



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**Peer Review of Draft NTP Approach to Genomic Dose-Response Modeling;  
Availability of Documents; Request for Comments; Notice of Expert Panel Meeting**

**SUMMARY:** The National Toxicology Program (NTP) announces an expert panel meeting and is obtaining comment on a proposed approach to genomic dose-response modeling. Prior to the expert panel meeting, NTP will host four webinars that present other approaches to genomic dose-response modeling. The expert panel meeting and four webinar presentations leading up to the meeting are open to the public. Registration is requested for both in-person meeting attendance and oral comment; registration is required to access the meeting webcast. URLs for live and archived pre-meeting webinars will be available at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>.

**DATES:** Pre-Meeting Webinars: Dates are posted on the meeting website (<https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>). Registration is not required to view the pre-meeting webinars.

Meeting: October 23–25, 2017; expert panel meeting begins at 8:30 a.m. Eastern Daylight Time (EDT) each day and continues until adjournment.

Document Availability: Draft document should be available by August 23, 2017, at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>.

Written Public Comment Submissions: Deadline is October 13, 2017.

Registration for Oral Comments: Deadline is October 13, 2017.

Registration for Meeting and/or to View Webcast: Deadline is October 25, 2017.

Registration to view the meeting via webcast is required.

**ADDRESSES:** Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Website: The draft document, preliminary agenda, registration, pre-meeting webinars details, and other meeting materials will be available at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>.

Webcast: The URL for viewing the expert panel meeting webcast will be provided to those who register.

**FOR FURTHER INFORMATION CONTACT:** Anna Stamatogiannakis, ICF, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293-1652, Fax: (919) 293-1645, Email: [anna.stamatogiannakis@icf.com](mailto:anna.stamatogiannakis@icf.com).

**SUPPLEMENTARY INFORMATION:**

**Background:** NTP proposes to use the approach embodied in the BMDExpress software to perform gene and pathway-level genomic dose-response modeling as part of Tox21 Phase 3 and in vivo screening level studies. NTP seeks external scientific input on its proposed approach by an expert panel. NTP's goal for implementing this approach considers a number of factors including methods accepted in the peer-review literature, ease of translation to risk assessment, and ease of understanding for the variety of potential end users that may not necessarily be experts in mathematical and systems modeling. A series of four pre-meeting webinars and the expert panel meeting aim to

review current approaches and discuss best practices. The webinar series will provide an overview of various current approaches and NTP's proposed approach to genomic dose-response modeling. The expert panel will consider information presented in the webinars as well as other technical factors during its peer review of NTP's proposed approach.

**Pre-Meeting Webinars Registration:** There is no registration required to attend the webinars. The URLs for live and archived webinars will be available on the meeting website at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>; please refer to this page for the most current information about the webinars and the meeting.

**Expert Panel Meeting and Registration:** The meeting is open to the public with time set aside for oral public comment. Interested individuals can attend the meeting in person or view the webcast. Attendance at NIEHS is limited only by the space available. For planning purposes, registration to attend the meeting at NIEHS or view the webcast is requested. Registration to attend the meeting in person and/or view the webcast is by October 25, 2017, at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>.

**Attending the Meeting:** Visitor and security information for those attending in person is available at <https://www.niehs.nih.gov/about/visiting/index.cfm>. Individuals with disabilities who need accommodation to participate in this event should contact Anna Stamatogiannakis by phone: (919) 293-1652 or email: [anna.stamatogiannakis@icf.com](mailto:anna.stamatogiannakis@icf.com). TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

**Meeting Materials:** The expert panel meeting agenda will be available on the meeting website at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/>. The draft document should be available by August 23, 2017. Additional information will be posted when

available or may be requested in hardcopy, see **FOR FURTHER INFORMATION CONTACT**.

Following the meeting, a report of the panel meeting will be prepared and made available on the NTP website. Individuals are encouraged to access the meeting website to stay abreast of the most current information regarding the meeting.

**Request for Comments:** NTP invites written and oral public comments on the draft NTP approach. The deadline for submission of written comments is October 13, 2017, to enable review by the peer review panel and NTP staff prior to the meeting. Written public comments and any other correspondence on NTP's proposed approach should be sent to the **FOR FURTHER INFORMATION CONTACT**. Persons submitting written comments should include their name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website and the submitter identified by name, affiliation, and/or sponsoring organization (if any). Guidelines for public comments are at [https://ntp.niehs.nih.gov/ntp/about\\_ntp/guidelines\\_public\\_comments\\_508.pdf](https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf).

Oral public comment at this meeting is welcome, with time set aside on October 23 for the formal presentation of oral remarks on the draft document. In addition to in-person oral comments at the NIEHS, public comments can be presented by teleconference line. There will be 50 lines for this call; availability is on a first-come, first-served basis. The lines will be open from 8:30 a.m. each day until adjournment. Oral comments will be received only during the formal public comment periods indicated on the preliminary agenda. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Each organization is allowed one

time slot. At least 7 minutes will be allotted to each time slot, and if time permits, the allotment may be extended to 10 minutes at the discretion of the chair. In addition to the formal public comment period, there will be several opportunities in the agenda for ad hoc comments.

Persons wishing to make oral comments during the formal comment period on October 23 are asked to register online at <https://ntp.niehs.nih.gov/about/org/ntpexpertpanel/> by October 13, 2017, and indicate whether they will present comments in person or via the teleconference line. Oral public commenters are asked to send a copy of their slides and/or statement or talking points to the **FOR FURTHER INFORMATION CONTACT** by October 13, 2017. Written statements can supplement and may expand the oral presentation. Registration for in-person oral comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for registered speakers and will be determined by the number of speakers who register on-site. Time is also being set aside in the agenda for ad hoc comments by both in-person attendees and webcast viewers. Information on how to make oral remarks during those ad hoc comment periods will be provided at the meeting.

**Background Information on Expert Panels:** NTP panels are technical, scientific advisory bodies established on an “as needed” basis to provide independent scientific peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing

information to regulatory agencies about alternative methods. NTP welcomes public comment for dose-response modeling.

Dated: August 15, 2017

John R. Bucher

Associate Director,

National Toxicology Program

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