eLearning Courses

The name that will appear on your certificate is **Marothi Peter LETSOALO**.

ICH Good Clinical Practice E6 (R2)

RESULTS **RETAKE**

100% complete

Quiz

Please ensure you have answered all questions before clicking the 'submit' button

Summary

Score for this module: 100%

Get certificate

1. Which of the following is NOT a principle of GCP: (Please select all that apply)
   - Any foreseeable risks and inconveniences must be weighed up against any benefits
   - Information must be recorded, handled and stored

in a manner that allows accurate reporting, interpretation and verification and which ensures the confidentiality of participants' records.

Publication of results is not required if the study results were not as expected. **Your correct answer**

The study protocol must provide inclusion and exclusion criteria, monitoring details and a publication policy.

Available non-clinical and clinical information on the investigational medicinal product being used must be adequate to support the study.

The study must be conducted according to the Nuremberg Code of 1947 **Your correct answer**

---

2. ICH-GCP guidelines are a legal requirement and studies found not following it will be terminated.

True

False **Your correct answer**

---

3. It is important for investigators in low-and middle-income countries to adopt good clinical practice guidelines because their studies will conseque...

True **Your correct answer**

False

---

4. Which of the following is NOT true about the informed consent process: (Please select all that apply)

IEC/IRB approval must be gained for all participant related materials and documents.

Details of any alternative treatments/options must be given to participants after they have given consent **Your correct answer**

Consent must be given freely without coercion or undue influence.

A participant can withdraw from the study at any time without providing a reason.

If the participant cannot read or write the consent form can be marked/signed at any time during participation as long as the participant has agreed to join the study. **Your**

correct answer

---

5. As long as you document the entire process, you can unblind a participant at the request of a site investigator who wants to enter the participant ...
   - True
   - **False** **Your correct answer**

---

6. Participants in a study with an investigational medicinal product should only contact the study physician if feeling unwell if their own physician ...
   - True
   - **False** **Your correct answer**

---

7. Approval from the IEC/IRB is not required for which of the following:
   - **Study management plan** **Your correct answer**
   - Study protocol
   - Compensation plans

---

8. The IMP temperature was not recorded for 3 days, according to protocol this should have been monitored daily; who will you hold responsible?
   - Laboratory technician
   - Sponsor
   - **Investigator** **Your correct answer**
   - Nurse

---

9. The protocol is replaced by which of the following:
   - GCP guidelines
   - Standard operating procedures
   - Statistical analysis plan
   - Study management plan
   - **None of the above** **Your correct answer**
   - All of the above

---

10. AEs and SAEs, as defined by the protocol, are:
    - Only recorded in the case of severe injury or death
    - **Carefully and systematically recorded** **Your**

correct answer

A routine part of all studies and should be ignored

---

11. Suspension or termination of the study by the investigator should be reported to which of the following groups:

    Sponsor

    DSMB

    IEC/IRB

    Collaborators

    All of the above **Your correct answer**

---

12. The investigator involved in running a study should be qualified by: (Please select all that apply)

    Training **Your correct answer**

    Education **Your correct answer**

    The World Health Organisation

    Experience **Your correct answer**

    An academic institution

---

13. Which of the following are GCP responsibilities of the investigator: (Please select all that apply)

    Ensuring all study staff are sufficiently qualified **Your correct answer**

    Communication with participants family members

    Compliance with study protocol **Your correct answer**

    Compensation of study participants

    Reporting Serious Adverse Events **Your correct answer**

---

14. What does IEC Stand for?

    Investigational Ethics Committee

    International Ethics Committee

    Institutional Ethics Committee

    Independent Ethics Committee **Your correct answer**

---

15. Which of the following are key principles of GCP (Please select all that apply)

The rights, safety and well-being of participants always take precedence over the interests of science and society. **Your correct answer**

Individuals involved in running studies should be qualified by training to perform their tasks. **Your correct answer**

The research protocol must receive approval from the IEC/ IRB and needs to be followed **Your correct answer**

Investigational products must be used in accordance with the standard operating procedure.

---

16. When conducting a clinical trial in accordance with GCP, what is the most important consideration above all else?

Protection of participants **Your correct answer**

Protocol adherence

Accuracy of data

Quality checks

---

17. In accordance with GCP the investigator must ensure which of the following: (Please select all that apply)

Recruitment of an adequate number of participants **Your correct answer**

An appropriate amount of time is scheduled to carry out and complete the study effectively **Your correct answer**

Appropriate facilities for the duration of the study **Your correct answer**

All staff receive appropriate training on the study protocol, the investigational product and their duties **Your correct answer**

---

18. Clinical studies should be run applying GCP principles because:

Applying the principles means that the investigator does not have to follow the study protocol

It means that the study will be run to a standard which assures the credibility and accuracy of the data and reported results **Your**

correct answer

Demonstrating that GCP principles are being followed means the study does not need to be audited

---

Your feedback helps us provide high quality, relevant training courses.
Please take a minute to tell us what you think of this course. Thank you!

SHARE YOUR FEEDBACK HERE

---

*This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by **TransCelerate BioPharma** as necessary to enable mutual recognition of GCP training among trial sponsors.*

ALERRT African coalition for Epidemic Research, Response and Training
REDe Research Capacity Network
Global Research Nurses
THE GLOBAL HEALTH NETWORK Enabling research by sharing knowledge

DOWNLOAD MATERIALS:

This Course (PDF)
Your Certificate(PDF)

CONTENT NAVIGATION

1. Contents
2. Course Objectives
3. What is Good Clinical Practice
    1. What is Good Clinical Practice
4. Who is Involved with GCP?
5. Recognition of GCP
6. Being GCP Qualified

7. Investigators' GCP Responsibilities
    1. Gaining informed consent from study participants
        1. Gaining informed consent from study participants
        2. Gaining informed consent from study participants
    2. Randomisation procedures and unblinding
    3. Medical care of participants
    4. IEC/IRB communication and approvals
    5. Investigational product(s) management
    6. Study protocol compliance
    7. Investigator qualifications and agreements
        1. Investigator qualifications and agreements
    8. Records and reports management
        1. Records and reports management
    9. Safety reporting
        1. Safety reporting
    10. Ensuring adequate resources
    11. Management of premature termination or suspension of a trial
    12. Progress reporting and final reports

8. Practical application of GCP
9. Key Points to Remember
10. References and Resources
11. Quiz