



## Productive FDA Meetings are Key to Drug and Device Development

Formal meetings with the US Food and Drug Administration (FDA) typically punctuate the development programs for new drugs, biologics and medical devices in the United States. The FDA is a crucial stakeholder, with decision-making power to approve or deny the eventual marketing application, so the importance of receiving and clarifying the agency's guidance on any development program can hardly be overstated. Formal meetings are a key mechanism for sponsors to present their thinking and engage directly with FDA reviewers.

**CTI tracks all announcements from the FDA, so that we are always have information on the most current regulatory procedures for our clients.**

Keeping up with changing FDA meeting practices can be a challenge. New and revised meeting guidances can be issued by the agency at any time, so that meeting options and requirements are not static. The most recent revision to the CDRH guidance on device meetings came out in February 2014, and a new Center for Drug Evaluation Research (CDER) and Center for Biologics Evaluation Research (CBER) guidance on drug and biologic meetings came out in March 2015. **CTI's regulatory group track all announcements**

**from the FDA, so that we always have information on the most current regulatory procedures for our clients.**

For drugs and biologics, FDA has designated three types of meetings: Type A meetings are those needed to help an otherwise stalled product development program proceed. Type B meetings are standard meetings reflecting key milestones in the drug development process. Type C meetings are those that do not fall into either Type A or Type B.

Meetings Authorized by the Prescription Drug User Fee Act			
	Type A	Type B	Type C
Meeting Date	• By 30 days after request	• By 60 days after request	• By 75 days after request
FDA Response	• Within 14 days	• Within 21 days	• Within 21 days
Briefing Document Due	• With meeting request	• 4 weeks before meeting	• 4 weeks before meeting
Examples of Meeting Reasons	• Dispute resolution • Clinical hold • PostNDA non-approval	• Pre-IND • End-of-Phase 1 or 2 • Breakthrough program	• End-of-Phase 2a • Anything else that is not Type A or Type B

For medical devices, the FDA has designated multiple meeting types as well. Requests for information from Center for Devices and Radiological Health (CDRH) are referred to as "Q-Submissions". For device products regulated by CDRH, it is possible to hold Pre-Submission, Informational, Agreement, Determination, Submission Issue, and Day-100 Meetings.

Any FDA meeting starts with submission of a meeting request document, containing background information and draft questions that the sponsor

### CTI Cares Spotlight



#### Mustard Seed Communities

Mustard Seed Communities is a non-profit organization dedicated to caring for the most vulnerable populations in society. MSC began in 1978 as a home for children with disabilities on the outskirts of Kingston, Jamaica. It has since expanded and built additional facilities in Nicaragua, Dominican Republic and Zimbabwe. The majority of its programs are dedicated to the care of children with serious physical and mental disabilities such as Down syndrome, hydrocephalus, cerebral palsy and muscular dystrophy. MSC also cares for children affected by HIV/AIDS in Jamaica and Zimbabwe.

[Click here for more information and to donate!](#)

wants the agency to answer in the meeting. Depending on the workload of an FDA review division and how appropriate and substantive the request is, the agency may grant or deny meeting requests. Meetings may be granted face-to-face or over the phone.

At the option of either the sponsor or the FDA, questions could be answered in a written response, with no meeting held. This can be a quicker and more efficient avenue for straightforward matters or follow-up of topics already discussed in detail. But meetings are preferable in most cases because they allow fuller engagement and more opportunity to exchange information and clarify misunderstandings.

Briefing documents are now expected to be submitted with the meeting request for CDER/CBER Type A meetings, all biosimilar meetings, and many CDRH meetings. For meeting types that do not require submission of the briefing document with the request, it is still a good practice to develop the briefing document in parallel with the meeting request. It should be at least partially complete at the time the meeting request is made. The briefing document can then be sent to FDA by the date communicated in the notice granting the meeting.

The most effective meetings with FDA occur when careful thought has gone into the questions to be asked, and a targeted and concise briefing document has been prepared. The sponsor should plan time to review the FDA's preliminary responses to questions and decide what to focus on during the meeting - typically the questions and answers that require the greatest clarification. Meetings should always be conducted using professional, non-confrontational demeanor, with the goal of seeking understanding among the parties and consensus where possible.

CTI's clinical and regulatory experts have years of specialist experience in our therapeutic focus areas, as well as long-established relationships with many FDA reviewers and divisions. CTI participates in FDA meetings 20-30 times per year, providing a combination of deep history and updated knowledge that helps guide these meetings to successful outcomes for sponsors.



For more information:  
[www.ctifacts.com](http://www.ctifacts.com)  
 513.598.9290

## Recent CTI Publications

5 abstracts have been accepted by ISPOR and will be presented during the meeting in May

## Upcoming Meeting Spotlight

American Transplant Congress Annual Meeting  
 Philadelphia, PA  
 May 2 - 6, 2015



Stop by and visit us at  
Booth #1000 throughout the meeting!

To schedule a meeting with us while we're here, please [click here](#).

## Upcoming Meeting Spotlight

International Society for Pharmacoeconomics and  
Outcomes Research  
20th Annual International Meeting  
Philadelphia, PA  
May 16 - 20, 2015



Stop by and visit us at  
Booth #711 throughout the meeting!

To schedule a meeting with us while we're here, please [click here](#).

### Upcoming Meetings We Will Be Attending

**American Transplant Congress  
(ATC) - Annual Meeting**  
Philadelphia, PA - May 2 - 6

**International Society for  
Pharmacoeconomics and  
Outcomes Research (ISPOR) - 20th  
Annual International Meeting**  
Philadelphia, PA - May 16 - 20

**Future Leaders in the Biotech  
Industry**  
New York, NY - May 20

**Drug Information Association (DIA)  
- 51st Annual Meeting**  
Washington DC - June 14 - 18

**Bio International 2015 Convention**  
Philadelphia, PA - June 15 - 18

To schedule a meeting with us at  
one of these, please [click here](#)

### New Additions & Promotions at CTI

Michelle Clifford promoted to Senior  
Study Coordinator

Jessica Cherry promoted to Assistant  
Study Manager

Michel Connor promoted to Project  
Manager

Johanna Hornung promoted to  
Clinical Project Manager Europe

Tyler Meer promoted to Senior  
Research Associate

Mackenzie Pater joins as Assistant  
Study Manager

Paul Ritter, Esq. promoted to Senior  
Vice President & Chief Legal Officer

Jeni White joins as Administrative  
Assistant / Receptionist

### Join our Team!! We're looking for individuals to fill these positions:

Clinical Research Associate  
(US, Germany, France, Australia,  
Brazil)

Director, Health Outcomes  
Research (Cincinnati, OH)

Manager, Business Development &  
Client Management (San Francisco,  
CA or West Coast)

Manager, Proposal Development  
(Cincinnati, OH)

Project Accountant (Cincinnati,  
OH)

Study Manager (Cincinnati, OH;  
Raleigh, NC; Philadelphia, PA; San  
Francisco, CA)

[Click here for more information and  
to apply!](#)

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