

Patient Safety Narratives in Clinical Studies

Patient safety narratives form an important part of clinical study reporting. This paper describes current regulatory requirements with regards to safety narratives, a proposed process for their development and review and examines ways to simplify the reporting process; thereby reducing the burden of time and cost.

Safety narratives should be prepared for all phases of clinical studies, whether conducted in healthy volunteers or in patients with the disease/condition under study. For ease of reporting, they shall be referred to as patient safety narratives throughout this paper (although narratives for healthy volunteers/subjects in Phase I studies should be considered included).

Guidance

According to the International Conference on Harmonisation (ICH) tripartite guideline on the Structure and Content of Clinical Study Reports (CSRs) E3 (Section 12.3.2), a CSR should contain brief narratives describing each death, each other serious adverse event, and other significant adverse events that are judged to be of special interest because of clinical importance.¹

The guidance document indicates that events clearly unrelated to the test drug/investigational product may be omitted or described very briefly. In the interests of transparent reporting, it is suggested herein that patient safety narratives be prepared for all criteria detailed above.

A patient safety narrative provides a full and clinically relevant, chronological account of the progression of an event experienced during or immediately following a clinical study.

Patient Narratives Clinical Study Report

Peter C. Gøtzsche



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