FDA Draft Guidance on Adaptive Design Clinical Trials for Drugs and Biologics

Event #10227 • May 5, 2010
11:00 AM-12:30 PM EDT  9:00 AM-10:30 AM MDT
10:00 AM-11:30 AM CDT  8:00 AM-9:30 AM PDT

INDIVIDUAL MEMBER $250* • GROUP SITE $799**
GROUP PLUS $995***

* Individual registration is a license for ONE internet login allowing one viewer.
** Group site registration is a license for ONE internet login allowing multiple viewers from one location.
*** Group Plus is a license for up to FIVE internet logins allowing one or more viewers at each login location.

Visit www.diahome.org and enter keyword 10227.

Discuss the Implementation of Adaptive Clinical Trial Design in Drug Development and Approval.

Due to their complexity, adaptive design development programs require more (and earlier) planning and documentation. This webinar will provide an overview of the FDA Draft Guidance on Adaptive Designs and discuss how to plan an adaptive trial prior to implementation.

FEATURED TOPICS

• Summary of the Draft Guidance
• Clarification of issues raised in the guidance
• Why adaptive design development programs require more (and earlier) planning and documentation and how this planning should be summarized and discussed with the FDA prior to implementing an adaptive trial

WHO SHOULD ATTEND

Professionals involved in:
• Biostatistics
• Clinical research
• Data analysis
• Regulatory affairs
• Quality assurance
**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://diahome.webex.com/ec0605l/eventcenter/support/eventManager.do?siteurl=diahome

---

**LEARNING OBJECTIVES**

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

- Explain the major issues when considering an adaptive design clinical trial
- Describe the range of clinical trial adaptive design methods
- Discuss which methods raise concerns and why these concerns are raised
- Outline how to effectively interact with FDA when planning or submitting a completed adaptive design clinical trial
- Explain how to formally submit comments to the draft guidance to the FDA Docket

---

**DIA Vision**

DIA is the global forum for knowledge exchange that fosters innovation to raise the level of health and well being worldwide.

---

**DIA Mission**

DIA fosters innovation to improve health and well being worldwide by:

- Providing invaluable forums to exchange vital information and discuss current issues related to health products, technologies, and services;
- Delivering customized learning experiences;
- Building, maintaining, and facilitating trusted relationships with and among individuals and organizations that drive and share DIA values and mandates; and
- Offering a multidisciplinary neutral environment, respected globally for integrity and relevancy.
CONTACT INFORMATION: Questions about this Webinar? Contact Wendy Moyer at the DIA office in Horsham, PA by telephone +1.215.293.5810, fax +1.215.442.6199, or email Wendy.Moyer@diahome.org.

WEBINAR: DIA accepts no liability for problems that may be encountered as a result of high traffic on the web. DIA will provide the Licensee with specific information for accessing the webinar. This information must be treated as proprietary and not given to anyone else.

INDIVIDUAL: Individual is a license for ONE internet log-in allowing one viewer. DIA will provide the registrant with specific information for accessing the webinar; this information must be treated as proprietary and should ONLY be used by the registrant or registrant designee.

GROUP SITE: Group site is a license for ONE internet login from one physical location, allowing multiple viewers. DIA will provide the registrant with specific information for accessing the webinar from this location; this information must be treated as proprietary and should ONLY be used by the site coordinator or site coordinator designee. Access from any additional physical location requires an additional registration.

GROUP PLUS: Group Plus is a license for up to FIVE internet logins, allowing one or more viewers at each login location. DIA will provide each designated registrant (please email Wendy.Moyer@diahome.org with the full contact information of each registrant) with specific information for accessing the webinar from his or her location.

CANCELLATIONS: No refunds will be provided in the event of a participant’s cancellation since all costs for this webinar have been prepaid by DIA. DIA reserves the right to modify or cancel programs and/or substitute presenters or panelists. DIA is not responsible for failure to deliver programs due to circumstances beyond its control.

REGISTRATION FORM
FDA Draft Guidance on Adaptive Design Clinical Trials for Drugs and Biologics
Event #10227 • May 5, 2010 • 11:00 AM-12:30 PM EDT

Individual Registration Fees
Individual Member US $250
Individual Nonmember US $295

Discounted Fees
Government (Full-time) US $125
Charitable Nonprofit/Academia (Full-time) US $175

GROUP SITE REGISTRATION FEE US $799

GROUP PLUS REGISTRATION FEE US $995

Email Wendy.Moyer@diahome.org within 48 hours of registering for this webinar with complete contact information for each additional login. DIA cannot guarantee that login information will be available if complete contact information is not received within 48 hours.

Please check the applicable category below:
- Academia
- Government
- Industry
- CSO
- Student

PAYMENT REGISTER ONLINE AT www.diahome.org or please check payment method:
- Credit Card number may be faxed to: +1.215.442.6199. Non-U.S. credit card payments will be subject to the currency conversion rate at the time of the charge.

- Visa
- MC
- AMEX

Exp Date _________________________

Signature _________________________

Please complete the information below and fax this entire page to DIA 215 442 6199.

Last Name First Name Middle Initial

Degrees
- Dr.
- Mr.
- Ms.

Job Title

Affiliation (Company)

Address

City State Zip Country
(Please write your address in the format required for delivery to your country.)

email (Required for confirmation.)

Telephone Number Fax Number (Required for confirmation.)

Registered attendees will receive a confirmation letter with access instructions one week prior to the Webinar.