ICH GCP guidelines, study protocol and applicable regulations are followed.● Carry out reporting and documentation for site monitoring activities as per regulatory standards.	

Annexure

Trainer Requirements

Trainer Prerequisites						
Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training Experience		Remarks
		Years	Specialization	Years	Specialization	
Graduate	B.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/Biotechnology)	7	Associate - Clinical Research Management (Pharma, Biologics and Medical devices)	0	NA	
Graduate	B.Pharmacy B.Tech (Biotechnology) M.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/Biotechnology) BAMS/BDS/BUMS/BHMS	6	Associate - Clinical Research Management (Pharma, Biologics and Medical devices)	0	NA	
Post Graduate	MBBS M.Tech (Biotechnology) M. Pharmacy	4	Associate - Clinical Research Management (Pharma, Biologics and Medical devices)	0	NA	
Vocation Qualification	Clinical Research Associate at NSQF Level 5, mapped to QP "LFS/Q0503, v1&LFS/Q3501 v1, v2	4	Associate - Clinical Research Management (Pharma, Biologics and Medical devices)	0	NA	

Trainer Certification	
Domain Certification	Platform Certification
Certified for Job Role: "Associate - Clinical Research Management (Pharma, Biologics and Medical devices)" mapped to QP: "LFS/Q3501, v3" with minimum accepted score of 80%.	Recommended that the Trainer is certified for the Job Role: "Trainer (VET and Skills)", mapped to the Qualification Pack: "MEP/2601, v3.0" with minimum score of 80%.

Associate-Clinical Research Management (Pharma, Biologics and Medical devices)

Assessor Requirements

Assessor Prerequisites						
Minimum Educational Qualification	Specialization	Relevant Industry Experience		Training/Assessment Experience		Remarks
		Years	Specialization	Years	Specialization	
Graduate	B.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/Biotechnology)	7	Associate - Clinical Research Management (Pharma, Biologics and Medical devices)	1	Teaching/ Assessment / Inhouse Training	
Graduate	B.Pharmacy B.Tech (Biotechnology) M.Sc. (Biology/Nursing/Medical Lab technician/Life Sciences/Biotechnology) BAMS/BDS/BUMS/BHMS	6	Associate - Clinical Research Management (Pharma, Biologics and Medical devices)		Teaching/ Assessment / Inhouse Training	
Post Graduate	MBBS M.Tech (Biotechnology) M. Pharmacy	4	Associate - Clinical Research Management (Pharma, Biologics and Medical devices)	1	Teaching/ Assessment / Inhouse Training	
Vocation Qualification	Clinical Research Associate at NSQF Level 5, mapped to QP "LFS/Q0503, v1 & LFS/Q3501 v1	4	Associate - Clinical Research Management (Pharma, Biologics and Medical devices)	1	Teaching/ Assessment / Inhouse Training	

Assessor Certification	
Domain Certification	Platform Certification
Associate - Clinical Research Management (Pharma, Biologics and Medical devices) mapped to the Qualification Pack: "LFS/Q3501, v3." with minimum accepted score of 80%.	Recommended that the Assessor is certified for the Job Role: "Assessor (VET and Skills)", mapped to the Qualification Pack: "MEP/Q2701, v3.0" with minimum score of 80%.

Associate-Clinical Research Management (Pharma, Biologics and Medical devices)

Assessment Strategy

This section includes the processes involved in identifying, gathering, and interpreting information to evaluate the learner on the required competencies of the program.

The assessment for the Training will be conducted toward the end of the training duration.

Assessment Process:

For Execution of the assessment for training, LSSSDC will be engaging more than one assessment agency/ body.

1.1 Criteria of selection of assessment body/agency:

The assessment body/agency is selected based on

- Prior experience and understanding of Life Sciences or similar sectors.
- Experience in conducting assessments for similar job roles.
- Manpower and Technical capabilities.
- Geographical reach
- Existing Network in the Life Sciences Sector
- Agencies internal policies to maintain standards, quality & professional Integrity
- Agencies policy in assessor management

1.2 Assessment tool for Training:

For the Training assessment, the assessment instrument development is done by the selected assessment body with close monitoring and support of LSSSDC at every stage.

1.2.1 Digital Written test for knowledge assessment:

Scope – Is used to test the knowledge component of the QP.

Tools –computer or tab based online or offline.

Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses.

Analysis – Question paper is divided into sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

2.2.2 Digital Written test for skill assessment:

Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested.

Associate-Clinical Research Management (Pharma, Biologics and Medical devices)

Tools – computer or tab based online or offline questions

Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations.

Analysis – Question paper is divided into sections. Each Section intends to assess a particular skill field of the trainee. Thus, section-wise calculation of marks gives a clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

2.3 Steps for assessment development:

- The selection of assessment tool(s) is done as per the assessment criteria prescribed in the Qualification Pack.
- For Associate - Clinical Research Management (Pharma, Biologics and Medical devices) assessment a blueprint of the question paper is part of the assessment tool for training.
- Development of layout of Question paper is such that the entire PCs (Performance Criteria) of that QP are covered.
- Score per question maps with the weightage given to that PC, in the assessment criteria, and the level of difficulty of the question.
- An expert from industry is selected who is called “Subject Matter Expert” (SME). This SME must have over 13-15 years of experience in the industry in Clinical Trials occupation.
- SME is screened and approved by LSSSDC. He is oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, and ending the desired outcome of the assessment.

2.4 Execution of Training Assessment:

- Once LSSSDC receives the OJT assessment results, the assessment date for training is decided with common agreement of Industry and LSSSDC, and in turn is directed to an assessment body/agency.
- Assessment agency ensures the availability of required infrastructure, tools for the assessment.
- The assessment is executed in two possible ways depending on the choice of the industry:

2.4.1 Tab based assessment using physical proctoring

2.4.2 Smartphone-based assessment using e-proctoring

2.4.1 Tab-based assessment using physical proctoring

- A representative from the Assessment agency is present on the day of assessment to execute the assessment at the venue in case of physical proctoring.
- The assessment agency representative carries an identity card and letter from the council authorizing to conduct the assessment.

Associate-Clinical Research Management (Pharma, Biologics and Medical devices)

- Assessment agency representative ensures the authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, Election card, etc)
- The assessment agency representative maintains the records of attendance, verified documents, and tablet instruments used in the assessment.
- Assessment agency representative collects evidence of the assessment in the best possible way (videos, pictures, voice recordings, etc)
- Assessment agency representative transfers the assessment scores from the tab to the assessment agency server, using a secure, encrypted web-based program.
- The assessment agency, after processing the results and putting them in standard format, hands it over to LSSSDC within 7 days of assessment.

2.4.2 Smartphone-based assessment using e-proctoring

- All trainees due for assessments are registered on an assessment tool application using their unique mobile number and e-mail ID along with a Govt. ID issued proof.
- An assessment link is sent to the mail ID of each trainee with a defined expiry date of the link.
- Trainee at any location can click on the link using his/her smartphone or a web camera-enabled computer system
- Using the unique credentials and Govt ID number, the trainee logs in for the start of assessment and completes the assessment.
- The authenticity of Trainee's identity is done by assessment application by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, election card, etc.) and a live photo capture
- A live video of the candidate during the assessment is captured to collect the evidence of the assessment
- Once the assessment is complete, the assessment application automatically assess scores to the assessment agency server, using a secure, encrypted web-based program.
- The assessment agency, after processing the results and putting them in standard format, hands it over to LSSSDC within 7 days of assessment.

References

Glossary

Term	Description
Declarative Knowledge	Declarative knowledge refers to facts, concepts, and principles that need to be known and/or understood to accomplish a task or to solve a problem.
Key Learning Outcome	The key learning outcome is the statement of what a learner needs to know, understand, and be able to do to achieve the terminal outcomes. A set of key learning outcomes will make up the training outcomes. Training outcome is specified in terms of knowledge, understanding (theory), and skills (practical application).
OJT (M)	On-the-job training (Mandatory); trainees are mandated to complete specified hours of training on-site
OJT (R)	On-the-job training (Recommended); trainees are recommended the specified hours of training on-site
Procedural Knowledge	Procedural knowledge addresses how to do something, or how to perform a task. It is the ability to work or produce a tangible work output by applying cognitive, affective, or psychomotor skills.
Training Outcome	Training outcome is a statement of what a learner will know, understand, and be able to do upon the completion of the training .
Terminal Outcome	The terminal outcome is a statement of what a learner will know, understand, and be able to do upon the completion of a module . A set of terminal outcomes helps to achieve the training outcome.

Acronyms and Abbreviations

Term	Description
QP	Qualification Pack
NSQF	National Skills Qualification Framework
NSQC	National Skills Qualification Committee
NOS	National Occupational Standards
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
WHO	World Health Organization
SOP	Standard Operating Procedure
MSDS	Material Safety Data Sheets
GDP	Good Documentation Practices
EHS	Environment Health Safety
PPE	Personal Protective Equipment
OOS	Out of Specification
OOT	Out of Trend