

CTTI - IND SA INVESTIGATORS- Production

Thank you for taking the time to complete this survey about IND Safety Reporting practices. The answers you give are confidential and completely anonymous, and they cannot be linked back to your email or personal information in any way. In order to further protect your confidentiality, please do not cite specific trials, sponsors, investigational products, or other potentially revealing information pertaining to projects on which you have worked in any free-text responses. The survey should take you less than 15 minutes to complete and must be completed in a single session. To ensure that your responses are recorded, do not exit from the survey or web browser until you've completed the entire survey. You may leave open the survey window in your internet browser if you need to navigate away to look up information (e.g. about the number of safety reports). If you have any questions, or would like assistance in completing the survey, please contact the study staff at ctti-indsaproject@duke.edu.

This survey is intended to gather information about the current practices in IND safety reporting processes, interpretations of regulatory obligations and management of IND safety reports. The information we collect will be used to inform activities and recommendations of the Clinical Trials Transformation Initiative (CTTI) IND Safety Advancement project. Your answers to this survey should pertain to your most common or most typical IND safety reporting processes. If you are unsure of how to answer a question, please give the best answer you can or skip the question if it doesn't apply to you.

Within the conduct of clinical trials, many different people at Investigative sites will ultimately interact with IND safety reports. Do you review or manage IND safety reports at your investigative site specifically for oncology clinical trials?

- Yes
- No

This survey is intended for people who have direct interactions with reviewing or managing IND safety reports at investigative sites specifically for oncology clinical trials. If you chose "No" in the previous question by error, please click the PREVIOUS button below and select "Yes" instead. If the previous statement doesn't apply to you, but you still feel you qualify to provide input into this survey, please select "Continue to Survey". Otherwise, please select "End Survey".

- Continue to Survey
- End Survey

Please describe your interactions with interactions with IND safety reports at your site, which you feel qualifies you to provide input with this survey

Information about You

We understand that people can "wear many hats" when conducting clinical trials. For the purposes of this survey on IND safety reports, in what capacity do you serve when you interact with IND safety reports?

- Principal Investigator (listed on 1572)
- Sub-Investigator
- Study Coordinator (delegated to manage certain aspects of trials; may include informed consent, CRF completion and/or managing research participant visits, etc.)
- Regulatory Coordinator (manage distribution and filing of safety reports)
- Compliance Officer
- Other Study Staff (please describe) _____
- Other - Not Study Staff (please describe) _____

How many years of experience have you had in this particular role?

- Less than 1 year
- About 1 - 3 years
- About 4 - 6 years
- About 7 - 10 years
- More than 10 years

How many years of experience have you had in clinical trials IN GENERAL?

- Less than 1 year
- About 1 - 3 years
- About 4 - 6 years
- About 7 - 10 years
- More than 10 years

What is the primary categorization of your investigative site? (Select the one that is most representative.)

- Academic
- Community-Based Private Practice
- Cancer Consortium
- Other (please describe) _____

Information about the TRIALS at your site

How many oncology clinical trials are currently active at your site (specifically studies for which you receive IND safety reports) ?

- Less than 5
- About 5 - 10
- About 11 - 20
- About 21 - 30
- More than 30 studies at once

What phase of trials are typically conducted by your site? (Please select all that apply.)

- Phase I
- Phase II
- Phase III
- Phase IV - Post Marketing Trials
- Other (please describe) _____

Estimate the mix of types of sponsors of the trials at your site by percentages. (Note: the total must equal 100%. For example you can enter 60% industry 40% government.)

_____ Industry

_____ Government

_____ Investigator-Initiated

_____ National Clinical Trials Network (formerly Cooperative Group)

_____ Other (please describe)

Information about the Number of Safety Reports

What is the estimated number of IND safety reports that you receive per month for the studies at your site?

- 1 - 10
- 11 - 20
- More than 20

Of the IND safety reports received at your site, what percentage gets reviewed by the Principal Investigator for the trial?

- Less than 25%
- About 25%
- About 50%
- About 75%
- More than 75%, but not all
- Every single one of them

What is the estimated number of staff hours per month that is required to manage IND safety reports?

- Less than 5 hrs
- About 5 - 10 hrs
- About 10 - 20 hrs
- More than 20 hrs

Are you aware that a new FDA rule related to IND safety reporting went into effect in 2011?

- Yes, aware of the new rule
- No, was not aware there was a new rule

Are you familiar with the CHANGES that were made by the rule and the accompanying guidance document?

- Yes; I am familiar with the changes made by the rule and guidance document
- No; I have heard about the rule but am not certain of the details of the changes

Have you noticed a decrease in the quantity of IND safety reports that you have received over the last year?

- Yes, significant decrease
- Yes, but only a small decrease
- Have not noticed any decrease in the number of reports

Over the past year, have you noticed that IND safety reports have become more useful, less useful or have you not noticed a change from before?

- Reports are more useful
- Reports are less useful
- No change to the usefulness of the reports we receive

Information about Report Management at your site

Upon receipt of IND safety reports at your site, does anyone initially review these reports before the Principal Investigator (PI) in order to determine which reports the PI must review?

- Always
- Most of the Time
- Sometimes
- Rarely
- Never

Who is the initial reviewer of the reports before the Principal Investigator?

- Study Coordinator/CRC
- Regulatory Coordinator
- Compliance Officer
- Other Investigator
- Other (please describe) _____

How does the initial reviewer determine which IND safety reports the Principal Investigator reviews?

- The PI is only sent IND safety reports that are related to a protocol change or consent change.
- The PI is sent IND safety reports based on the severity of the AE reported.
- The PI is sent ALL of the IND safety reports.
- Other (please describe) _____

Is there a Standard Operating Procedure in place at your site for the management of IND safety reports?

- Yes
- No
- Not Sure

Is there variability in the practice of reviewing these reports based on the type of trial or other determining factor?

- Yes
- No

Please describe the factors that contribute to the variability in handling IND reports at your site.

Potential barriers to report review and management

If IND safety reports are distributed via a sponsor safety reporting portal, do you have difficulty accessing the IND safety reporting portal?

- Yes
- No
- Do not receive safety reports electronically

Please describe the difficulty you have accessing the IND safety reporting portal:

Has your site ever refused to receive or process IND safety reports?

- Yes
- No
- Not Sure

What is the reason your site has refused to process IND safety reports? (Please select all that apply.)

- Storage issues
- IT issues
- Workload issues
- Do not meet IRB reporting requirements
- Do not meet the FDA reporting rule requirements
- Other (please describe) _____

Do you share safety report information with research participants?

- Yes, but only when it requires a consent change or protocol change
- Yes, whenever the information may be relevant to the research participant, not just when it requires a protocol or consent change
- Other (please describe) _____
- Not sure
- No, we don't share safety report information with research participants.

Some IND safety reports DO NOT generate a protocol change or consent change. Are these types of reports still useful in managing the care of research participants at your site?

- Always
- Most of the Time
- Sometimes
- Rarely
- Never

How are these types of reports still useful? (Please select all that apply.)

- To initiate a conversation with research participants about new safety information
- To stop study drug
- To remove research participants from trials
- Other (please describe) _____

Why aren't these types of reports still useful?

- Information provided is not interpretable
- Not enough information is available to influence care
- The information is not relevant to the research participants
- Other (please describe) _____

IND safety reports are intended to notify Investigators of serious adverse events identified during the course of a clinical trial. In your opinion, what do you feel is the main utility of the safety reports for the Investigators? (Drag and drop the statements into the order of most important to least important.)

- _____ To inform Investigators of new adverse events they may not have been expecting with the treatment
- _____ For Investigators to get a broader picture of the risks involved with the treatment
- _____ For Investigators to inform research participants of the changes in risk
- _____ To meet certain ethical and legal requirements imposed by the IRB
- _____ Other - please describe (If no other, leave blank with a rank of 5)

To end the survey, we would like to ask you to share your opinions about IND safety reporting practices at your site

What things about the current IND safety reporting system are especially useful?

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

If you were starting from scratch, what would an ideal IND safety reporting system look like?