

A Single Grade Can Change the Trajectory of a Trial

Why Accurate Adverse Event Grading Matters in Early-Phase Oncology Studies

An AE Occurs in a Patient

How Is It Graded?

Accurate Grading

Supports reliable study decisions and protects patients and data.



Inaccurate Grading

May lead to incorrect study decisions and put the trial at risk.

A Grading Decision May Influence



Dose escalation

Appropriate escalation decisions



Phase transition

Predefined transition rules may be met



Safety data

Safety signals may be misread or misinterpreted



Trial direction

Trial path may be steered by inaccurate data

Why It Matters in Early-Phase Oncology

Many early-phase oncology trials use model-assisted dose-finding designs, such as Bayesian Optimal Interval (BOIN).

These designs may include accelerated escalation with pre-specified transition rules.



In some studies, a single **grade 2 or higher** AE can trigger a phase transition.



Potential Consequence

If a grade 2 AE is over-called as grade 3 — or a grade 3 AE is under-called as grade 2 — the trial may be steered on inaccurate data.

Risk Mitigation

Built-in checks can help de-risk grading:



Source Data Verification

Targeted checks on graded events



Medical Review

Prompt review of graded events



Site Queries

Timely queries to sites as needed



These checks help de-risk grading without second-guessing the investigator.



A single grading decision can shape the course of an early-phase oncology trial. Accurate grading helps protect patients and ensures critical study decisions are made on reliable safety data.

Connect with Premier's medical experts to strengthen AE management across your oncology program. 



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