

**CTTI RECOMMENDATIONS:  
IMPROVING REPORTING OF UNEXPECTED SERIOUS ADVERSE  
EVENTS (SAEs) TO INVESTIGATIONAL NEW DRUG (IND)  
INVESTIGATORS**

- Decrease the volume of uninterpretable and irrelevant safety reports to investigators
  - The FDA's new IND safety reporting rule may decrease the number of such individual expedited reports of serious adverse events
- Supply investigators with meaningful reports that would improve investigators' understanding of a drug's safety (benefit-risk) profile. This may include:
  - Providing only clinically relevant and significant individual adverse event reports
  - Communicating aggregate datasets with context that would allow generalization and application to various populations
- Engage patient groups to discuss optimal systems for safety reporting to investigators and patients during the conduct of a trial

## References

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Flynn KE, Kramer JM, Dombeck CB, et al. Participants' Perspectives on Safety Monitoring in Clinical Trials. *Clinical Trials* May 2013; 10(4):552-559.

Kramer JM, Vock D, Greenberg HE, et al. Investigators' Experience With Expedited Safety Reports Prior to the FDA's Final IND Safety Reporting Rule. *Therapeutic Innovation & Regulatory Science* January 2014; 48(4): 413-419.

Sundee SS, Kramer JM, Gagnon S, et al. Industry Practices for Expedited Reporting to Investigators Conducting Research Under an IND. *Therapeutic Innovation & Regulatory Science* May 2014; 48(6): 741-748.

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- ▶ *These recommendations are based on results from CTTI's [SAE Reporting Project](#).*
  - ▶ *CTTI's [Executive Committee](#) approved the recommendations.*
  - ▶ *Released in May 2011*