### Preliminary Agenda:
The meeting will consist of lecture-based didactic sections, break-out working group sessions and a mini-symposium (see below). While the formal agenda is being finalized the following outline describes the proposed workshop flow:

### Reception – April 22, 2012 at 6:30pm

### Registration Hours –
April 22, 2012 from 5:30pm – 11pm
April 23, 2012 from 7:30am – 12pm

### Day 1 – April 23, 2012
Morning Sessions: Operational Features of a Pediatric Clinical Trial
- Clinical conduct, IRB, consent/assent, etc
- Working with investigators, parents and children
- Setting up multicenter trials
- Formulation Concerns (Hospital and Industry opinion)

Afternoon Sessions: Pediatric vs Adults - Modeling & Simulation Focus
- Physiologic Considerations: Impact on ADME and PD
- Allometry
- Leveraging adult data
- In silico approaches
- M&S Considerations for fulfilling regulatory requirements

### Day 2 – April 24, 2012
Morning Session: Case Studies
- Industry
- Academic
- Preclinical; in silico

Afternoon Session – Group Breakouts:
- Technical Emphasis – Modeling and Simulation approaches and techniques
  - NONMEM / R
  - Trial Simulator
- Regulatory – Expectations for registration
  - PIP, EMA vs FDA timelines

### Day 3 – April 25, 2012
Morning Session: Pediatric Trial Game – Working Groups
Team 1: Phase I PK trial
Team 2: Phase II Dose-finding trial
Team 3: Phase III Efficacy trial

Afternoon Session: Industry Mini-symposium (see below for preliminary details)

### Industry Mini-symposium
The International Consortium for Innovation and Quality in Drug Development (IQ Consortium) is an association of 27 pharmaceutical companies with the aim to advance pharmaceutical development through scientifically-based standards. The Consortium is governed by a Board of Directors and composed of 8 leadership groups. The Clinical Pharmacology Leadership Group (CPLG) of the IQ Consortium has graciously offered to provide a mini-symposium address some of the unique challenges facing industry in the arena of pediatric research and development. Topics discussed at the mini-symposium include:
- Operational Challenges in pediatric clinical trials from an industry perspective
- Case Studies in Industrial Pediatric Development
- Maximizing the value of Regulatory Authority Interactions