

## *General Session #2*

# *Flexibility in Clinical Trials*

## *How Do We Deal With It?*

### *Chair*

Sue-Jane Wang, Ph.D.  
Associate Director, Adaptive Designs

Office of Biostatistics, Office of Translational Sciences  
Center for Drug Evaluation and Research, U.S. FDA

*FDA/Industry Workshop, September 28, 2006*

# Prospectively Planned Major Events

- **PhRMA Adaptive Designs working group**
  - Executive Summary on AD - JBS 16:275-283, 2006
  - Full White Paper - to appear in DIJ in Nov 2006
- *Special Issues in Pharmaceutical statistics, Biometrical Journal, etc., Workshops in US, EU, Asia regions*
- *EMA Reflection Paper On Methodological Issues in Confirmatory Clinical Trials with Flexible Design and Analysis Plan*
- **PhRMA/FDA conference on Adaptive Design: Opportunities, Challenges and Scope in Drug Development, Nov. 13-14, 2006**

# Presentations

- 10:20am** Just How Flexible Can a Prospective Clinical Trial Be?  
*Donald Berry, Ph.D., M.D. Anderson Cancer Ctr*
- 10:45am** Considerations in Enhancing Flexibility of Clinical Trial Design in Drug Development  
*H.M. James Hung, Ph.D., FDA*
- 11:10am** Strategies for Implementing Adaptive Clinical Trials  
*Jerry Schindler, Ph.D., Cytel Inc.*
- 11:35am** Discussion  
*Sue-Jane Wang, Ph.D., FDA*
- 11:45am** Session ends

# Remarks

- Flexibility in the planning that provides opportunity for increasing the chance of a successful late phase clinical trial
- Efficiency in saving patient number and/or in saving the drug development time in the entire clinical development program - History will tell
- Assuming better efficiency with AD, Are we ready for prospectively designed adaptive trial that are run by automata that might allow trial integrity?

# Discussion Topics

- Questions/Comments to Speakers
- Implementing Adaptive Clinical Trials
- Infrastructure, Logistics, Trial Integrity
- Bias, Estimation, etc.

We look forward to the  
further discussions at the  
**PhRMA/FDA Adaptive Design  
Workshop**

**Nov. 13-14, 2006**

**Marriott Bethesda North Hotel & Conference Center  
5701 Marinelli Road**

**North Bethesda, MD 20852**

Wang SJ, Flexibility in RCT,  
FDA/Industry Workshop 2006