

# **Adverse Event Reporting**

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- 2000 active clinical studies
- 4 primary IRBs
- 600 new IRB applications/year
- 4 IRBs affiliated institutions
- 3 DSMBs

# Adverse Event Reporting Report to the IRB

- Single site study
- Multi-site study, AE in institution

# But What To Do About:

- Multi-site studies, AE in other sites?
  - (a) no context
  - (b) no synthesis
  - (c) no analysis
  - (d) overworked staff
  - (e) overwhelming volume

# Adverse Event Reports From Other Sites

## July 1, 2004-February 28, 2005

- 11 ft. high tower of reports
- Paperwork from one study alone = 17 inches
- Not limited to serious or unanticipated AEs
- Not limited to specific experimental protocol
- Not limited to AE reports





30-05

HREC 307-02 FMLH 2-149

1025

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405 -

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# Experience with AE Reports From Other Sites

1. The event reported occurred in a study involving the investigational product in a combination with drugs other than those studied at our site.

# Experience with AE Reports From Other Sites

2. The event reported occurred in a different population than the population participating in the study at our site.

# **Experience with AE Reports From Other Sites**

3. The event reported occurred in a different study for a different medical condition than is under study at our site.

# Experience with AE Reports From Other Sites

4. The report received is in follow up to a previously filed report; the updated information may not alter the previously reported determination regarding causality and seriousness.

# Experience with AE Reports From Other Sites

5. The report may not contain all the information necessary to understand the impact of the occurrence of the event.

# Experience with AE Reports From Other Sites

6. Only a portion of the external serious adverse event reports received contain information regarding the number of reports of that particular event under the IND for the study drug.

# Question

Should IRB responsibilities for multi-site trials differ from those for single-site trials?

# Question

Are there circumstances under which IRBs should receive information about AEs that are not both serious and unexpected?

# Question

What can be done to provide IRB's AE information that will enable them to better assess the implications of reported events for study subjects?

# Multi-Site Studies

- Single repository of AE reports
- Summary reports of serious/unanticipated events from
  - (1) project manager/office
  - (2) sponsor
  - (3) DSMB
  - (4) principal investigator
  - (5) or?
- Recommended action(s) to sites