



Agenda Meeting of Invited Experts

Findings and Implications of a Project Sponsored by the Clinical Trials Transformation Initiative (CTTI):

“Improving the System of Reporting and Interpreting Unexpected Serious Adverse Events to Investigators Conducting Research Under an Investigational New Drug Application”

October 3 and 4, 2010

Marriott Inn & Conference Center, University of Maryland University College.
3501 University Blvd. East, Hyattsville, MD, 20783

Key Objectives:

- Discuss and integrate empirical findings from all components of this project
- Consider implications of the FDA’s new safety regulations
- Develop a set of recommendations for optimal reporting of unexpected serious adverse events to investigators that will improve human subject protection

Sunday, October 3, 2010

Location: Rooms 2100 and 2102 (second floor)

Facilitator: Judith Kramer, CTTI

Agenda:

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| 5:00 pm | Dinner |
| 6:00 pm | Welcome, introductions, and meeting objectives
Judith Kramer, CTTI |
| 6:15 pm | SAE Project Overview
Jose Vega, Amgen |
| 6:45 pm | Current Practices – Workstream 1 Summary of Findings
Sundeep Sethi, Amgen |
| 7:15 pm | Investigator Time and Perceived Value – Workstream 2 Summary of Findings
Howard Greenberg, ACCP |
| 7:45 pm | Comparison of Alternative Models – Workstream 3 Summary of Findings
Lynda Szczech, Duke University |
| 8:15 pm | Patient Perspectives – Workstream 4 Summary of Findings
Kevin Weinfurt, Duke University |
| 8:45 pm | Summary of findings from all workstreams and goal for October 4 th meeting
Judith Kramer, CTTI |
| 9:00 pm | Questions for meeting participants to consider
Judith Kramer, CTTI |
| 9:15 pm | Adjourn |



Monday, October 4, 2010

Location: Chesapeake and Ft. Henry Room (Main Concourse)

Facilitator: Robert Califf, CTTI

Agenda:

- 7:00 am Breakfast (Chesapeake and Ft. Henry Room)
- 7:30 am Recap of important findings and recommendations from Workstreams 1–4
Judith Kramer, CTTI
- 7:45 am Statement of the problem and goals of meeting
Robert Califf, CTTI
- 8:00 am Highlights of new FDA rule on premarketing safety reporting issued on September 28, 2010
Janet Norden, Office of Medical Policy, CDER, FDA
- 8:30 am Discussion:
 1. What are the likely implications of the FDA's new premarket safety rule for sponsor practices in reporting serious and unexpected suspected adverse reactions to investigators?
 2. What do you think will be the impact of the FDA's new premarket safety rule on patients' perceptions of the adequacy of adverse event monitoring and communication in clinical trials?
- 9:30 am Break
- 9:45 am Discussion:
 1. Propose alternative models for reporting important new safety information to investigators and patients during the conduct of a trial.
 - a. Consider impact of alternative models on investigators' ability to interpret the significance of notifications and on resource demands.
 - b. How can we address concerns about conflicts of interest of sponsors and investigators?
 2. What practices are currently being used by sponsors that will facilitate compliance with the new premarket safety requirements, and what systems should be developed?
 3. Are there methodological approaches that would allow a continuous evaluation of safety for a new product during the conduct of multiple clinical trials in all indications under study, while accounting for multiple comparisons and potential confounding?
- 11:45 am Lunch (boxed lunches available)
- 12:00 pm Discussion:

Develop a list of actionable recommendations that would improve protections for trial participants by optimizing the reporting to investigators of serious and unexpected suspected adverse reactions.
- 1:00 pm Summary of recommendations and next steps
- 1:30 pm Closing of meeting