Module 5: Principles applied in the Initiation of the Study

Case Scenario:

Dr. Chen is preparing to launch a multinational clinical trial on a new antiviral medication. The IRB/IEC and regulatory approvals are in place. Before recruitment starts, Dr. Chen organizes a study initiation meeting with site staff and the sponsor. During the preparation phase, she ensures that the Trial Master File (TMF) is set up with delegation logs, SOPs, training records, and IRB correspondence. Each team member completes training in GCP, protocol procedures, and handling of investigational products. The investigational product (IP) is delivered and logged with a chain-of-custody form and stored under recommended conditions (2–8°C) using a calibrated temperature monitor.

1. **What must happen before participant recruitment begins?**

   A) Advertisements should be posted online
   B) IRB/IEC and regulatory approvals are confirmed, and team training is completed
   C) Investigators need to visit and evaluate all potential sites
   D) The study protocol must be published in a peer reviewed journal

2. **Why is it important to document the condition of the investigational product on arrival?**

   A) To ensure the product's integrity and safety for use in the trial
   B) To complete customs paperwork
   C) To track courier performance
   D) To satisfy participants' curiosity

3. **What is one key role of the Trial Master File (TMF) during the study initiation phase?**

   A) It is used to store patient lab samples
   B) It documents essential study materials, training, and compliance to facilitate regulatory inspections
   C) It manages trial advertisements
   D) It tracks hospital facility maintenance

Answers and Feedback

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Feedback: According to ICH E6(R3), recruitment cannot begin until all relevant regulatory and ethical approvals have been obtained, and staff are adequately trained. This ensures participant safety, study quality, and regulatory compliance. All of this must be documented in the Trial Master File before the trial begins.

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   A) To ensure the product's integrity and safety for use in the trial
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   C) To track courier performance
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Feedback: The investigational product (IP) must be maintained within specified conditions (e.g., temperature control). Documenting its condition upon arrival and maintaining the chain of custody ensures that it has not been compromised, which is crucial for trial validity and patient safety. This is part of the sponsor's and site's responsibilities, according to ICH E6(R3) and the IP handling standards.

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Feedback: The TMF is an essential record containing all critical study documentation, including ethics approvals, training records, SOPs, delegations of duties, and correspondence. Keeping it organized and up-to-date is essential to demonstrate compliance during regulatory audits and inspections, as required by ICH E6(R3), Quality Management and Essential Documentation section.