Associate - Clinical Research

Aligned to Qualification Pack: LFS/Q03501,

Level 5 of Life Science Sector Skill Development Council

VERSION 1

SYLLABUS

SHRM Version	1.0
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Course Objective

Sl.No.	Learning Outcomes
1.	Perform role as Associate-Clinical Research Management in compliance with Good Manufacturing Practices (GMP) and GCP(Good Clinical Practices) and other environmental regulatory guidelines.
2.	Design Protocol sample, Demonstrate how to conduct clinical trial monitoring and site coordination.
3.	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)
4.	Demonstrate how to coordinate with supervisor, colleagues and respond to audit queries during GMP/ regulatory audits.
5.	Demonstrate sensitivity towards genders, cultures and specially-abled persons.
6.	Thorough understanding of the required elements of the informed consent, impact of quality assurance and audits in clinical research
7.	Learn how to manage adverse impact, site management, project monitoring etc.
8.	Perform the required activities to effectively report and document the clinical trials monitoring process
9.	Monitor the working environment and ensuring requirements for health, safety, security in the testing/ pharmaceutical/ contract research/ biopharmaceutical facility/ manufacturing/ analysis/ research laboratory
10	Work effectively in a team, coordination with team members , coordinate with the site/ CRO team for clinical research and coordinate with principal investigator, site manager, vendor, clinical research coordinator for clinical trial
11	Able to respond to audit queries by citing evidence of work done.

Course Anatomy

Total duration of the course	355 hours (of theory and practical sessions) and 1020 hours of Apprenticeship
	Semester I : Six months of Training - Theory and Practical (500 hours) Theory - 164 hours | Practical 191 hours | Elective - Additional 145 Hours Students will have options to select electives in any or more of a) Site Management. b) Clinical Research Study Monitoring, c) Data Management Semester II : Six months of Apprenticeship (1020 hours) On any of the electives
Course structure	One year | Two Semesters Three Electives a) Site Management b) Clinical Research Trial Management c) Data Management Students can take one or more electives. First two electives have been built as compulsory electives Semester 2 - Apprenticeships under NAPS OR Internship Apprenticeship will be with companies based on any elective they select
Assessment Criteria	Students will be assessed by Life Science Sector Skill Council at the end of semester 1.
Training Input	In blended mode Practicals supported by few healthcare organisations and CRO and also in demo and mock environment
Lesson Planning	The session duration of 1.5 hour per session and number of sessions of 2 per day is indicative. Trainer can suitable modify these suiting their local requirement. This has to be done at the beginning of each batch after getting the same approved by SHRM

(*) 1.5 hour per session, and 2 sessions a day

What industry is looking for

Clinical Research is a Life Science domain that has grown significantly in recent times and there is tremendous dearth of skilled resources.

Any organisation intending to get into Clinical Research will need skilled resources as Clinical Research associate so that they can confidently create clinical research sites in their organisation.

Going by increased health consciousness, Pharma companies are coming with newer drugs, enhancing efficacy and new processes

As a result several healthcare establishments and CROs are getting into Clinical Research as a business opportunity. Consequently there is a manifold increase in CR sites. But industry is not getting resources who can support in the entire value chain from pre-site works to site readiness, site management, regulatory works, data management and reports

Program uniqueness

1. The course covers the entire lifecycle of Clinical trial and research that an associate has to perform. The person will be the key resource in the entire trial and research process
2. Curriculum designed in collaboration with industry and Life Science Sector Skill Development Council (LSSSDC) that covers entire value chain from pre-site works to site readiness, site management, trial coordination, regulatory works, data management and reports

3. Students get the opportunities to do field work at the actual sites even before the internship starts, thus providing live experiences. Industry tie up with key users of the resources for training support and internship
4. Six months of paid internship/ apprenticeship is built in the curriculum. Students earn in last 6 months
5. Several project assignments and interactive sessions, contents and Certification from LSSSDC, Govt of India.
6. Golden opportunity for bio science, pharma students, bio-technology, micro-biology, physiology/ pharmacology, BDS/ BHMS students to boost their career in their study domain for career in the emerging clinical trial landscape
7. Delivered by Doctors and Clinical Research experts engaged with clinical trial and research
8. Extensive soft skill classes and grooming

Role Description

Clinical Research Associate (CRA) is involved in all stages of the clinical trial, including supporting the identification of an investigational site and setting up, initiating, monitoring and closing down the trial. The person will be responsible for supporting clinical trial activities, carrying out reporting and documentation of research activities and data management.

As a part of supporting clinical trial activities, the CRA carries out reporting and documentation for monitoring of research activities so as to ensure regulatory compliance and good clinical practices. Tasks vary depending on the employer and level of experience. However, CRAs typically need to:

- Will be involved in the entire value chain of clinical trial and research right from regulatory approval, protocol, managing trial sites, trial monitoring, research reports and approval support.
- Clinical trial site readiness, engagement during trials, impact of quality assurance and audits in clinical research
- Will be able to monitor clinical trials for effectiveness, ethical practices, Safety, and participants during a clinical trial for safety and their rights
- Perform the required activities to effectively report and document the clinical trials monitoring process
- Develop and write trial protocols (outlining purpose and methodology)
- Present trial protocols to a steering committee
- Design data collection forms, known as case report forms (CRFs)
- Coordinate with the ethics committee, which safeguards the rights, safety and wellbeing of all trial subjects
- Manage regulatory authority applications and approvals that oversee the research and marketing of new and existing drugs
- Identify & assess the suitability of facilities to use as the clinical trial site
- Identify/select an investigator who will be responsible for conducting the trial at the trial site
- Thorough understanding of the required elements of the informed consent, managing adverse impact, managing the patient for trial
- Liaise with doctors, consultants or investigators on conducting the trial
- Set up the trial sites - ensuring each centre has the trial materials, including the trial drug often known as the investigational medicinal product (IMP)
- Train the site staff to trial-specific industry standards

- Monitor the trial throughout its duration, which involves visiting the trial sites on a regular basis
- Verify that data entered on to the CRFs is consistent with patient clinical notes, known as source data/document verification (SDV)
- Collect completed CRFs from hospitals and general practices
- Write visit reports and file and collate trial documentation and reports
- Ensure all unused trial supplies are accounted for
- Close down trial sites on completion of the trial
- Discuss results with a medical statistician, who writes technical trial reports and archive study documentation and correspondence
- Provide data management support

Who can apply

B. Sc. (Biology, Nursing, Medical Lab technician, Life Sciences , Biotechnology, Pharmaceutical Science)/ B. Pharma / B. Tech (Bio Technology)/ Micro Biology

M. Pharma/ M. Sc/ PhD in Pharmacology

BDS/ BUMS/ BAMS/ BHMS. Medical Graduates will also qualify

Added prerequisites

Flair for research, process orientation, attention to details, documentation

Broad Coverage and Lesson Structure

The curriculum (also to be read as syllabus) comprises of 18 modules of which 16 modules are based on NOS aligned to the Qualification Pack (QP) indicated. These include two electives modules as mandatory and one elective module as optional. There are 1 bridge modules and few auxiliary modules to enable the trainers to meet the course objectives.

Semester 1 : (6 months I 355 Hours, including two electives | Extra 145 Hours for 3rd Elective)

Lesson Modules	NOS	Theory (Hours)	Practical (Hours)	Total (Hours)
Start Up Modules		**58**	**52**	**110**
Module 1: Introduction to Life Sciences industry and the job role	Bridge Module	5		5
Module 2 : Introduction to Clinical Research	LFS/N0509	8	2	10
Module 3 : Basic Principles of Clinical Pharmacology and Drug Action	LFS/N0509	15	5	20
Module 4 : Clinical Trial Protocol and Amendments	LFS/N0509	20	40	60
Module 5 : Ethical Guidelines for Clinical Research	LFS/N0508	10	5	15
Site Management		**34**	**41**	**75**
Module 6 : Clinical trial site coordination, : Manage CRA activities at the site	NOS - LFS/N3503	20	25	45
Module 7 : Reporting and documentation for site coordination - Carry out reporting and documentation for site coordination activities as per regulatory standards	NOS - LFS/N3504	10	15	25
Module 8 : Safety and Hygiene at Clinical Trial Site and workplace	NOS Code LFS/N0101	4	1	5

Lesson Modules	NOS	Theory (Hours)	Practical (Hours)	Total (Hours)
Clinical Study Monitoring		**48**	**62**	**110**
Module 9 : Clinical trial monitoring - Informed Consent	NOS Code LFS/N0509	8	7	15
Module 10 : Clinical trial monitoring - Clinical trial master file	NOS Code LFS/N0509	4	6	10
Module 11 : Clinical trial monitoring - Monitor the clinical trial site to ensure that ICH GCP guidelines, study protocol and applicable regulations are followed	NOS : LFS/N3501	10	10	20
Module 12 :Reporting and documentation for site monitoring - Carry out reporting and documentation for site monitoring activities as per regulatory standards	NOS : LFS/N3502	10	20	30
Module 13 : Project Management in Clinical Trials.	NOS Code LFS/N0508	6	4	10
Module 14 : Safety Definitions and Adverse Event Reporting Requirements.	NOS Code LFS/N0508	10	15	25
Data Management (Compulsory)		**15**	**25**	**40**
Module 15: Clinical data management - Provide support for clinical data management activities	NOS - LFS/N3505	15	25	40
Auxiliary Module		**9**	**11**	**20**
Module 16: Managing environmental sustainability	NOS : LFS/N0119	3	2	5
Module 17 : Display sensitivity towards all genders and people with disability	NOS : LFS/N0119	3	2	5
Module 18 : : Coordinate with team members and site :	NOS Code LFS/N0510	3	7	10
TOTAL	**W/O Data Mgm** **Data Mgmt** **Total**	**164** **45** **209**	**191** **100** **291**	**355** **145** **500**

SYLLABUS

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

Learning Outcome

Program Orientation. Understanding of the overview of the Life Sciences industry in regulation applicable to Associate Clinical Research Management. Understanding the importance of a skilled Associate-Clinical Research Management

Sub Module	Duration
1. Program Orientation 2. Life Sciences industry in Indian and global context. 3. Organizational structure and employment benefits in the life sciences industry 4. Regulations, legislation, and good practices to be followed by AssociateClinical Research Management in a life sciences facility. 5. Basic skills required to perform the job of Associate-Clinical Research Management. 6. Importance of a skilled Associate-Clinical Research Management for efficient clinical trial and patient safety	
PRACTICAL / DEMONSTRATION	
Tools and Documents Guidelines for Good clinical practices (GCP), Indian Council of Medical Research (ICMR) guidelines, good documentation practices (GDP), and Good Laboratory Practices (GLP)	

Module 2: Introduction to Clinical Research : NOS Code LFS/N0509

Learning Outcome

Understanding basic concept of clinical research and trial

Sub Module	Duration
1. Define the basic concepts of clinical research 2. Describe the development process of medical products and the related regulations.	

3. Explain different type of clinical trial 4. Discuss different phases of clinical trial 5. Discuss in detail about good clinical practices (GCP), Indian Council of Medical Research (ICMR) and key regulatory guidelines 6. Discuss in detail about good documentation practices (GDP), and Good Laboratory Practices (GLP) guidelines 7. Steps for corrective actions/ follow up actions needed for ensuring Good Clinical Practices (GCP) compliance 8. Attributable, Legible, Contemporaneous, Original, and Accurate Plus (ALCOA +) principle and its importance. 9. Characteristics of the investigational drug in the clinical study.	
PRACTICAL / DEMONSTRATION	
Tools and Documents	

Module 3 :Basic Principles of Clinical Pharmacology and Drug Action : NOS Code LFS/N0509

Learning Outcome

Understanding basic concepts of clinical pharmacology and drug actions as foundation to any clinical trials. This knowledge is fundamental to the course initiation

Sub Module	Duration
1. Discuss the fundamental concepts of clinical pharmacology encompassing all aspects of the relationship between drugs and humans 2. Describe the relevance of pharmacokinetics and pharmacodynamics in clinical trials 3. Explain the basics of bioavailability and bioequivalence (BA-BE) in clinical studies 4. Discuss the bioassay parameters used in clinical trials 5. What could be various event/adverse event/ serious adverse event/ serious adverse reaction in a BA-BE Study	

or clinical trial which would need attention for patient/ volunteer safety	
PRACTICAL / DEMONSTRATION	
6. Explain the pharmacology concepts with the help of clinical trial protocol samples 7. DEMO - BA - BE Studies samples and student engagements	
Tools and Documents	

Module 4 :Clinical Trial Protocol and Amendments NOS Code LFS/N0509

Learning Outcome

Understanding various clinical trial protocols which would be the basis for any work related to clinical trials including sample protocol design , whatever electives chosen

Sub Module	Duration
1. Explain the main objectives of a clinical trial protocol 2. Discuss the different parts and elements of a clinical trial protocol 3. Describe various types of study design used in clinical research Protocols 4. Explain how to define eligibility criteria for a trial with inclusion and exclusion criteria 5. Discuss how to define safety and adverse event, serious adverse events in protocol 6. Demonstrate how to develop, draft, and write the trial protocols. 7. Basic statistics required in Clinical Research. 8. Explain the statistical calculations required for the protocol design 9. Discuss how to ensure human subjects Protection while drafting protocol 10. Discuss how the research subject`s safety, rights and welfare are protected in a clinical trial while making protocol 11. Identify the investigational product accountability	

requirements and impact of the reconciliation process on the study 12. Discuss in brief about the clinical trial registry of India (CTRI) and the process of clinical trial registration on CTRI	
PRACTICAL / DEMONSTRATION	
13. Exercise of making a study design, with inclusion and exclusion eligibility for a sample trial and making the protocol design 14. Sample statistical calculations required for the protocol design with some sample project 15. Develop a sample clinical trial protocol 16. Fill in the application for online submission of a clinical trial protocol (in a mock situation) 17. Demonstrate how to maintain amendments to protocols and report them to the regulatory authority with dummy/ live samples 18. Mock demonstration of clinical trial registration in CTRI	
Tools and Documents Sample Clinical trial protocol, Sample investigation brochure, sample product insert	

Module 5 : Ethical Guidelines for Clinical Research NOS Code LFS/N0508

Learning Outcome

Sub Module	Duration
1. Explain the core ethical principles of clinical research 2. Discuss how the research subject`s safety, rights and welfare are protected in a clinical trial 3. Summarize the ethical guidelines available in India e.g. national ethical guidelines for biomedical and health research involving human participants 4. Explain the role and responsibilities of the ethical committee (EC) 5. Summarize the process for taking NOC from the ethical committee 6. Importance of ethics committee and regulatory body's communication and approvals before start the clinical trial	

or BA/BE Study. 7. Various communication requirement with ethics committee and regulatory body by CROs before and during the clinical trial / BA-BE study	
PRACTICAL / DEMONSTRATION	
8. Mock sessions to demonstrate process for taking NOC from the ethical committee 9. Organize group meetings to do a mock session with EC members	
Tools and Documents National ethical guidelines for biomedical and health research involving human participants by ICMR	

Module 6 : Clinical trial site coordination : NOS - LFS/N3503

Learning Outcome

Various scenarios at work that demand coordination and collaboration with the manager, team, and cross-functional stakeholders.
The effective coordination and collaboration with manager, cross-functional teams. How to participate in audit interviews.

Sub Module	Duration
1. Roles and responsibilities of sponsors, CRO (Clinical Research Organizations) and SMO (Site Management Organizations) 2. List the functional and cross-functional stakeholders in site management/ coordination. 3. Best strategies of collaborating with cross functional teams and vendors involved in clinical trial / BA-BE Study. 4. Process of a site monitoring and role of a site coordinator in the same 5. Process of site inspection by regulatory agency or by ethics committee 6. How to Respond to regulatory audit questions. DEMO in a mock audit situation. 7. 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 to ensure patient/	

volunteer safety and Good Clinical Practices (GCP) compliance 8. 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 9. Importance and role of a protocol and its training to all site team before execution of a clinical research project at site 10. Techniques for gaining emotional stability. Discuss various ways for conflict resolution.	
PRACTICAL / DEMONSTRATION	
1. 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. 2. 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 site 3. 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.	

Module 7 : Reporting and documentation for site Management : NOS - LFS/N3504

Learning Outcome

Methods of reporting and documentation as per ALCOA+. 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

Sub Module	Duration
1. Types of documentation at a clinical trial site and the importance of maintaining the records. 2. Method of reporting and documentation for clinical	

research site management as per Good Documentation Practices(GDP), Good Clinical Practices (GCP) and other regulatory guidelines. 3. Use of eCRF and eConsent Form and other digital tools in site related documentation during a Clinical Trial or BA/BE study. 4. 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. 5. Steps for generating an internal audit report and audit response to sponsor/ regulatory audit observations.	
PRACTICAL / DEMONSTRATION	
6. Demonstrate mock reporting and documentation for various site coordination / management activities and scenarios in compliance with study protocol, GCP and regulatory guidelines. 7. Demonstrate the steps to prepare audit reports as per internal audit performed in a simulated environment 8. Demonstrate the steps to prepare an audit observation response for a dummy audit report	
Tools and Documents ICH-GCP guideline book, Sample of Formats used at a Clinical Research Site, Open Source software for Clinical Trial documentation	

Module 8 : Safety and Hygiene at Clinical Trial Site and workplace : NOS Code LFS/N0101

Learning Outcome

Sub Module	Duration
1. Explain the basic concepts of safety including hazards,	

accidents, safety signs and signals 2. Explain Heinrich pyramid and practice all above in while at a clinical trial site 3. Explain the biohazards at a clinical trial site 4. List appropriate personal protection equipment (PPEs) for entry and exit in the lab area 5. Explain the fire safety procedure to be followed in case of fire emergency at the workplace 6. Demonstrate emergency and first aid measures	
PRACTICAL / DEMONSTRATION	
7. Demonstrate through mock sessions	
Tools and Documents	

Module 9 : Clinical trial monitoring - Informed Consent NOS Code LFS/N0509

Learning Outcome

Taking informed consent from volunteers

Sub Module	Duration
1. Discuss the importance and purpose of informed consent in a clinical trial 2. Discuss how to document informed consent form for clinical trials 3. Discuss the use of electronic informed consent in clinical investigation 4. Conduct mock consent session	
PRACTICAL / DEMONSTRATION	
5. Design a sample informed consent form 6. Role play for developing the same	
Tools and Documents Sample informed consent form	

Module 10 : Clinical trial monitoring - Clinical trial master file NOS Code LFS/N0509

Learning Outcome

Clinical trial monitoring using the trail master file

Sub Module	Duration
1. Explain the structure and contents of a Trial master file 2. Discuss security and control of the trial master file 3. Demonstrate archival and retention of the trial master file	
PRACTICAL / DEMONSTRATION	
4. Design a sample trial master file 5. sample data for developing the same	
Tools and Documents Sample trial master file	

Module 11 : Clinical trial monitoring : NOS Code - LFS/N3503

Learning Outcome

Clinical trial monitoring protocols.

Site monitoring for a clinical trial site / BA/BE study site. Importance of clinical trial site monitoring for patient/ volunteer safety

Sub Module	Duration
1. Licensing requirement for drug import and biological sample exports. 2. Site monitoring process during a site visit 3. Drug related safety events and adverse events	
PRACTICAL / DEMONSTRATION	
4. Perform source data verification for evaluating the participant's eligibility and protection of participant's rights in a mock setting. 5. Demonstrate how to conduct clinical site monitoring and audits. 6. Demonstrate how to review case report forms (CRFs).	
Tools and Documents ICH GCP guidelines books,Sample participant consent forms ,	

Sample case report forms, case study reports, Sample audit reports, Open source software for Clinical Trial documentation	

Module 12 : Reporting and documentation for site monitoring : NOS - LFS/N3504

Learning Outcome

How to perform documentation during a Clinical Trial Site initiation and activation

How to perform Clinical Trial Site monitoring reporting

How to write and report clinical trial progress at a site

Sub Module	Duration
1. WHO regulations and ICH- Good Clinical Practices (GCP) guidelines for documentation. 2. Discuss the importance of documentation in the clinical trial 3. Purpose and methodology of a clinical trial reporting. 4. Steps of drafting a site initiation/ activation report. 5. Format and steps of writing site monitoring visit reports and Clinical trial progress report 6. Discuss the reports required to be developed for any serious adverse event/ serious adverse reaction 7. Operating procedure of eCRFs and e-reporting in an open source clinical research management software	
PRACTICAL / DEMONSTRATION	
8. Perform reporting and documentation for each stage of clinical site monitoring in compliance with regulatory guidelines. 9. Demonstrate how to prepare site monitoring visit reports. 10. Demonstrate the steps to write the reports for any serious adverse event/ serious adverse reaction 11. Demonstrate the operating steps for reviewing eCRFs and submission of e-reports in an open source clinical research management software	
Tools and Documents ICH-GCP guideline book, Sample of Formats used at a Clinical Research Site, Open Source software for Clinical Trial	

documentation	

Module 13 : Project Management in Clinical Trials. NOS Code LFS/N0508

Learning Outcome

Sub Module	Duration
1. Explain the possible roadblocks and showstoppers in a clinical trial 2. Explain the possible strategies for effective project management of a clinical trial 3. Discuss the client relationship management strategies for clinical trial management 4. Explain the periodic reports and updates required for effective project management of a clinical trial	
PRACTICAL / DEMONSTRATION	
5. Perform mock session of client update calls 6. Demonstrate how to write and update client call minutes report for a clinical trial monitoring project	
Tools and Documents Sample Client update report format	

Module 14 : Safety Definitions and Adverse Event Reporting Requirements. NOS Code LFS/N0508

Learning Outcome

Sub Module	Duration
1. Explain the importance of safety practices during a clinical trial 2. Determine GCP for ensuring the safety of the research subject and the validity of a clinical trial .	

3. Discuss the source of safety Information and safety evaluation 4. Drug related safety events and adverse events. Define adverse events (AEs) by categorizing them based on causality, seriousness, and relatedness 5. Explain safety monitoring during the trial and responsibilities of the investigator 6. Demonstrate how to report drug related adverse events to all concerned stakeholders and ethics committee. 7. Discuss in detail about the safety reporting requirements of Investigational New Drug (IND) 8. Define adverse events (AEs) by categorizing them based on causality, seriousness, and relatedness 9. Discuss safety reporting and case report form (CRF) 10. Explain post-marketing safety and reporting	
PRACTICAL / DEMONSTRATION	
11. A project on adverse events and creating a report 12. Conduct a mock session for recording CRF based on the said project	
Tools and Documents Sample CRF	

Module 15 : Clinical data management : NOS - LFS/N3505

Learning Outcome

Importance and need of Clinical Data Management in a Clinical Trial/ BA-BE Study

Various methods and processes in clinical data management Operating procedures of various softwares used in clinical data management

Sub Module	Duration
1. Concepts of medical coding. Discuss medical, clinical research, and Data Management process and terminology. 2. Clinical data management (CDM) Process and methods to collect, store, and disseminate clinical trial data.	

3. Method of eCRF design and basics of Database design 4. Concepts of edit check design and edit check 5. Steps for data validation and data cleaning 6. Processes for locking the databases and freezing the data extraction 7. Demonstrate how to coordinate with Clinical Trial team for any discrepancy or coordination for clinical data management 8. Use of AI and Cloud computing softwares for enrolment, selection and tracking of volunteers/ patients during and after the clinical trial 9. Methods and strategies for discrepancy management in CDM Discuss the operating steps of a clinical data management software	
PRACTICAL / DEMONSTRATION	
1. Demonstrate how to design and develop the eCRF. 2. Demonstrate how to fill the data in 2 sample CRF(s) for data base testing. 3. Demonstrate how to create eCRFs using any of the EDC tools. 4. Demonstrate the steps for Data Validation and data cleaning 5. Demonstrate the steps for database lock and freezing data extraction	
Tools and Documents Open Source Clinical Data Management Software / EDC tool for Clinical Trials, Open Source Clinical Database	

Module 16 :: Coordinate with team members and site : NOS Code LFS/N0510

Sub Module	Duration
1. Explain the general reporting process, protocol and escalation policy of the organization	
2. Explain the reporting structure of the clinical research team	

3. Discuss different interdepartmental strategies for collaborating with other groups and divisions to achieve organizational goals
4. Explain how to deal with various issues at site and site team by building problem solving skills
5. Explain the strategies for dealing with site investigator and principal investigator

Module 17 : Managing environmental sustainability : NOS : LFS/N0119

Learning Outcome

Importance of environmental sustainability.
Adoption of environmental sustainability methods at work for minimizing pollution, water wastage, and maximizing energy conservation

Sub Module	Duration
1. Concept and importance of energy conservation. 2. Possible actions to optimize energy consumption and minimize energy wastage. 3. Concept of environmental pollution and its impact on the health of self, community, and planet. 4. Possible actions to be taken to minimize environmental pollution at work. 5. Various guidelines to be followed for hazardous waste management and disposal of waste.	
PRACTICAL / DEMONSTRATION	
1. Create a checklist of energy conservation practices during and post-work. 2. Classify waste into recyclable, nonrecyclable, and hazardous. 3. Demonstrate the sustainable waste disposal- process.	
Tools and Documents Color-coded waste bin bag, color-coded waste container	

Module 18 : : Display sensitivity towards all genders and people with disability : NOS : LFS/N0119

Learning Outcome

Understanding of the Prevention of Sexual harassment (POSH) Act at the workplace. How to respect all genders and cultures.
Importance of sensitivity towards people with disability.

Sub Module	Duration
1. Rules laid by the Sexual Harassment of Women at Workplace (Prevention, Prohibition, and Redressal) Act and the provided penalties for violation. 2. Importance of gender sensitive behaviour. Explain the procedure to report inappropriate behaviour e.g. sexual harassment. 3. Importance of an equal opportunity work culture. 4. Importance of respecting other's cultures, religion, and caste. 5. Need for sensitivity towards people with disabilities. 6. Correct ways of communication and collaboration with people with disabilities in compliance with the legal framework. 7. Identify stereotypes and prejudices associated with people with disabilities and the negative consequences of prejudice and stereotypes	
PRACTICAL / DEMONSTRATION	
8. Demonstrate appropriate verbal and nonverbal communication that is respectful of gender, religion, disability, etc. 9. Prepare a list of gender neutral communication terms	

Module 19 : : Communication, soft skills and organisational behaviour

Learning Outcome

Sub Module	Duration
1. Communication with team, seniors, patients, stakeholders 2. Organisational skills 3. Personality Development 4. Aspiration & Mindset mapping and goal setting	

5. Core competency, Life Skills and self assessment 6. Grooming for career growth and interview preparedness	
PRACTICAL / DEMONSTRATION	
7. Various practice sessions and soft skill sessions on core communication skills and professional skills to meet the work output requirements	

Some documents, samples and other tools to support class and demos

1. Guidelines
    a. Guidelines for Good clinical practices (GCP)
    b. Indian Council of Medical Research (ICMR) guidelines
    c. Guidelines Good documentation practices (GDP)
    d. Guidelines for Good Laboratory Practices (GLP)
    e. National ethical guidelines for biomedical and health research involving human participants by ICMR
    f. ICH-GCP guideline book
2. Sample documents and forms
    a. Sample Clinical trial protocol
    b. Sample investigation brochure
    c. Sample product insert
    d. Sample of Formats used at a Clinical Research Site,
    e. Sample informed consent form
    f. Sample trial master file
    g. Sample participant consent forms

h. Sample case report forms, case study reports
i. Sample audit reports
j. Sample Client update report format
k. Sample CRF

3. Open Source software
    a. Open Source software for Clinical Trial documentation
    b. Open Source Clinical Data Management Software
4. EDC tool for Clinical Trials, Open Source Clinical Database
5. Color-coded waste bin bag, color-coded waste container