Qualification Pack

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

Electives: Study Monitoring

QP Code: LFS/Q3501 Instantiated QP Code: LFS/Q3501-SI002

Version: 3.0

NSQF Level: 5.5

Qualification Pack

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Qualification Pack

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LFS/Q3501-SI002: Associate-Clinical Research Management (Pharma, Biologics and Medical devices)

Brief Job Description

Associate-Clinical Research Management (Pharma, Biologics and Medical devices Facility) supports clinical trial activities, carries out reporting and documentation for monitoring of research activities to ensure regulatory compliance and current Good Clinical Practices (GLP) as per ICH and coordinates with site staff members, investigators, Site Management Organization and Sponsor. The role holder is expected to assist in the Biostatistics analysis of clinical trial data with the help of artificial intelligence.

Personal Attributes

The individual should have excellent communication skills and analytical skills. The person should possess good critical thinking, attention to detail, and decision-making skills. The role holder should be proactive in planning and organizing skills.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. LFS/N3507: Introduction to life sciences industry and basics of Clinical trial occupation
2. LFS/N0119: Ensure environment sustainability and sensitivity towards all genders and people with disability
3. LFS/N3506: Carry out management activities related for clinical trial
4. DGT/VSQ/N0103: Employability Skills (90 Hours)

Electives*(mandatory to select at least one):*

Elective : Study Monitoring

This elective is about Associate-Clinical Research Management performing clinical study monitoring activities.

1. LFS/N3501: Monitor the clinical trial site to ensure that ICH GCP guidelines, study protocol and applicable regulations are followed
2. LFS/N3502: Carry out reporting and documentation for site monitoring activities as per regulatory standards

Qualification Pack (QP) Parameters

Qualification Pack

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Medical Devices and In Vitro Diagnostic (IVD), Biotechnology, Contract Research
Occupation	Clinical Trials, Bio Availability-Bio Equivalence
Country	India
NSQF Level	5.5
Credits	19
Aligned to NCO/ISCO/ISIC Code	NCO 2015/3512.0601
Minimum Educational Qualification & Experience	Completed 3 year UG degree (Biology, Nursing, Medical Lab Technician, Life Sciences, Biotechnology) OR Completed 3 year UG degree program after 12th (B.E/ B. tech. Biotech) OR Completed 3 year UG degree program after 12th (B. Pharma) OR Medical Graduate (BAMS/ BDS/ BUMS/ BHMS/ MBBS)
Minimum Level of Education for Training in School	
Pre-Requisite License or Training	NA
Minimum Job Entry Age	18 Years
Last Reviewed On	NA
Next Review Date	08/04/2028
NSQC Approval Date	08/04/2025
Version	3.0
Reference code on NQR	QG-5.5-LS-00251-2025-V2-LSSSDC
NQR Version	2.0

Qualification Pack

LFS/N3507: Introduction to life sciences industry and basics of Clinical trial occupation

Description

This NOS is about an Associate-Clinical Research Management Individual Introduction to life sciences industry and basics of Clinical trial occupation

Scope

The scope covers the following :

- Life sciences industry and clinical trial occupation

Elements and Performance Criteria

Life sciences industry and clinical trial occupation

To be competent, the user/individual on the job must be able to:

PC1. Identifies major players, key products, and innovations in the life sciences industry.

PC2. Explain the key regulations and legislations governing clinical research in India (e.g., Schedule Y, ICH-GCP) and compares them with global standards.

PC3. Follow key regulations and legislations governing clinical research

PC4. Identify the workflow and key responsibilities in clinical trial roles

PC5. Explain the importance subject/patient confidentiality and consent.

PC6. Explains the impact of errors or negligence by unskilled personnel on clinical trials and public health.

PC7. Demonstrates the ability to identify gaps in compliance in a clinical trial

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. principles of ICH-GCP, Indian GCP and ICMR guidelines, Good Documentation Practices and Good Laboratory Practices

KU2. SOPs and organizational policies about communication, code of conduct

KU3. clinical research team reporting structure

KU4. correct method for carrying out corrective actions outlined for trial-related problems

KU5. sponsors and CRO roles and responsibilities

KU6. site roles and responsibilities

KU7. working in cross functional, cross geographical and cross -cultural teams

KU8. information security and confidentiality policy

KU9. clinical trial-related regulations and compliances

KU10. sample handling procedures

KU11. principles of trial protocol

Generic Skills (GS)

User/individual on the job needs to know how to:

GS1. use written communication skills to accurately record the required details in a given format as per SOP and guidelines in the English language

GS2. use reading and comprehension skills of various coding systems to read instructions, guidelines, procedures, rules, and signage

GS3. use listening skills to interpret the instructions and procedures to be followed

GS4. use verbal communication skills to interact with supervisor, teammates, and cross-functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person

GS5. use team-building skills while dealing with teammates and while managing the difficult/stressful or emotional situations at work

GS6. apply problem-solving skills to find solutions for workflow-related difficulties

GS7. apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements

GS8. apply critical thinking skills to analyze and identify what and when to report an issue/concern to the supervisor/ QA team / any other stakeholder

GS9. apply customer-centricity while generating and securing documents

GS10. apply customer-centricity to remain compliant with data integrity rules, GMP guidelines and to evaluate the impact of wrongdoings

GS11. apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Life sciences industry and clinical trial occupation	**60**	**-**	**20**	**20**
PC1. Identifies major players, key products, and innovations in the life sciences industry.	-	-	-	-
PC2. Explain the key regulations and legislations governing clinical research in India (e.g., Schedule Y, ICH-GCP) and compares them with global standards.	-	-	-	-
PC3. Follow key regulations and legislations governing clinical research	-	-	-	-
PC4. Identify the workflow and key responsibilities in clinical trial roles	-	-	-	-
PC5. Explain the importance subject/patient confidentiality and consent.	-	-	-	-
PC6. Explains the impact of errors or negligence by unskilled personnel on clinical trials and public health.	-	-	-	-
PC7. Demonstrates the ability to identify gaps in compliance in a clinical trial	-	-	-	-
NOS Total	**60**	**-**	**20**	**20**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N3507
NOS Name	Introduction to life sciences industry and basics of Clinical trial occupation
Sector	Life Sciences
Sub-Sector	Contract Research
Occupation	Clinical Trials
NSQF Level	5.5
Credits	1.00
Version	1.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

LFS/N0119: Ensure environment sustainability and sensitivity towards all genders and people with disability

Description

This NOS unit is about role holder ensuring environment sustainability and sensitivity towards gender, and people with disabilities at the workplace

Scope

The scope covers the following :

- Environment sustainability
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Environment sustainability

To be competent, the user/individual on the job must be able to:

PC1. ensure energy conservation by switching off the machine and equipment post operations

PC2. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes

PC3. ensure energy conservation by optimizing the machine/ equipment performance

PC4. identify recyclable and non-recyclable, and hazardous waste generated

PC5. segregate waste into different categories to achieve minimum pollution of land and water

PC6. check for water leakage in plant/ work area and take corrective actions

Sensitivity towards all genders and people with disability

To be competent, the user/individual on the job must be able to:

PC7. respect all genders, religions, and caste

PC8. empathize with the people with disability

PC9. offer support or help to a person with a disability only when asked

PC10. ensure to adhere to the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

PC11. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

KU2. methods of workplace communication

KU3. methods of team coordination

KU4. the types of possible disabilities among people with disability (PWD)

KU5. the challenges faced by PWD

KU6. importance of displaying empathy towards PWD

KU7. the right way to use the laws, acts, and provisions defined for PwD by the statutory bodies

KU8. the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act

KU9. the guidelines related to environmental sustainability

KU10. the WHO guidelines and ICH-cGMP rules for waste disposal and waste management

Generic Skills (GS)

User/individual on the job needs to know how to:

GS1. use reading and comprehension skills to gauge the relevant information manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments

GS2. use written communication skills to record and communicate details of work done to appropriate stakeholders by using written or computer-based record/electronic mail

GS3. use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person while interacting with teammates

GS4. use team-building skills while dealing with teammates to manage the difficult/stressful or emotional situations at work

GS5. apply problem-solving skills to find solutions for workflow-related difficulties

GS6. apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Environment sustainability	**15**	**25**	**5**	**5**
PC1. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
PC2. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-
PC3. ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
PC4. identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-
PC5. segregate waste into different categories to achieve minimum pollution of land and water	-	-	-	-
PC6. check for water leakage in plant/ work area and take corrective actions	-	-	-	-
Sensitivity towards all genders and people with disability	**15**	**25**	**5**	**5**
PC7. respect all genders, religions, and caste	-	-	-	-
PC8. empathize with the people with disability	-	-	-	-
PC9. offer support or help to a person with a disability only when asked	-	-	-	-
PC10. ensure to adhere to the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC11. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0119
NOS Name	Ensure environment sustainability and sensitivity towards all genders and people with disability
Sector	Life Sciences
Sub-Sector	Bio Pharmaceutical, Pharmaceutical, Contract Research
Occupation	Clinical Trials
NSQF Level	5.5
Credits	1.00
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

Qualification Pack

LFS/N3506: Carry out management activities related for clinical trial

Description

This NOS is about an Associate-Clinical Research Management Individual Carrying out management activities related for clinical trial

Scope

The scope covers the following :

- Planning, Development, and Compliance
- Financial Management, Data Integrity, and Quality Assurance

Elements and Performance Criteria

Planning, Development, and Compliance

To be competent, the user/individual on the job must be able to:

PC1. Develop and implement comprehensive plans for the initiation, execution, and completion of clinical trials, ensuring alignment with project goals and timelines.

PC2. Monitor progress and make adjustments as necessary to meet milestones and deadlines.

PC3. Contribute to the creation and refinement of study protocols, ensuring they clearly define the methodology, objectives, and participant selection criteria.

PC4. Ensure the protocol aligns with scientific and regulatory standards, addressing all critical study requirements.

PC5. Identify and evaluate potential clinical trial sites based on patient demographics, facilities, and regulatory compliance.

PC6. Ensure site readiness and capability to meet trial requirements, including recruitment capacity and adherence to protocols.

Financial Management, Data Integrity, and Quality Assurance

To be competent, the user/individual on the job must be able to:

PC7. Manage the financial aspects of the clinical trial, ensuring adherence to the allocated budget.

PC8. Make informed decisions to optimize resource utilization while maintaining cost-effectiveness.

PC9. Oversee data collection and management processes to ensure accuracy, completeness, and compliance with regulatory standards.

PC10. Implement measures to prevent data discrepancies and ensure data quality throughout the trial.

PC11. Proactively identify and address challenges that may arise during the trial, ensuring patient safety and the integrity of the study.

PC12. Make timely and informed decisions to resolve issues effectively and maintain trial integrity.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. SOPs and organizational policies about communication, code of conduct
KU2. clinical research team reporting structure
KU3. correct method for carrying out corrective actions outlined for trial-related problems
KU4. sponsors and CRO roles and responsibilities
KU5. site roles and responsibilities
KU6. working in cross functional, cross geographical and cross -cultural teams
KU7. information security and confidentiality policy
KU8. clinical trial-related regulations and compliances
KU9. sample handling procedures
KU10. principles of trial protocol

Generic Skills (GS)

User/individual on the job needs to know how to:

GS1. use written communication skills to accurately record the required details in a given format as per SOP and guidelines in the English language
GS2. use reading and comprehension skills of various coding systems to read instructions, guidelines, procedures, rules, and signage
GS3. use listening skills to interpret the instructions and procedures to be followed
GS4. use verbal communication skills to interact with supervisor, teammates, and cross-functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person
GS5. use team-building skills while dealing with teammates and while managing the difficult/stressful or emotional situations at work
GS6. apply problem-solving skills to find solutions for workflow-related difficulties
GS7. apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements
GS8. apply critical thinking skills to analyze and identify what and when to report an issue/concern to the supervisor/ QA team / any other stakeholder
GS9. apply customer-centricity while generating and securing documents
GS10. apply customer-centricity to remain compliant with data integrity rules, GMP guidelines and to evaluate the impact of wrongdoings
GS11. apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Planning, Development, and Compliance	**15**	**30**	**5**	**10**
PC1. Develop and implement comprehensive plans for the initiation, execution, and completion of clinical trials, ensuring alignment with project goals and timelines.	-	-	-	-
PC2. Monitor progress and make adjustments as necessary to meet milestones and deadlines.	-	-	-	-
PC3. Contribute to the creation and refinement of study protocols, ensuring they clearly define the methodology, objectives, and participant selection criteria.	-	-	-	-
PC4. Ensure the protocol aligns with scientific and regulatory standards, addressing all critical study requirements.	-	-	-	-
PC5. Identify and evaluate potential clinical trial sites based on patient demographics, facilities, and regulatory compliance.	-	-	-	-
PC6. Ensure site readiness and capability to meet trial requirements, including recruitment capacity and adherence to protocols.	-	-	-	-
Financial Management, Data Integrity, and Quality Assurance	**10**	**20**	**5**	**5**
PC7. Manage the financial aspects of the clinical trial, ensuring adherence to the allocated budget.	-	-	-	-
PC8. Make informed decisions to optimize resource utilization while maintaining cost-effectiveness.	-	-	-	-
PC9. Oversee data collection and management processes to ensure accuracy, completeness, and compliance with regulatory standards.	-	-	-	-
PC10. Implement measures to prevent data discrepancies and ensure data quality throughout the trial.	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. Proactively identify and address challenges that may arise during the trial, ensuring patient safety and the integrity of the study.	-	-	-	-
PC12. Make timely and informed decisions to resolve issues effectively and maintain trial integrity.	-	-	-	-
NOS Total	**25**	**50**	**10**	**15**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N3506
NOS Name	Carry out management activities related for clinical trial
Sector	Life Sciences
Sub-Sector	Contract Research
Occupation	Clinical Trials
NSQF Level	5.5
Credits	1.00
Version	1.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

Qualification Pack

DGT/VSQ/N0103: Employability Skills (90 Hours)

Description

This unit is about employability skills, Constitutional values, becoming a professional in the 21st Century, digital, financial, and legal literacy, diversity and Inclusion, English and communication skills, customer service, entrepreneurship, and apprenticeship, getting ready for jobs and career development.

Scope

The scope covers the following :

- Introduction to Employability Skills
- Constitutional values - Citizenship
- Becoming a Professional in the 21st Century
- Basic English Skills
- Career Development & Goal Setting
- Communication Skills
- Diversity & Inclusion
- Financial and Legal Literacy
- Essential Digital Skills
- Entrepreneurship
- Customer Service
- Getting ready for Apprenticeship & Jobs

Elements and Performance Criteria

Introduction to Employability Skills

To be competent, the user/individual on the job must be able to:

PC1. understand the significance of employability skills in meeting the current job market requirement and future of work

PC2. identify and explore learning and employability relevant portals

PC3. research about the different industries, job market trends, latest skills required and the available opportunities

Constitutional values – Citizenship

To be competent, the user/individual on the job must be able to:

PC4. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.

PC5. follow environmentally sustainable practices

Becoming a Professional in the 21st Century

To be competent, the user/individual on the job must be able to:

PC6. recognize the significance of 21st Century Skills for employment

PC7. practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life

PC8. adopt a continuous learning mindset for personal and professional development

Basic English Skills

To be competent, the user/individual on the job must be able to:

PC9. use basic English for everyday conversation in different contexts, in person and over the telephone

PC10. read and understand routine information, notes, instructions, mails, letters etc. written in English

PC11. write short messages, notes, letters, e-mails etc. in English

Career Development & Goal Setting

To be competent, the user/individual on the job must be able to:

PC12. identify career goals based on the skills, interests, knowledge, and personal attributes

PC13. prepare a career development plan with short- and long-term goals

Communication Skills

To be competent, the user/individual on the job must be able to:

PC14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings

PC15. use active listening techniques for effective communication

PC16. communicate in writing using appropriate style and format based on formal or informal requirements

PC17. work collaboratively with others in a team

Diversity & Inclusion

To be competent, the user/individual on the job must be able to:

PC18. communicate and behave appropriately with all genders and PwD

PC19. escalate any issues related to sexual harassment at workplace according to POSH Act

Financial and Legal Literacy

To be competent, the user/individual on the job must be able to:

PC20. identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.

PC21. carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook

PC22. identify common components of salary and compute income, expenses, taxes, investments etc

PC23. identify relevant rights and laws and use legal aids to fight against legal exploitation

Essential Digital Skills

To be competent, the user/individual on the job must be able to:

PC24. operate digital devices and use their features and applications securely and safely

PC25. carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.

PC26. display responsible online behaviour while using various social media platforms

PC27. create a personal email account, send and process received messages as per requirement

PC28. carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications

PC29. utilize virtual collaboration tools to work effectively

Entrepreneurship

To be competent, the user/individual on the job must be able to:

PC30. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research

PC31. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion

PC32. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity

Customer Service

To be competent, the user/individual on the job must be able to:

PC33. identify different types of customers and ways to communicate with them

PC34. identify and respond to customer requests and needs in a professional manner

PC35. use appropriate tools to collect customer feedback

PC36. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

To be competent, the user/individual on the job must be able to:

PC37. create a professional Curriculum vitae (Résumé)

PC38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively

PC39. apply to identified job openings using offline /online methods as per requirement

PC40. answer questions politely, with clarity and confidence, during recruitment and selection

PC41. identify apprenticeship opportunities and register for it as per guidelines and requirements

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. need for employability skills and different learning and employability related portals

KU2. various constitutional and personal values

KU3. different environmentally sustainable practices and their importance

KU4. Twenty first (21st) century skills and their importance

KU5. how to use English language for effective verbal (face to face and telephonic) and written communication in formal and informal set up

KU6. importance of career development and setting long- and short-term goals

KU7. about effective communication

KU8. POSH Act

KU9. Gender sensitivity and inclusivity

KU10. different types of financial institutes, products, and services

KU11. components of salary and how to compute income and expenditure
KU12. importance of maintaining safety and security in offline and online financial transactions
KU13. different legal rights and laws
KU14. different types of digital devices and the procedure to operate them safely and securely
KU15. how to create and operate an e- mail account
KU16. use applications such as word processors, spreadsheets etc.
KU17. how to identify business opportunities
KU18. types and needs of customers
KU19. how to apply for a job and prepare for an interview
KU20. apprenticeship scheme and the process of registering on apprenticeship portal

Generic Skills (GS)

User/individual on the job needs to know how to:

GS1. read and write different types of documents/instructions/correspondence in English and other languages
GS2. communicate effectively using appropriate language in formal and informal settings
GS3. behave politely and appropriately with all to maintain effective work relationship
GS4. how to work in a virtual mode, using various technological platforms
GS5. perform calculations efficiently
GS6. solve problems effectively
GS7. pay attention to details
GS8. manage time efficiently
GS9. maintain hygiene and sanitization to avoid infection

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Introduction to Employability Skills	**1**	**1**	**-**	**-**
PC1. understand the significance of employability skills in meeting the current job market requirement and future of work	-	-	-	-
PC2. identify and explore learning and employability relevant portals	-	-	-	-
PC3. research about the different industries, job market trends, latest skills required and the available opportunities	-	-	-	-
Constitutional values – Citizenship	**1**	**1**	**-**	**-**
PC4. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.	-	-	-	-
PC5. follow environmentally sustainable practices	-	-	-	-
Becoming a Professional in the 21st Century	**1**	**3**	**-**	**-**
PC6. recognize the significance of 21st Century Skills for employment	-	-	-	-
PC7. practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life	-	-	-	-
PC8. adopt a continuous learning mindset for personal and professional development	-	-	-	-
Basic English Skills	**3**	**4**	**-**	**-**
PC9. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
PC11. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
Career Development & Goal Setting	**1**	**2**	**-**	**-**
PC12. identify career goals based on the skills, interests, knowledge, and personal attributes	-	-	-	-
PC13. prepare a career development plan with short- and long-term goals	-	-	-	-
Communication Skills	**2**	**2**	**-**	**-**
PC14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings	-	-	-	-
PC15. use active listening techniques for effective communication	-	-	-	-
PC16. communicate in writing using appropriate style and format based on formal or informal requirements	-	-	-	-
PC17. work collaboratively with others in a team	-	-	-	-
Diversity & Inclusion	**1**	**1**	**-**	**-**
PC18. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC19. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
Financial and Legal Literacy	**2**	**3**	**-**	**-**
PC20. identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.	-	-	-	-
PC21. carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC22. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
PC23. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
Essential Digital Skills	**3**	**5**	**-**	**-**
PC24. operate digital devices and use their features and applications securely and safely	-	-	-	-
PC25. carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.	-	-	-	-
PC26. display responsible online behaviour while using various social media platforms	-	-	-	-
PC27. create a personal email account, send and process received messages as per requirement	-	-	-	-
PC28. carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications	-	-	-	-
PC29. utilize virtual collaboration tools to work effectively	-	-	-	-
Entrepreneurship	**2**	**3**	**-**	**-**
PC30. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
PC31. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
PC32. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
Customer Service	**1**	**2**	**-**	**-**
PC33. identify different types of customers and ways to communicate with them	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC34. identify and respond to customer requests and needs in a professional manner	-	-	-	-
PC35. use appropriate tools to collect customer feedback	-	-	-	-
PC36. follow appropriate hygiene and grooming standards	-	-	-	-
Getting ready for apprenticeship & Jobs	**2**	**3**	**-**	**-**
PC37. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC39. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC40. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC41. identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
NOS Total	**20**	**30**	**-**	**-**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0103
NOS Name	Employability Skills (90 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	5
Credits	3
Version	1.0
Last Reviewed Date	18/02/2025
Next Review Date	18/02/2028
NSQC Clearance Date	18/02/2025

LFS/N3501: Monitor the clinical trial site to ensure that ICH GCP guidelines, study protocol and applicable regulations are followed

Description

This NOS is about Associate-Clinical Research Management performing clinical research study site monitoring activities to effectively support the clinical research project

Scope

The scope covers the following :

- Monitor clinical trails
- Monitor participants during a clinical trial for safety and rights of participants

Elements and Performance Criteria

Monitor clinical trials

To be competent, the user/individual on the job must be able to:

PC1. organize investigator's start-up meeting and study site initiation meetings

PC2. carry out clinical trials as per ICH GCP guidelines, study protocol, and applicable regulations

PC3. communicate effectively with principal investigator, co-investigator, and clinical research coordinators to gather relevant information

PC4. review and assess the clinical trial process

PC5. ensure to study procedures that are consistently carried out by the study team across all participants

PC6. ensure that principal investigator is submitting documents to the ethics committee in a timely manner

PC7. perform source data verification, review source documents, informed consent procedures and forms for evaluating the participant's eligibility and assessing the protection of participant's rights

PC8. review efficacy related aspects of the participants, investigational product compliance by participants, and review case report forms (CRFs)

PC9. conduct site audits to ensure that all investigational products are stored, and drug accountability is maintained as per SOP

PC10. ensure optimal usage of resources by effective deployment of the same

Monitor participants during a clinical trial for safety and rights of participants

To be competent, the user/individual on the job must be able to:

PC11. ensure safety and rights of participants during all phases of clinical trials

PC12. review safety events and ensure that drug- related Adverse Events (AE) are identified and promptly reported to all concerned stakeholders and ethics committee within prescribed timelines and as per SOPs

PC13. record and review the rate of subject recruitment, visits that subjects fail to make, and tests that are not conducted

PC14. ensure documentation exists at the site to follow up with the patient for any missing test/ procedure and recommend participant enrolment and retention plan with the principal investigator and co- investigator

PC15. ensure the documentation of the withdrawals of enrolled subjects with reasons on the CRFs by the site coordinators and principal investigators

PC16. identify anomalies in study conduct from a misconduct or fraud perspective

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. organization SOPs

KU2. impact of various practices on cost, quality, productivity, delivery and safety

KU3. principles of clinical research

KU4. country regulations and compliances relevant to clinical trial process

KU5. physiology and reason of disease condition

KU6. standard of care, treatment options and dose of medication

KU7. clinical trial protocol

KU8. the characteristics of the investigational drug in the study

KU9. relevant licenses for study drug import and biological sample exports

KU10. procedures and responsibility for reporting research and performance information

KU11. basics of finance and accounts to keep a track of site payments and patient compensation

KU12. principles of ICH-GCP, Indian GCP and ICMR guidelines, Good Documentation Practices and Good Laboratory Practices

Generic Skills (GS)

User/individual on the job needs to know how to:

GS1. use reading and comprehension skills to read and understand manuals, SOPs, health and safety instructions, memos, reports, and notes/comments from the supervisor

GS2. use written communication skills to record and communicate details of work done to appropriate stakeholders by using written/typed report or computer-based record/electronic mail

GS3. apply problem-solving skills to find solutions for workflow-related difficulties

GS4. apply critical thinking skills to analyze and identify when to report an issue/concern to the in-charge and when to deal with a colleague individually, depending on the type of concern

GS5. apply analytical skills in choosing a well-defined written smooth methods/instruction to resolve day to day problems

GS6. apply planning and organizing skills to plan and organize tools and material required to fulfil own work requirements on time

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Monitor clinical trials	**15**	**30**	**10**	**5**
PC1. organize investigator's start-up meeting and study site initiation meetings	-	-	-	-
PC2. carry out clinical trials as per ICH GCP guidelines, study protocol, and applicable regulations	-	-	-	-
PC3. communicate effectively with principal investigator, co-investigator, and clinical research coordinators to gather relevant information	-	-	-	-
PC4. review and assess the clinical trial process	-	-	-	-
PC5. ensure to study procedures that are consistently carried out by the study team across all participants	-	-	-	-
PC6. ensure that principal investigator is submitting documents to the ethics committee in a timely manner	-	-	-	-
PC7. perform source data verification, review source documents, informed consent procedures and forms for evaluating the participant's eligibility and assessing the protection of participant's rights	-	-	-	-
PC8. review efficacy related aspects of the participants, investigational product compliance by participants, and review case report forms (CRFs)	-	-	-	-
PC9. conduct site audits to ensure that all investigational products are stored, and drug accountability is maintained as per SOP	-	-	-	-
PC10. ensure optimal usage of resources by effective deployment of the same	-	-	-	-
Monitor participants during a clinical trial for safety and rights of participants	**10**	**20**	**5**	**5**
PC11. ensure safety and rights of participants during all phases of clinical trials	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. review safety events and ensure that drug-related Adverse Events (AE) are identified and promptly reported to all concerned stakeholders and ethics committee within prescribed timelines and as per SOPs	-	-	-	-
PC13. record and review the rate of subject recruitment, visits that subjects fail to make, and tests that are not conducted	-	-	-	-
PC14. ensure documentation exists at the site to follow up with the patient for any missing test/ procedure and recommend participant enrolment and retention plan with the principal investigator and co- investigator	-	-	-	-
PC15. ensure the documentation of the withdrawals of enrolled subjects with reasons on the CRFs by the site coordinators and principal investigators	-	-	-	-
PC16. identify anomalies in study conduct from a misconduct or fraud perspective	-	-	-	-
NOS Total	**25**	**50**	**15**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N3501
NOS Name	Monitor the clinical trial site to ensure that ICH GCP guidelines, study protocol and applicable regulations are followed
Sector	Life Sciences
Sub-Sector	Contract Research
Occupation	Clinical Trials, Bio Availability-Bio Equivalence
NSQF Level	5.5
Credits	7.0
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

LFS/N3502: Carry out reporting and documentation for site monitoring activities as per regulatory standards

Description

This NOS is about a Associate-Clinical Research Management performing the reporting and documentation for site monitoring activities

Scope

The scope covers the following :

- Pre research activities
- Research process activities
- Post research activities

Elements and Performance Criteria

Pre research activities

To be competent, the user/individual on the job must be able to:

PC1. outline the purpose and methodology of a trial

PC2. develop, draft, and write the Trial Protocols

PC3. present trial protocols to a steering committee

PC4. generate regulatory authority applications and approvals

PC5. identify, select and evaluate trial sites and investigators and provide inputs in investigator grants and agreements

Research process activities

To be competent, the user/individual on the job must be able to:

PC6. develop training materials for site for site initiations

PC7. prepare follow up letters to principal investigator, complete site monitoring documentation

PC8. prepare site monitoring visit reports, maintain records of communication with site staff and investigator, letters of agreement, lab reference ranges and schedule of payment

PC9. maintain project files including : ethics committee approvals; curriculum vitae of investigators and study personnel; Investigator’s Undertaking etc.

Post research activities

To be competent, the user/individual on the job must be able to:

PC10. provide inputs to medical/ scientific teams as well as bio-statistician, who analyses technical trial data and writes technical trial reports

PC11. provide support in preparing final reports, occasionally manuscripts for publication

PC12. archive study documentation, and trial related correspondence

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. ICH-GCP guidelines, legislation and regulations as applicable and impact of non-conformance/poor practices

KU2. how to implement the relevant company SOPs for the fulfilment of each clinical trial

KU3. procedures and responsibility for reporting research and performance information

KU4. the reason and impact of the occurrence of problems

KU5. basics of finance and accounts to keep a track of site payments and patient compensation

Generic Skills (GS)

User/individual on the job needs to know how to:

GS1. use reading and comprehension skills of various coding systems to read instructions, guidelines, procedures, rules, and signage

GS2. use listening skills to interpret the instructions and procedures to be followed

GS3. use verbal communication skills to interact with supervisor, teammates, and cross-functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person

GS4. use team-building skills while dealing with teammates and while managing the difficult/stressful or emotional situations at work

GS5. apply problem-solving skills to find solutions for workflow-related difficulties

GS6. apply planning and organizing skills to plan and organize tools and material required to fulfil documentation related requirements

GS7. apply critical thinking skills to analyze and identify what and when to report an issue/concern to the supervisor/ QA team / any other stakeholder

GS8. apply customer-centricity while generating and securing documents

GS9. apply customer-centricity to remain compliant with data integrity rules, GMP guidelines and to evaluate the impact of wrongdoings

GS10. apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Pre research activities	**10**	**15**	**5**	**5**
PC1. outline the purpose and methodology of a trial	-	-	-	-
PC2. develop, draft, and write the Trial Protocols	-	-	-	-
PC3. present trial protocols to a steering committee	-	-	-	-
PC4. generate regulatory authority applications and approvals	-	-	-	-
PC5. identify, select and evaluate trial sites and investigators and provide inputs in investigator grants and agreements	-	-	-	-
Research process activities	**10**	**15**	**5**	**5**
PC6. develop training materials for site for site initiations	-	-	-	-
PC7. prepare follow up letters to principal investigator, complete site monitoring documentation	-	-	-	-
PC8. prepare site monitoring visit reports, maintain records of communication with site staff and investigator, letters of agreement, lab reference ranges and schedule of payment	-	-	-	-
PC9. maintain project files including : ethics committee approvals; curriculum vitae of investigators and study personnel; Investigator's Undertaking etc.	-	-	-	-
Post research activities	**5**	**15**	**5**	**5**
PC10. provide inputs to medical/ scientific teams as well as bio-statistician, who analyses technical trial data and writes technical trial reports	-	-	-	-
PC11. provide support in preparing final reports, occasionally manuscripts for publication	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. archive study documentation, and trial related correspondence	-	-	-	-
NOS Total	**25**	**45**	**15**	**15**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N3502
NOS Name	Carry out reporting and documentation for site monitoring activities as per regulatory standards
Sector	Life Sciences
Sub-Sector	Contract Research
Occupation	Clinical Trials
NSQF Level	5.5
Credits	6.0
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

1. Criteria for assessment for each Qualification Pack will be created by Life Sciences Sector Skill Development Council (LSSSDC)

2. Each Element will be assigned marks proportional to its importance in NOS. LSSSDC will also lay down the proportion of marks for Theory, Practical, Project, and Viva for each Element.

3. The assessment for the theory part will be based on the knowledge bank of questions created by the LSSSDC.

4. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.

5. LSSSDC as assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and via for every student at each examination/training center based on this criterion.

6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied

assessment component.

7. To pass the Qualification Pack, every trainee should score a minimum of 50-70%% of marks in each NOS to successfully clear the assessment. In the case of a Govt funded program, the program guidelines will be overarching on the pass percentage rules.

8. In case of unsuccessful completion, the trainee may seek re-assessment on the Qualification Pack.

Minimum Aggregate Passing % at QP Level : 70

(**Please note**: Every Trainee should score a minimum aggregate passing percentage as specified above, to successfully clear the Qualification Pack assessment.)

Minimum Passing % at NOS Level: 70

(**Please note**: A Trainee must score the minimum percentage for each NOS separately as well as on the QP as a whole.)

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N3507.Introduction to life sciences industry and basics of Clinical trial occupation	60	0	20	20	100	10
LFS/N0119.Ensure environment sustainability and sensitivity towards all genders and people with disability	30	50	10	10	100	10
LFS/N3506.Carry out management activities related for clinical trial	25	50	10	15	100	10
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	10
Total	**135**	**130**	**40**	**45**	**350**	**40**

Elective: 1 Study Monitoring

Qualification Pack

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N3501.Monitor the clinical trial site to ensure that ICH GCP guidelines, study protocol and applicable regulations are followed	25	50	15	10	100	30
LFS/N3502.Carry out reporting and documentation for site monitoring activities as per regulatory standards	25	45	15	15	100	30
Total	**50**	**95**	**30**	**25**	**200**	**60**