



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2016-N-0001]

Tenth Annual Drug Information Association/Food and Drug Administration Statistics Forum--2016; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA), in co-sponsorship with the Drug Information Association (DIA), is announcing a public conference entitled “Tenth Annual DIA/Food and Drug Administration Statistics Forum--2016.” This public conference is intended to be an open forum for the timely discussion of topics of mutual theoretical and practical interest to statisticians and clinical trialists who develop and review new drugs and biologics. A primary focus for this public conference will be to establish an ongoing dialogue between industry and regulatory Agencies--emphasizing the regulatory and statistical challenges associated with innovative approaches to the design and analysis of clinical trials and measuring the progress being made in designing and implementing innovative solutions.

DATES: The main meeting will be held over 3 days: April 25, 2016, from 1 p.m. to 5:30 p.m.; April 26, 2016, from 8:30 a.m. to 5 p.m.; and April 27, 2016, from 8:30 a.m. to 3:30 p.m. On April 25, there will also be pre-meeting tutorials from 8:30 a.m. to 12 p.m. and a scientific working group session from 5:40 p.m. to 7 p.m.

ADDRESSES: The meeting will be held at the Marriott Bethesda North Hotel and Conference Center, 5701 Marinelli Rd., North Bethesda, MD 20852, 301-822-9200.

FOR FURTHER INFORMATION CONTACT: Meredith Kaganovskiy, DIA, 800 Enterprise Rd., Horsham, PA 19044, 215-442-6117, Meredith.Kaganovskiy@DIAglobal.orgM; or Stephen Wilson, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 3630, Silver Spring, MD 20993-0002, 301-796-0579, Stephen.Wilson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA and DIA will sponsor an open public discussion between industry, academia, contract research organizations, regulatory scientists, and other parties on topics related to the innovative statistical methodologies and quantitative approaches used by sponsors to provide evidence for the approval of new therapies.

The forum will provide a unique opportunity for all of the relevant stakeholders to collaboratively describe the issues and discuss appropriate solutions. It is important that all of the stakeholders examine their roles in making the necessary changes and improvements in the framework used to develop evidence for the regulatory decisions and work to foster a mutual understanding of relevant scientific issues and challenges.

The conference will benefit FDA by enhancing communication with the broader statistical community.

The goals of the program are as follows:

- Explore and implement innovative statistical solutions to important issues associated with the quantitative evidence needed for the regulatory review of therapeutic drugs and biologics
- Describe the application of statistical methodologies and thinking regarding the development of new therapeutic biologics and drugs

- Assess the impact of regulations and guidance on statistical practice
- Discuss ideas for improving the communication between industry statisticians and regulatory reviewers

A description of the planned activities of the working groups can be found at

<http://www.diaglobal.org/en/conference-listing/meetings/2016/04/dia-fda-statistics-2016-forum>.

II. Registration and Accommodations

A. Registration

There is a registration fee to attend this meeting. The registration fee is to help defray the costs of the event; including meeting facilities, program materials, refreshments, staff time and administrative overhead, and costs involved in getting speakers to the events; and will not result in any profits. Seats are limited, and registration will be on a first-come, first-served basis. On-site registration will be available to the extent that space is available on the day of the conference.

Please note: Registration will open at 7:30 a.m. each day.

To register, please complete registration online at

<http://www.diaglobal.org/en/conference-listing/meetings/2016/04/dia-fda-statistics-2016-forum/register>. (FDA has verified the Web address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.) The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives	\$1,350
Charitable Nonprofit/Academic (Full time)	\$675
Government (Full time)	\$405

Tutorial Fees	\$405
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All registrants will be required to pay the applicable fee, with the exception of a limited number of speakers/organizers who will have a complimentary registration.

B. Accommodations

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the Bethesda North Marriot Hotel and Conference Center, 5701 Marinelli Rd., North Bethesda, MD 20852 are eligible for a reduced rate of \$199, not including applicable taxes.

The Marriott Bethesda North Hotel and Conference Center has a limited number of rooms available at the discounted rate of \$199 per night until April 1, 2016, or until the block is filled. To receive the reduced rate, hotel reservations must be made with onPeak, <https://compass.onpeak.com/e/72FOR16>, and not directly with the hotel. If you need special accommodations due to a disability, please contact Stephanie.Ritter@DIAglobal.org at least 7 days in advance.

Dated: March 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-05219 Filed: 3/8/2016 8:45 am; Publication Date: 3/9/2016]