

**2006 FDA/Industry Statistics Workshop  
Agenda**

<b>Wednesday, September 27, 2006</b>		
8:30 - 12:00 pm	<b>Room: Virginia</b>	<b>Room: Wilson</b>
	<i>Short Course #1</i> Recent Innovations in Bayesian Clinical Trials Don Berry	<i>Short Course #2</i> Generalized Linear Mixed Models and the New GLIMMIX Procedure in SAS/STAT® Oliver Schabenberger
12:00 – 1:30 pm	<b>Lunch (on own)</b>	
1:30 - 5:00 pm	<b>Room: Virginia</b>	<b>Room: Wilson</b>
	<i>Short Course #3</i> Adaptive Clinical Trials Keaven Anderson, Vladamir Dragalin, Paul Gallo, Jeff Maca	<i>Short Course #4</i> The Statistical Evaluation of Surrogate Endpoints in Clinical Trials Geert Molenberghs
<b>Thursday, September 28, 2006</b>		
7:30 - 8:15 am	<b>Room: Cotillion Foyer</b>	
	Continental Breakfast	
8:15 - 8:30 am	<b>Room: Cotillion Ballroom</b>	
	Opening Remarks	
8:30 - 10:00 am	<b>Room: Cotillion Ballroom</b>	
	General Session 1 - Statistics in the FDA and Industry: Past, Present, and Future	
10:00 - 10:15am	<b>Room: Cotillion Foyer</b>	
	Refreshment Break	
10:15 - 11:45 am	<b>Room: Cotillion Ballroom</b>	
	General Session 2 - Flexibility in Clinical Trials: How Do We Deal With It?	
11:45 am - 1:00 pm	<b>Room: Salon 2</b>	
	Luncheon Roundtables	
1:00 - 2:25 pm	<b>Room: Cotillion Ballroom</b>	
	General Session 3 - Surrogate Endpoints and Accelerated Approval	
2:25 - 2:40 pm	<b>Room: Cotillion Foyer</b>	
	Refreshment Break	
2:40 - 4:10 pm	<b>Room: Cotillion Ballroom</b>	
	General Session 4 - Interpreting Subgroups for Regulatory Purposes	
4:10 - 4:20 pm	Stretch Break (to provide time for speaker change on the podium)	
4:20 - 5:50 pm	<b>Room: Cotillion Ballroom</b>	
	General Session 5 -Data Monitoring Committees: Getting a New Perspective on an Old Issue	
5:50 -7:30 pm	<b>Room: Salon 2</b>	
	<i>Workshop Reception (open to all registrants)</i>	

**Friday, September 29, 2006**

7:30 - 8:20 am	<b>Room: Cotillion Foyer</b>			
	Continental Breakfast			
8:20 - 9:40 am	<b>Room: Cotillion South</b>	<b>Room: Cotillion North</b>	<b>Room: Wilson C</b>	<b>Room: Wilson AB</b>
	<i>Parallel Session 1</i>  The Role of the Statistician in Post-Marketing, Including Surveillance	<i>Parallel Session 2</i>  Biomarker Analysis	<i>Parallel Session 3</i>  Bridging Studies, Migration Studies, and Related Topics	<i>Parallel Session 4</i>  Statistical Issues in Medical Device Trials
9:40 - 10:10 am	<b>Room: Cotillion Foyer</b>			
	Refreshment Break			
10:10am - 11:30 pm	<b>Room: Wilson C</b>	<b>Room: Cotillion South</b>	<b>Room: Cotillion North</b>	<b>Room: Wilson AB</b>
	<i>Parallel Session 5</i>  High Dimensional Expression Data: Consistency across Platforms and Statistical Prediction Modeling	<i>Parallel Session 6</i>  Advantages and Challenges of Bayesian Clinical Trials	<i>Parallel Session 7</i>  Standards and Processes for Effective Communication with the FDA	<i>Parallel Session 8</i>  Diagnostic Medical Imaging
11:30 - 1:00 pm	Lunch (on own)			
1:00 - 2:20 pm	<b>Room: Wilson C</b>	<b>Room: Wilson AB</b>	<b>Room: Cotillion South</b>	<b>Room: Cotillion North</b>
	<i>Parallel Session 9</i>  Guidance and Standards for Diagnostic Devices	<i>Parallel Session 10</i>  FDA's Quality by Design Initiative	<i>Parallel Session 11</i>  Smart Choices: Decision Analysis Approaches to Clinical Trials	<i>Parallel Session 12</i>  Use of Historical Control Data in the Development of Medical Products
2:20 - 2:30 pm	Break			
2:30- 3:50 pm	<b>Room: Cotillion North</b>	<b>Room: Cotillion South</b>	<b>Room: Wilson C</b>	<b>Room: Wilson AB</b>
	<i>Parallel Session 13</i>  Classifiers in Combination Rx/Dx Submissions	<i>Parallel Session 14</i>  Case Studies in Modeling and Simulation	<i>Parallel Session 15</i>  Assessing Agreement	<i>Parallel Session 16</i>  Rare Events Estimation using Insurance Claims Databases
3:50 pm	Workshop Concludes			