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
  o 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:
  o Providing only clinically relevant and significant individual adverse event reports
  o 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


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