Module 3: Key Stakeholders in Clinical Research: Roles and Skills for the Application of Good Clinical Practice Principles

Case Scenario:

During a regional outbreak of viral haemorrhagic fever in West Africa, an international organization is collaborating with local health authorities to implement a Phase II/III clinical trial evaluating a novel oral antiviral. The study is considered of global health interest and aims to accelerate the development of effective treatments in an emergency.

The protocol has been approved by regulatory authorities and local ethics committees (IECs). However, 20 days after the start of the trial, the ethics committee found that the consent materials did not include sufficient information regarding the possibility of airlifting patients to regional centres in case of complications. Furthermore, local communities expressed distrust due to past experiences with inadequately explained studies.

The sponsor, in collaboration with community leaders and the principal investigator, convened a risk review committee, incorporated community representatives into the information process, updated consent forms, translated documents into local languages, and implemented a new audiovisual consent module.

Questions:

1. **Which aspect reflects a key ethical responsibility of the IEC in this context?**

   A) Manage relations with international media
   B) Approve the antiviral distribution strategy
   C) Demand clear information on logistical procedures relevant to the participant
   D) Determine the statistical efficacy of the antiviral

2. **What was a good practice adopted by the sponsor that is aligned with ICH E6(R3)?**

   A) Develop a consent module with an audiovisual approach and local translations
   B) Request to omit the signing of the consent for reasons of urgency
   C) Establish sanctions for those who do not participate in the study
   D) Conduct the study without communicating intermediate findings to the community

3. **What was an appropriate action by the principal investigator based on his or her responsibilities in global health and GCP?**

   A) Ignore community concerns to avoid delays
   B) Completely delegate consent to logistics personnel

C) Coordinate the updating of consent and ensure its implementation
D) Allow community leaders to decide which participants should register

Answers and Feedback:

1. **Which aspect reflects a key ethical responsibility of the IEC in this context?**

   A) Manage relations with international media
   B) Approve the antiviral distribution strategy
   C) Demand clear information on logistical procedures relevant to the participant
   D) Determine the statistical efficacy of the antiviral

Feedback: The IEC is responsible for ensuring that participants receive comprehensive and understandable information about all relevant aspects of the study, including indirect risks such as relocation to other centers, especially in vulnerable or emergency settings.

2. **What was a good practice adopted by the sponsor that is aligned with ICH E6(R3)?**

   A) Develop a consent module with an audiovisual approach and local translations
   B) Request to omit the signing of the consent for reasons of urgency
   C) Establish sanctions for those who do not participate in the study
   D) Conduct the study without communicating intermediate findings to the community

Feedback: ICH E6(R3) emphasizes the importance of adapting the consent process to local sociocultural and linguistic conditions and promoting understanding among vulnerable populations. The use of audiovisual media and community involvement reinforce the ethical and participatory approach.

3. **What was an appropriate action by the principal investigator based on his or her responsibilities in global health and GCP?**

   A) Ignore community concerns to avoid delays
   B) Completely delegate consent to logistics personnel
   C) Coordinate the updating of consent and ensure its implementation
   D) Allow community leaders to decide which participants should register

Feedback: The principal investigator is responsible for ensuring that the consent process complies with GCP and is ethical, even in the context of a health emergency. Coordinating the implementation of consent updates is part of their role to protect rights and well-being.

Case Scenario:

A sponsor is overseeing a decentralized clinical trial using mobile health apps to monitor cardiovascular health. During a data audit, they discover that some patient-reported outcomes submitted via the app are missing timestamps and geolocation metadata. This lack of traceability creates doubts about the reliability of the data. The sponsor works with the data governance team and updates the protocol to include mandatory metadata fields. The IRB/IEC is notified of the protocol amendment and approves it.

1. **What was the main data governance issue in this scenario?**

   A) Participants not using the app properly
   B) Missing data affecting traceability
   C) Informed consent on data not collected
   D) Investigators were not blinded to the issue

2. **Which action should the sponsor take to resolve the issue?**

   A) End the trial early and review the process
   B) Ignore the missing data if it is not more than 20% of the outcomes
   C) Implement a validation tool and amend the protocol
   D) Replaced the entire research team

3. **Why is data traceability important in clinical trials?**

   A) It speeds up recruitment
   B) It reduces the amount of data collected
   C) It ensures reliability, auditability, and regulatory compliance
   D) It allows participants to skip follow-up visits

Answers and Feedback

1. **What was the main data governance issue in this scenario?**

   A) Participants not using the app properly
   B) Missing data affecting traceability
   C) Informed consent on data not collected
   D) Investigators were not blinded to the issue

Feedback: Data traceability is essential in any clinical trial. The absence of time stamps and geolocation metadata compromises the verifiability, reliability, and validity of the reported data. According to ICH E6(R3), data must be complete, accurate, and attributable, which is not met if they cannot be properly audited.

2. **Which action should the sponsor take to resolve the issue?**

   A) End the trial early and review the process
   B) Ignore the missing data if it is not more than 20% of the outcomes
   C) Implement a validation tool and amend the protocol
   D) Replaced the entire research team

Feedback: The sponsor acted appropriately by updating the protocol and notifying the IRB/IEC. In line with ICH E6(R3), protocol modifications must be documented, justified, and submitted for approval (called amendments). Implementing validation tools strengthens the quality and traceability of the collected data.

3. **Why is data traceability important in clinical trials?**

   A) It speeds up recruitment
   B) It reduces the amount of data collected
   C) It ensures reliability, auditability, and regulatory compliance
   D) It allows participants to skip follow-up visits

Feedback: Traceability allows any data to be traced back to its source, ensuring integrity and compliance with regulatory requirements. This is essential to maintain the credibility and scientific integrity of the study, protect the safety of participants, and enable effective audits by health authorities or sponsors, according to ICH E6(R3), section on data governance and quality.