

Public Workshop - Using Scientific Research Data to Support Pediatric Medical Device Claims, December 5, 2011

U.S. Food & Drug Administration

The Food and Drug Administration (FDA) is announcing a public workshop entitled: "Using Scientific Research Data to Support Pediatric Medical Device Claims: A Public Dialogue." The purpose of the public workshop is to receive public comment on the use of scientific research data, including published scientific literature, to extrapolate effectiveness claims from adults to children and between pediatric subpopulations in order to support and establish pediatric indications for medical devices.

The topics to be discussed are the ways scientific research data can be used to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance; the scientific and regulatory limitations and issues of using existing scientific research data to support pediatric effectiveness claims and pediatric indication approvals for medical devices; and methods to overcome the pitfalls and data gaps, including statistical approaches and modeling.

This workshop will support FDA's efforts to define pathways for approving pediatric device indications by leveraging available scientific research data. An important, but not the only focus, will be a discussion of how to determine when it is appropriate to use, and how to use, existing scientific research data, including that in published scientific research, to determine pediatric effectiveness based on a similar course of a disease or condition or a similar effect of a device on adults and similar extrapolation between pediatric subpopulations. We are looking to establish a framework to support the establishment of pediatric effectiveness claims.

- [Date, Time, and Location](#) [1]
- [Federal Register Notice](#) [2]
- [Background](#) [3]
- [Workshop Details](#) [4]
- [Agenda](#) [5]
- [Registration](#) [6]
- [Contact Us](#) [7]

This workshop will be held December 5, 2011 from 8:30 am to 5:00 p.m. EST at:

FDA White Oak Campus
10903 New Hampshire Ave
The Great Room (Room 1503), White Oak Conference Center, Bldg 31
Silver Spring, MD, 20903

- [FDA Campus Information \(includes directions & parking\)](#) [8]

The demand by health care professionals and consumers for safe and effective pediatric medical devices continues to steadily increase. Pediatric medical devices prevent, treat or diagnose diseases and conditions occurring from birth through the 21st year of life, in the pediatric spectrum of infancy, childhood and adolescence. Some devices are designed specifically for pediatric use, while others are adopted from specific adult device applications or produced for more general use.

Childhood, from before birth through adolescence, is characterized by a rapid biologically determined developmental trajectory during which the child undergoes predictable change in every body system. Designing pediatric medical devices can be challenging: children are often smaller and more active than adults, body structures and functions grow and evolve throughout childhood, and children may be long-term device users - raising concerns about device longevity and the impact of long-term exposure to implanted materials. The current medical device market for children has a higher demand than supply. FDA is committed to supporting the development and availability of safe and effective pediatric medical devices.

In 2007 Congress passed the Pediatric Medical Device Safety and Improvement Act. One approach that the Act addresses pediatric device needs is by allowing for a pediatric device approval pathway that permits extrapolation of adult effectiveness data to support a pediatric indication based on similar course of the disease or condition or a similar effect of the device.

Extrapolation of effectiveness across populations (for example, from adults to pediatric patients) simplifies the requirements for establishing a pediatric intended use claim. It reduces the need for and complexity of clinical efficacy studies to establish pediatric claims. This facilitates efforts to address the unmet medical device need for children by making optimal use of what is already known to increase efficiency, and reducing the regulatory burden. Due to the unique safety issues of the pediatric population, extrapolation of safety is not authorized.

Through this effort, FDA and stakeholders will take steps to increase awareness of a path for approval of pediatric devices that uses extrapolation of existing scientific research data, including from clinical trials or scientific literature. FDA will advance this goal through collaboration with medical device and health care industries, and the healthcare provider, academic and consumer communities.

Additional background about the [Pediatric Medical Device Safety and Improvement Act and pediatric medical devices](#) [9] is available.

Workshop Format

This workshop is structured as plenary overview presentations and topic-focused interactive breakout sessions, intended to foster constructive dialogue between stakeholders with diverse perspectives. Moderators of each breakout group will summarize each group's observations for presentation to all participants.

Webcast

The plenary portions of this workshop, which will include summaries of the breakout session discussions, will be webcast. The individual breakout session discussion will not be webcast. Webcast viewers will not be able to participate in large group or breakout session discussion.

Persons interested in viewing the webcast must register online by 5 p.m. on November 28, 2011. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but view using one connection per location. Webcast participants will be sent technical system requirements after registration, and will be sent connection access information after November 28 th. If you have never attended a Connect Pro event before, we advise you to test your connection in advance of the meeting at: https://collaboration.fda.gov/common/help/en/support/meeting_test.htm [10]. To get a quick overview of the Connect Pro program, visit: http://www.adobe.com/go/connectpro_overview [11] FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites.

Written or electronic comments

In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting written or electronic comments on the workshop topics. Regardless of attendance at the public workshop, interested persons may submit written or electronic comments. Submit electronic comments to <http://www.regulations.gov> [12]. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Duplicate submissions are not required. The deadline for submitting comments related to this public workshop is January 5, 2012. Please identify comments with the docket number FDA-2011-N-0754, and if responding to specific topics, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at <http://www.regulations.gov> [13].

Food and beverages

Food and beverages will be available for purchase by participants during the workshop breaks.

Time	Topic
8:30- 8:40 AM	Plenary Session: Welcome: Structure of the Day and Logistics
8:40 - 9:00 AM	Plenary Session: Overview on the use of Extrapolated Data to establish Pediatric Device Effectiveness
9:00 - 9:30 AM	Plenary Session: Topic 1: Defining the Useful Research Data Landscape
9:30 - 10:30AM	Breakout Session: Topic 1: Defining the

Public Workshop - Using Scientific Research Data to Support Pediatric Medical Devices

Published on Medical Design Technology (<http://www.mdtmag.com>)

	Useful Research Data Landscape. Focus Questions: What are the sources of available and useful research data? How might this data be used to establish effectiveness for the pediatric patients or subsets of them? What factors should the FDA consider in using available data sources to establish effectiveness claims?
10:30 - 10:45 AM	Break
10:45 - 11:30 AM	Plenary Session: Moderators report back from Breakout Session on Topic 1
11:30 AM - 12:30 PM	Lunch Break
12:30 - 12:45 PM	Plenary Session: Topic 2 : Defining the scientific and regulatory challenges and limitations with use of existing research data and published literature.
12:45 - 1:45 PM	Breakout Session: Topic 2: Defining scientific and regulatory the challenges and limitations and with the use of existing research data and published literature. Focus Question: Considering the landscape of data sources identified in Breakout Session #1, what are the scientific and regulatory challenges and limitations the FDA must consider when using these data to extrapolate or establish pediatric effectiveness for various medical devices?
1:45 - 2:00 PM	Break
2:00 - 2:30 PM	Plenary Session: Report back from Breakout Session on Topic 2
2:30 -3:30 PM	Breakout Session #3: Overcoming the challenges and limitations: Identifying methods to address the pitfalls and data gaps , including statistical approaches and modeling. Focus Question: Considering the challenges and limitations identified in Breakout Session #2, how might the FDA address these challenges and limitations? How might statistical modeling and limited clinical or other research address these challenges and limitations?
3:30 - 4:00 PM	Plenary Session: Report back from Breakout Session on Topic 3
4:00 - 5:00 PM	Closing Plenary Session: Summary of Dialogue and the Road Ahead.
5:00 PM	Adjournment

There is no fee to register for the Workshop and registration will be on a first-come, first-served basis. If you wish to attend this Workshop, you must register by 5 pm EST on November 28, 2011. Early registration is recommended because registration will be limited to 120 participants due to the interactive nature of the workshop. Therefore, FDA may limit the number of participants from each organization. Registrants are requested to notify the FDA as soon as possible if they will not be able to attend, to permit wait-listed registrants to attend. This website will be updated to indicate whether on-site registration will be available on the day of the public workshop.

To register for the public workshop, please select either the In-Person Workshop Attendance registration, or the Online Webcast Viewing registration on the form below. Please provide complete contact information for each attendee, including name, title, affiliation, email address, and telephone number. For those without Internet access, please call the Contact Person to register. Registrants will receive confirmation once they have been accepted. You will be notified if the available attendance slots are filled, and you are on a waitlist.

Attendance		In-Person Webcast			
Title	Mr.	Mrs.	Ms.	None	
First Name *					
Last Name *		M.D.	Ph.D.		
Email *	Please enter Email again for verification :				
Phone Number *	(No dashes or spaces in phone numbers please)				
Company or Organization *					
Representation	If you will be representing another company or organization, please specify:				
Primary Affiliation *	Industry Provider	Academic	Health Care		
	Consumer	FDA	Other		

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov> [12]. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857. A link to the transcripts and an archived file of the webcast will also be available on this webpage approximately 45 days after the public workshop.

For information regarding registration and special accommodations, contact:

Cynthia Garris

Office of Communication, Education, and Radiation Programs

Center for Devices and Radiological Health

Food and Drug Administration

10903 New Hampshire Avenue

Bldg 66, Room 4459

Silver Spring, MD 20993

Phone: 301-796-5861

Email: Cynthia.Garris@fda.hhs.gov [14]

For information regarding the program, contact:

Carol Krueger

Office of the Center Director

Center for Devices and Radiological Health

Food and Drug Administration

10903 New Hampshire Avenue

Bldg 66, Room 5437

Silver Spring, MD 20993

Phone: 301-796-3241

Email: Carol.Krueger@fda.hhs.gov [15]

[SOURCE](#) [16]

Source URL (retrieved on 09/20/2014 - 4:19am):

<http://www.mdtmag.com/news/2011/11/public-workshop-using-scientific-research-data-support-pediatric-medical-device-claims-december-5-2011>

Links:

[1] <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#date>

[2] <http://www.gpo.gov/fdsys/pkg/FR-2011-11-01/html/2011-28244.htm>

[3] <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#background>

[4]

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#workshop>

[5]

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#agenda>

[6] <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#registration>

[7]

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences#contacts>

[8] <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>

[9]

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ucm135104.htm>

[10] https://collaboration.fda.gov/common/help/en/support/meeting_test.htm

[11] http://www.adobe.com/go/connectpro_overview

[12] <http://www.regulations.gov>

[13] <http://www.regulations.gov/>

[14] <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/mailto:Cynthia.Garris@fda.hhs.gov>

[15] <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/mailto:Carol.Krueger@fda.hhs.gov>

[16] <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm278053.htm>