

Conducting CNS Clinical Trials in the Developing World

INTRODUCTION

Larry Alphas

Housekeeping

- Reception & Dinner
- “Thorny Issues”
- Business meeting
- Videotaping
 - Microphones
 - Cell phones
 - Corrections
 - Website
- Evaluations
- Topics for future meetings

Conducting CNS Clinical Trials in the Developing World

- **Issue:**
 - Tremendous growth in CNS clinical trial work conducted in sites outside of traditional Western countries

1985

1990

1995

2000

2005

- Prehistory—work between west and east was poorly coordinated

- Increasing amount of primarily safety data gathered from developing world for Western regulatory submissions

- Increasing amounts of efficacy as well as safety data gathered from developing world for Western submissions

Conducting CNS Clinical Trials in the Developing World

- **Clinical/Academic Questions**
 - Disease priorities and nature of the questions being asked, endpoints, instrumentation
 - Nature of diseases studied
- **Industry/Other trialists**
 - Study designs
 - Endpoints/Assessments
 - Logistics
- **Regulatory**
 - Populations studied
 - Study conduct
- **Ethical questions**
 - Informed consent

Conducting CNS Clinical Trials in the Developing World

- What is the developing world?
 - Getting a global perspective

Presentations

Page (Industry Regulatory)	<i>Clinical Trials in the Developing World: Background and Changing Role</i>
Kiev (Academic)	<i>Multi-National Trials in the Developing World: Conceptualizing the Trials—An Academic Perspective</i>
Anand (Industry Development)	<i>Multi-National Trials in the Developing World: Conceptualizing the Trials—An Industry Perspective</i>
Kalali (CRO)	<i>Setting Up and Implementing Protocols in the Developing World</i>
Venkateswarlu (Khanna- Regulatory)	<i>Reviewing the Protocol Submissions: An Indian Regulatory Perspective on Issues to Be Considered in Approving a Global Trial</i>
Trivedi (Trialist)	<i>Setting Up and Implementing the Protocol: A Site Perspective on How to Take a Protocol and Adapt It for Local Issues in the Developing World</i>

Presentations

Sharma/Mohs (Vendor/Industry)	Case Studies: Evaluating Cognition In Multi-National in Developing World Trials
Khin (FDA)	Reviewing Data from Multi-National Trials in the Developing World: FDA Perspective
Pons (EMA)	Reviewing Data from Multi-National Trials in the Developing World: European Regulatory Perspective
Ethics Panel	Ethics of Multi-National Trials in the Developing World <i>S Khanna</i> <i>G Gharabawi</i> <i>R Mahmoud</i> <i>JP Lindenmayer</i> <i>A Gilman</i>