CANNeCTIN Cutting Edge Symposium on Advanced Biostatistics and Methodological Issues in Clinical Trials
April 28-29, 2011

The David Braley Cardiac, Vascular and Stroke Research Institute (DBCVSRI)
Hamilton General Hospital, 237 Barton Street East
Hamilton, Ontario, Canada

Thursday April 28, 2011
***Note:* Shuttle Service will be provided by Blue Line Taxi from the Crowne Plaza Hotel to the DBCVSRI for hotel guests.**

TIME	EVENT	Presenter	Duration	Discussion
6:50 am	**Continental Breakfast – All Guests – DBCVSRI – Atrium**		1:05	
7:55 am	**Welcome**	Organization Committee	0:05	
Session I - Composite Outcomes *- Chaired by Dr. Anne Holbrook*				
8:00 am	"Issues in Measurement of Composite Endpoints"	Dr. Gordon Guyatt	0:20	0:10
8:30 am	"The Challenge in Interpreting Treatment Effects Based on Composite Endpoints"	Dr. Richard Cook	0:20	0:10
9:00 am	"Composite Outcome Measures – *Does the devil hath power to assume a pleasing shape?"*	Dr. Nick Freemantle	0:20	0:10
9:30 am	Floor Discussion		0:30	
10:00 am	**Break**		0:20	
Session II - Surrogate Outcomes - *Chaired by Dr. Stuart Connolly*				
10:20 am	"Surrogate Variables: Background to the Major Issues on the Role of Surrogate Variables in Clinical Trials"	Dr. Ralph D'Agostino	0:20	0:10
10:50 am	"Meta-analytic Methods for Surrogate Outcome Evaluation Using Trial Level Data"	Dr. George Wells	0:20	0:10
11:20 am	"The Role of Network Analyses in Research on Prevention of HIV Infection"	Dr. Victor De Gruttola	0:20	0:10
11:50 am	Floor Discussion		0:30	
12:20 pm	**Lunch – DBCVSRI – Atrium**		1:10	

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1:30 - 2:45 pm	**Breakout Groups Session I** *Chaired by Drs. Mitchell Levine and Jerry Lawless*	1:15	
	Group A: *Room C4-115*		
	Group B: *Room C3-113*		
2:45 am	**Break**	0:15	
3:00 pm	**Reports from Each Breakout Group** *Chaired by Drs. Eva Lonn and David Matthews*	1:00	
4:00 pm	**Adjournment followed by refreshments**		
Dinner Session*- Chaired by Dr. George Wells*			
5:00 pm	**Cutting Edge Symposium on Advanced Biostatistics and Methodological Issues in Clinical Trials Special Presentation** **Speaker - *Dr. Deborah Ashby*** **"More Transparent Decision-Making for Drug Regulation: What do Bayes and other Formal Statistical Approaches have to Offer?"** Location: DBCVSRI Auditorium ***Dinner at 6:30 pm*** Location: DBCVSRI Atrium	3:30	

Questions to be Considered During Breakout Sessions:

- What is state of the art? Where do we stand right now on each topic?
- What are the outstanding issues that need to be addressed? Some of these may already have partial solutions.
- What guidance can we provide on these issues based on the current knowledge?
- What research needs to be done to fully address the issues?

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TIME	TOPIC	PRESENTER	Duration	Discussion
6:50 am	**Continental Breakfast – DBCVSRI – Atrium**		1:05	
7:55 am	**Welcome**	Organization Committee	0:05	
Session I - Adaptive Designs *- Chaired by Dr. Tim Ramsay*				
8:00 am	"An Overview on Essentials of Design Adaptation in Clinical Trial"	Dr. Hsien-Ming James Hung	0:20	0:10
8:30 am	"Points to Consider when Opting for an Adaptive Clinical Trial"	Dr. Robert Noble	0:20	0:10
9:00 am	"Response-Adaptive Randomization in Clinical Trials: Bayesian and Group-Sequential Approaches"	Dr. Theodore G Karrison	0:20	0:10
9:30 am	Floor Discussions		0:30	
10:00 am	**Break**		0:20	
10:20 am - 11:50 pm	**Breakout Groups Session II** *Chaired by Drs. Robert Platt and Marek Smieja*		1:30	
	Group A: *Room C5-111*			
	Group B: *Room C3-113*			
11:50 pm	**Reports from Each Breakout Group** *Chaired by Drs. PJ Devereaux and George Wells*		0:40	
12:30 pm	**Wrap up Session** *Drs George Wells, Lehana Thabane, and other members of the Organizing Committee*		0:15	
12:45 pm	**LUNCH and Adjournment**			