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QUESTION 1

Company X and Company Y both have products for the treatment of rare genetic diseases. Company X would like to acquire Company Y but does not know enough about Company Y to make an offer. What is the MOST appropriate approach that Company X should take to acquire more information about Company Y?

A. Enter into an agreement with Company Y to perform due diligence.

B. Recruit a professional to gather confidential intelligence on Company Y.

C. Request the needed information from the Board of Directors of Company Y.

D. Perform a thorough library search to gather detailed information on Company Y.

Correct Answer: A

QUESTION 2

A company\\'s product was approved by a regulatory authority with the condition that further studies must be completed prior to full approval of the product. To minimize product-associated risk to patients during the period of conditional approval, what is the LEAST effective way to achieve this goal?

A. Label the product for use in appropriate populations.

B. Educate patients and healthcare providers on how to use the product

C. Delay product launch until required studies are completed.

D. Promote off-label use to a carefully selected patient population.

Correct Answer: D

QUESTION 3

Which of the following is NOT considered a serious adverse event in a cardiovascular clinical trial?

A. Subject is hospitalized due to complications of the product administration.

B. Subject is hospitalized for the purpose of product administration.

C. Subject\\'s hospitalization is due to an unscheduled hip operation.

D. Subject\\'s hospitalization is prolonged during the clinical trial.

Correct Answer: BC

QUESTION 4

Company X is planning to acquire the rights for a product marketed by Company Y. As part of due diligence, what is the MOST important information the Company X regulatory affairs professional should ask senior management to request from Company Y?

A. Intellectual properly

B. Clinical trial data

C. Safety issues

D. Marketing materials

Correct Answer: C

QUESTION 5

What are the MOST important elements that global regulatory agencies want to know before approving a new product for sale in their countries?

A. Safety and failure risk

B. Safety and effectiveness

C. Quality and failure risk

D. Quality and effectiveness

Correct Answer: B