

Recruitment & Retention: Technology Trends and Global Concerns



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, \$32). 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 **August 2010 Monitor Home Study** is based on the following three articles in this issue:

- 1. Trends and Technologies for Recruitment in the e-Enabled World**
Sharib A. Khan, MBBS, MA, MPH | Chintan Patel, PhD | Vivek Garg, MBA, all at Applied Informatics Inc/TrialX
- 2. From Policy to Practice: Understanding and Enhancing Minority Participation in Clinical Trials**
Cynthia A. Spiker, MPH, Instructor, Department of Medicine, and Project Manager, Eliminating Disparities in Clinical Trials (EDICT) Project in the Chronic Disease Prevention & Control Research Center, Baylor College of Medicine | Deborah Vollmer Dahlke, MPAff, Director of Clinical Trials, Texas Life Science Foundation | Patricia R. Sanders, APR, Senior Project Manager, P&E Associates | Armin D. Weinberg, PhD, Professor of Medicine and Director of Chronic Disease Prevention & Control Research Center, Baylor College of Medicine | Venus M. Ginés, MA, Instructor, Department of Medicine, and Associate, Chronic Disease Prevention & Control Research Center, Baylor College of Medicine
- 3. Toward Evidence-Based Decision Making: Forecasting and Modeling Techniques for Predicting Enrollment Performance**
Robert Andes, MS, Senior Vice President of Life Sciences, Idhasoft, Inc. | Brian P. Schrock, MBA, Director of Global Enrollment Optimization, Eli Lilly & Co.

HOME STUDY LEARNING OBJECTIVES

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

1. the new technologies that can be applied to patient recruitment.
2. the current issues related to the underrepresentation of minorities in clinical trials and to describe the Eliminating Disparities in Clinical Trials (EDICT) Project policy recommendations and practical application of these policies in community initiatives.
3. how modeling and simulation techniques can be used to provide an evidence-based prediction methodology to enrollment performance.

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-2010-HMS-008.



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 11147-10-008. 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:

- Eileen Caramanica, MS, RN, CCRA, Merck
- Gary W. Cramer, ACRP
- Jean Fourcroy, MD, PhD, MPH, Fourcroy Consulting
- Iris Gorter de Vries, PhD, Consultant
- Vikram Kumar, CCRC, Urban Estate, Phase I
- Sandra O'Donnell, MA, MT(ASCP), CCRA, Clinsys
- Axel Olsen, PhD, Quintiles, Inc.
- Al O. Pacino II, TrainingCampus.com
- A. Veronica Precup, ACRP
- Andrea G. Procaccino, CCRT, CMT, Johnson & Johnson Pharmaceutical R&D
- Debbie Rosenfelder, RN, BSN, CCRC, Paragon Biomedical, Inc.
- Erika Stevens, MA, Dartmouth Hitchcock Medical Center
- Linda G. Strause, PhD, Vical, Inc.
- Theresa Straut, BA, CIP, RAC, Consultant
- Lynn Van Dermark, RN, BSN, MBA, CCRA, RAC, MedTrials, Inc.
- Liz Wool, BSN, CCRA, CMT, QD-Quality & Training Solutions, Inc.

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QUESTIONS 1–10

Trends and Technologies for Recruitment in the e-Enabled World

- 1** PHR is the abbreviation for:
- Personal Health Record.
 - Public Health Record.
 - Private Health Record.
 - Patient Health Record.
- 2** EHR is the abbreviation for:
- Emergency Health Record.
 - Electronic Health Record.
 - Environmental Health Record.
 - Electronic Human Response.
- 3** Which of the following are PHR platforms?
- Facebook.com
 - PatientsLikeMe.com
 - Google Health
 - Microsoft HealthVault
- 1 and 2 only
 - 1 and 3 only
 - 2 and 4 only
 - 3 and 4 only
- 4** Approximately what percentage of online Americans search for health information?
- 50%
 - 60%
 - 80%
 - 100%
- 5** Which of the following are potential concerns/barriers to adoption of PHRs by patients?
- Expense to the patient
 - Privacy and confidentiality
 - Usefulness
 - Availability
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

- 6** Which of the following are the possible sources of data in a PHR?
- Patients
 - Pharmacies
 - Clinical laboratories
 - Clinical trials
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

- 7** Which of the following are social media sites?
- Twitter.com
 - Flickr.com
 - MSN.com
 - NYTimes.com
- 1 and 2 only
 - 1 and 4 only
 - 2 and 3 only
 - 3 and 4 only

- 8** Characteristic features of Web 2.0 sites allow users to:
- create information.
 - rate content.
 - share information.
 - use content only once.
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only

- 9** According to the article, which of the following is the fundamental problem with the current process of finding eligible patients for clinical trials?
- Inadequate marketing budgets
 - Asymmetry of locus of control and information
 - Insufficient trial marketing materials
 - Nonresponsiveness of sponsors to site needs

- 10** How many Americans are projected to be using PHRs by 2013?
- 10 million
 - 50 million
 - 80 million
 - 150 million

QUESTIONS 11–20

From Policy to Practice: Understanding and Enhancing Minority Participation in Clinical Trials

- 11** Populations that are commonly underrepresented in clinical trials include:
- elderly
 - women
 - men
 - adolescents
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only
- 12** The Eliminating Disparities in Clinical Trials (EDICT) Project developed policy recommendations in nine areas, including:
- Technology Applications
 - Community Involvement
 - Biomedical Publications
 - Reallocation of Research Funding
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only
- 13** The NIH Revitalization Act of 1993 mandates the inclusion of which of the following populations in clinical trials?
- Minorities
 - Women
 - Disabled
 - Adolescents
- 1 and 2 only
 - 1 and 4 only
 - 2 and 3 only
 - 3 and 4 only
- 14** The FDA Modernization Act of 1997 generally has been ineffective because it only:
- addresses privately funded corporate research.
 - implements strict penalties for limited population inclusion.
 - provides data collection guidance on minority populations.
 - offers optional resources upon request.

CORRECTIONS

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

15 In what year did CMS authorize payment of routine medical costs for Medicare recipients participating in clinical trials?

- A. 1985
- B. 1990
- C. 1995
- D. 2000

16 Currently, approximately how many states in the U.S. have legislation related to insurance coverage of clinical trials?

- A. 15
- B. 20
- C. 25
- D. 30

17 What has been shown to be an effective tool for communicating with African American audiences about clinical trials?

- A. Radio and television commercials
- B. Internet advertising
- C. Billboards and direct mail
- D. Face-to-face interaction by culturally specific staff

18 The most commonly cited barrier to trial participation within the Latino and African American communities is:

- A. mistrust of medical research.
- B. transportation to medical visits.
- C. lack of childcare.
- D. no financial compensation for their time.

19 Technology applications developed to address patient barriers to clinical trials include:

- A. robotic telesales calls.
- B. bilingual case management.
- C. online screening surveys.
- D. mobile enrollment capability.

20 Methods to improve recruitment of minority populations include:

- 1. trial staff reflective of community diversity.
 - 2. collaboration with community leaders.
 - 3. trend analyses of minority healthcare use.
 - 4. culturally and linguistically appropriate materials.
- 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 21–30 Toward Evidence-Based Decision Making: Forecasting and Modeling Techniques for Predicting Enrollment Performance

21 Pharma has consistently missed predicting the duration of which time period in a clinical trial?

- A. Protocol approval to first patient visit
- B. First patient enrolled to last patient enrolled
- C. Study treatment cycle time
- D. Last patient enrolled to database lock

22 Advanced mathematical modeling is a tool that will:

- 1. assist in better planning.
- 2. cost more in the long run.
- 3. help identify potential risks.
- 4. allow more accurate cost estimates.

- 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 Evidence-based prediction includes which of the following?

- 1. Understanding required data and metrics
- 2. Using psychometrics principles
- 3. Using basic modeling and simulation
- 4. Increasing study planning accuracy

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

24 What is one of the key indicators for successful enrollment?

- A. Study planner's confidence level
- B. Study planner's experience
- C. Historical enrollment metrics
- D. Primary site enrollment experience

25 Which of the following elements are important in leveraging evidence-based decision technologies?

- 1. Understanding the collected data
- 2. Identifying key information requirements
- 3. Identifying gaps in data
- 4. Understanding the protocol design

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

26 Which is the least valuable metric when trying to improve enrollment prediction?

- A. Available study capacity by investigator
- B. Enrollment rates by therapeutic area
- C. Historical percentage of poor enrolling sites
- D. Study startup cycle times

27 The metric representing “front loading” of site initiation is known as:

- A. site startup rate.
- B. enrollment rate.
- C. dropout ratio.
- D. patients per site per month.

28 In constructing a trial simulation, which of the following are sources useful in building requirements and metrics?

- 1. Electronic health records
- 2. Resource costs
- 3. Investigator experience
- 4. Standards of care

- 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 Which variables would you expect to see in a simulation model for enrollment?

- 1. Site performance data
- 2. Disease prevalence
- 3. Study costs
- 4. Key opinion leader opinions

- 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 best ways to produce more accurate enrollment predictions are to:

- 1. understand captured data.
- 2. identify information required for informed decisions.
- 3. produce metrics to capture the enrollment process.
- 4. understand protocol complexity.

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