injured by an automobile accident, for example, on the way to the clinic, this injury is classified as an AE (65,66,67,68,69,70,71). Although some publications may state that injuries from accidents are not AEs (72), it is actually improper to exclude accidents from AEs. The layperson can readily appreciate the fact that drugs can cause drowsiness, or result in impaired vision (73), where the result is an accident that produces injury.

c. Classification of Adverse Events by Considerations Used by Statisticians

Adverse events can also be classified according to how a statistician would approach the data. These approaches include the following reporting (74):

- AEs by ITT analysis;
- AEs by PP analysis;
- Use of a severity threshold, that is, reporting of AEs only above a certain severity grade;
- Use of a prevalence threshold, that is, reporting of AEs occurring only above a certain percentage of patients;
- Outcomes of AEs, such as treatment discontinuations, dose reductions, and withdrawals from the study.

Although these types of adverse events generally fall under the umbrella of the biostatistician serving a clinical study, a typical medical writer will be familiar with all of these concepts.

d. ITT Analysis Versus PP Analysis for Assessing Safety

Clinical trials in regulated settings require collection of data on safety and efficacy. The FDA grants marketing approval for drug

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