

Questions Reported on for the CTTI ABDD Pediatrics Investigator Survey

Thank you for agreeing to participate in this survey about pediatric antibacterial clinical trials. You are free to discontinue the survey at any time or decline to answer any questions.

Demographics

We will begin by asking you questions about you and where you work.

1. What is your specialty? *(select all that apply)*
 - a. Pediatric Infectious Disease
 - b. Pediatric Intensivist
 - c. Neonatologist
 - d. Pediatric Hematologist/Oncologist
 - e. Pediatrician (General)
 - f. Pharmacologist
 - g. Other (please specify)

2. For how many years have you conducted pediatric antibacterial drug trials?
 - a. <5 years
 - b. 5-10 years
 - c. >10 years
 - d. I do not conduct pediatric antibacterial trials *[end of survey]*

3. In what type of facility do you conduct pediatric antibacterial drug trials?
 - a. Private clinic
 - b. Community clinic
 - c. Small Community Hospital (<100 beds)
 - d. Large Community Hospital (>100 beds)
 - e. University Children’s Hospital
 - f. Other (please specify)

[If any “Clinic” choice or “Other” is selected, Skip to Q4.]

- 3a. Does the hospital have a NICU?
 - a. Yes
 - b. No

4. We will now ask you questions about your experiences with implementing pediatric antibacterial drug trials.

4a. Based on your experience in conducting pediatric antibacterial drug trials, how important to successful implementation is each of the following factors?

Access to Potential Study Participants	Response option					
	Very Important	Somewhat Important	Somewhat Unimportant	Unimportant	Unsure	Not Applicable
Being able to recruit potential study patients from my practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having others refer potential study patients to your study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4ax. List here any other factor(s) related to **access to potential study participants** that is important for successful implementation of pediatric antibacterial drug trials.

4b. Based on your experience in conducting pediatric antibacterial drug trials, how important to successful implementation is each of the following factors?

Staff Support	Response option					
	Very Important	Somewhat Important	Somewhat Unimportant	Unimportant	Unsure	Not Applicable
Having site research personnel available to assist with enrolling study patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Getting adequate support from clinic or hospital nursing personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Getting adequate support from clinic or hospital laboratory personnel	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having adequate administrative support for research-related logistical activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having staff with expertise in regulatory submissions and follow-up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having staff with expertise in developing and negotiating site budgets	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Partnering with a clinical research organization (CRO) to facilitate the research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having staff with expertise in IRB submission and follow-up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4bx. List here any other factor(s) related to **staff support** that is important for successful implementation of pediatric antibacterial drug trials.

4c. Based on your experience in conducting pediatric antibacterial drug trials, how important to successful implementation is each of the following factors?

Clinic Space	Response option					
	Very Important	Somewhat Important	Somewhat Unimportant	Unimportant	Unsure	Not Applicable
Having adequate office space for research administration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having adequate clinic space for patient study visits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4cx. List here any other factor(s) related to **clinic space** that is important for successful implementation of pediatric antibacterial drug trials.

4d. Based on your experience in conducting pediatric antibacterial drug trials, how important to successful implementation is each of the following factors?

Finance	Response option					
	Very Important	Somewhat Important	Somewhat Unimportant	Unimportant	Unsure	Not Applicable
Receiving adequate funding from sponsor for your (investigator) salary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Receiving adequate funding from sponsor to cover other trial implementation costs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4dx. List here any other factor(s) related to **finance** that is important for successful implementation of pediatric antibacterial drug trials.

4e. Based on your experience in conducting pediatric antibacterial drug trials, how important to successful implementation is each of the following factors?

Miscellaneous	Response option					
	Very Important	Somewhat Important	Somewhat Unimportant	Unimportant	Unsure	Not Applicable
Using electronic data collection and medical record management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4ex. List here any other factor(s) important for successful implementation of pediatric antibacterial drug trials.

5a. Based on your experience in conducting pediatric antibacterial clinical drug trials, **how much of a barrier** have each of the following factors been in trial implementation?

Ethics and Regulatory	Response option					
	Major Barrier	Moderate Barrier	Somewhat of a Barrier	Not a Barrier	Unsure	Not Applicable
Obtaining parental consent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Obtaining child assent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Working through IRB questions and concerns	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Preparing the regulatory documentation required to conduct the research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The logistics of expeditiously obtaining consent from both parents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Obtaining consent from both parents when disagreement is evident	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5ax. List here any other factor(s) related to **ethical and regulatory issues** that was a barrier.

5b. Based on your experience in conducting pediatric antibacterial clinical drug trials, **how much of a barrier** have each of the following factors been in trial implementation?

Study Protocol	Response option					
	Major Barrier	Moderate Barrier	Somewhat of a Barrier	Not a Barrier	Unsure	Not Applicable
Having overly narrow inclusion/exclusion criteria	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Frequency of patient study visits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Length of patient study visits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Study Protocol	Response option					
	Major Barrier	Moderate Barrier	Somewhat of a Barrier	Not a Barrier	Unsure	Not Applicable
Number of study procedures to be completed at each patient study visit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amount of data to be collected at each patient study visit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Completing the electronic case report forms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Completing the paper case report forms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5bx. List here any other factor(s) related to *the study protocol* that was a barrier.

5c. Based on your experience in conducting pediatric antibacterial clinical drug trials, *how much of a barrier* have each of the following factors been in trial implementation?

Parental Concerns	Response option					
	Major Barrier	Moderate Barrier	Somewhat of a Barrier	Not a Barrier	Unsure	Not Applicable
Concerns about blinding/not knowing which drug their child would be taking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Concerns about being randomized to a placebo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Concerns about child taking a drug not previously tested in children	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Concerns about the side effects of the drug	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Perception the child will be at an increased risk for physical harm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Perception of insufficient study benefits for child	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Concerns about the number of blood draws	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Concerns about the number of invasive procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Concerns about consent length and complexity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5cx. List here any other factor(s) related to *parental concerns* that was a barrier.

5d. Based on your experience in conducting pediatric antibacterial clinical drug trials, *how much of a barrier* have each of the following factors been in trial implementation?

Parental and Child Logistics	Response option					
	Major Barrier	Moderate Barrier	Somewhat of a Barrier	Not a Barrier	Unsure	Not Applicable
Frequency of study visits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Length of study visits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Insufficient compensation for time and transportation costs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Parental and Child Logistics	Response option					
	Major Barrier	Moderate Barrier	Somewhat of a Barrier	Not a Barrier	Unsure	Not Applicable
Childcare concerns (e.g., other children in the household requiring care)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Parents' work schedules	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Children's school schedules	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Transportation difficulties for parents/children (e.g., distance from research site/travel requirements)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5dx. List here any other factor(s) related to **parental and child logistics** that was a barrier.

5e. Based on your experience in conducting pediatric antibacterial drug trials, **how much of a barrier** have each of the following factors been in trial implementation?

Miscellaneous	Response option					
	Major Barrier	Moderate Barrier	Somewhat of a Barrier	Not a Barrier	Unsure	Not Applicable
The child does not want to participate in the study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Insufficient budget to cover trial costs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5ex. List here any other factor(s) that was a barrier.

5f. Based on your experience in conducting pediatric antibacterial clinical drug trials, **how much of a barrier** have each of the following factors been in trial implementation?

For this question, we are interested in hearing from you about any resistance you may get when trying to work with others at your institution in conducting pediatric antibacterial drug trials.

Colleagues' concerns	Response option					
	Major Barrier	Moderate Barrier	Somewhat of a Barrier	Not a Barrier	Unsure	Not Applicable
Concerns about the number of blood draws needed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Concerns about the use of investigational agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Perception child will be at increased risk for physical harm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Concerned that they (i.e., your colleagues) would lose control over what procedures are conducted with their patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Your colleagues' mindset and belief system that they know what is best for their patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5fx. List here any other factor(s) related to **your colleague's concerns** that was a barrier.

6. In your experience, what have been the **top three challenges** to implementing pediatric antibacterial drug trials?

Challenge 1:

Challenge 2:

Challenge 3: