



**Organized by:**



# **Sensible Guidelines for the Conduct of Clinical Trials**

## **2012**

**May 24<sup>th</sup> & 25<sup>th</sup>, 2012**

**The Sutton Place Hotel**  
955 Bay Street  
Toronto, Ontario, Canada

**The Organizing Committee gratefully acknowledges the support of:**



# AGENDA

## DAY 1, Thursday 24<sup>th</sup> May, 2012

7:30	<b>Registration and Breakfast 60 min</b>	<b>WELLESLEY ROOM</b>
8:30	Welcome and Introduction to the Meeting 15 min; <b>Salim Yusuf</b>	<b>ROYAL SUTTON BALLROOM</b>

### SESSION I: Ensuring Quality of Trials

**ROYAL SUTTON BALLROOM**

<b>Co-Chairs:</b>	<b>Jean Rouleau and Chris Granger</b>	
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8:45	What Matters in Terms of Clinical Trial Quality? <i>15 min talk/5 min discussion</i>	<b>David DeMets</b>
9:05	Ensuring Quality: The Role of Monitoring <i>15 min talk/5 min discussion</i>	<b>Martin Landray</b>
9:25	Is Our Current Approach to AE Safety Reporting Sensible and Efficient? <i>15 min talk/5 min discussion</i>	<b>Patrick Archdeacon</b>
9:45	<i>Coping with Adverse Event Reporting: The Cancer Cooperative Group Experience</i> <i>15 min talk/5 min discussion</i>	<b>Joe Pater</b>
10:00	<i>Research Ethics Board Harmonization Efforts in Canada</i> <i>15 min talk/5 min discussion</i>	<b>Penny Moody-Corbett</b>
10:20	Panel Discussion: Quality in Clinical Trials <i>30 min</i>	<b>Featuring: Keith Fox and Session Speakers</b>
10:50	<b>Break - 15 min</b>	<b>WELLESLEY ROOM</b>

### SESSION II: Obstacles to Trial Initiation and Conduct

**ROYAL SUTTON BALLROOM**

<b>Co-Chairs:</b>	<b>Rory Collins</b>	
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11:05	<b>Streamlining Regulatory Issues: Achievements Thus Far &amp; Challenges Ahead</b> <ul style="list-style-type: none"> <li>Challenges from Recent International Trials <i>2 talks of 10 min each plus 10 min discussion</i></li> <li>European Regulatory Perspective <i>15 min talk/5 min discussion</i></li> <li>USA Regulatory Perspective <i>15 min talk/5 min discussion</i></li> <li>Industry Perspective <i>15 min talk/5 min discussion</i></li> </ul>	<b>Jackie Bosch and Jim Neaton</b>
11:35		<b>Fergus Sweeney</b>
11:55		<b>Bob Temple</b>
12:15		<b>Steve Pyke</b>
12:35	<b>Lunch - 45 min</b>	<b>WELLESLEY ROOM</b>
1:20	<b>Special Regulatory Issues in Different Regions</b> <ul style="list-style-type: none"> <li>China – <i>10 min</i></li> <li>South America - <i>2 talks of 10 min each</i></li> <li>India - <i>10 min</i></li> <li>Africa - <i>10 min</i></li> <li>Japan - <i>10 min</i></li> </ul>	<b>Lixin Jiang</b>
1:40		<b>Alvaro Avezum &amp; Rafael Diaz</b>
2:00		<b>Prem Pais</b>
2:10		<b>Trudie Lang</b>
2:20		<b>Yasuhisa Fujii</b>

2:50	Panel Discussion: Streamlining Regulatory Issues 30 min	<i>Featuring: Karen Sliwa and Session Speakers</i>
<b>Privacy Issues and the Effect on Study Conduct</b>		
3:10	1. How does privacy legislation influence screening, recruitment, follow-up, and event documentation? 15 min talk/5 min discussion	<i>Joe Pater</i>
3:30	2. Is Privacy Legislation Really a Barrier to Research? 15 min talk/5 min discussion	<i>Don Willison</i>
<b>3:50</b>	<b>Break - 20 min</b>	<b>WELLESLEY ROOM</b>
4:10	2. Using existing databases to identify and contact participants: Lessons from the ASCEND Study 15 min talk/5 min discussion	<i>Louise Bowman</i>
4:30	Panel Discussion: Privacy issues and effective database use 30 min	
5:00	<b>Overview – Day 1</b> 15 min	
<b>5:15 – 6:45</b>	<b>Adjournment for Cocktail Reception</b>	<b>QUEEN VICTORIA BALLROOM</b>

## DAY 2, Friday 25<sup>th</sup> May, 2012

7:30	<b>Breakfast - 60 min</b>	<b>WELLESLEY ROOM</b>
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### SESSION II Continued: Obstacles to Trial Initiation and Conduct

**ROYAL SUTTON BALLROOM**

<b>Co-Chairs:</b>	<b>John Cairns and Bob Temple</b>
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8:30	Onerous and Wasteful Practices Emanating from ICH GCP 15 min talk/5 min discussion	<i>PJ Devereaux</i>
<b>Good Clinical Practices: How can GCP be modified to have a more sensible approach?</b>		
8:50	1. GCP: Regulatory perspective 15 min talk/5 min discussion	<i>Ann Meeker-O'Connell</i>
9:10	2. GCP: Industry perspective 15 min talk/5 min discussion	<i>Jeanne Varrone</i>
9:30	3. GCP Patient perspective 15 min talk/5 min discussion	<i>Nancy Roach</i>
9:50	4. GCP: Academic perspective 15 min talk/5 min discussion	<i>Chris Granger</i>
10:10	Panel Discussion: Sensible Modifications to GCP 30 min	
<b>10:40</b>	<b>Break - 30 min</b>	<b>WELLESLEY ROOM</b>

### SESSION III: Trial Designs that Maximize Efficiency: How can we ensure they are used more often?

**ROYAL SUTTON BALLROOM**

<b>Chair:</b>	<b>Salim Yusuf</b>
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11:10	Pragmatic trials: Why they are uncommon and difficult to implement? 15 min talk/5 min discussion	<i>David Sackett</i>
11:30	Sensible sub-group interpretation guidelines allow factorial designs 20 min talk/10 min discussion	<i>Richard Peto</i>
12:00	Additional innovative designs: cluster crossover designs, randomized observational trials; links between registries and trials, use of electronic records. 15 min talk/5 min discussion	<i>John Eikelboom</i>

<b>12:20</b>	<b>Working Lunch – 1 Hour 40 min</b> <ul style="list-style-type: none"> <li>SESSION I: Ensuring Quality of Trials - Jean Rouleau and Chris Granger – Royal Sutton Ballroom</li> <li>SESSION II: Obstacles to Trial Initiation and Conduct – Rory Collins and Ian Roberts - Rosedale Room</li> <li>SESSION III: Privacy Issues and the Effect on Study Conduct – Joe Pater - Venice Suite</li> <li>SESSION IV: GCP – John Cairns and Bob Temple - Paris Suite</li> <li>SESSION V: Trial Designs that Maximize Efficiency – David Sackett and Salim Yusuf - Vienna Suite</li> </ul>	<b>WELLESLEY ROOM</b>
2:00	Adaptive designs: Are they practical and efficient? <i>15 min talk/5 min discussion</i>	<b>Janet Wittes</b>
2:20	Panel Discussion: How can we facilitate the use of efficient designs? <i>30 min</i>	
<b>Conducting Trials in Special Circumstances</b>		
2:50	1. Emergent and Life-threatening situations <i>15 min talk/5 min discussion</i>	<b>Ian Roberts</b>
3:10	2. Epidemics <i>15 min talk/5 min discussion</i>	<b>Laura Merson</b>
3:30	3. Vulnerable Populations <i>15 min talk/5 min discussion</i>	<b>Trudie Lang</b>
3:50	<b>Overview – Day 2: Major Outstanding Hurdles We Must Fix Within the Next 3-5 Years</b> - <i>20 min talk/10 min discussion</i>	<b>Rory Collins</b>
4:20	<b>How can we change the system?</b> <i>15 min</i>	<b>Salim Yusuf</b>
<b>4:35</b>	<b>Adjournment and Break</b>	<b>WELLESLEY ROOM</b>