



HESI

ILSI Health and Environmental Sciences Institute

NON-CLINICAL / CLINICAL SAFETY CORRELATIONS TECHNICAL COMMITTEE WORKSHOP

SEPTEMBER 20-21, 2007

WASHINGTON, DC

WORKSHOP PROGRAM

September 20, 2007

9:00	Welcome / Workshop Goals	<i>Michael Holsapple</i> HESI
9:15	Project Background	<i>James Sanders</i> Johnson & Johnson Pharmaceuticals
9:45	Stage I Project Overview and Conclusions	<i>Harry Olsen</i> Olsen Consulting
10:15	Stage II Data Collection Effort	<i>Edward Kadyszewski</i> Pfizer Pharmaceuticals
10:45	Charge to Breakout Sessions	<i>Karluss Thomas</i> HESI

Breakout Session Discussions

11:00	Breakout Sessions
	<ul style="list-style-type: none">▪ Cardiovascular▪ Gastrointestinal▪ Hematology▪ Hypersensitivity▪ Liver Function▪ Neurological

12:00 Lunch

1:00	Breakout Sessions cont'd.
	<ul style="list-style-type: none">▪ Cardiovascular▪ Gastrointestinal▪ Hematology

- Hypersensitivity
- Liver Function
- Neurological

3:30 Break

- 4:00 Breakout Report Development
- 5:00 Wrap-Up / Overview of Day 2 Activities
- 5:15 Adjourn
- 6:30 Reception

September 21, 2007

- 8:00 Continental Breakfast
- 8:30 Finalize Breakout Session Reports

10:30 Break

- 10:45 Day 1 Summary / Expectations for Day 2

Breakout Session Reports

- 11:00 Cardiovascular Session Report
- 11:30 Gastrointestinal Session Report
- 12:00 Hematology Session Report

12:30 Lunch

- 1:30 Hematology Session Report
- 2:00 Hypersensitivity Session Report
- 2:30 Liver Function Session Report
- 3:00 Neurological Session Report

3:30 Break

- 3:45 Panel or Group Discussion to Address Focus Questions
- 5:00 Summary & Conclusions
- 5:30 Adjourn