CTTI IND Safety Advancement Sponsor Interview Questions

1) FDA intends that full implementation of the FDA final rule on IND expedited safety reporting will lead to a 90% reduction in IND expedited safety reporting. Is this realistic? What would it take to achieve this?

2) If you have not already fully implemented the FDA final rule on IND expedited safety reporting requirements, what would help your organization accelerate implementation?

3) There may be misconceptions about the content of the final rule on IND expedited safety reporting, published in 2010. Many of the changes implemented were aimed at reducing the volume of uninformative expedited premarket (IND) safety reports. Two of these changes are 1) reliance on sponsor rather than investigator determined causality and 2) protocol-specified aggregate collection of serious adverse events that are common in the study population (anticipated) due to the disease, concomitant therapies, or co-morbidities.

   Do you believe these suggested changes are clearly evident in the final rule on IND expedited safety reporting, and the associated guidance?

   Are there other key changes you perceive to be part of the final rule?

4) Since the FDA final rule on IND expedited safety reporting requirements went into effect, what changes have been implemented?

   a. Organization/Structural

   b. Processes

   c. Technological

   d. Cultural

   Why have you implemented these specific changes?
   How have you implemented these specific changes?

5) What changes do you perceive are still needed within your organization in order to fully comply with the FDA final rule on IND expedited safety reporting requirements?

   Why haven't these changes yet been implemented?

6) What are the greatest drivers to changing IND expedited safety reporting practices?

7) What are the greatest drivers to maintaining the status quo in IND expedited safety reporting practices?

8) Is it your perception that it is more cost effective to just report all events, or to fully review each item to determine whether a report is warranted or not?

9) What things about the current IND expedited safety reporting system should be changed?

10) What would an ideal IND expedited safety reporting system look like?

11) What clarifications to current FDA guidance would be most helpful?

12) If your company has implemented the FDA final rule on IND expedited safety reporting, can you describe the process used internally to determine when the threshold is reached – based on review of accumulating aggregate clinical trial data for a trial or program – to trigger expedited safety reporting to FDA?

13) Is there anything else you would like to share?

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?