Module 6: The principles applied in the Execution of the Study and in Risk Management

Case Scenario:

Dr. Alvarez is conducting a trial on a new anticoagulant. During the study, one participant experiences an unexpected serious adverse event (SAE). Dr. Alvarez consults the Investigator's Brochure (IB) and determines that the event is not listed in the Reference Safety Information (RSI). He reports the SAE to the sponsor and IRB/IEC within 24 hours. Meanwhile, the data governance team initiates a review to ensure that similar events haven't been under-reported and confirms the trial data remains traceable and verifiable.

Questions:

1. **What did Dr. Alvarez use to determine whether the SAE was expected?**

   A) Patient's feedback form
   B) Reference Safety Information (RSI) in the Investigator's Brochure
   C) Social media alerts
   D) Hospital billing records

2. **What is the role of the data governance team in this scenario?**

   A) Manage participant travel logistics
   B) Submit trial results for publication
   C) Ensure the integrity, traceability, and quality of trial data
   D) Handle participant recruitment

3. **Which action demonstrates compliance with safety reporting standards?**

   A) Waiting until the end of the study to report
   B) Reporting the SAE to the sponsor and IRB/IEC within 24 hours
   C) Discussing the SAE only with site staff
   D) Removing the participant from the trial records

Answers and Feedback:

1. **What did Dr. Alvarez use to determine whether the SAE was expected?**

   A) Patient's feedback form
   B) Reference Safety Information (RSI) in the Investigator's Brochure
   C) Social media alerts
   D) Hospital billing records

Feedback: The RSI contained in the Investigator's Brochure is the official source for determining whether an adverse event is expected or unexpected. This procedure is essential for fulfilling pharmacovigilance obligations and ensuring the ethical and scientific evaluation of participant safety, in accordance with ICH E6(R3) and international regulations.

2. **What is the role of the data governance team in this scenario?**

   A) Manage participant travel logistics
   B) Submit trial results for publication
   C) Ensure the integrity, traceability, and quality of trial data
   D) Handle participant recruitment

Feedback: The data governance team plays a central role in maintaining the integrity, completeness, verifiability, and auditability of clinical trial data—key principles of ICH E6(R3). This applies to other designs based on the responsibility for data protection, confidentiality, and participant safety. Its review following an SAE demonstrates a proactive, risk-based response, which contributes to both the transparency and reliability of study results.

3. **Which action demonstrates compliance with safety reporting standards?**

   A) Waiting until the end of the study to report
   B) Reporting the SAE to the sponsor and IRB/IEC within 24 hours
   C) Discussing the SAE only with site staff
   D) Removing the participant from the trial records

Feedback: Timely reporting (within 24 hours) of serious and unexpected adverse events is an ethical and regulatory obligation. This allows for rapid risk assessment and implementation of corrective actions if necessary. Dr. Álvarez acted responsibly and in accordance with ICH E6(R3) and participant safety principles.