Regulatory Updates for Clinical Research Professionals Learning Module v.18

This Learning Module is intended to encourage the reader to maintain an understanding of current activities involved in the conduct of research involving human subjects. The module offers one SOCRA continuing education unit to those who complete the review and correctly answer ten of eleven questions.
The module is offered at no cost as a public service. The readers should complete the module at their own pace – there is no time limit.
Once the questions have been answered "off-line," please proceed to the "on-line" module to complete this process and to print your certificate of completion.

When you are prepared to access the "on-line" module, please go to https://socra.elevate.commpartners.com/, to enter your contact information and to complete the "on-line" module, and to receive your certificate of completion.

This recertification module focuses on diversity in clinical trials. Ensuring people from diverse backgrounds join clinical trials is key to advancing health equity.

It is based on:
FDA Guidance and answer the questions below:
Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry

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Please review the FDA Guidance and answer questions 1-9.
Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry

1) **Which of the following applies to the regulatory authority of all FDA Guidance Documents?**
    A) Provide regulatory authority to enforce compliance as law.
    B) Outline the international ethical and scientific quality standard.
    C) Do not establish legally enforceable responsibilities. Instead describe the Agency's current thinking on a topic.
    D) Document Federal law establishing quality standards for food, drugs, medical devices, cosmetics and tobacco.

2) **Which of the following are non-demographic characteristics of study populations?**
    A) Sex
    B) Weight range
    C) Ethnicity
    D) Location of residency

3) **Unnecessary exclusion of clinically relevant populations may lead to failure to discover evidence that relates to:**
    A) Effectiveness
    B) Safety
    C) Cost
    D) Both A and B

4) **Characterizing - in early clinical development- drug metabolism and clearance across populations that may metabolize or clear the drug differently (e.g., older adults and participants with liver or kidney dysfunction) will help avoid later exclusions and, more generally, will allow dose adjustment to optimize effectiveness and safety across different populations.**
    A) True
    B) False

5) **An approach that allows a study to utilize enrichment strategies to help demonstrate effectiveness while also providing information on effectiveness and safety in a broader population and increasing the chances of achieving success on the primary clinical endpoint is:**
    A) A pharmacokinetic sampling approach
    B) A totally randomized approach
    C) A broadening of eligibility approach
    D) A representative sampling approach

6) **The FDA considers reimbursement for reasonable travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to not raise issues regarding undue influence.**
   A) True
   B) False

7) **Recruitment for clinical trials of investigational drugs intended to treat a rare disease presents a unique set of challenges. Which of the following is a strategy to ensure that a broad spectrum of the patient population is represented?**

   A) Waiting until post marketing of clinical trials to engage patient advocacy groups
   B) Re-enrollment of participants from early-phase trials into later-phase randomized trials
   C) Do not allow open label extension studies due to potential of adverse events
   D) Do not restrict eligibility criteria to the specific rare disease population to improve retention

8) **According to the Guidance, the FDA suggests which of the following enrollment and retention practices:**

   A) Hold recruitment events often and during weekend and evening hours.
   B) Work directly with community representatives, patients, patient advocates and caregivers to address participants' needs.
   C) Include clinical trial sites with racial and ethnic minority patients.
   D) All of the Above

9) **Which of the following is a strategy for supporting diverse participation in clinical trials?**
   A) Standardized eligibility criteria that focus on specific populations
   B) Consistent and continued community engagement
   C) Focus only on sites at academic institutions
   D) Exclude patients and IRB/IECs from study design