

CRA ACRP Practice Exam Questions and Answers explanations

A screening log is useful for determining which of the following?

1. trial reimbursement
2. subject IP compliance
3. active recruitment efforts
4. trends regarding evaluable subjects - **Correct Answer** ☐ 1 and 3 only.

E6 8.3.20 A screening log will provide evidence of an investigator's efforts to recruit subjects even if they are unable to identify subjects that meet entry criteria, which can help discriminate sites who are failing to make an effort to recruit from sites who have been unable to enroll subjects despite substantial efforts to do so. In addition, site contracts routinely contain provisions that allow for payment for some or all of the screen failures evaluated at the site, even if these subjects are not enrolled. Information on subject IP compliance and evaluability is captured elsewhere and would not appear on the screening log.

A trial protocol amendment is required if there is

- A. a replacement of a site.
- B. a site investigator change.

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