

**CTSA Consortium
Child Health Oversight Committee
(CC-CHOC)**

**Pediatric Drug & Devices
Workgroup**

May 1st, 2009

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Original Goals

- Facilitate regulatory processes
 - IRB and contract templates
 - Consider central IRB
- Reciprocal CTSA scientific approval process
- Consortium for performing studies (investigator & industry-initiated)
- Post-marketing device surveillance registry
- Provide consultative services

Accomplishments

CTSA Consortium Pediatric Drug and Medical Device Development Workshop

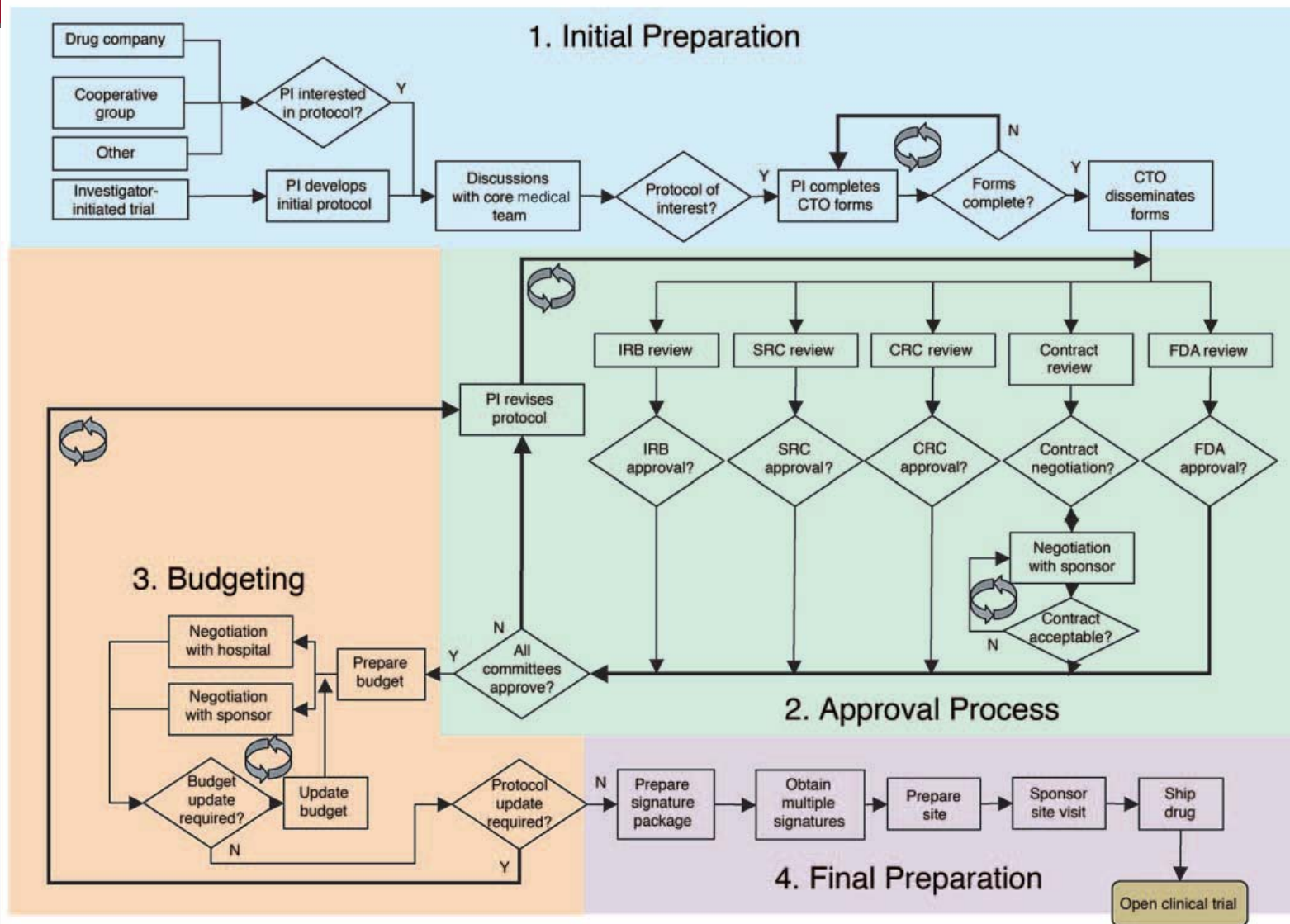
February 26, 2009

Meeting Purpose

To formulate specifications for a national child health clinical research infrastructure to effectively and efficiently develop drugs and medical devices for children

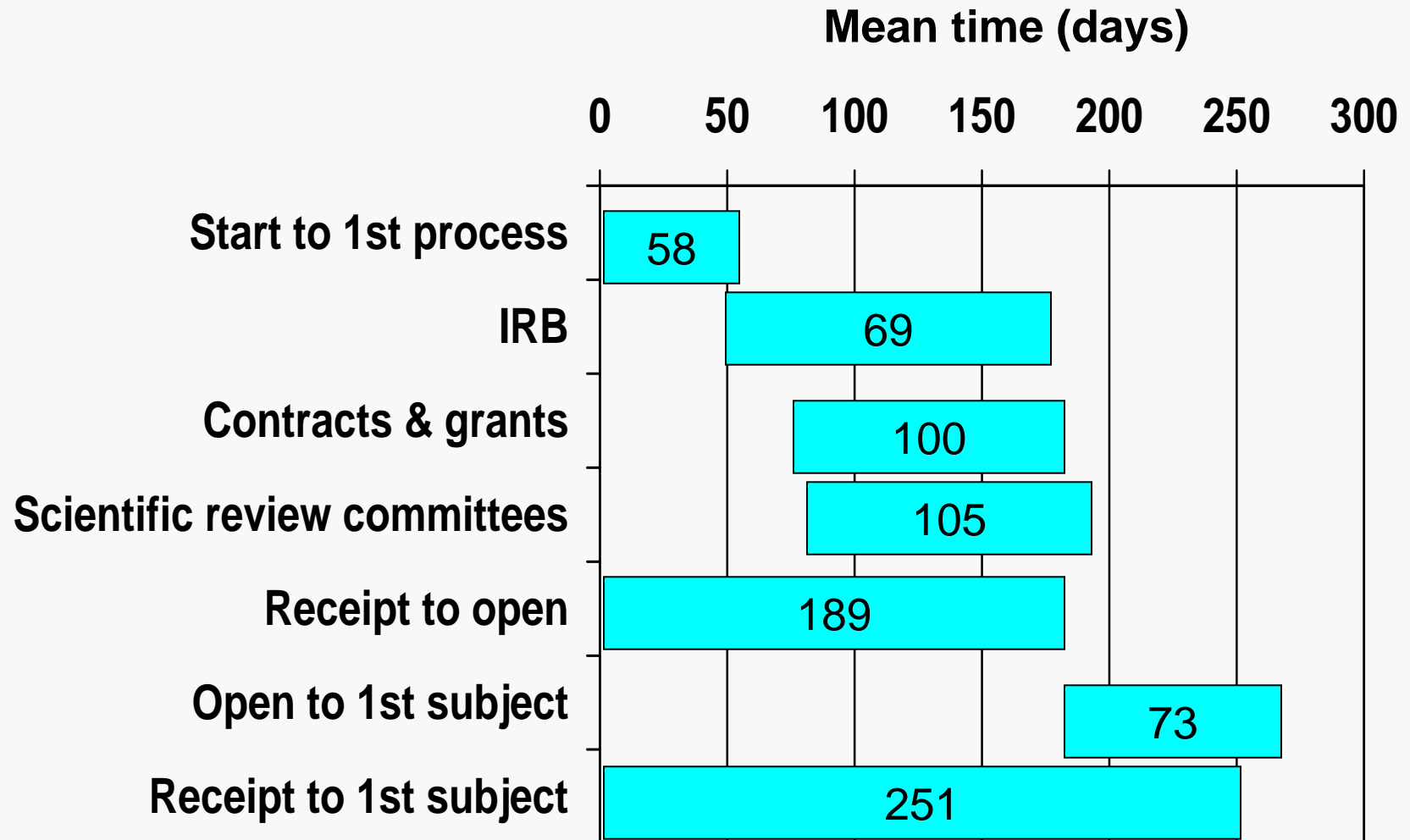
- 232 pre-registered
- 165 attendees
- Academics and industry

Process for Opening a Clinical Trial



Dilts, *J Clin Oncol* 2006; 24:4545

Mean Number Of Days Per Process



Dilts, *J Clin Oncol* 2006; 24:4545

Current Problems With Pediatric Academic Multicenter Studies

- IRB delays
- Technology transfer delays
- Scientific review delays

Overall Conclusions & Next Steps

Infrastructure for pediatric clinical trials for drug & device development is insufficient & fragmented

- *First step today has been to assemble the key stakeholders, experts, & decision makers to define priorities*

Complex and redundant regulatory & legal requirements

- *Next steps: Webinar on alternative IRB models for multi-site pediatric clinical trials to be held April 23, 2009*

Inadequate training in and understanding of GCP

- *Next steps: Training in GCP for academic clinical investigators to be held on NIH campus as trans-NIH event September 2009*
- *Development of on-line modules*

Prioritization process for pediatric pharmaceuticals & medical devices, October 2009

Current Initiatives (1)

- Follow-up on conference
- Exploring methods to facilitate and expedite regulatory processes, while ensuring subject safety and scientific integrity
 - Explore possibility of IRB and contract templates in conjunction with other CTSA efforts
 - Consider central IRB mechanisms in conjunction with other work forces
 - Reciprocal CTSA scientific approval process
- Instituted monthly conference calls
- Have started exploring other models for developing a research consortium
- Reviewing other CTSA committees' charges in relation to ours

Additional goals

In addition to current initiatives:

- Develop a consortium for performing pediatric drug & device studies
- Develop a post-marketing device surveillance registry
- Provide consultative services
- Catalogue CTSA research infrastructure assets

SGC & KFC Mapping

- **Propose connections to Strategic Goal Committees (SGC) and Key Function Committees (KFC)**
- **Suggest ideas for interacting with those SGCs and KFCs**
- Representation on the Regulatory Knowledge KFC

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- However, our priorities are not currently being actively addressed by this KFC

SGC & KFC Mapping

SGC	Involvement
National clinical & translational research capability	
Training	
Enhancing consortium-wide collaborations	
Enhancing health of communities/nation	
KFC	Involvement
Administration	
Biostatistics/epidemiology/research design	
Clinical research ethics	
Clinical research management	
Communications	
Community engagement	
Education/career development	
Evaluation	
Informatics	
PCIR	
Public private partnerships	
Regulatory knowledge	Have a liaison member
Translational	

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- Representation on the Regulatory Knowledge KFC
 - However, our priorities are not currently being actively addressed by this KFC
- Suggest connections via umbrella CC-CHOC Committee