

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

1. Curricular and Training Needs of Pharmaceutical Physicians in the United States: An Online Survey

Peter Stonier, MB ChB, PhD, FRCP, FPPM, Visiting Professor of Pharmaceutical Medicine, King's College London; Medical Director, Amdipharm plc; Director of Education and Training, Faculty of Pharmaceutical Medicine, Royal College of Physicians, U.K. | Carl Naraynassamy, MAEd, LLB, BSc, FSB CBIol, Chairman and Principal Consultant, Explicator Ltd | Katherine S. MacGilchrist, BSc (Hons), MSc, Clinical Research Professional Consultant

2. ISO/FDIS 14155: The Long-Awaited Changes for International Medical Device Clinical Trials

Joy L. Frestedt, PhD, RAC, CCTI, President and CEO, Frestedt Inc. | Pamela Wolfe, MS, MBA, Strategic Project Manager, Frestedt Inc.

3. Benefits of a Single Versus Multicenter Approach in Early-Phase Patient Studies: A Case Study of Multiple Sclerosis Patients

Keith Sean Berelowitz, BSc (Hons), MSc, Director of Operations, Richmond Pharmacology Ltd. | Christian Wolf, MD, MPPM, Managing Partner, Lycalis SPRL | Jörg Täubel, MD, FPPM, Medical Practitioner and CEO, Richmond Pharmacology Ltd.

HOME STUDY LEARNING OBJECTIVES

After reading these articles, participants should be able to:

1. discuss the curricular needs of pharmaceutical physicians working in the U.S.
2. recognize the changes and limitations of ISO 14155:2011 as related to the earlier version of this ISO standard.
3. identify what factors to consider when conducting early-phase patient trials and then discuss if these trials can and should be conducted in a single-center or multicenter approach.

This test expires on OCTOBER 31, 2012

(original release date: 10/01/2011)

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The Association of Clinical Research Professionals (ACRP) is an approved provider of medical, nursing, and clinical research continuing education credits.



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The Association of Clinical Research Professionals (ACRP) provides 3.0 contact hours for the completion of this educational activity. These contact hours can be used to meet the certifications maintenance requirement. (ACRP-2011-HMS-009)



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The California Board of Registered Nursing (Provider Number 11147) approves the Association of Clinical Research Professionals (ACRP) as a provider of continuing nursing education. This activity provides 3.0 nursing education credits. (Program Number 11147-2011-HMS-009)



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QUESTIONS 1–10

Curricular and Training Needs of Pharmaceutical Physicians in the United States: An Online Survey

- 1** What was the purpose of the survey described in the article?
- To revise APPI's existing core training syllabus in pharmaceutical medicine.
 - To ascertain the training received in pharmaceutical medicine by pharmaceutical physicians practicing in the U.S.
 - To justify the wholesale replication of the European training programs into the U.S. for pharmaceutical physicians.
 - To determine the increased financial costs of introducing quality training in pharmaceutical medicine.
- 2** Which of the following were among the most common areas of activity of the respondents?
- Clinical research
 - Pharmacovigilance
 - Management
 - Preclinical research
- 1, 2, and 3 only
 - 1, 2, and 4 only
 - 1, 3, and 4 only
 - 2, 3, and 4 only
- 3** What percentage of respondents had a current license to practice medicine in the U.S.?
- 70%
 - 60%
 - 50%
 - 40%
- 4** Which was the preferred learning method of the respondents?
- Collaborative learning
 - Individual learning
 - Training or tutoring others
 - Responding to multiple-choice questions on articles in journals
- 5** Which respondents had a greater propensity for learning by supervising, appraising, and assessing others?
- Those who disliked online learning as much as individual learning
 - Those with initial medical qualifications from outside the U.S.
 - Those who had been pharmaceutical physicians for a longer time
 - Those who already had training roles within their professional careers

6 Which type of interpersonal and transferable skills were important to survey respondents' work?

- Critical thinking
- Media skills
- Teamwork
- Communication and presentation

- 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 business management sets of skills were important to survey respondents' work?

- Decision making
- Financial management
- Crisis management
- Project planning

- 1, 2, and 3 only
- 1, 2, and 4 only
- 1, 3, and 4 only
- 2, 3, and 4 only

8 Which area of training was most needed by the survey respondents?

- Economics of healthcare
- Information technology
- Medical devices
- Regulatory affairs

9 Which one conclusion is made about online learning?

- Employers should increasingly rely on this format.
- Its suitability and effectiveness should be investigated.
- Online learning is less popular among physicians trained outside the U.S.
- It is not suitable for pharmaceutical physicians.

10 Which was not acknowledged as a limitation of the survey results?

- The heavy contingent of industry physicians working in clinical research
- The response rate
- The strong identification of respondents with being pharmaceutical physicians
- The low desire of physicians for online training

QUESTIONS 11–20

ISO/FDIS 14155: The Long-Awaited Changes for International Medical Device Clinical Trials

11 What is an ISO standard considered?

- Law
- Regulation
- Guidance
- Framework

12 What difference between medical device and pharmaceutical trials was addressed in the new ISO 14155:2011?

- Following the protocol
- Using an informed consent process
- Including ICH-GCP concepts
- Ensuring regulatory compliance

13 Why did the original ISO 14155 standard fail to become a unified global standard?

- The original ISO 14155 was too flexible.
- Several countries did not adopt ISO 14155.
- The original ISO 14155 had too much content.
- Manufacturers refused to use ISO 14155.

14 What missing elements were added to ISO 14155:2011?

- Legal proceedings documents
- Regulatory submission documents
- Contractual agreement documents
- Essential clinical investigation documents

15 In what year was the previous version of ISO 14155 issued?

- 2001
- 2003
- 2005
- 2011

16 What types of devices are outside the scope of ISO 14155:2011?

- In vitro diagnostic devices
- Nonsignificant risk devices
- Significant risk devices
- Investigational devices

17 What international document was harmonized within ISO 14155:2011 to require documentation of risk mitigation strategies during development of medical devices?

- GHTF SG5
- ICH-E6 GCP
- ISO 14971
- MDD 2.7.1

18 In what section of ISO 14155:2011 is information provided about case report forms?

- Administrative
- Project Management
- Responsibilities
- Annexes

19 What will adopting the same standard in most countries reduce?

- Disparities between countries
- Safety reviews
- Costs of conducting trials
- Regulatory oversight

20 What concept is not addressed by ISO 14155:2011?

- Vulnerable populations
- Significant vs. nonsignificant risk
- Serious adverse events
- Language discrepancies

QUESTIONS 21–30

Benefits of a Single Versus Multicenter Approach in Early-Phase Patient Studies: A Case Study of Multiple Sclerosis Patients

21 Oncology trials in patients at Phase I account for what percentage of Phase I trials in the United Kingdom?

- 10%
- 20%
- 30%
- 40%

22 What apprehensions do sponsor companies have regarding using a Phase I setting for early-phase patient trials?

- Ability to recruit large patient panels
- Tolerance of patient populations for a Phase I environment
- Trial intensity
- Cost of conduct

- 1, 2, and 3 only
- 1, 2, and 4 only
- 1, 3, and 4 only
- 2, 3, and 4 only

23 What are the benefits of employing a single-center vs. a multicenter approach to early-phase patient trials?

- Scalability and reach
- Geographical uniformity
- Reduced variability of trial conduct and data collected
- Greater value for money

- 1, 2, and 3 only
- 1, 2, and 4 only
- 1, 3, and 4 only
- 2, 3, and 4 only

24 Which of these is often a limiting factor in early-phase clinical trials conducted by academic units requiring specific patient panels?

- Reach within the patient community
- Lead clinician's availability
- Monitoring of these sites
- Sponsor site involvement with the site

25 What will sponsor companies typically do in a multicenter study to limit the risk of sites not meeting their individual site targets?

- Change the inclusion/exclusion criteria on a site-by-site basis to make enrollment easier
- Initiate more sites than may be required
- Provide a larger marketing budget to each site at setup stage
- Provide funding for additional human resources to deal with the recruitment requirements

26 What may affect the “control” sponsor companies require of early-phase multicenter trials?

- Variation in process among sites
- Accessibility of the target population
- Regular monitoring of sites by a qualified third party
- Data quality variation among sites

- 1, 2, and 3 only
- 1, 2, and 4 only
- 1, 3, and 4 only
- 2, 3, and 4 only

27 What can sponsor companies do to limit data variability between sites?

- Ask investigators to qualify the proposed volunteers with the sponsor directly prior to inclusion
- Limit the number of volunteers that can be included per site
- Use standardized case report forms
- Only allow one or two “named” individuals per site to work on a study

28 What is the driving force behind the inclusion of a large number of patients into multicenter studies in order to demonstrate statistical significance?

- The ability of sites to recruit suitable volunteers
- The ability of sites to retain suitable volunteers throughout the study
- Data variability between sites
- Staffing variability between sites

29 Which factors typically result in multicenter studies being more costly than a single-center approach?

- Under-recruitment from several sites
- Initiating several sites
- Monitoring several sites
- Collating data from several sites

- 1, 2, and 3 only
- 1, 2, and 4 only
- 1, 3, and 4 only
- 2, 3, and 4 only

30 A clear benefit to conducting multicenter studies instead of single-center studies is the ability to do which of the following?

- Collate data from active hospital sites providing large patient panels
- Gather data from patients with well-documented clinical histories providing ideal candidates for inclusion
- Reduce the risk of study failure as a result of poor retention of volunteers
- Collect data over wider geographical areas providing greater generalizability

CORRECTIONS

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