

CTTI IND Safety Advancement Project – Sponsor Survey

1. What category best fits the company for whom you work?
 - a. Large biopharmaceutical industry (> \$10 billion annual revenue)
 - b. Midsize biopharmaceutical industry (\$1 - \$10 billion annual revenue)
 - c. Small biopharmaceutical industry (< \$1 billion annual revenue)
 - d. Other (please describe)

2. Does your organization?
 - a. Specialize only in oncology products/therapeutics
 - b. Have a diverse portfolio with many different therapeutic areas, of which oncology is a part

3. What is your role in your organization?
 - a. Safety/Pharmacovigilance
 - b. Regulatory
 - c. Medical Function
 - d. Clinical Operations
 - e. Legal
 - f. Compliance or Quality Functional Role
 - g. CEO or COO
 - h. Other (please describe)

4. How many oncology clinical trials are currently active at your organization?
 - a. Less than 10
 - b. About 11-30
 - c. About 31-50
 - d. More than 50 trials at once

5. What phase of trials are typically sponsored by your company? (Please select all that apply.)
 - a. Phase I
 - b. Phase II
 - c. Phase III
 - d. Phase IV - Post Marketing Trials
 - e. Other (please describe)

6. What is the average number of expedited IND safety reports for clinical trials (initial plus follow up, all therapeutic areas) reported to the FDA per year by your organization?
 - a. For Jan-Dec 2012
 - b. For Year To Date (YTD) 2014
 - c. For Jan-Dec 2013

7. With your organization's implementation of the FDA final rule on IND safety reporting requirements (update of 21 CFR 312.32), did you see a reduction in the volume of initial safety reports distributed by your organization to US Investigators and FDA?
 - a. Yes
 - b. No
 - c. Not Sure

8. Approximately what percent reduction did you see?
 - a. Less than 10%
 - b. About 10-25%
 - c. About 25-50%
 - d. About 50-75%
 - e. More than 75% reduction

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9. What department at your organization is primarily responsible for interpreting the FDA final rule on IND safety reporting requirements?
 - a. Regulatory Department
 - b. Legal Department
 - c. Pharmacovigilance Department
 - d. Clinical Operations
 - e. Cross-Functional Committee
 - f. Therapeutic Areas Individually
 - g. Other (please describe)

10. What department at your organization is primarily responsible for setting organizational policy on interpretation of FDA IND safety reporting requirements?
 - a. Regulatory Department
 - b. Legal Department
 - c. Pharmacovigilance Department
 - d. Clinical Operations
 - e. Cross-Functional Committee
 - f. Therapeutic Areas Individually
 - g. Other (please describe)

11. How do you interpret what is an “unexpected” adverse event based on the FDA final rule on IND safety reporting requirements?
 - a. Event that is not listed anywhere in the Investigator Brochure
 - b. Event that is list in the Investigator Brochure, but is occurring more frequently or more severely than anticipated
 - c. Other (please describe)
 - d. Event that is not listed in the adverse reaction section of the Development Core Safety Information section of the Investigator Brochure

12. Since the FDA final rule on IND safety reporting requirements went into effect, what organizational changes have been implemented? (Please select all that apply.)
 - a. We are now pre-specifying in the protocol which events should no longer be reported (i.e. what to expect related to the disease).
 - b. We have developed and implemented SOPs that guide actions to fully comply with the rule.
 - c. We are no longer submitting reports based on investigator-determined causality.
 - d. We have made personnel changes so that we have the correct resources on staff to be able to comply with the rule.
 - e. We have made technology changes to allow us to comply with the rule. (Please describe the type of changes made.)
 - f. No changes have been made.
 - g. Other (please describe)

13. What changes do you perceive are still needed within your organization in order to fully comply with the FDA final rule on IND safety reporting requirements? (Please select all that apply.)
 - a. We need to pre-specify in the protocol which events should no longer be reported (i.e. what to expect related to the disease).
 - b. We need to develop and implement SOPs that guide actions to fully comply with the rule.
 - c. We are to discontinue submitting reports based on investigator-determined causality.
 - d. We need to make personnel changes so that we have adequate resources on staff to be able to comply with the rule.

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- e. We need to make technology changes to allow us to comply with the rule.
(Please describe the type of changes that are needed.)
 - f. I believe we have done all we can do to fully comply with the rule.
 - g. Other (please describe)
 - h. We need to make protocol changes to existing INDs regarding which events should no longer be reported.
14. What are the internal organizational barriers to full implementation of the FDA final rule on IND safety reporting requirements? (Please select all that apply.)
- a. Liability Concerns
 - b. FDA regulatory compliance concerns (if IND safety reporting is dramatically reduced)
 - c. Regulatory compliance concerns arising from varying international requirements
 - d. Difficulty defining the threshold at which a numerical imbalance of safety events reaches significance and therefore should be reported to FDA
 - e. Technical/IT challenges to pre-programming IND safety reporting rules due to varying international requirements
 - f. Infrastructure limitations (financial and/or human resources)
 - g. Vendor or third-party limitations
 - h. Not Sure
 - i. Other (please describe)