

Ground Zero Pharmaceuticals, Inc.

*Innovative Product Discovery
and Development Consulting,
Company- Building and Joint
Ventures in Pharmaceuticals,
Biologics and Medical Devices*

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Leveraging - Collaborating With Stakeholders

Safety Assurance in Clinical Trials

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Regulatory Concerns

- ▶ 21 CFR Parts 50 and 56
- ▶ 21 CFR 312 *et seq.*
- ▶ 21 CFR 314 *et seq.*
- ▶ Disbarment
- ▶ Spillover of Effects to other Programs
- ▶ Effects on the System of Voluntary Compliance

Clinical Development Issues

- ▶ Critical Planning vs. Time Constraints
- ▶ Protection of Subjects and Patients
- ▶ “Scientist vs. Clinician” Identification
- ▶ Training of Investigators and Staff
- ▶ Conflict of Interest in Research
- ▶ Data Management at the Sites
- ▶ Clinical vs. Statistical Conclusions

Investigator Responsibility

- ▶ Protection of Participants
- ▶ Clinical Judgement vs. Protocol
- ▶ Regulation vs. Clinical Practice
- ▶ Clinical Information Intake
- ▶ Information Assessment
- ▶ Communication to Sites and Sponsor

Sponsor Responsibility

- Regulatory Requirements
- Protection of Participants
- Research Success
- Financial Accountability
- Corporate Management Pressures
- Communication of Results

Inherent Risks and Benefits to Patients

- ▶ Personal Responsibility for Health
- ▶ Relationship to Healthcare System
- ▶ Continuing Therapeutic Innovation vs. Personal Safety
- ▶ Sacrifice vs. Personal Benefit

The Need for a Compact Amongst the Parties

- ▶ Congruency of Regulatory Process and Clinical Innovation
- ▶ Recognition of Economic, Political and Public Health Changes
- ▶ Requirement for Both Participant Safety and Data Quality

Some Solutions

- ▶ Recognize the Need for Faster, More Cost-Effective Product Development
- ▶ Form A Collaborative Team Composed of FDA, Sponsor, Investigator(s), Others
- ▶ 3rd Party Certification, e.g. Consultants
- ▶ Mandate Faster and More Complete Reporting of Safety Data
- ▶ Assure Communication Without Fear

Conclusions

- ▶ Assess Early- through Late-Phase Development Programs Continuously
- ▶ Improve Strategic Planning and Execution
- ▶ Educate Investigators and Patients
- ▶ Assess Critical Responsibility for Safety
- ▶ Form A Compact Amongst All Parties
- ▶ Establish 3rd Party Review Certification

Philosophy

“Lack of Timely Decision Making, in a Thoughtful and Logical Manner, is the Singular Cause of Delays, Wasted Effort and Needless Expenditures in Product Development”

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