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PHASE 1 ARCHIVED Online Training Series

Investigator Responsibilities: The Good, the Bad, and the Ugly
Navigating the Regulatory Landscape - Setting Your GPS to Avoid Compliance Pitfalls
Identifying the Best Early Phase Site for the Study - Are You That Site?

Part 1: Investigator Responsibilities: The Good, the Bad, and the Ugly

Event Code: 11476A

This archived online training course will provide an overview of the key responsibilities of investigators and investigative sites according to three key sets of guidance: The FDA guidance published in October 2009 ("Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects"); the Good Clinical Practice: Consolidated Guidance as described in ICH E6 published in 1996, in particular the 13 sub-sections of section 4, "The Investigator"; and agreements the PI makes in signing the FDA 1572, "Statement of Investigator".

FACULTY:

HOWARD E. GREENBERG, MD, MSE, MBA, FCP
Principal, HEG Associates

WHAT YOU WILL LEARN

- Dual responsibilities of a physician investigator and their potential conflicts
- Functions of Principal Investigator: before, during, and after conduct of a clinical study
- The good, bad and ugly aspects of investigator responsibilities
- Key 21 CFR chapters to know
- "Hot buttons" of delegated tasks
- How to ensure adequate PI supervision
- What is 'reasonable' medical care?
- The nine commitments of the PI in the "Statement of Investigator"
- ICH Guidance: the major topics, the elements of GCP, and the investigator sub-sections

WHO SHOULD ATTEND:

This archived online training course is designed primarily for investigators and others at the investigative site, including coordinators, project managers, regulatory, laboratory and clinical support staff. Additionally, sponsors of clinical research trials and their staff who interact with investigative sites, i.e. clinical research associates and monitors would also benefit.

LEARNING OBJECTIVES

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

- Perform better clinical research that adheres to principles of good clinical practices (GCPs)
- Describe the 13 key investigator responsibilities according to ICH E6 section 4, "The Investigator"
- Recognize the nine agreements the PI makes in signing the legally binding FDA 1572 document
- Evaluate the quality of investigators, their staff and the site
- Identify investigators and investigative sites

Part 2: Navigating the Regulatory Landscape - Setting Your GPS to Avoid Compliance Pitfalls

Event Code: 11477A

While regulatory compliance is important throughout drug development, it is particularly relevant in the early phase research for protecting study subjects before a drug's safety profile in humans is clearly defined. As such, compliance with Good Clinical Practice (ICH E6) and FDA regulations is paramount. This online training course will focus on key areas for success – aspects of Good Clinical Practice (GCP), working with Institutional Review Boards (IRBs), informed consent, and regulatory document submissions and management. The presentation will provide investigators and research staff at all levels with an overview of the current regulatory landscape as well as caveats for avoiding compliance issues during regulatory or sponsor audits.

FACULTY:

NANCY A. LASS, MD, FAAP, FCP
President, NL Specialty Consulting, Inc.

WHAT YOU WILL LEARN

- Protocol development and compliance
- Working with IRBs and informed consent
- Essential documents needed prior to initiating studies
- Safety and regulatory reporting
- Recordkeeping
- "Audit-Ready Mode"

WHO SHOULD ATTEND

This archived online training course is designed for individuals involved in early phase research at the investigator site, including investigators, study coordinators, project managers, and regulatory, laboratory and clinical support staff. It may also be of interest to sponsors of early phase trials and staff interacting with the study site, e.g. clinical research managers and monitors.

LEARNING OBJECTIVES

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

- Identify at least two common problems with protocol compliance
- Describe at least three elements of an IRB protocol review
- Identify at least three documents necessary prior to the early clinical phase of a study
- Describe the regulatory requirements for expedited safety reporting

For information about these archived online training courses, please contact Colleen Buckley at +1.215.442.6108 or Colleen.Buckley@diahome.org

Phase 1 ARCHIVED Online Training Series

Part 3: Identifying the Best Early Phase Site for the Study - Are You That Site?

Event Code: 11478A

The complexity of the early phase environment requires a different approach to site selection than one would consider with late phase. There are criteria in early phase development that are important to ensuring that the sponsor identifies the best site for the study. Considering these criteria as part of the site selection process is critical to identifying a strong early phase investigator site. How the early phase sites prepare for and respond to these questions often determines if they are awarded the study. This presentation will guide the sponsor in asking the right questions and guide the site in establishing processes that meet the needs of the sponsor.

FACULTY

DONNA W. DOROZINSKY, RN, MSN, CCRC
President, DWD & Associates, Inc.

WHAT YOU WILL LEARN

- Key criteria for identifying and selecting an early phase investigator site
- Identifying site qualities to promote as part of the site selection process and key processes to establish to ensure that you are prepared for sponsor requirements
- Questions to ask of the site as part of the site selection process

WHO SHOULD ATTEND

This archived online training course is designed for individuals involved in the selection of Phase I clinical sites, as well as individuals from Phase I clinical sites.

LEARNING OBJECTIVES

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

- Identify three key factors to consider when selecting an early phase investigator site
- Describe three important operational processes in the site selection process
- Explain the five site processes that are core to the conduct of an early phase study

PHASE 1 ARCHIVED Online Training Series Available to Purchase

PART 1 INVESTIGATOR RESPONSIBILITIES: THE GOOD, THE BAD, AND THE UGLY #11476A

PART 2 NAVIGATING THE REGULATORY LANDSCAPE - SETTING YOUR GPS TO AVOID COMPLIANCE PITFALLS #11477A

PART 3 IDENTIFYING THE BEST EARLY PHASE SITE FOR THE STUDY - ARE YOU THAT SITE? #11478A

Purchase one or two archived courses from this series for $150.00 each

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Archived Online training courses are available for 30 days from date of purchase

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association.

Continuing education credits are not available for the archived online training series.

For information about these archived online training courses, please contact Colleen Buckley at +1.215.442.6108 or Colleen.Buckley@diahome.org

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WebEx OS and Browser Support

	Windows	Mac OS X	Linux
Operating Systems	2000, XP, 2003, 32-bit Vista, 64-bit Vista (not including Remote Access and Productivity Tools), 32-bit Windows 7, 64-bit Windows 7 (not including Remote Access and Productivity Tools)	10.4, 10.5, 10.6	"Ubuntu 9.04, Red Hat 5, Open SuSE 11.1, Fedora 11"
Minimum System Requirements			
Processor	Intel or AMD	PowerPC or Intel	Intel or AMD
JavaScript	JavaScript and cookies enabled	JavaScript and cookies enabled	JavaScript and cookies enabled
Other	Active X enabled (unblocked for IE is recommended)	Apple Java 5 or above	"Sun Java 5 or above, libstdc++ 6.0, GNOME/KDE windowing system"
Browsers (Recommended browsers are shown in bold)			
Internet Explorer	6, **7, 8**		
Mozilla			1.7
Firefox	2/**3/3.5**	2/**3/3.5**	2/**3/3.5**
Safari		**4-Mar**	
Chrome	**3**		

Internet Connection Speed 56k or faster

Display 800x600 pixel resolution or greater (1024x768 pixels recommended)

To test your system compatibility, click on the link below. http://www.webex.com/lp/jointest

Phase 1 ARCHIVED Online Training Series

CONTACT INFORMATION: ***Questions about this Archived Online Training Series?*** Contact Colleen Buckley at the DIA office in Horsham, PA by telephone +1.215.442.6108, fax +1.215.442.6199, or email Colleen.Buckley@diahome.org.

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