



Use of Foreign Trial Data for NDA Approval

September 25, 2009

11:00 AM-12:30 PM EDT

10:00 AM-11:30 AM CDT

9:00 AM-10:30 AM MDT

8:00 AM-9:30 AM PDT

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and Chief Medical Officer
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For information about this and other upcoming webinars, contact Jo Ann Boileau at DIA.

- Tel +1-215-442-6175
- Fax +1-215-442-6199
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How to Use Foreign Trial Data in Your NDA Approval Process

While the law allows 100 percent of pivotal data to come from foreign trials, there have been very few such submissions accepted by FDA – mainly in limited therapeutic areas. Given lower costs and shorter recruiting times, the use of foreign sites is appealing to all drug developers, especially generic and 505(b)(2). Due to shortcomings found during site inspections, lack of inspection resources and the general tightening of FDA safety reviews, FDA has started imposing some “unwritten” requirements for the acceptance of such data. This webinar explores these requirements and how you can ensure compliance.

FEATURED TOPICS

- Guidances and regulations that govern the FDA's acceptance of foreign trial data as pivotal data for NDA approval
- What you can do to ensure compliance
- Design considerations and requirements for foreign trials

WHO SHOULD ATTEND

Professionals involved in:

- ▶ Regulatory affairs
- ▶ Clinical safety/pharmacoepidemiology
- ▶ Clinical research & development
- ▶ Clinical supplies
- ▶ GCP
- ▶ Investigative sites
- ▶ Outsourcing
- ▶ Research & development/strategic issues

See page 2 for Technical Requirements and Continuing Education Credit information

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Technical Requirements for Audience Members

Browser

Microsoft® Internet Explorer 5.2 or higher
Netscape® Navigator 7

Computer

166Mhz Pentium-based PC with Microsoft® Windows® 98, NT, ME, XP or 2000

Sun JVM 1.4* for Microsoft JVM (all versions supported by Microsoft Windows OS shown above)

Sun SPARCstation with Solaris 8 or 9

Audience: 64 MB RAM

**If you need to install Java Virtual Machine (JVM) on your system, please download it from the Sun Microsystems website.*

Internet Connection Speed

56k or faster

Display

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

Attendees using Macintosh OS

Microsoft IE 5.2

Macintosh OS 10.2X

To test your system compatibility, click on the link below.

<https://developers.webex.com/api/jointest/index.php>

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LEARNING OBJECTIVES

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

- ▶ Identify which guidances and regulations govern the FDA's acceptance of foreign trial data as pivotal data for NDA approval;
- ▶ Discuss how FDA is implementing these rules and what you can do to assure compliance; and
- ▶ Recognize design considerations and requirements for foreign trials.

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CONTACT INFORMATION: Questions about this Webinar? Contact Jo Ann Boileau at the DIA office in Horsham, PA by telephone +1-215-442-6175, fax +1-215-442-6199, or email JoAnn.Boileau@diahome.org.

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