

CTTI IND Safety Advancement – Investigator Work Group Interview Questions

Interviewees (5-6 total):

- Group from single site that could include Investigator, Research coordinator, Regulatory coordinator
- Interview different type sites
 - Academic (2)
 - Private
 - Network (1)
 - Non-network (1)
 - Phase I unit (1)

Questions:

1. Describe your process for handling expedited safety reports. What works well? What doesn't?
 - a. Does each team member have a clearly defined role in handling expedited safety reports? Describe your role.
 - b. If there is variability in practice of how expedited safety reports are routinely process, what drives that variability? Are SOPs in place to guide the process?
2. Is distribution of expedited safety reports is delegated to someone other than the PI? If so, how is that process determined? How is that process justified based on federal regulations?
3. Describe how expedited safety reports are used. More specifically, describe how expedited safety reports that do not generate protocol or consent changes are used.
4. What things about the current expedited safety reporting system are especially useful?
5. What things about the current expedited safety reporting system don't work well? How do you propose mitigating the things that don't work well?
6. What would an ideal IND safety reporting system look like?
7. Should the content and frequency of expedited safety reports vary based on phase or type of trial, or by nature of the investigational product?