2006 FDA/Industry Statistics Workshop
Agenda

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

Friday, September 29, 2006				
7:30 - 8:20 am	**Room: Cotillion Foyer**			
	Continental Breakfast			
8:20 - 9:40 am	**Room: Cotillion South**	**Room: Cotillion North**	**Room: Wilson C**	**Room: Wilson AB**
	Parallel Session 1 The Role of the Statistician in Post-Marketing, Including Surveillance	*Parallel Session 2* Biomarker Analysis	*Parallel Session 3* Bridging Studies, Migration Studies, and Related Topics	*Parallel Session 4* Statistical Issues in Medical Device Trials
9:40 - 10:10 am	**Room: Cotillion Foyer**			
	Refreshment Break			
10:10am - 11:30 pm	**Room: Wilson C**	**Room: Cotillion South**	**Room: Cotillion North**	**Room: Wilson AB**
	Parallel Session 5 High Dimensional Expression Data: Consistency across Platforms and Statistical Prediction Modeling	*Parallel Session 6* Advantages and Challenges of Bayesian Clinical Trials	*Parallel Session 7* Standards and Processes for Effective Communication with the FDA	*Parallel Session 8* Diagnostic Medical Imaging
11:30 - 1:00 pm	Lunch (on own)			
1:00 - 2:20 pm	**Room: Wilson C**	**Room: Wilson AB**	**Room: Cotillion South**	**Room: Cotillion North**
	Parallel Session 9 Guidance and Standards for Diagnostic Devices	*Parallel Session 10* FDA's Quality by Design Initiative	*Parallel Session 11* Smart Choices: Decision Analysis Approaches to Clinical Trials	*Parallel Session12* Use of Historical Control Data in the Development of Medical Products
2:20 - 2:30 pm	Break			
2:30- 3:50 pm	**Room: Cotillion North**	**Room: Cotillion South**	**Room: Wilson C**	**Room: Wilson AB**
	Parallel Session 13 Classifiers in Combination Rx/Dx Submissions	*Parallel Session 14* Case Studies in Modeling and Simulation	*Parallel Session 15* Assessing Agreement	*Parallel Session16* Rare Events Estimation using Insurance Claims Databases
3:50 pm	Workshop Concludes			