

# The Future of Clinical Research

**HS**

In this issue of the ACRP *Monitor*, three articles have been selected as the basis for a Home Study test that contains 30 questions. For your convenience, the articles and questions are provided in print as well as online (members only) in the form of a PDF (requires Adobe Reader and text file). This activity is anticipated to take three hours.

**Answers must be submitted using the electronic answer form online (members only, \$27).** Those who answer 70% of the questions correctly will receive an electronic statement of credit by e-mail within 24 hours. Those who do not pass can retake the test for no additional fee.

**Hardware/Software Requirements:** Home Study tests require version 4.x browsers or higher from Internet Explorer, Mozilla Firefox, or Safari. A browser that can run Adobe Flash 9.0 is required to view the digital edition of *The Monitor*, and Adobe Acrobat is required to view PDFs of the Home Study test.

The **December 2009 Monitor Home Study** is based on the following three articles in this issue:

- 1. Clinical Rating Scales in Practice and Research: Methods for Success-Ensuring Competency through Scale Training**  
Geri L. Cramer, RN, BSN, MBA, Senior Clinical Research Specialist with a leading medical device manufacturer
- 2. The Learning Healthcare System: Clinical Research's Future Role**  
David M. Vulcano, LCSW, MBA, CIP, RAC, Associate Vice President for Clinical Research, Hospital Corporation of America
- 3. Operations and the Future of Adaptive Research**  
Michael Rosenberg, MD, MPH, Founder, President, and Chief Executive Officer, Health Decisions

## HOME STUDY LEARNING OBJECTIVES

With knowledge inferred from the articles above, respectively, learners will be able to:

1. understand the use and importance of thorough assessment and training when using clinical rating scales in a clinical research trial.
2. analyze the role clinical research currently plays in the learning healthcare system and the expected role in the future.
3. explain the importance of adaptive clinical operations to the future of drug development, focusing on the increasingly requisite roles of fast, accurate information (trial data and smarter metrics) and shorter decision cycles, not only for trials employing adaptive designs, but for all types of clinical studies.

## CONTINUING EDUCATION INFORMATION

The *Monitor* home study tests offer ACRP, nursing, pharmacy, and continuing medical education credits.

 The Association of Clinical Research Professionals (ACRP) provides 3.0 continuing education credits for the completion of this educational activity. These credits can be used to meet the certification maintenance requirement under provider number ACRP-2009-HMS-012.



**Continuing Medical Education:** The Association of Clinical Research Professionals (ACRP) is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

ACRP designates this educational activity for a maximum of 3.0 AMA PRA Category 1 credits™. Each physician should only claim credit commensurate with the extent of their participation in the activity.



**Continuing Nursing Education:** The California Board of Registered Nursing (Provider Number 11147) approves the Association of Clinical Research Professionals as a provider of continuing nursing education. The CBRN program number is 11147-2009-HMS-012. Each home study offering grants 3.0 nursing credits.

## DISCLOSURES

The following persons who have access to influence the content of *The Monitor* have the following affiliations to disclose:

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## QUESTIONS 1–10

### Clinical Rating Scales in Practice and Research: Methods for Success—Ensuring Competency through Scale Training

**1** In the fictional study described at the beginning of the article, what did the sponsor fail to consider when training selected sites?

- A. Investigator/research coordinator responsibilities
- B. Protocol
- C. Clinical rating scales
- D. FDA rules/regulations

**2** Rating scales are tools used to measure:

- 1. A situation.
- 2. A condition.
- 3. An outcome.
- 4. Objective data.

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

**3** PRO stands for:

- A. Patient-reported outcome.
- B. Physician-reported outcome.
- C. Physician reimbursement organization.
- D. Patient regulatory organization.

**4** One reason a clinical rating scale may fail to become widely accepted is that the scale:

- A. is difficult to read.
- B. is not developed through collaboration.
- C. is disliked by sponsors.
- D. is a good measurement tool for one parameter.

**5** Which are commonly cited reasons against use of clinical rating scales?

- 1. Physician judgment is sounder than a scale.
- 2. The FDA does not accept the use of scales.
- 3. Not all subjects fit nicely into scales.
- 4. Scales are harder to get approved by IRBs.

- A. 1 and 2 only
- B. 1 and 3 only
- C. 2 and 4 only
- D. 3 and 4 only

## CORRECTIONS

Corrections to Home Studies can be found on the ACRP website and are incorporated directly into the online test.

**6** What is a major problem for future researchers to solve related to clinical rating scales?

- A. Incorporating GCP language into clinical rating scales
- B. Creating a clinical rating scale training program
- C. Obtaining regulatory approval for scales
- D. Comparing old data from invalidated scales to new data from studies using validated scales

**7** Benefits of rating scales include:

- 1. Greater understanding of a disease process
- 2. New opportunities to research unusual cases
- 3. Tool for generalists to accurately assess certain conditions
- 4. Always give the right subject diagnosis

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

**8** Rating scales provide a challenge when used in clinical trials because they:

- 1. disrupt data analysis.
- 2. are subjective rather than objective.
- 3. do not ensure intra- and inter-rater reliability.
- 4. cannot always be located when needed.

- A. 1 and 2 only
- B. 2 and 3 only
- C. 2 and 4 only
- D. 3 and 4 only

**9** A rating scale training program for a study should be constructed during:

- A. site qualification.
- B. protocol development.
- C. site initiation.
- D. final monitoring and data lock.

**10** To ensure receipt of valid data from rating scales:

- 1. choose the most widely accepted scale.
- 2. conduct a thorough assessment of rater skills.
- 3. provide a well-defined training program.
- 4. conduct ongoing rater competency assessment.

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

## QUESTIONS 11–20

### The Learning Healthcare System: Clinical Research's Future Role

**11** Considering “Clinical Research” as the first step, what are the four remaining steps, in order, in the learning healthcare system cycle?

- A. Patient Care – Evidence – Outcome Data – Clinical Decision Support
- B. Evidence – Clinical Decision Support – Patient Care – Outcome Data
- C. Outcome Data – Clinical Decision Support – Patient Care – Evidence
- D. Patient Care – Outcome Data – Evidence – Clinical Decision Support

**12** Which of the following show the potential fallibility of the “Clinical Research-to-Evidence” transition?

- 1. Data not complete
- 2. Data not reliable
- 3. Data not valid
- 4. Data not published

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

**13** Which of the following show the potential fallibility of the “Evidence-to-Clinical Decision Support” transition?

- 1. Results never published
- 2. Results published in nonobjective manner
- 3. Warning fatigue
- 4. Limited ability to receive or aggregate evidence

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

**14** The assurance that all evidence is integrated and presented to a provider in a useful manner is the purpose of which step in the cycle?

- A. Clinical Research to Evidence
- B. Clinical Decision Support to Patient Care
- C. Outcome Data to Evidence
- D. Evidence to Clinical Decision Support

**15** FDA's plan to access disparate data sources to establish a postmarketing risk identification infrastructure is called the:

- A. Clinical Trials Transformation Initiative (CTTI).
- B. FDA Amendments Act (FDAAA).
- C. Sentinel Initiative.
- D. Postmarketing eSurveillance Program.

**16** Clinical decision paralysis is most likely to occur with studies:

- A. designed for marketing purposes.
- B. with more than two arms.
- C. that show a high number of adverse events.
- D. that show no efficacy separation of the test article from placebo.

**17** One website that posts results of clinical trials is

- A. www.fda.gov
- B. www.ciscrp.org
- C. www.aahrpp.org
- D. www.clinicaltrials.gov

**18** There is more focus now than ever before on which of the following aspects affecting the quality of clinical research?

- A. Conflict of interest
- B. Coordinator training
- C. Investigational site improvements
- D. Geographical locations

**19** According to the article, a good practitioner relies on \_\_\_\_\_ for best outcomes.

- A. Articles in journals
- B. Instinct
- C. Evidence-based protocols
- D. Sales pamphlets

**20** Shortfalls in new standards of care established through research can lead to

- A. Business opportunities.
- B. Hypotheses for new clinical research.
- C. Opportunity for government intervention.
- D. Reasons to refer patients outside of the system.

## QUESTIONS 21–30

### Operations and the Future of Adaptive Research

**21** What are the two types of broad clinical trial elements to which adaptive principles can be applied?

- A. Analysis and monitoring
- B. Operations and data capture
- C. Design and operations
- D. Design and monitoring

**22** To provide adaptive solutions for operational problems, study managers need timely status updates on these key components:

- 1. Enrollment
- 2. Monitoring
- 3. Query Processing
- 4. Quality Control

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

**23** Successful execution of design adaptations can be blocked by delays in:

- A. monitoring reports.
- B. quality assessments.
- C. revised inclusion criteria.
- D. accurate subject data.

**24** Which of the following is typically the root cause for the failure of design adaptations?

- A. Weak query-processing systems
- B. Lack of effort by study team
- C. Lack of timely access to key information
- D. Poor decision-making in tool selection

**25** To reliably increase the standard of study operations to meet design adaptations, we must:

- A. apply the same principles to operations and design.
- B. ensure adaptations are deployed independently.
- C. provide specific measures for the adaptations.
- D. prepare the adapted database prior to implementation.

**26** The main cause of inefficiency in study operations is:

- A. lack of timely information.
- B. inadequate study planning.
- C. therapeutic area limitations.
- D. poor protocol design.

**27** High query rates indicate which of the following?

- 1. Low site productivity
- 2. Inefficiency in study operations
- 3. Inadequate use of performance metrics
- 4. Failure to identify query trends

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

**28** Examples of operational adaptation include which of the following?

- 1. Enrollment
- 2. Protocol preparation
- 3. Database lock
- 4. Field monitoring

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

**29** Successful adaptations include which of the following?

- 1. Efficient data capture & validation systems
- 2. Rapid query resolution
- 3. Role-specific training for CRAs & project managers
- 4. Pooling of queries for completion during scheduled monitoring visits

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only

**30** The long-term goals of adaptive research include making:

- 1. development of a continuous process.
- 2. earlier decisions about candidate viability.
- 3. more flexible regulatory standards of data integrity.
- 4. a more effective process for study management.

- A. 1, 2, and 3 only
- B. 1, 2, and 4 only
- C. 1, 3, and 4 only
- D. 2, 3, and 4 only