Good Clinical Practice Professional Certification Scheme (GCPPCS)

MINIMUM STANDARD OF COMPETENCE (MSC)

Developed by
Clinical Development Services Agency (CDSA),
Translational Health Science and Technology Institute (THSTI), Department of Biotechnology, Ministry of Science & Technology, Government of India

Version history

Version	Date	Comment
8.0	24 April 2020	Initial version

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1. Abbreviations

ADR:	Adverse Drug Reaction
AE:	Adverse Event
CDSCO:	Central Drugs Standard Control Organisation
CDM:	Clinical Data Management
CRF:	Case Report Form
eCRF:	electronic- Case Report Form
CRO:	Contract Research Organization
CRA:	Clinical Research Associate
CRC:	Clinical Research Coordinator
CSR:	Clinical Study Report
CTA:	Clinical Trial Assistant
CTA:	Clinical Trial Agreement
DCGI:	Drug Controller General of India
D & C Act:	Drugs and Cosmetics Act
DSMB:	Data Safety Monitoring Board
EC:	Ethics Committee
EDC:	Electronic Data Capture
GCP:	Good Clinical Practice
GLP:	Good Laboratory Practice
IB:	Investigator's Brochure
ICD:	Informed Consent Document
ICF:	Informed Consent Form
ICH:	International Conference on Harmonization
ICMR:	Indian Council of Medical Research

1	IEC:	Independent or Institutional Ethics Committee
2	IMP:	Investigational Medicinal Product
3	IND:	Investigational New Drug
4	IRB:	Institutional Review Board
5	IP:	Investigational Product
6	ISF:	Investigator Site File
7	ISO:	International Organization for Standardization
8	ITT:	Intent-to-Treat
9	IVRS:	Interactive Voice Recognition System
10	LAR:	Legally Acceptable Representative
11	MCI:	Medical Council of India
12	MedDRA:	Medical Dictionary for Regulatory Activities
13	MW:	Medical Writing
14	NDA:	New Drug Application (or Non-Disclosure Agreement)
15	PD:	Pharmacodynamics
16	PI:	Principal Investigator
17	PK:	Pharmacokinetics
18	PMS:	Post Marketing Surveillance
19	PP:	Per Protocol
20	QA:	Quality Assurance
21	QC:	Quality Control
22	QMP:	Quality Management Plan
23	QoL:	Quality of Life
24	RBM:	Risk Based Monitoring
25	SAE:	Serious Adverse Event
26	SAP:	Statistical Analysis Plan

SDV:	Source Document Verification
SIV:	Site Initiation Visit
SMF:	Site Master File
SMO:	Site Management Organization
SMV:	Site Monitoring Visit
SOP:	Standard Operating Procedure
TEAE:	Treatment Emergent Adverse Events
TMF:	Trial Master File
WHO:	World Health Organization
WHO-UMC:	Uppsala Monitoring Centre

2. Glossary

1. **Act**

Wherever relevant, the Act means Drugs & Cosmetics Act 1940 (23 of 1940) and the Rules made thereunder.

2. **Academic Trials**

Academic clinical trial means a clinical trial of a drug already approved for a certain claim and initiated by any investigator, academic or research institution for a new indication or new route of administration or new dose or new dosage form, where the results of such a trial are intended to be used only for academic or research purposes and not for seeking approval of the central licensing authority or regulatory authority of any country for marketing or commercial purpose

3. **Adverse Drug Reaction (ADR)**

In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product mean that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out. Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or modification of physiological function (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

4. **Adverse Event (AE)**

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can, therefore, be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

5. **Audit Trail**

Documentation that allows reconstruction of the course of events.

6. **Biomedical Research (Health Research)**

Biomedical and Health Research means research including studies on basic, applied and operational research or clinical research, designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioural); their detection and cause; and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation but does not include a clinical trial (as defined in #9 below).

7. **Blinding/Masking**

A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s).

Single-blinding usually refers to the subject(s) being unaware, and double-blinding usually refers to the subject(s), the investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

8. **Case Record Form (CRF)**

A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

9. **Clinical Trial/Study**

Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

10. **Human/Clinical Pharmacology trials (Phase I)**

The objective of phase I of trials is to determine the maximum tolerated dose in humans; pharmacodynamic effect, adverse reactions, if any, with their nature and intensity; and pharmacokinetic behaviour of the drug as far as possible. These studies are often carried out in healthy adult volunteers using clinical, physiological and biochemical observations. At least 2 subjects should be used on each dose.

Phase I trials are usually carried out by investigators trained in clinical pharmacology and having the necessary facilities to closely observe and monitor the subjects. These may be carried out at one or two centres.

11. **Exploratory trials (Phase II)**

In phase II trials a limited number of patients are studied carefully to determine possible therapeutic uses, effective dose range and further evaluation of safety and pharmacokinetics. Normally 10-12 patients should be studied at each dose level. These studies are usually limited to 3-4 centres and carried out by clinicians specialized in the concerned therapeutic areas and having adequate facilities to perform the necessary investigations for efficacy and safety.

12. **Confirmatory trials (Phase III)**

The purpose of these trials is to obtain sufficient evidence about the efficacy and safety of the drug in a larger number of patients, generally in comparison with a standard drug and/or a placebo as appropriate. These trials may be carried out by clinicians in the concerned therapeutic areas, having facilities appropriate to the protocol. If the drug is already approved/marketed in other countries, phase III data should generally be obtained on at least 100 patients distributed over 3-4 centres primarily to confirm the efficacy and safety of the drug, in Indian patients when used as recommended in the product monograph for the claims made.

Data on ADRs observed during clinical use of the drug should be reported along with a report on its efficacy in the prescribed format. The selection of clinicians for such monitoring and supply of a drug to them will need the approval of the licensing authority under Rule 21 of the Act.

13. **Phase IV**

Studies performed after marketing of the pharmaceutical product. Trials in phase IV are carried out on the basis of the product characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, assessment of therapeutic value, treatment strategies used and safety profile. Phase IV studies should use the same scientific and ethical standards as applied in pre-marketing studies.

After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc. are normally considered as trials for new pharmaceutical products.

14. **Comparator (Product)**

An investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

15. **Confidentiality**

Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or a subject's identity.

16. **Contract**

A written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters. The protocol may serve as the basis of a contract.

17. **Coordinating Investigator**

An investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial.

18. **Clinical Research Organization (CRO)**

A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

19. **Documentation**

All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

20. **Escape Treatment**

A supplementary treatment, usually given to alleviate pain in placebo-controlled trials, to relieve the trial subject of the symptoms caused by the investigated disease in a study.

21. **Essential Documents**

Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

22. **Ethics Committee (EC)**

An independent review board or committee comprising medical/scientific and non-medical/non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a study. The independent review provides public reassurance by objectively, independently and impartially reviewing and approving the "Protocol", the suitability of the investigator(s), facilities, methods and material to be used for obtaining and documenting "Informed Consent" of the study participants and adequacy of confidentiality safeguards.

23. **Final Report**

A complete and comprehensive description of the study after its completion. It includes a description of experimental and statistical methods and materials, presentation and evaluation of the results, statistical analyses and a critical ethical, statistical and clinical appraisal. The Investigator's declaration closing the study is a part of the Final Report.

24. **Good Clinical Practice (GCP)**

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected.

25. **Impartial Witness**

A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

26. **Independent Ethics Committee (IEC)**

An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving/providing a favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

27. **Informed Consent**

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to

participate. Informed consent is documented by means of a written, signed and dated informed consent form.

28. **Inspection**

The act by a regulatory authority (ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority (ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority (ies).

29. **The institution (medical)**

Any public or private entity or agency or medical or dental facility where clinical trials are conducted.

30. **Institutional Review Board (IRB)**

An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing a continuing review of the trial protocol and amendments and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

31. **Investigator**

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and maybe called the principal investigator. See also Sub-investigator.

32. **Investigational Labelling**

Labelling developed specifically for products involved in the study.

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33. **Investigator's Brochure**

A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.

34. **Monitoring**

The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

35. **Multicentre Trial**

A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

36. **Non-clinical Study**

Biomedical studies not performed on human participants (also includes studies on their biological materials and data).

37. **Non-Therapeutic Study**

A study in which there is no anticipated direct clinical benefit to the Subject(s). Such studies, unless an exception is justified, should be conducted in the patient(s) having a disease or condition for which the Investigational Product is intended. Subject(s) in these studies should be particularly closely monitored and should be withdrawn if they appear to be unduly distressed.

38. **Pharmaceutical Product(s)**

Any substance or combination of substances which has a therapeutic, prophylactic or diagnostic purpose or is intended to modify physiological functions, and presented in a dosage form suitable for administration to humans.

39. **Principal Investigator**

The investigator who has the responsibility to coordinate between the different Investigators involved in a study at one site or different sites in case of a multicentre study.

40. **Protocol**

A document that states the background, objectives, rationale, design, methodology (including the methods for dealing with AEs, withdrawals etc.) and statistical considerations of the study. It also states the conditions under which the study shall be performed and managed. A list of items to be included in the Protocol is compiled in a subsequent chapter. The content and format of the protocol should take into consideration the adopted SOPs, the regulatory requirements and the guiding principles of GCP. The term Protocol, unless otherwise specified, relates to the latest amended version of the document, read in conjunction with all its appendices and enclosures.

41. **Protocol Amendment**

A written description of a change(s) to or formal clarification of a protocol.

42. **Quality Assurance (QA)**

All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

43. **Quality Control (QC)**

The operational techniques and activities are undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

44. **Randomization**

The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

45. **Regulatory Authorities**

Bodies having the power to regulate. In the ICH GCP Guideline, the expression Regulatory Authorities includes the authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities.

46. **Raw Data**

It refers to all records or certified copies of the original clinical and laboratory findings or other activities in a clinical study necessary for the reconstruction and evaluation of the trial.

47. **Schedule**

Unless repugnant to the context, the Schedule means Schedule Y to the Drugs & Cosmetics Rules.

48. **Serious Adverse Event (SAE)**

An AE that is associated with death, inpatient hospitalisation (in case the study was being conducted on out-patients), prolongation of hospitalisation (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life-threatening.

49. **Source Data**

All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

50. **Sponsor**

An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.

51. **Standard Operating Procedures (SOPs)**

Detailed, written instructions to achieve uniformity of the performance of a specific function.

52. **Sub-investigator**

Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). See also, Investigator.

53. **Subject/Research Subject or Participant**

An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.

54. **Study Subject (Subject) or Participant**

An individual participating in a clinical trial as a recipient of the Investigational Product(s) or as a control. A Study Subject/participant may be a healthy person volunteering in a trial or a person with a medical condition that is unrelated to the use of the Investigational Product or a person whose medical condition is relevant to the use of the Investigational Product.

55. **Subject or Participant Identification Code**

A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial-related data.

56. **Study Management**

Steering, supervising, data management and verification, statistical processing and preparation of the study report.

57. **Validation**

Validation of Study: The process of proving, in accordance with the principles of Good Clinical Practice, that any procedure, process equipment, material, activity or system leads to the expected results

3. Introduction and Scope

Good Clinical Practice (GCP) is a national or international standard for biomedical studies which encompasses the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that assures that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected.

The fundamental tenet of GCP is that in research on man (human), the interest of science and society should never take precedence over considerations related to the well-being of the study subject. It aims to ensure that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical substances under investigation are properly documented. The guidelines seek to establish two cardinal principles. They are the protection of the rights of human subjects and the authenticity of biomedical data generated.

To ensure that results from global clinical trials can support authorization of investigational products internationally, the principles of GCP have been adopted by regulatory authorities across the globe although initiated by Japan, the United States, and the European Union through The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and implemented through the ICH GCP guideline E6. A need was, however, felt to develop Indian guidelines to ensure uniform quality of clinical research throughout the country and to generate data for registration for new drugs before use in the Indian population. An expert committee set up by CDSCO in consultation with clinical experts had formulated the Indian GCP Guidelines (2001). The Drug Technical Advisory Board (DTAB), the highest

technical body under the D&C Act had endorsed the adoption of these GCP guidelines for streamlining the clinical studies in India. After the release of ICH GCP 2016, current Indian GCP is under the process of getting revised to harmonise with the former and Indian requirements.

These principles have also been adopted by the International Organization for Standardization (ISO), an independent, non-governmental membership organization made up of 164 member countries, through ISO-14155:2011. Although it was recognized that industry sponsors of trials had a standard requirement for all study personnel (regardless of previous experience and training) engaged in their clinical trial to be trained in GCP, there was a lack of standard as to what a professional who is to be trained/certified needed to follow.

Not only does the clinical research workforce requires an influx of newly qualified professionals, it also requires that the current workforce to continuously enhance its competence and skills through various professional development activities. Standards and norms required to be followed in clinical research and training are required in the updated ICH Guidelines and the Declaration of Helsinki (World Medical Association, 2013).There is no generally agreed-upon set of core competencies upon which educational programs and training requirements for either entry-level professionals or continuing professional development would be based/assessed.

Competence is defined as “ability to apply knowledge and skills to achieve intended results”. Since competencies are observable, they can be measured and assessed to ensure that they are imbibed. However, in the clinical research domain, the term ‘competence’ should be restricted to the skill itself, while ‘competence’ is an “array of abilities across multiple domains or aspects of professional performance in a certain context”. Competence is a point on the spectrum of improving performance; it is multi-dimensional and dynamic and changes with time, experience, and setting.

3.1 GCP Professional Certification Scheme (GCPPCS)

The scheme is designed to evaluate and certify self-directed, practice-based learning rather than supervised training. The scheme is envisaged to promote, maintain and develop the competencies e.g. professionalism, knowledge, skill and attributes of the individual professional, which are essential for meeting the changing needs of research, patients/participants and the healthcare delivery system. It will encourage applicants to plan, record and reflect on professional development and requirement needs, as part of their pursuit for lifelong learning and demonstrating the required competence standards.

The Scheme Owners CDSA-THSTI has set up a multi-stakeholder Steering Committee (SC) to manage the scheme with the goal to develop the competency profile by the Technical Committee (TC), periodically identifying updates to maintain the currency of the Minimum Standard of Competence (MSC) of the Good Clinical Practice Professional (GCPP) and improve the overall utility of this document. Based on the MSC document, the Assessment Committee (AC) would prepare the evaluation and assessment criteria for certification of the GCP Professionals and the accreditation of the Training Institutes and Certification Bodies.

The Scheme Owner through the SC, TC and AC developed:

- The domains and competence criteria for GCP Professional Certification Scheme (GCPPCS).
- Required MSC for the GCP Professionals.
- Defining competence (knowledge, skill and attributes) standards to reflect current terminology in the field and to ensure uniformity and provide more clarity to the technical requirements.
- Mapping of the competency requirements and the job roles within clinical research to which it will be applicable.
- Standard job descriptions for GCP Professionals in the clinical research enterprise.

The Task Force for creation of MSC decided to use Indian GCP guideline (2001), ICH GCP E6 (R2, 2016) guidelines and New Drugs and Clinical Trial Rules (2019)and National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017) as reference documents for drawing up competence requirements. The certification scheme will reflect a common, strong foundation of knowledge and practice in research regulations and Good Clinical Practice (GCP) both ICH and Indian GCP. The Task Force appreciates that Clinical Research Professionals come from a wide variety of backgrounds, e.g. Medical, Dental, Nursing, AYUSH, Pharmacy, Life sciences, Statistics, Computer, Business administration to name a few. These professionals also work in various settings including the industry (pharmaceutical, medical device, vaccines, phytopharmaceuticals, biotechnology companies); Clinical Research Organizations (CROs); Site Management Organizations (SMOs); independent research and development organizations; organizations involved in the management of clinical trials, academia, government, Non-Government Organisations (NGOs), private and trust/charity hospitals etc. These varying backgrounds and settings contribute to the unique knowledge and diverse expertise of professionals involved in clinical research and those practicing GCP are known as ‘GCP professionals’.

Independent or affiliated (government or private) with a research institution, CROs, SMO, sponsor, the research personnel includes but not limited to the following:

- Clinical Investigator (includes Investigators – Principal, Sub-investigator, Co-Investigator
- Clinical Research Coordinator (CRC)
- Clinical Data Manager (CDM)
- Clinical Research Associate (CRA) or Clinical Monitor
- Medical Monitor (MM)
- Auditor
- Research Nurse
- Pharmacist
- Clinical Project Manager
- Bio-Statistician
- EC staff (Basic Medical Scientist, Clinician, Legal / Layperson, Non-scientific member)
- Regulator
- Medical Writer
- Other clinical trials/research professionals

The duties of a GCP Professional include but are not limited to:

- data collection
- monitoring
- analysis
- site coordination and managing study participants
- recruitment and enrollment of human participants
- protection of participants and their rights
- development of informed consent documents
- seeking informed consent from the human participants
- dispensing of Investigational Medicinal Product (IMP) or Investigational Product (IP)
- collection of clinical samples (viz., blood, urine, stool, etc.) and various other tests like ECG, CT scan, MRI, etc. for testing and analysis, as specified in the study
- protocol preparation of adverse event experience reports
- construction or monitoring of case report forms
- maintenance of drug accountability records

- development of grants and budgets
- preparation of reports
- educating other healthcare professionals, patients or families about clinical trials
- protocol development
- project management and safety management
- auditing
- managing the clinical data
- medical monitoring and oversight
- inspection
- documentation
- regulatory and EC submissions

The following qualifications for job roles in India for the requirement of GCP training are:

- Investigator (Site Coordinator)
- Ethics committee
- Sponsor (monitors, auditors, project manager, biostatistician, data management)
- As per the ICH GCP E6 (R2), 2016 and Indian GCP, 2001 there are specific mentions about the qualifications that are required for the following professionals:

Table 1. Educational qualifications/ Experience for job roles in clinical research as per the regulations/guidelines in India

GCP Professional	Education/ Qualification/Experience	Reference in the guidance document
Investigator	The investigator should be qualified by education, training and experience to assume responsibility for the proper conduct of the study and should have the prescribed qualifications by the Medical Council of India (MCI). The investigator should provide a copy of the curriculum vitae and/or other relevant documents requested by the sponsor, the ethics committee, the CRO or the regulatory authorities.	Indian GCP 3.3.1 ICH 4.1.1

	She/he should clearly understand the time and other resource demands the study is likely to make and ensure they can be made available throughout the duration of the study. The investigator should be thoroughly familiar with the safety, efficacy and appropriate use of the investigational product as described in the protocol, investigator's brochure and other information sources provided by the sponsor from time to time. The investigator should be aware of and comply with GCP, SOPs and the applicable regulatory requirements. All trial investigators should have access to such investigational and treatment facilities as are relevant to the proposed trial protocol. A qualified physician who is an investigator or a sub-investigator for the trial should be responsible for all trial-related medical decisions. The Investigator(s) should possess appropriate medical qualifications and relevant experience for conducting pharmacokinetic studies. Laboratories used for generating data for clinical trials should be compliant with good laboratory practices.	NDCT Rules, 2019; Third Schedule; 1(iv) NDCT Rules, 2019; Table 4(2) NDCT Rules, 2019; Fourth Schedule; 2.1.3(a)
Monitor	The monitor should have adequate medical, pharmaceutical and/or scientific qualifications and clinical trial experience. Monitor should be fully aware of all the aspects of the investigational product(s) and the protocol (including its annexures and amendments). Monitors should be appointed by the sponsor. Monitors should be appropriately trained, and should have the scientific and/or clinical	Indian GCP 3.2.1

	knowledge needed to monitor the trial adequately. Monitor's qualifications should be documented. Monitors should be thoroughly familiar with the investigational product(s), the protocol, written informed consent form and any other written information to be provided to participants, the sponsor's SOPs, GCP, and the applicable regulatory requirement(s).	ICH 5.18.2
Ethics Committee Member	1. Chairperson/Vice Chairperson Non-affiliated; a well-respected person from any background with prior experience of having served/serving in an EC. 2.Member Secretary/Alternate Member Secretary Affiliated; should be a staff member of the institution; should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills; should be able to devote adequate time to this activity which should be protected by the institution. 3. Basic Medical Scientist(s) Affiliated or non-affiliated; non-medical or medical person with qualifications in basic medical sciences; in case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist. 4. Clinicians(s) Affiliated or non-affiliated; should be individuals with recognized medical qualification, expertise and training. 5. Legal expert(s)	ICMR Guidelines 2017 [Table 4.1 (1)] ICMR Guidelines 2017 [Table 4.1 (2)] ICMR Guidelines 2017 [Table 4.1 (3)] ICMR Guidelines 2017 [Table 4.1 (4)]

	Affiliated or non-affiliated; should have a basic degree in Law from a recognized university, with experience. Desirable -Training in medical law.	ICMR Guidelines 2017 [Table 4.1 (5)]
	6.Socialscientist/philosopher/ethicist/theologian Affiliated or non-affiliated; should be an individual with social/behavioural science/ philosophy/religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities.	ICMR Guidelines 2017 [Table 4.1 (6)]
	7. Lay person(s) Non-affiliated; literate person from the public or community; has not pursued a medical science/ health-related career in the last 5 years; may be a representative of the community from which the participants are to be drawn; is aware of the local language, cultural and moral values of the community. Desirable: involved in social and community welfare activities.	ICMR Guidelines 2017 [Table 4.1 (7)]
	*Medical members are clinicians with appropriate medical qualifications. Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example social sciences.	ICMR Guidelines 2017 4.3.6
	One independent member from any other related field such as social scientist or representative of-governmental voluntary agency or philosopher or ethicist or theologian. The members of the Ethics Committee shall follow the provisions of these rules, Good Clinical Practice Guidelines and other regulatory requirements to safeguard the rights, safety and well-being of trial subjects.	NDCT Rules, 2019; Chapter III; Rule 7(6)

	Every member of the Ethics Committee shall be required to undergo such training and development programmes as may be specified by the Central Licencing Authority from time to time; Provided that any member, who has not successfully completed such training and developmental programmes, shall be disqualified to hold the post of member of the Ethics Committee and shall cease to be a member of such committee. The members representing medical scientists and clinicians shall possess at least post-graduate qualification in their respective area of specialisation, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.	NDCT Rules, 2019; Chapter III; Rule 7(7) NDCT Rules, 2019; Chapter III; Rule 7(8)

There is no required educational qualifications (other than those stated broadly in the regulations and guidelines)or defined set of competencies that are necessary to become a GCP Professional who is engaged in clinical research

3.2. Defining roles and competence of GCP professionals

The Task Force established for the development of the MSC by the TC created a grid which lists the different job roles within the clinical trial enterprise and the level of competence required to perform the stated job role whether at a Basic (B), or Advanced (A) level. The Basic level can be deemed as the entry-level requirement for functioning any job role in clinical research. The advanced levels are either a current attribute of the Professional who is in the role for several years or the deemed requirement of a particular job role for optimal performance. The Advanced levels of competence can also be looked at as the requirement for a trainer for these competence domains.

Table 2. Clinical Research Roles and the competence level for a GCP Professional for that Role

Role/ Domains	**C I**	**C II**	**C III**	**CIV**	**C V**	**C VI**
Investigator	A	A	A	A	A	B

Clinical Research Coordinator	B	B	B	B	B	B
Clinical Research Associate	B	A	A	A	A	B
Auditor	B	B	B	B	B	B
Project Manager	A	A	A	A	A	B
Biostatistician	A	B	B	B	B	B
Clinical Data Manager	B	B	B	B	B	A
Medical Monitor	A	A	A	B	B	B
Basic Medical Scientist (EC)	A	A	A	A	A	B
Clinician (EC)	A	A	A	A	A	B
Lay Person (EC)	B	B	B	B	B	B
Legal Person (EC)	B	B	B	B	B	B
Social Worker (EC)	B	B	B	B	B	B
Regulator (CDSCO)	B	A	B	B	B	B
Pharmacist	B	B	B	B	B	B
Research Nurse	B	B	B	B	B	B

3.3. Evaluation of GCP professionals

GCPPCS is developed to evaluate a GCP professional's knowledge, understanding, and application in the conduct of clinical research involving humans in accordance with the International Guideline for Good Clinical Practice – ICH/GCP E6(R2)(2016), Indian GCP Guidelines (2001), NDCT Rules (2019) and the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, (2017). This evaluation does NOT test on any Ministry of Health & Family Welfare, local, or other government or private institutional policy. This certification is not intended for those professionals following Good Laboratory Practice (GLP) and/or Good Manufacturing Practice (GMP) regulations.

3.3.1 Sub-competencies

For each specific competency, there may be several sub-competencies. Sub-competencies are learning outcomes that may be measured to help assess an individual's capacity to perform the

specific competency. Sub-competencies are primarily of value to educators and to others with responsibility for assessing proficiency.

3.3.2 Interpretations of sub-competencies

Each sub-competency includes a specific performance action verb. Verbs have been selected from taxonomies to delineate their relative complexities.

The ability to perform sub-competencies requires learning in one or more of three domains: Affective (attitudes and values), Cognitive (knowledge and thinking skill) and Psychomotor (physical actions). The taxonomies are shown below. Although many of the verbs in the taxonomies are in everyday usage, users of the MSCs for GCPPCS are cautioned that sub-competency statements should be interpreted only in the context of definitions in the following tables.

Table 3. Verbs used in the MSC

A. Affective Actions *(Not ranked in any order of importance, just alphabetical listing)*		
Sl.	**Attitudes / Beliefs**	**Definition**
1	Assist	To give help or support
2	Acknowledge	To recognize as being valid.
3	Choose	To select from some alternatives.
4	Justify	To show to be reasonable.
B. Cognitive Actions *(Ranked in order of increasing complexity)*		
Sl	**Knowledge**	**Definition**
1	List	To create a related series of names, words or other items.
2	Identify	To ascertain the origin, nature or definitive characteristics of an item.
3	Define	To state the precise meaning
4	Describe	To give an account of, in speech or writing.
5	Discuss	To examine or consider (a subject) in speech or writing.
6	Organize	To put together into an orderly, functional, structured whole.
7	Distinguish	To differentiate between
8	Explain	To make plain or comprehensible
9	Apply	To prepare information for use in a particular situation
15	Evaluate	To examine and judge carefully; to appraise.
C. Psychomotor Actions *Grouped as **L**ow, **M**edium, **H**igh complexity*		
Level	**Physical Skills**	**Definition**
L	Demonstrate	To show clearly and deliberately a behaviour
M	Communicate	To convey information about; to make known; to impart
M	Perform	To take action as per the requirements
H	Adjust	To change to match, or fit; to cause to correspond

This is developed by the Scheme Owner for Clinical Research Professional in order to create a national/internationally accepted Minimum Standard of Competence by which GCP professionals will be recognized worldwide by the clinical research community after having undertaken the voluntary evaluation for Personal Certification as per ISO 17024:2012 Standard and Scheme requirements. Those individuals so recognized may be encouraged to use the "**Certified GCP Professional®– Basic**" designation.

Recertification/Certification Renewal: To maintain active certification status, the Certified GCP professional must apply for renewal of certification to the GCPPCS as per the validity period defined in the Scheme.

4. Core knowledge required for the GCP professionals

The agreed-upon Minimum Standards for Competence for GCPPCS should include the knowledge and skills understanding and application of the following- ICH GCPE6(R2) (2016), Indian GCP (2001) and NDCT Rules (2019), National Ethical Guidelines for Biomedical and Health Research involving Human Participants(2017) - to clinical research.

5. Core competence domains for GCP professionals

Competence domains are broad categories of knowledge, skill and attributes, which are necessary to successfully function within one's field of expertise. Competencies also need to be mapped for the role (e.g. clinical study coordinator vs. clinical research associate vs. clinical investigator).

5.1 Protocol

Encompasses knowledge of scientific concepts related to the design of clinical research.

- Need, rationale, objectives (primary, secondary)
- Endpoints and the expected outcome
- Identify a clinically important question
- Explain key elements (statistical, epidemiological, and operational)
- Demonstrate knowledge of pathophysiology, pharmacology, and toxicology, etc. related to the protocol

5.2 Investigational product development and regulations

Encompasses knowledge of how drugs, devices, and biologicals are developed and regulated.

- Describe the roles and responsibilities of the various institutions and individuals participating in the Investigational Product (IP) development process
- Explain the development process and the activities (including GMP) that are involved in the life cycle management of medical products
- Summarize the current regulatory requirements
- Describe the specific processes and phases necessary to seek marketing authorization
- Describe the safety reporting requirements

5.3 Ethical considerations for patient safety and well being

Encompasses care of research participants for their rights, safety and wellbeing.

- Discuss the historical events that led to the evolvement of ethical guidelines and regulatory processes
- Understand the requirements for human participant protection described in different national and international guidelines
- Define the concepts of “clinical equipoise” and “therapeutic misconception” as related to the conduct of a clinical research
- Explain sample size suitability, inclusion and exclusion criteria and other scientific criteria to assure protection of human participants
- Describe the ethical issues related to the vulnerable population and the need for additional safeguards
- Explain the requirement of the informed consent process and learn its key elements
- Reimbursement for participation, compensation (medical and/or financial) as applicable

5.4 Clinical study operations

Encompasses study management and GCP compliance; safety management and handling of investigational product.

- Describe the roles and responsibilities of the clinical investigation team
- Evaluate the design, conduct and documentation of clinical trials
- Understand AE, SAE, causality assessment, management, reporting requirements and compensation
- Describe appropriate control, handling and dispensing of investigational products
- Describe the role and process for monitoring
- Describe the roles and purpose for audit
- Understand post-marketing activities

5.5 Study and site management

Encompasses resources (human resources, infrastructure, finances) necessary for clinical research at the study site.

1. Describe the process of site selection and its supervision

2. Develop a plan for financial management, timelines requirements and cross-disciplinary personnel resources
3. Apply management concepts and effective training methods to manage risk and improve quality
4. Understand steps in clinical project management
5. Identify the legal responsibilities, issues, liabilities, involved in the study
6. Understand the procedures, documentation, and oversight management by stakeholders

5.6 Data management and informatics

Encompasses how data are acquired and managed during clinical research, including source data, data entry, queries, quality control, and correction and the concept of a locked database.

- Understand the role of biostatistician
- Describe the typical flow of data throughout a clinical trial
- Summarize the process of electronic data capture and the importance of information technology in data collection, capture, and management
- Describe the GCP requirements for data correction and queries
- Describe the significance of data quality assurance systems and how standard operating procedures are used to guide these processes

One of the more difficult aspects of competency assessment is the actual assessment of an individual's competence. Using the internationally recognized Joint Task Force Framework(Joint Task Force for clinical trial competency and clinical research professional workforce development- https://mrctcenter.org/clinical-trial-competency/), we adapted the specific examples developed for each competence level providing an intentional approach that describes the competence level of a GCP professional, ranging from "Basic Advanced". This is an initial step to use for competence assessment and consistent expectations across industry, academia, research groups, or regions. It was also felt that the broader adoption and utility of the MSC for GCPPCS would be facilitated by defining the competencies at basic and advanced levels so that they could be applied across a wider range of roles. Presently this document focuses on the requirements for meeting the 'basic' category, which is mentioned in **Appendix 1**.

Knowledge refers to learning concepts, principles and information regarding a particular subject(s) by a person through books, media, encyclopedias, academic institutions and other sources. **Skill** refers to the ability to use contextually that information and applying it appropriately. We have not considered attribute here.

Table 4.Competence Domain, their breakdown into Knowledge and Skill and the time required for teaching

The table intends to provide only broad details (not comprehensive) against each domain at the **basic level of competence**.

Sr. no.	Domain	Knowledge	Skill	Time required for teaching
1	**Protocol**	Encompasses knowledge of scientific concepts related to the design of clinical research. • Need, rationale, objectives (primary, secondary) • Endpoints and the expected outcome • Identify the clinically important question • Explain key elements (statistical, epidemiological, and operational) • Demonstrate knowledge of pathophysiology, pharmacology, and toxicology, etc. related to the protocol	• Identify and explain all the key elements of the protocol as per the current regulatory requirements and applicable guidelines in India. • Demonstrate and identify various study designs. • Justify how to ensure if the correct study design is employed in a clinical study. • Explain the rationale, research question, primary and secondary study objectives, expected outcomes, etc. • Demonstrate knowledge of regulatory pharmacology and toxicology as per the current regulatory requirements in India	For 2-day course = 2 hours For 5-daycourse = 4 hours
2	**Investigational product (IP) development and regulation**	Encompasses knowledge of how drugs, devices, and biologicals are developed and regulated. • Describe the roles and responsibilities of the various institutions and individuals participating in the Investigational	• Demonstrate the working knowledge of product development (new drugs, devices, biologicals, etc.) and its regulation in India	For2-day course for 2 sessions) = 2 hours For 5-day course = 3 hours

		Product (IP) development process • Explain the IP development process and the activities (including GMP) that are involved in the life cycle management of medical products • Summarize the current regulatory requirements • Describe the specific processes and phases necessary to seek marketing authorization • Describe the safety reporting requirements	Identify the life-cycle of IP (manufacture, storage, transport, dispensing, storage, handling, discard, accountability etc.) requirements) • Regulations: related the regulations/guidelines for developing the drug (e.g. basic preclinical studies required before the drug can be tested in humans) including GMP • Exhibit working proficiency of current regulatory requirements for conducting clinical research in India • Explain NDCT Rules 2019 basic requirements especially the specific processes and phases in clinical research and steps for seeking marketing authorization in India. Explain the safety reporting requirements as per the current regulations	
3	**Ethical considerations for patient**	Encompasses care of research participants for their rights, safety and wellbeing.		For 2-day course = 2.5hours

	safety and wellbeing	• Discuss the historical events that led to the evolvement of ethical guidelines and regulatory processes • Understand the requirements for human participant protection described in different national and international guidelines • Define the concepts of "clinical equipoise" and "therapeutic misconception" as related to the conduct of a clinical research • Describe sample size suitability, inclusion and exclusion criteria and other scientific criteria to assure protection of human participants • Describe the ethical issues related to the vulnerable population and the need for additional safeguards • Explain the requirement of the informed consent process and learn its key elements • Reimbursement for participation, compensation (medical and/or financial) as applicable	• Demonstrate applicable ethical principles for research involving humans • Compare the different guidelines and regulations related to human research and comply with the national ones. • Explain the ethical considerations for designing clinical research and prevent therapeutic misconception • Demonstrate sample size; inclusion and exclusion criteria for justified selection of patient groups by balancing risk and benefit • Define vulnerable populations and suitable protection safeguards • Identify the key elements of informed consent document contextually, and the type of informed consent process, documents applicable; assess participant's understanding of the informed consent process. Differentiate reimbursement and compensation for injury; discuss, SAEs and ADRs, the causality (relatedness) and reporting timelines to IECs, sponsors and regulatory authorities	For 5-day course = 6 hours

4	**Clinical trial operations**	Encompasses study management and GCP compliance; safety management and handling of investigational product. • Describe the roles and responsibilities of the clinical investigation team • Evaluate the design, conduct and documentation of clinical trials • Understand AE, SAE, causality assessment, management, reporting requirements and compensation • Describe appropriate control, handling and dispensing of investigational products • Describe the role and process for monitoring • Describe the roles and purpose for audit • Understand post-marketing activities	• Describe the roles and responsibilities of all stakeholders in clinical research • • Explain the various resources necessary for running a successful clinical trial operation • Describe all the documents necessary before, during and after the trial • Explain all the safety management requirements, compensation, financial and non-financial requirements in the clinical trial. • Describe all IP requirements and management • Describe the purpose and process for monitoring clinical trials. • Describe the purpose and process of clinical trial audits. • Evaluate the conduct and documentation of clinical trials as required for compliance with GCP guidelines. • Explain all post-marketing activities (PMS, PSUR, etc.)	For 2-day course = 1.5 hours For 5-day course = 5 hours

5	**Study and site management**	Encompasses resources (human resources, infrastructure, finances) necessary for clinical research at the study site. 1. Describe the process of site selection and its supervision 2. Develop a plan for financial management, timelines requirements and cross-disciplinary personnel resources 3. Apply management concepts and effective training methods to manage risk and improve quality 4. Understand steps in clinical project management 5. Identify the legal responsibilities, issues, liabilities, involved in the study 6. Understand the procedures, documentation, and oversight management by stakeholders	• List practical applications of GCP in clinical trials. • • Explain the site selection process, feasibility analysis, etc. • • Explain financial and non-financial requirements for study and site management • • Recognize management and training approaches to mitigate risk to improve clinical trial conduct. • Develop strategies to manage participant recruitment, study activities, and track progress. • Describe the various methods by which safety issues are identified and managed during the phases of clinical trials. • Identify the legal and regulatory responsibilities, liabilities, and accountabilities that are involved in the conduct of clinical trials. • Explain good documentation practice and all documentation necessary by the study and site management team	For 2-day course = 2 hours For 5-day course = 5 hours

6	**Data management and informatics**	Encompasses how data are acquired and managed during clinical research, including source data, data entry, queries, quality control, and correction and the concept of a locked database. • Understand the role of biostatistician • Describe the typical flow of data throughout a clinical trial • Summarize the process of electronic data capture and the importance of information technology in data collection, capture, and management • Describe the GCP requirements for data correction and queries • Describe the significance of data quality assurance systems and how standard operating procedures are used to guide these processes	• Describe the life cycle of clinical data throughout a clinical research study. • Describe the roles and responsibilities of a biostatistician • Summarize the process of electronic data capture and the importance of information technology in data collection, capture, and management. • Describe the GCP requirements for data correction and queries. • Explain the importance of quality assurance in clinical data management and informatics. • Basic working proficiency (ability to write and understand) SOPs used in clinical data management and informatics	For 2-day course = 2 hours For 5-day course = 3 hours
				Total : 2-day workshop (12 hours) 5-day workshop (26 hours)

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1 # Appendix 1. Different elements of the basic competence domain

DOMAIN 1: Protocol: Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials/ research	
1.1	Apply principles of biomedical science to clinical research
	Basic level Learner/GCP professional shall: 1. **Recognize** the need to apply rationale and scientific principles to the discovery and development of biomedical investigational products and clinical research. 2. **Explain** the basic scientific principles that should be applied during the development of biomedical investigational products and clinical research. **Example:** *When reviewing a clinical research protocol, the researcher describes the objective and scientific techniques used to design and implement biomedical research.*
1.2	Identify study hypotheses, the rationale for the study and doses of drugs/devices/interventions used in the study
	Basic level Learner/GCP professional can: 1. **Articulate** the purpose of the study. 2. **Describe** the importance of the study. **Example:** *Identifies the following elements in selected study protocols: Study title, the key purpose of the study, why this study is important to be done, which specific population will be selected for the study. Identifies and discusses the two comparators in a controlled clinical trial and why each has been selected.*
DOMAIN 2: Investigational Products Development and Regulations: Encompasses knowledge of how investigational products are developed and regulated	
2.1	Discuss the background of regulatory processes in clinical research
	Basic level Learner/GCP Professional can: 1. **Identify** the key events that influenced the current regulatory environment in India. 2. **Describe** the regulations and Guidelines for regulatory clinical trials and academic trials (DHR 2019). **Example**: Identifies and describes the differences in regulations between Industry-sponsored regulated clinical trials and Academic clinical studies.
2.2	Describe the roles and responsibilities of the various stakeholders participating in the investigational products development process
	Basic level Learner/GCP Professional can:

	1. **Identify** differences between responsibilities of investigators, sponsors, CROs and regulatory bodies. 2. **Demonstrate** an understanding of the role of IECs in approving protocols, assessing risk, and determining exemptions. **Example**: Describes the role of an investigator.
2.3	Summarize the regulatory framework required in clinical research and drug development
	Basic level Learner/GCP Professional can: 1. **Describe** how to access the appropriate regulatory guidance that applies to the development and registrations of IPs, and the clinical trials process required to register such products applicable at the geographical location. 2. **Describe** the specific activities of preclinical and clinical research and how they contribute to the filing of an IND. 3. **Recognize** the significance of preclinical, and clinical (phase I-III) data contribute to the filing of an IND. **Example**: Accesses the relevant guidance in their country for informed consent, drug development and approval, IRBs/ECs, Conflict of interest, Investigator responsibilities, sponsor responsibilities. Knowledge of different tests used in preclinical studies (toxicology, carcinogenicity etc.).
2.4	Describe the safety reporting requirements
	Basic level Learner/GCP Professional can: 1. **Identify** different safety reporting requirements during the clinical trial stage and the post-marketing period. 2. **Understand** the reporting requirements for different types of adverse events to regulatory agency/IEC. **Example**: Identify the differences between AE, SAE, ADR, SUSAR, etc. Difference between PSUR, PMS and spontaneous reporting.
DOMAIN 3: Ethical consideration for patient safety and well being: Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial	
3.1	Differentiate between the standard of care and clinical study activities

	Basic level Learner/GCP Professional can: 1. **Explain** that a clinical study is unconfirmed research and not accepted treatment/ standard of care. 2. **Understands** the implication of therapeutic misconception. **Example:** *Explains to a study participant that procedures that are part of the protocol are not necessarily treatment/standard of care and thus remove the doubt of therapeutic misconception.*
3.2	Apply relevant principles of human participant protection and privacy throughout all stages of a clinical study
	Basic level Learner/GCP Professional can: 1. **Enumerate** the different national and international guidance and Indian regulations with regards to participant safety 2. **Explain** the importance of complying with global guidelines and recommendations, as well as local regulations regarding the safety, wellbeing, and rights of all participants participating in a clinical trial anywhere **Example:** *Identifies examples of autonomy, justice and beneficence in the recruitment and consent process for a clinical protocol. e.g. Nazi experiments and Tuskegee study and the ethical implications*
3.3	Explain the principles and process of informed consent and key elements.
	Basic level Learner/GCP Professional can: 1. **Identify** the historical events which have led to the development of the current informed consent requirements. 2. **Identify** the key documents that ensure the protection of human participants in clinical research (Nuremberg Code, Declaration of Helsinki, Belmont Report, National Ethical Guidelines). **Example:** *Identifies and explains the three principles of the Belmont Report, key elements in National Ethical Guidelines and the difference between NDCT 2019, Indian GCP Guidelines and ICH GCP guidelines. Identifies elements of the AV recording of IC process in the case of a vulnerable patient.*

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3.4	Describe the ethical issues involved when dealing with vulnerable populations and what additional safeguards should be in place for those populations
	Basic level Learner/GCP Professional can: 1. **Identify** which populations are considered vulnerable. 2. **Understand** that guidelines and regulations are in place to protect vulnerable populations. **Example:** *Understands these groups as being vulnerable due to absent or reduced autonomy: children, pregnant women, prisoners, mentally challenged persons, lower in hierarchy, economically or educationally disadvantaged persons and accurately describes additional applicable safeguards for each group.*
3.5	Explain the basis for sample size, inclusion, exclusion, and other scientific criteria in a clinical protocol to assure human participant protection and justified selection.
	Basic level Learner/GCP Professional can: 1. **Recognize** the need to know the sample size and eligibility criteria for study participants (e.g., that include and exclude participants) based on factors such as age, gender, the type and stage of a disease, treatment history, and other medical conditions that allow the research team to determine whether *the participants,* can take part in the study safely. 2. **Determine** potential eligibility of study participants for a non-complex study (e.g., registries, survey, observational studies). **Example:** *Understands about sample size and identifies the inclusion and exclusion and other scientific criteria from a set of sample cases for an upcoming clinical study.*

DOMAIN 4: Clinical Trial Operations: Encompasses study management and GCP compliance; safety management (AE identification and reporting, PMS, and PV, etc.), and handling of IP.	
4.1	Describe the roles and responsibilities of the clinical study team
	Basic level Learner/GCP Professional can: 1. **Describe** the roles and responsibilities as defined in the current ethical guidelines, and regulations. 2. **Describe** own role and is aware of the roles of others in the study team as set forth in the current guidelines and regulations. 3. **Understand** the concepts of the delegation of authority and scope of practice. **Example:** *Clearly articulates own role responsibilities and describes limits of one's role in the performance of clinical study activities.*
4.2	Various documentation process and archival in clinical research in compliance with GCP requirements.
	Basic level Learner/GCP Professional can: 1. **Describe** various documents (Protocol, Informed Consent Document, CRF, CSR, etc.) and archival. **Example:** *Describe what, how, how long each document should be maintained (elaborate).*
4.3	Describe appropriate control, storage and dispensing of investigational product
	Basic level Learner/GCP Professional can: 1. **Understand** that investigational products require specific control, storage and dispensing. 2. **Identify** and follow existing Standard Operating Procedures for control, storage, and dispensing of IP. **Example:** *Locates and applies an SOP for the receipt, storage and usage of the investigational product for a clinical study at the clinical research site.*

4.4	Differentiate the types of adverse events (AEs), Serious Adverse Events (SAE), understand the casuality assessment and know the reporting requirements.
	Basic level Learner/GCP Professional can: 1. **Recognize** the differences between the different types of adverse events. 2. **Recognize** when an SAE occurs during the conduct of a clinical trial and report it within the appropriate time frame per the NDCT 2019 regulations. 3. Understand causality assessment, relatedness, know reporting requirements for SAE. **Example:** *Applies accurate classification of adverse events from sample cases (AE, SAE, Serious and Unexpected AE, Adverse Drug Reaction, etc.).*
4.5	Describe the role and process of monitoring a clinical research
	Basic level Learner/GCP Professional can: 1. **Recognize and understand** the rationale for clinical monitoring and related regulations and guidelines. 2. **Understand the need to adhere to** the monitoring plan and applicable SOPs. 3. With guidance and oversight, **perform** monitoring tasks as per the monitoring plan and inform others when confronted with issues not detailed in the monitoring plan. **Example:** *Participates in local QA audits of clinical studies in preparation of a CRO monitoring visit.*
4.6	Describe the role and purpose of clinical study audits/inspection
	Basic level Learner/GCP Professional can: 1. **Describe** the steps taken to prepare for an audit/inspection. 2. **Name** the entities which have the authority to conduct audits. 3. **Locate and explain** the federal regulations governing audits and inspections. **Example:** *Assists with preparation for clinical study audits and understands the roles of the team during an audit.*

DOMAIN 5: Study and Site Management: Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs).	
5.1	Describe the requirements for setting up a clinical study at an investigator site
	Basic level Learner/GCP Professional can: 1. **Demonstrate** a basic understanding of baseline determinants of the new study selection process at a research site. 2. **Understand** the purpose of pre-site evaluation visits. 3. **Participate** in virtual or face-to-face pre-site visits. **Example:** *Given a new potential protocol, understands study-related needs to be able to do the study at the site, including the availability of a specific study population.*
5.2	Develop and manage the clinical study budget, timeline, and personnel resources necessary to conduct a clinical study
	Basic level Learner/GCP Professional can: 1. **Identify** the parts of a clinical trial budget. 2. **Identify and perform** delegation of duties at a study site. **Example:** *Organizes study visits and requisite labs using correct requisition and account numbers for the study and is able to track and reconcile those documents.*
5.3	Describe the management and training approaches to mitigate risk to improve clinical study conduct
	Basic level Learner/GCP Professional can: 1. **Identify** the mechanisms used in a research study that has been put in place to mitigate risk. 2. **Understand** how risk assessments are conducted for clinical study operations and patient safety. **Example:** Identifies withdrawal criteria, rescue criteria etc. for the study. *Articulates potential reasons why a key performance indicator might be compromised (e.g., study participants not completing study visits within the protocol-defined study window) and operations that might ensure the lowest risk of occurrence.*

5.4	Develop strategies to manage participant recruitment, retention, compliance and track study activities.
	Basic level Learner/GCP Professional can: 1. **Articulate** expected recruitment, enrolment and retention rate. 2. **Identify** and use tools, strategies, and procedures for implementation and tracking of participant recruitment and retention. **Example:** *Identifies documents and systems used to track recruitment and retention of participants.*
5.5	Identify the legal responsibilities, liabilities and accountabilities that are involved in the conduct of clinical studies
	Basic level Learner/GCP Professional can: 1. **Organize and maintain** study regulatory and grants/contracts documents for regulatory and institutional compliance audits. 2. **Understand** the purpose of study legal materials including contract, budgets, indemnification, confidentiality disclosure agreements, and conflict of interest reporting, EC/IRB approvals in a compliant study site. **Example:** *When asked by an investigator to obtain samples in the freezer to ship to another investigator site or lab, a researcher at the Basic Level should know some of the regulatory requirements (need for Export license) before making the shipment.*

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DOMAIN 6: Data Management and Informatics: Encompasses how data are acquired and managed during a clinical study, including source data, data entry, queries, quality control, and correction and the concept of a locked database	
6.1	Describe the role and importance of biostatistics and data management in clinical studies
	Basic level Learner/GCP Professional can: 1. **Understand** the basic purpose of biostatistics and data management as applied in clinical studies (e.g., randomization, sample size, adverse events, analysis, and results). **Example:** *When reviewing a protocol and case report form, recognizes the data points that are associated with the analysis of safety and efficacy endpoints.*
6.2	Describe the origin, flow, and management of data through a clinical study
	Basic level Learner/GCP Professional can: 1. **Describe** the basic concepts of clinical data management. 2. **Identify** the various sources of data that contribute to a clinical study and can distinguish the different industry standards to be used in their handling. **Example:** *Understands the purpose and scope, as well as the process workflow defined in a data management plan.*
6.3	Describe best practices and resources required for standardizing data collection, capture, management, analysis, and reporting
	Basic level Learner/GCP Professional can: 1. **Identify and apply** standard and best practices for data management in clinical research. 2. **Identify** documents and resources related standards and best practices associated with the collection, data capture, data management, data analysis, and data reporting in clinical research. **Example:** *When given standardized scenarios, the researcher identifies a standard or best practice (for data collection, capture, management, analysis, and reporting).*
6.4	Describe, develop, and implement processes for data quality assurance
	Basic level Learner/GCP Professional can: 1. **Identify and understand** the processes that assure data quality. 2. **Recognize** whether individual pieces of data collected in a clinical study are attributable, accurate, complete and verifiable from the source data. **Example:** *Enters and corrects data from a source document into an electronic data collection form.*

The Minimum Standard of Competence for GCP Professional Certification Scheme will be utilized as a basic framework to produce the more granular and specific competency statements which include knowledge, skills and attributes which define the many roles which exist in the clinical research enterprise in India.

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