

CTSA Consortium
Child Health Oversight Committee
(CC-CHOC)

**Pediatric Drug & Devices
Workgroup**

May 1st, 2009

Carole L. Marcus, MBBCh

Jennifer Li, MD

**Off-Label Status of Medication Available
For Pediatric Use, by Class**

Class of Medications	Percent Off-Label
Cardiac	57
Gastroenterology	54
Antidotes	44
Derm/eye/ear	44
Hematology	40
Neurology	38
Psychiatric	36
Analgesics	32
Antivirals	30
Endocrine	25
Anticonvulsants	21
Antifungals/antiparasitics	21
Metabolic	18
Immunologic/rheumatologic	17
Sedation/anesthetics	13
Antibiotics	13
Respiratory	13
Steroids	8
Allergy/asthma	3

Yoon, *Clin Pediatr*
2006; 45:75

Need For Pediatric Medical Device Development



Goals

- Facilitate collaborative translational and clinical research so that safer drugs and devices are developed for children
- Partner with industry to increase research resulting in approval of drugs and devices for children

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