

**CTSA Consortium Child Health Oversight Committee (CC-CHOC)
Pediatric Drugs and Devices Group
March 13, 2009
Meeting Summary**

CC-CHOC Pediatric Drugs and Devices Group

Time: 4:00 PM – 5:00 PM ET

The primary issues arising from the recent 2/26/09 NIH CTSA Consortium Meeting on Development of Pediatric Drugs & Devices were discussed.

1. CONTRACTS

Contract wording and negotiations are major causes of delays for multicenter studies. We discussed models of centralized contract templates, such as that by NCI. Currently, two committees within the CTSA consortium are looking into this issue: the CTSA Regulatory and Public Private Partnership committees.

Action items:

1. We request volunteers to be liaisons on the CTSA Regulatory and Public Private Partnership committees. Volunteers should please submit their names to Jennifer Li or Carole Marcus. If necessary, we will ask for further volunteers at the May 1 CC-CHOC meeting.
2. In addition, Jennifer/Carole will contact the CTSA Regulatory and Public Private Partnership committees and ask whether they would like to have representation on our committee.

2. CENTRAL CTSA SCIENTIFIC REVIEW PROCESS

Centralizing the scientific review process is a relatively rapidly achievable goal, and will facilitate and expedite multicenter studies. A number of models were discussed, including the Cystic Fibrosis TDN model. It was suggested that we begin with a narrow focus, such as setting up a central CTSA scientific review panel for pediatric drug and device research. Further details, such as the composition and infrastructure of the panel, will need to be developed.

Action items:

1. Pam Zeitlin will circulate information regarding the cystic fibrosis TDN structure. Other members are encouraged to circulate information regarding other networks. Please send this information to the committee via Paymon.
2. Further discussion will be held at the CC-CHOC meeting.

3. OTHER BUSINESS

Other issues requiring future discussion include means of dissemination of information regarding relevant issues, such as a format for requesting details regarding specific research populations, information on central DSMBs, etc. need to be discussed in the future.

Issues of a post-marketing device registry also need to be discussed in the future.