

**DIA/FDA Statistics Forum 2013:
PDUFA V Statistical Topics and Emerging New Issues
April 29 – May 1, 2013
Bethesda North Marriott Hotel, Bethesda, Maryland**

The organizing committee invites you to propose, and volunteer to lead, a roundtable luncheon discussion.

Deadline for submission is February 28, 2013 and selections will be made by March 15, 2013.
Roundtable luncheon discussions will be held on April 30, 2013.

Proposals should be submitted by form. [Click here](#) to view form and/or submit proposal.

The information you'll need to submit your proposal:	Potential Round Table Discussion Topics
<ol style="list-style-type: none"> 1. Your name 2. Your phone number 3. Your email address 4. Your professional affiliation 5. The roundtable discussion title 6. A general theme/topic (see potential discussion topics) 7. A short (2-3 sentences) description of the roundtable topic and 2-3 questions you plan to discuss 	<p>The potential topics include (<i>but are not limited to</i>) the following related themes of the 2013 DIA/FDA Statistics Forum:</p> <ul style="list-style-type: none"> • Statisticians as Leaders • Multiplicity • Enriched Populations • Dichotomizing Continuous Measures for Primary Efficacy Endpoint – Are we Substantially Compromising Statistical Power? • Pre-Competitive Collaboration • Meta-analysis for Safety Data • Companion Diagnostics • Benefit-risk Assessments (Pre-Marketing) • Comparative Effectiveness Research – Post-marketing Benefit-Risk • Missing Data

Each of these broad topics may have subtopics that you wish to expand upon in your luncheon dialogue--feel free to be creative. Furthermore, you are welcome to submit a roundtable topic that is unrelated to the meeting themes, though we will give preference to topics that are related.

If selected, you will be responsible for all costs (e.g., registration, travel, and lodging).

NOTE: The submission form does not allow for updates. If you need to update your submission, please completely resubmit your proposal. *There is a field at the end of the form to indicate that it is a resubmission.*

Please send questions and inquiries to either of the following persons:

<p>Conference: Constance Burnett, Content Lead Phone: 215-293-5800 Fax: 215-442-6199 Constance.Burnett@diahome.org</p>	<p>Meeting Logistics: Ellen Diegel, Event Planner Phone: 215-293-5810 Fax: 215-442-6199 Ellen.Diegel@diahome.org</p>
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We look forward to receiving your proposals by February 28, 2013,
and in your participation at the conference April 29-May 1, 2013.

The DIA/FDA Statistics Forum 2013 Roundtable Chairpersons

Tammy Massie
CBER, FDA

Brenda Crowe
Eli Lilly and Company