

Member Early-bird Rate — Register by April 14 and Save \$190!



Early Drug Development: Navigating the Treacherous Rapids

May 5-6, 2009 | Hilton Washington DC/Silver Spring, Silver Spring, MD, USA

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GlaxoSmithKline, Inc.

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Associate Director for Regulatory Affairs
Office of New Drugs, CDER, FDA

JULIE RIVERS, MA, MS QA/RA IN PROGRESS

Program Manager, Regulatory Affairs
GlaxoSmithKline, Inc.

WHO SHOULD ATTEND

Professionals, especially from small to mid-size companies and CROs, involved in:

- ▶ Regulatory affairs
- ▶ Clinical research
- ▶ Project management
- ▶ Academia

Learn Strategies to Address the Key Issues Facing Project Teams in the Early Drug Development Continuum.

OVERVIEW

This dynamic, interactive workshop will incorporate a hands-on, small team, discussion-based approach with targeted presentations that discuss real-world strategies that can be immediately applied to your development programs.

Professionals from industry and FDA will facilitate all sessions, including team breakout and report-back sessions.

FEATURED TOPICS

- Candidate selection to three months post-candidate selection
 - Evaluating general toxicity and genotoxicity
 - Assessing genotoxic impurities
 - CMC activities and issues
- Three to eight months post-candidate selection
 - IND format and content
 - Strategic considerations for IND submissions
 - Dose selection
 - FDA meetings
- Eight months post-candidate selection to IND submission and FDA review
 - IND clinical hold
- IND active to end of Phase 1
 - Orphan drug designation
 - Fast-track designation
 - End of Phase 1 meetings
- End of Phase 1 to end of Phase 2a
 - End of Phase 2a meetings

LEARNING OBJECTIVES At the conclusion of this meeting, participants should be able to:

- ▶ Identify issues that commonly arise during the early stage of drug development;
- ▶ Integrate the regulatory context (e.g. guidance documents, FDA interaction opportunities) into strategies for addressing emerging issues;
- ▶ Contribute to the development of strategies to address issues arising during this dynamic development stage; and
- ▶ Apply hands-on experience with selected IND sections and components of FDA meeting requirements and requests.

CONTACT INFORMATION

Conference: Carrie Dunn, Phone +1-215-442-6181/email carrie.dunn@diahome.org

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

TRAVEL AND HOTEL The most convenient airports are Baltimore/Washington International, Reagan National, and Dulles Airports and attendees should make airline reservations as early as possible to ensure availability. The Hilton Washington DC/Silver Spring Hotel is holding a block of rooms at the reduced rate below until April 13, 2009, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single \$174 Double \$174

Please contact the Hilton Washington DC/Silver Spring Hotel by telephone at +1-800-445-8667 or +1-301-589-5200 and mention the DIA event. The hotel is located at 8728 Colesville Road, Silver Spring, MD 20910, USA.

CONTACT INFORMATION

Contact Carrie Dunn at the DIA office by telephone +1-215-442-6181 fax +1-215-442-6199 or email carrie.dunn@diahome.org.

Participants with Disabilities

DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

CANCELLATION POLICY: On or before APRIL 29, 2009

Administrative fee that will be withheld from refund amount: Member/Nonmember = \$200 • Government/Academia/Nonprofit (Member/Nonmember) = \$100 • Tutorial = \$50
Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

PLEASE CONSIDER THIS FORM AN INVOICE

Early Drug Development: Navigating the Treacherous Rapids

Meeting I.D. # 09013 – May 5-6, 2009
Hilton Washington DC/Silver Spring, Silver Spring, MD, USA

Registration Fees

If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons and reception and will be accepted by mail, fax, or online.

MEMBER EARLY-BIRD OPPORTUNITY

Available on nondiscount member fee only.

	On or before	After
	APRIL 14, 2009	APRIL 14, 2009

Member Fee	US \$1260 <input type="checkbox"/>	US \$1450 <input type="checkbox"/>
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Join DIA now to qualify for the early-bird member fee! www.diahome.org/en/Membership/AboutMembership/AboutMembership

MEMBERSHIP
US \$ 130

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.

Nonmember Fee	US \$1580 <input type="checkbox"/>
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A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member I do NOT want to be a DIA member

Discount Fees	MEMBER	NONMEMBER*
Government (Full-time)	US \$ 365 <input type="checkbox"/>	US \$ 495 <input type="checkbox"/>
Charitable Nonprofit/Academia (Full-time)	US \$ 730 <input type="checkbox"/>	US \$ 860 <input type="checkbox"/>

*If paying a nonmember fee, please check one box above, indicating whether you want membership.

PAYMENT REGISTER ONLINE AT www.diahome.org or please check payment method:

CHECK drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

CREDIT CARD number may be faxed to: +1-215-442-6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

Visa MC AMEX Expiration Date _____

Card # _____

Signature _____

BANK TRANSFER When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.** To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

Please indicate that this form is part of a group registration by checking this box.

Please list below the names of the other three registrants from your company.

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2. _____
3. _____

Please complete the information below.

Please check the applicable category: Academia Government Industry CSO Student (Call for registration information)

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Job Title _____ Affiliation (Company) _____

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

email (Required for confirmation.) _____ Telephone Number _____ Fax Number (Required for confirmation.) _____

I cannot attend but please keep me informed of DIA's future events.