



# StaR Child Health

www.starchildhealth.org

International Forum of Standards for Research With Children



## 2<sup>nd</sup> StaR Child Health Summit 10 – 11 September 2010, Vancouver, Canada

**Opening Address:** Dr. Michael Kramer, Scientific Director of the CIHR Institute of Human Development, Child and Youth Health

### Plenary 1: Standards Development

1. WebCast with Liverpool (Paula Williamson, Ian Sinha and associates) :  
*presentation on COMET (Core Outcome Measures in Effectiveness Trials)*  
<http://www.liv.ac.uk/nwhtmr/comet/comet.htm>
2. Reports from the StaR Child Health Standards Development working groups
3. **Data Standards** Steven Hirschfeld, MD PhD, Associate Director for Clinical Research, Acting Director, National Children's Study, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, MD

### Plenary 2: Where's the Evidence? From the Trenches

Moderator – **Professor Jonathan Craig** *Professor Clinical Epidemiology, Public Health, School of Public Health Sydney, Australia*

The intent of this plenary session is to hear from investigators about issues with trial design and conduct; and to hear from individuals with expertise in regulatory evaluation of trials.

1. **Lisa Hartling** [CD]: A state of the science with reference to pediatric trials
2. **Jonathan Craig** [Aust]: Trial - Antibiotic prophylaxis for recurrent UTI
3. **Bruce Carleton** [CD]: Evidence (or not) on Synegis for RSV prophylaxis
4. **Lorne Clarke** [CD]: Trial - Enzyme Therapy for rare Metabolic Disorders
5. **Bob Peterson** Executive Director, CIHR Drug Safety and Evaluation Network [CD]

### Plenary 3: What about me? Involvement of Patients and Families

Moderator: **Dr. Martin Offringa**, *Director, Medicines for Children, Netherlands*

The intent of this plenary session is to hear from investigators who are working to involve patients/families in research study design and determination of outcome measures. Also, recent developments around the ethics of (Phase 1-2) trials in children are addressed.

1. **Jenny Newman**, MCRN Consumer Liaison Officer [UK] – Patient and family involvement
2. **Patrina Caldwell** [Aust] – Participation in Trials
3. **Martine de Vries** [Leiden] - Are we too tight with children?
4. **Lisa Bero** [USA] International ethical guidelines regarding clinical trials for inclusion of children

### Plenary 4: Knowledge Translation & Publishing pediatric trials

Moderator: Dr. Terry Klassen, *Director, Alberta Research Center for Health Evidence*



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A panel discussion will hear from Editors of leading medical/pediatric journals on topics including trials registration, trials reporting, and what they look for re: quality in pediatric trials.

1. **Virginia Moyer**, Editor in Chief , Current Problems in Pediatrics and Adolescent Health Care; Deputy Editor, Pediatrics
2. **Dimitri A. Christakis, MD, MPH**, Seattle, Washington (*Archives Pediatrics & Adolescent Medicine*)
3. **Paul Hebert**, Editor in Chief, Canadian Medical Association Journal
4. **Fiona Godlee** (*Editor in Chief, BMJ*)\*

*\*pending confirmation*

### **Plenary 5: Considering Cultures and Communities: Trials in Developing and Aboriginal Nations**

Moderator: **Dr. Stuart MacLeod**, *VP-Academics, Provincial Health Services Authority*

The intent of this plenary session is to hear perspectives on the challenges health researchers face in developing and aboriginal nations.

Speakers are being coordinated with WHO.

### **Workshops**

1. Interim and Sequential analysis and roles of data monitoring committees
2. Bias in Pediatric Trials
3. Effective Recruitment Strategies for Pediatric Trials
4. Trials Methodology/Complex Interventions in randomized trials
5. Editors Workshop: Trials Registration and Reporting Standards – improving quality of the trials reporting

### **Satellite Meetings**

1. **STAR Satellite meeting:** International Standards Development working groups, Wed-Thurs. Sept 8<sup>th</sup>,9<sup>th</sup>
2. **STAR Satellite meeting:** Global Pediatric Emergency Research Network – Sun Sept 12<sup>th</sup>
3. **STAR Satellite meeting:** WHO-Pediatric Trials in Developing Nations – Sun Sept 12<sup>th</sup>

### **Social Program**

1. **Salmon BBQ** at the Museum of Anthropology (Friday September 10<sup>th</sup>)
2. **Dine Out Vancouver!** (Wednesday September 8<sup>th</sup>, Thursday September 9<sup>th</sup>; Saturday September 11<sup>th</sup> – for participants of satellite workshops and those who stay in Vancouver for the weekend)