CLINICAL TRIALS TRANSFORMATION INITIATIVE

# 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


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.

Sundeep 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.



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