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Question: 1

Which of the following elements of a protocol define the criteria for selecting and enrolling participants into a study?

- A. Investigational product characteristics
- B. Study objective(s) and end points/outcomes
- C. Subject eligibility requirements
- D. Supplemental/rescue/comparator/placebo product(s)

Answer: C

Explanation: Subject eligibility requirements are elements of a protocol that define the criteria for selecting and enrolling participants into a study. These requirements specify the characteristics and criteria that potential participants must meet in order to be eligible for participation.

Question: 2

When reviewing background information for a clinical trial, which of the following should be considered?

- A. Study concept
- B. Product development plan
- C. Investigational Brochure (IB)
- D. Target product profile
- E. All of the above

Answer: E

Explanation: When reviewing background information for a clinical trial, all of the listed factors should be considered. The study concept provides an overview of the research question and objectives. The product development

plan outlines the steps involved in developing the investigational product. The Investigational Brochure (IB) contains detailed information about the product, and the target product profile describes the desired characteristics of the final product.

Question: 3

When evaluating a protocol for scientific soundness, which of the following factors should be taken into account?

- A. Risk and benefit assessment
- B. Validity of study procedures
- C. Endpoints
- D. Hypothesis generation
- E. All of the above

Answer: E

Explanation: When evaluating a protocol for scientific soundness, all of the listed factors should be taken into account. Risk and benefit assessment ensures that the potential risks to participants are justified by the potential benefits of the study. Validity of study procedures ensures that the methods used are appropriate for addressing the research question. Endpoints define the specific outcomes that will be measured to assess the effectiveness of the intervention. Hypothesis generation involves formulating research questions and hypotheses based on existing knowledge.

Question: 4

What is the purpose of evaluating a protocol for scientific soundness?

- A. To assess the feasibility of the study
- B. To determine the expected or unexpected results

- C. To review the background information
- D. To assess the risk, benefit, and validity of study procedures

Answer: D

Explanation: Evaluating a protocol for scientific soundness involves assessing the risk, benefit, and validity of the study procedures. This evaluation helps to ensure that the study design is scientifically rigorous and capable of generating reliable and valid results.

Question: 5

Which of the following is a statistical principle commonly used in clinical research?

- A. Confidence interval
- B. Study power
- C. Sample size calculation
- D. Randomization
- E. All of the above

Answer: E

Explanation: All of the listed options are statistical principles commonly used in clinical research. Confidence interval provides an estimate of the range within which the true effect size is likely to fall. Study power refers to the probability of detecting a true effect if it exists. Sample size calculation determines the number of participants needed to achieve adequate statistical power. Randomization is a method used to assign participants to different treatment groups in a controlled and unbiased manner.

Question: 6

What is the purpose of including supplemental/rescue/comparator/placebo products in a study design?

- A. To provide an alternative treatment option for participants who do not respond to the investigational product
- B. To compare the efficacy and safety of the investigational product with other available treatments or a placebo
- C. To increase the sample size of the study
- D. To fulfill regulatory requirements
- E. To reduce the cost of the study

Answer: B

Explanation: The purpose of including supplemental/rescue/comparator/placebo products in a study design is to compare the efficacy and safety of the investigational product with other available treatments or a placebo. This allows for an assessment of the relative effectiveness and safety of the investigational product compared to existing options or a control group.

Question: 7

What key components should be considered when developing a protocol for a clinical trial?

- A. Inclusion and exclusion criteria
- B. Schedule of events
- C. Safety and efficacy parameters
- D. Procedures to be followed during the trial
- E. All of the above

Answer: E

Explanation: When developing a protocol for a clinical trial, all of the listed

components should be considered. Inclusion and exclusion criteria define the characteristics of eligible participants, the schedule of events outlines the timing and sequence of study procedures, and safety and efficacy parameters establish the measures for assessing the product's effectiveness and safety. Procedures to be followed during the trial ensure standardized conduct across study sites.

Question: 8

Which of the following terms refers to the unexpected results associated with investigational products?

- A. Regression
- B. Neglect
- C. Adverse events
- D. Denial

Answer: C

Explanation: Adverse events refer to the unexpected results associated with investigational products or interventions. These events may include side effects, complications, or any undesirable or unintended outcomes that occur during the course of a study.

Question: 9

Which of the following elements are typically found in a protocol?

- A. Investigational product characteristics
- B. Study objective(s) and end points/outcomes
- C. Treatment assignments
- D. Supplemental/rescue/comparator/placebo product(s)

Answer: B

Explanation: A protocol typically includes study objective(s) and end points/outcomes. These elements define the purpose and specific goals of the study, as well as the intended outcomes that will be measured and evaluated.

Question: 10

Which of the following study design characteristics involves the random assignment of participants to different treatment groups?

- A. Confidence interval
- B. Study power
- C. Double-blind
- D. Randomization

Answer: D

Explanation: Randomization is a study design characteristic that involves the random assignment of participants to different treatment groups. This helps to ensure that the treatment groups are comparable at the beginning of the study and minimizes the influence of confounding factors.

Question: 11

When analyzing study results, which of the following sources might provide relevant information?

- A. Journal article
- B. Investigational Brochure (IB)
- C. Clinical study report
- D. All of the above
- E. None of the above

Answer: D

Explanation: When analyzing study results, all of the listed sources—journal articles, Investigational Brochures (IBs), and clinical study reports—can provide relevant information. Journal articles often contain published study findings, while IBs and clinical study reports provide detailed information on the study design, methods, results, and conclusions.

Question: 12

Which of the following is an element of an Investigational Brochure (IB) or investigational device use (instructions for use)?

- A. Study design characteristics
- B. Statistical principles
- C. Investigational product characteristics
- D. Subject eligibility requirements

Answer: C

Explanation: Investigational product characteristics, such as its mechanism of action and stability, are important elements that are typically included in an Investigational Brochure (IB) or investigational device use instructions. These characteristics provide essential information about the investigational product being studied.

Question: 13

Which of the following elements of a protocol helps to define the study objective(s) and end points/outcomes?

- A. Inclusion and exclusion criteria
- B. Safety and efficacy parameters

- C. Study design characteristics
- D. Treatment assignments
- E. Investigational product characteristics

Answer: B

Explanation: Safety and efficacy parameters play a crucial role in defining the study objective(s) and end points/outcomes. These parameters establish the specific measures that will be used to assess the safety and effectiveness of the investigational product, thereby guiding the overall goals of the study.

Question: 14

What is the rationale for including subject eligibility requirements in a clinical trial protocol?

- A. To ensure participant safety and well-being
- B. To minimize potential confounding factors
- C. To maximize the likelihood of observing a treatment effect
- D. To facilitate recruitment and retention of participants
- E. All of the above

Answer: E

Explanation: Subject eligibility requirements are included in a clinical trial protocol to achieve multiple objectives. They help to ensure participant safety and well-being by identifying individuals who are most likely to benefit from the intervention and least likely to experience harm. Eligibility requirements also minimize potential confounding factors that could obscure the treatment effect being investigated. Additionally, they help maximize the likelihood of observing a treatment effect by selecting participants who are more likely to respond to the intervention. Finally, eligibility criteria aid in the recruitment and retention of participants by clearly defining the target population for the

study.

Question: 15

What is the role of statistical principles in clinical research?

- A. To determine the expected or unexpected results
- B. To assess the feasibility of the study
- C. To evaluate the protocol for scientific soundness
- D. To make inferences and draw conclusions from collected data

Answer: D

Explanation: Statistical principles play a crucial role in clinical research by providing methods and techniques to analyze, interpret, and draw conclusions from collected data. They help researchers make inferences about the study population and assess the likelihood of observed results occurring by chance.

Question: 16

When developing a protocol, which of the following should be considered in terms of feasibility?

- A. Site-specific considerations
- B. Risk and benefit assessment
- C. Validity of study procedures
- D. Practicality of execution

Answer: D

Explanation: Feasibility in protocol development refers to the practicality of executing the study. This includes considerations such as the availability of

resources, logistical constraints, and the ability to recruit and retain study participants. Site-specific considerations fall under feasibility but are not the only aspect to be considered.

Question: 17

Which of the following is an essential element of an Investigational Brochure (IB) or instructions for use of an investigational device?

- A. Study concept and product development plan
- B. Inclusion and exclusion criteria
- C. Mechanism of action of the investigational product
- D. Safety and efficacy parameters
- E. Target product profile

Answer: C

Explanation: The Investigational Brochure (IB) or instructions for use of an investigational device typically include information about the mechanism of action of the investigational product. This information provides an understanding of how the product works and its intended mode of action.

Question: 18

Which of the following is an example of a study design characteristic?

- A. Confidence interval
- B. Study power
- C. Double-blind
- D. Randomization

Answer: C

Explanation: Double-blind is a study design characteristic that refers to the practice of keeping both the participants and the investigators unaware of the treatment assignment. This helps to minimize bias and ensure the objectivity of the study results.

Question: 19

Which of the following best describes a double-blind, randomized study design?

- A. The participants and the investigators are unaware of the treatment assignments, which are randomly determined.
- B. The participants are unaware of the treatment assignments, but the investigators are aware.
- C. The investigators are unaware of the treatment assignments, but the participants are aware.
- D. Both the participants and the investigators are aware of the treatment assignments, which are randomly determined.
- E. Both the participants and the investigators are unaware of the treatment assignments.

Answer: A

Explanation: In a double-blind, randomized study design, both the participants and the investigators are unaware of the treatment assignments, which are randomly determined. This helps to minimize bias and ensure that the results are not influenced by the expectations or preferences of either the participants or the investigators.

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