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QUESTION 1

In which section of the ICH Common Technical Document will the overview of clinical data appear?

A. Module 1

B. Module 2

C. Module 3

D. Module 4

Correct Answer: BC

QUESTION 2

During several monitoring visits, a clinical trial monitor identifies serious and repeated noncompliance on the part of the PI. What action should the sponsor take?

A. Increase the frequency of monitoring visits.

B. Inform the institution that granted a medical license to the Pi.

C. Send a letter of complaint to the Ethics Committee that approved the site.

D. Terminate the PI and inform the regulatory authorities.

Correct Answer: D

QUESTION 3

During an audit of a contract manufacturing facility by a potential client, the auditor requested to be left alone in the records room. The records room contains information on all products produced by the contract manufacturer.

Which action is MOST appropriate for the regulatory affairs professional to take?

A. Allow the auditor access to the room and records due to the current audit.

B. Allow the auditor accompanied access to the room to retrieve the records.

C. Deny the auditor access to the room and retrieve only the requested records.

D. Deny the auditor access to the room and records due to confidentiality concerns.

Correct Answer: B

QUESTION 4

A protocol for a pivotal registration trial of a new product is submitted to a major regulatory authority for review and approval. The regulatory authority issues the company a written commitment that if the studies are completed as outlined in the protocol and the results meet the pre-specified criteria for efficacy and safety, the product will be approved.

During the final week of the review of the marketing application, which has fully met all pre- specified criteria, the company receives a letter from the regulatory authority stating that it no longer believes that the product will be approved based on a recent withdrawal of a similar product in another country.

What is the BEST response?

A. Notify the regulatory authority regarding Its obligation to honor the commitment to approve the application.

B. Consult with the legal department to discuss the best course of action.

C. Review the regulatory guidelines to determine how to proceed.

D. Request a meeting with the regulatory authority to discuss the application.

Correct Answer: D

QUESTION 5

A request was received from a regulatory authority asking the company to conduct product testing in compliance with a newly issued regulation.

What should be done. What action should the company take FIRST?

A. Initiate testing immediately to ensure compliance.

B. Consult with colleagues about the request.

C. Contact the regulatory authority that issued this request and discuss the requirement.

D. Send a letter back to the regulatory authority indicating why the regulation does not apply to the product.

Correct Answer: C