ASCO Recommends Improvements to the Accuracy and Attribution of Serious Adverse Events Reporting in Oncology Clinical Trials

ASCO Cites CTTI's Safety Reporting Recommendations

SUMMARY

When the American Society of Clinical Oncology (ASCO) reached out to its members to learn about common pain points in oncology clinical trials, one topic came up nearly every time: adverse event reporting. ASCO used CTTI's Safety Reporting Recommendations to help inform a multi-stakeholder workshop, develop recommendations for streamlining reporting, and ultimately to develop a decision aid for improving the accuracy and attribution of serious adverse events in oncology clinical trials.

GOAL(S)

Timely and accurate safety reporting is critically important in clinical research and patient safety. However, there is an exceedingly high volume of reports that may do more harm than good. ASCO created a task force to develop a roadmap for making the adverse event reporting process as meaningful and informative as possible.

CHALLENGES

Adverse event reports often lack information on whether the reported events are relevant to specific trials. They may also be causally associated with the therapeutic agents being studied or include anticipated events described in the study protocol or investigator brochure.[1] Researchers and the U.S. Food and Drug Administration (FDA) are frequently left to review a high volume of uninformative reports, which often lack advice or guidance on the clinical interpretation of the event and the appropriate action to be taken.[2,3] This high volume of inadequate information may actually contribute to greater patient risk, not less.

SOLUTION(S)

ASCO hosted a multi-stakeholder workshop in 2017, with representatives from academic and community oncology practices, the FDA, the National Cancer Institute (NCI), industry, contract research organizations (CROs), and patient advocates. ASCO was aware of CTTI's Safety Reporting initiative and was able to leverage the associated recommendations in the workshop, as well as in the development of ASCO's own recommendations for streamlining reporting, and ultimately the development of a decision aid for improving the accuracy and attribution of serious adverse events in oncology clinical trials. CTTI's work was not oncology-specific, but served as a good starting point. The CTTI recommendations outline communication approaches for better assessment of safety issues with a focus on reducing irrelevant reports and increasing their adherence to FDA requirements.

TAKING ACTION

CTTI's recommendations provided context to ASCO on what had been done to improve safety reporting, and the ASCO task force set out to create a roadmap for making the adverse event reporting process as meaningful and informative as possible. CTTI's recommendations, case studies, and webinar on the topic were foundational in this ASCO initiative on adverse event reporting.

IMPACT

In response to input they received during the workshop, ASCO developed recommendations for streamlining reporting and developed a decision aid for improving the accuracy and attribution of serious adverse events in oncology clinical trials. The decision aid was designed to assist physician-investigators and research staff with determining whether an adverse event should be reported to the sponsor as a serious adverse event and attributed to the investigational drug. An article in the *JCO Oncology Practice* reports the results of a preliminary study that assessed real-world usage and impact of the decision aid. The study found that, while the decision aid generally did not increase accuracy in determining seriousness (whether the investigator should submit a serious adverse event report to the sponsor), it did increase accuracy in determining whether a serious adverse event should be attributed to the investigational drug. The majority of study participants indicated that the decision aid was helpful and that they would use it in practice. [4]

ADVICE

One ASCO Steering Committee member feels it saved significant time and avoided recreating the wheel by using CTTI's recommendations as a starting point for their effort. CTTI's willingness to partner also helped ASCO to ensure an effective solution and desired impact on the research community. Other organizations looking to establish best practices and resources could consider partnering with CTTI and/or ASCO to leverage prior work to minimize redundancy and solve challenges in this area.

CITATIONS

1. Levit LA, Perez RP, Smith DC, Schilsky RL, Hayes DF, Vose JM. Streamlining Adverse Events Reporting in Oncology: An American Society of Clinical Oncology Research Statement. Journal of Clinical Oncology. 2018;36(6):617-23.
2. Perez R, Archdeacon P, Roach N, Goodwin R, Jarow J, Stuccio N, et al. Sponsors' and investigative staffs perceptions of the current investigational new drug safety reporting process in oncology trials. Clinical Trials. 2017;14(3):225-33.
3. Jarow JP, Casak S, Chuk M, Ehrlich LA, Khozin S. The Majority of Expedited Investigational New Drug Safety Reports Are Uninformative. Clinical Cancer Research. 2016;22(9):2111-3.
4. Mileham KF, Schenkel C, Chuk MK, Buchmeier A, Perez RP, Hurley P, et al. Assessing an ASCO Decision Aid for Improving the Accuracy and Attribution of Serious Adverse Event Reporting From Investigators to Sponsors. Journal of Oncology Practice. 2019;15(12).

ORGANIZATION

American Society of Clinical Oncology

CONTACT

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ORGANIZATION TYPE

Professional Society

IMPLEMENTATION DATE

2017

TOPIC

Safety Reporting

RELATED CTTI PROJECT

IND Safety

CTTI RESOURCES

CTTI Recommendations: IND Safety Assessment and Communication