

Solutions-Based Technology

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, \$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 **June 2011 *Monitor* Home Study** is based on the following three articles in this issue:

1. A Universal Cloud-Based Education Management Network: Improving Education, Training, and Certification Through Better Management Processes

Kim I. Bishop, PhD, Founder and President,
Global Pharma Consultancy, LLC

2. Virtual CROs Drive Cost Savings for Product Development

Joy Frestedt, PhD, RAC, CCTI, President and Chief Executive Officer,
Frestedt Incorporated | Pamela Wolfe, MS, MBA, Virtual Consultant,
Frestedt Incorporated

3. Meeting the Real-Time Informational Needs of a Successful Clinical Trial

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Research Dynamics Consulting Group Ltd. | Maria A. Durkin, MBA,
Vice President, Chief Operating Officer, and Director of Marketing and
Customer Support, Bio-Optronics

HOME STUDY LEARNING OBJECTIVES

At the conclusion of this course, participants should be able to:

1. describe at least five key characteristics/benefits of a universal CB-EMN for the healthcare industry.
2. recognize the concepts attributed to a virtual CRO and the differences between a vCRO and the traditional CRO model.
3. identify informational needs for their organization and plan for selection and implementation of CTMS to meet those needs.

This test expires on JUNE 30, 2012

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QUESTIONS 1–10

A Universal Cloud-Based Education Management Network: Improving Education, Training, and Certification Through Better Management Processes

1 What does the acronym CB-EMN stand for?

- A. Central Broadcast Education Management News
- B. Complete Blended Education Management Network
- C. Cloud-Based Education Management Network
- D. Comprehensive Benefits Emergency Management News

2 A universal healthcare CB-EMN can:

- 1. provide complete audit trails.
- 2. foster global collaboration.
- 3. create a silo repository.
- 4. share learning assets.

- 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 What is the primary force cited in the article behind the lag and resistance for “buy-in” to collaboration?

- A. Fear regarding protection of intellectual property
- B. Fear of a standardized cyberinfrastructure
- C. Fear of aggregating and consolidating educational assets
- D. Fear of blended learning practices

4 What is the central principle of a cloud-based solution?

- A. Ability to upload an e-pedigree
- B. Ability to eliminate fraud
- C. Ability to stop trial drift
- D. Ability to share resources

5 A first key step in the transition to a universal healthcare CB-EMN is to move away from:

- A. adopting common systems and processes.
- B. managing learning in traditional silo environments.
- C. aggregating and consolidating high-efficiency learning resources.
- D. measuring evidence-based education.

6 Why is a universal CB-EMN inherently democratizing?

- 1. Anybody who has any type of education can participate.
- 2. Those with a limited budget can participate.
- 3. Only certain geographies would be appropriate to participate.
- 4. Authors, government, and corporations can participate.

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

7 What are some value-added characteristics of a CB-EMN?

- 1. Copyright and privacy are protected.
- 2. Redundant education is minimized.
- 3. Professional records can be verified.
- 4. Administrative burdens are increased.

- 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 What is necessary for a CB-EMN to work anytime, anywhere in the world?

- A. Digital television
- B. Internet cafe
- C. Standard web browser
- D. DVD player

9 Increased global regulatory oversight has created the need for a higher level of:

- 1. business transparency.
- 2. documentation of qualifications.
- 3. professional development compliance.
- 4. chunking teaching strategy.

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

10 A universal healthcare CB-EMN is a powerful tool because it:

- 1. discourages standardized education.
- 2. helps meet regulatory compliance requirements.
- 3. improves efficiencies and productivity.
- 4. saves time and costs and streamlines processes.

- 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

Virtual CROs Drive Cost Savings for Product Development

11 What is the virtual CRO model based upon?

- A. Bricks and mortar operation
- B. Strategic outsourcing
- C. Fully automated processes
- D. Internet-based

12 What are the common types of CRO/sponsor relationships?

- 1. Strategic partner
- 2. Tactical alliance
- 3. Global platforms
- 4. Preferred vendor

- 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 What percentage of small development companies uses CROs?

- A. 20-40%
- B. 40-60%
- C. 60-80%
- D. 80-100%

14 What is one of the reasons vCROs have less overhead costs?

- A. Centralized office buildings are required for meeting space.
- B. Work is done from home-based offices as needed.
- C. Employees work specified hours each week.
- D. High fixed costs are needed for facilities.

15 What is the key for the employee at the vCRO to balance the risks and benefits of employment?

- A. Flexibility to work variable hours
- B. Fixed schedule providing standard salary
- C. Microproject management
- D. Payment of self-employment taxes

CORRECTIONS

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

16 Why would a sponsor want to use a vCRO?

1. Get a project done when staff are not available
 2. Increase flexibility and decrease timelines overall
 3. Supplement in-house staff with specific experts
 4. Company information is not accessible externally
- A. 1, 2, and 3 only
B. 1, 2, and 4 only
C. 1, 3, and 4 only
D. 2, 3, and 4 only

17 What types of work can be done virtually?

1. Patient exam
 2. Monitoring
 3. Data management
 4. Technical writing
- A. 1, 2, and 3 only
B. 1, 2, and 4 only
C. 1, 3, and 4 only
D. 2, 3, and 4 only

18 What type of structure does a vCRO have?

- A. Hierarchical
B. Conglomerate
C. Traditional office
D. Flexible network

19 What types of technical experts are most commonly available through a vCRO?

1. Clinical research associates
 2. Manufacturing engineers
 3. Regulatory consultants
 4. Data analysts
- A. 1, 2, and 3 only
B. 1, 2, and 4 only
C. 1, 3, and 4 only
D. 2, 3, and 4 only

20 Which benefit do investigators perceive from virtual investigator meetings?

- A. Easy to stay engaged in the meeting
B. Less time away from patients
C. Travel to a nice location for training
D. Must be done outside of workplace

QUESTIONS 21–30

Meeting the Real-Time Informational Needs of a Successful Clinical Trial

21 Single-entity CTMS:

- A. manage only one part of the information, such as project management.
B. provide limited information to a subset of team members.
C. can only be used for one site at a time.
D. are for sponsors only.

22 Enterprise CTMS:

1. combine multifunctional information.
 2. can be used only by large organizations.
 3. incorporate workflow for real-time data.
 4. cannot be used for information exchange.
- A. 1 and 2 only
B. 1 and 3 only
C. 2 and 3 only
D. 3 and 4 only

23 Which of the following are important features of real-time CTMS?

1. Large database software
 2. Flexibility for each project
 3. Ability to integrate into workflow process
 4. Electronic signature
- A. 1 and 2 only
B. 1 and 4 only
C. 2 and 3 only
D. 3 and 4 only

24 Which of the following are important for determining the specifications of your CTMS?

1. Daily use of the system
 2. User interface
 3. Location of the CTMS database
 4. Number of studies
- A. 1 and 2 only
B. 1 and 3 only
C. 2 and 3 only
D. 2 and 4 only

25 Which of the following represent the most typical data found in a CTMS?

- A. Patient CRF data
B. Patient randomization codes
C. Regulatory document inventories
D. Protocol deviations

26 CTMS can be used for:

1. IVRS responses.
 2. milestone scheduling and study progress tracking.
 3. financial management.
 4. document exchange.
- A. 1 and 4 only
B. 2 and 4 only
C. 1, 3, and 4 only
D. 2, 3, and 4 only

27 Which of the following are required for successful implementation of a CTMS?

1. Redesigning workflow to eliminate spreadsheets
 2. Extensive knowledge of programming
 3. Role-based user training
 4. Hardware upgrade
- A. 1 and 2 only
B. 1 and 3 only
C. 1 and 4 only
D. 2 and 3 only

28 When implementing a CTMS, you must:

- A. define roles and responsibilities.
B. design spreadsheets to track data.
C. combine it with your CDMS system.
D. create worksheets to enter the data.

29 Which additional functionality can be achieved with a CTMS?

- A. Checks can be printed for milestone payments for investigators.
B. Version numbers can be generated on documents.
C. FDA submissions can be filed electronically.
D. Regulatory documents can be shared through one system.

30 A CTMS is used for:

- A. managing patient data.
B. developing project management GANT charts.
C. research team information exchange.
D. assigning patient treatments.