

# Schedule of Events



## Sunday, May 3, 2009

7:00 AM – 5:00 PM Registration – International Ballroom Foyer

### Pre-Conference Workshops

8:00 AM – 12:00 PM

<p><b>Workshop 1</b> <i>Design and Analysis of Group Randomized Trials</i></p> <p>– International Ballroom D</p>	<p><b>Workshop 3</b> <i>Adaptive Clinical Trials</i></p> <p>– Dogwood A</p>	<p><b>Workshop 5</b> <i>Trial and Site Management for Multi-Center Trials</i></p> <p>– Dogwood B</p>	<p><b>Workshop 7</b> <i>Non-Classical Trial Designs: Equivalence and Non-Inferiority Trials</i></p> <p>– Cottonwood AB</p>	<p><b>Workshop 9</b> <i>Surrogate Outcomes: Getting Beyond the Basics</i></p> <p>– Redwood</p>
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1:00 PM – 5:00 PM

<p><b>Workshop 2</b> <i>Comparison of Survival Distributions: From Theory to Practice</i></p> <p>– International Ballroom D</p>	<p><b>Workshop 4</b> <i>Hot Topics in Clinical Trials</i></p> <p>– Dogwood A</p>	<p><b>Workshop 6</b> <i>Dissemination of Trial Results</i></p> <p>– Dogwood B</p>	<p><b>Workshop 8</b> <i>A Global Challenge: Harmonizing the Clinical Research Ethics Submission and Review Process in 2009</i></p> <p>– Cottonwood AB</p>	<p><b>Workshop 10</b> <i>Implementing Systems for Electronic Data Capture and Study Management</i></p> <p>– Redwood</p>
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8:00 AM – 5:00 PM

<p><b>Workshop 11 (Full day)</b> <b>Fundamentals of Randomized Clinical Trials (co-sponsored by Atlanta Clinical and Translational Science Institute)</b> – International Ballroom AB</p>				
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## Monday May 4, 2009

7:00 AM – 5:00 PM Registraton – International Ballroom Foyer

8:30 AM – 8:45 AM Welcome – SCT President: Kay Dickersin – International Ballroom DEF

8:45 AM – 9:30 AM **Keynote Address – Tikki Pang, World Health Organization**

9:30 AM – 10:00 AM Presentation of Class of 2009 Fellows: Barry Davis

10:00 AM – 10:30 AM Break – Prefunction Lobby 1 & 2

10:30 AM – 12:00 PM

<p><b>Session 1</b> <i>HIV Epidemic: Current Research Challenges</i></p> <p>– International Ballroom AB</p>	<p><b>Session 2</b> <i>Data Safety Monitoring Board (DSMB) Function at the National Institute of Allergy and Infectious Diseases (NIAID): Two Case Studies</i></p> <p>– International Ballroom C</p>	<p><b>Session 3</b> <i>Covariate adjustments in clinical trials: are they worth the added complexity?</i></p> <p>– International Ballroom D</p>	<p><b>Session 4</b> <i>Is a Null Result a Failure? Can Anything Good Come out of Null Results?</i></p> <p>– International Ballroom E</p>	<p><b>Session 5</b> <i>Current Controversies in Clinical Trials: Perspectives from SCT Fellows.</i></p> <p>– International Ballroom F</p>
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12:00 PM – 1:20 PM Lunch – Atrium Terrace A

1:20 PM – 2:40 PM **Contributed Paper Session I**

2:40 PM – 3:30 PM Poster Prime Time – Prefunction Lobby 1&2

<p><b>CPS IA</b> <i>Data Management</i></p> <p>– International Ballroom AB</p>	<p><b>CPS IB</b> <i>Information Technology: Web Utilization</i></p> <p>– International Ballroom C</p>	<p><b>CPS IC</b> <i>Recruitment Strategies and Results</i></p> <p>– International Ballroom D</p>	<p><b>CPS ID</b> <i>Pre-Efficacy Trial Design: Phase I-II &amp; Pilot Studies</i></p> <p>– International Ballroom E</p>	<p><b>CPS IE</b> <i>Thomas Chalmers Student Scholarship</i></p> <p>– International Ballroom F</p>
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2:40 PM – 3:30 PM Break – Prefunction Lobby 1 & 2

3:30 PM – 5:00 PM

**Plenary Session I:**  
**Trial of the Year and Project ImpACT** – International Ballroom DEF

5:15 PM – 6:30 PM Board of Directors Meeting – Cottonwood AB

6:30 PM – 8:00 PM Full Conference Reception: Celebrating 30 Years of SCT Meetings – Atrium Terrace A

# Schedule of Events

## Tuesday May 5, 2009

7:00 AM – 5:00 PM Registraton – International Ballroom Foyer

8:40 AM – 10:00 AM **Contributed Paper Session II**

<p><b>CPS IIA</b> <i>Approaches to Quality Assurance and Monitoring</i></p> <p>– International Ballroom AB</p>	<p><b>CPS IIB</b> <i>Statistical Methods</i></p> <p>– International Ballroom C</p>	<p><b>CPS IIC</b> <i>Trial Conduct: Implementation Lessons and Strategies</i></p> <p>– International Ballroom D</p>	<p><b>CPS IID</b> <i>Factors to Consider in Clinical Trial Design</i></p> <p>– International Ballroom E</p>	<p><b>CPS IIE</b> <i>Clinical Epidemiology</i></p> <p>– International Ballroom F</p>
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10:00 AM – 10:30 AM Break – Prefunction Lobby 1 & 2

10:30 AM – 12:00 PM **Invited Sessions**

<p><b>Session 6</b> <i>Recent Advances and Regulatory Implications in the Design and Analysis of Clinical trials utilizing Patient Reported Outcomes (PRO's) for Assessment of Pain and Clinical Symptoms.</i></p> <p>– International Ballroom AB</p>	<p><b>Session 7</b> <i>Panel Session – The Aprotinin Story: The Need for Large Clinical Trials</i></p> <p>– International Ballroom C</p>	<p><b>Session 8</b> <i>The Link Between Meta-Analysis and Clinical Practice – When is the Answer In?</i></p> <p>– International Ballroom D</p>	<p><b>Session 9</b> <i>Methicillin-resistant Staphylococcus Aureus (MRSA) and Staphylococcal Vaccines</i></p> <p>– International Ballroom E</p>	<p><b>Session 10</b> <i>Clinical Trials in Obesity</i></p> <p>– International Ballroom F</p>
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12:00 PM – 1:20 PM Lunch/SCT Business Meeting – Atrium Terrace A

1:20 PM – 2:20 PM **Contributed Paper Session III**

<p><b>CPS IIIA</b> <i>Building Structures for Managing Ethics and Regulatory</i></p> <p>– International Ballroom AB</p>	<p><b>CPS IIIB</b> <i>Study Coordination Challenges</i></p> <p>– International Ballroom C</p>	<p><b>CPS IIIC</b> <i>Trial Development and Conduct</i></p> <p>– International Ballroom D</p>	<p><b>CPS IIID</b> <i>Statistical Issues</i></p> <p>– International Ballroom E</p>	<p><b>CPS IIIE</b> <i>International Aspects of Public Disclosure of Results of Clinical Trials</i></p> <p>– International Ballroom F</p>
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2:20 PM – 3:20 PM **Contributed Paper Session IV**

<p><b>CPS IVA</b> <i>Information Technology</i></p> <p>– International Ballroom AB</p>	<p><b>CPS IVB</b> <i>Strategies for Participant Retention</i></p> <p>– International Ballroom C</p>	<p><b>CPS IVC</b> <i>Methods for Trial Management</i></p> <p>– International Ballroom D</p>	<p><b>CPS IVD</b> <i>Trial conduct and Analysis</i></p> <p>– International Ballroom E</p>	<p><b>CPS IVE</b> <i>Atlanta Clinical &amp; Translational Science Institute</i></p> <p>– International Ballroom F</p>
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3:20 PM – 4:00 PM Break – Prefunction Lobby 1&2

3:20 PM – 4:00 PM Poster Prime Time – Prefunction Lobby 1&2

4:00 PM – 5:30 PM

**Plenary Session II:**  
**Panel Discussion: Conflicts around Conflicts of Interest**  
– International Ballroom DEF

## Wednesday May 6, 2009

7:00 AM – 11:00 AM Registraton – International Ballroom Foyer

8:00 AM – 8:40 AM **Founders Lecture: Fiona Godlee, Editor in Chief, BMJ** – International Ballroom EF

8:40 AM – 10:10 AM **Invited Sessions**

<p><b>Session 11</b> <i>Interim Monitoring for Lack of Benefit and Futility</i></p> <p>– International Ballroom AB</p>	<p><b>Session 12</b> <i>The Use of Adaptive Designs in an NIH-Funded Clinical Trials Environment</i></p> <p>– International Ballroom C</p>	<p><b>Session 13</b> <i>Benefit Risk Assessment from Clinical Trials</i></p> <p>– International Ballroom D</p>	<p><b>Session 14</b> <i>Risk Management Based Adaptive Monitoring</i></p> <p>– International Ballroom EF</p>
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10:10 AM – 10:30 AM Break

10:30 AM – 12:00 PM

**Plenary Session III:**  
**Public Reporting of Results of Clinical Trials on ClinicalTrials.gov**  
– International Ballroom EF