

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

**Amir Kalali, Sheldon Preskorn, Joseph
Kwentus**



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Unveiling the Energy of Verbal Beauty: An Emotional Sojourn through **Patient Narratives Clinical Study Report**

In some sort of inundated with screens and the cacophony of instant conversation, the profound power and psychological resonance of verbal artistry usually fade into obscurity, eclipsed by the continuous assault of sound and distractions. Yet, nestled within the lyrical pages of **Patient Narratives Clinical Study Report**, a fascinating perform of literary elegance that pulses with natural emotions, lies an wonderful journey waiting to be embarked upon. Composed by a virtuoso wordsmith, that interesting opus books viewers on a psychological odyssey, lightly revealing the latent possible and profound affect stuck within the complex internet of language. Within the heart-wrenching expanse of this evocative analysis, we shall embark upon an introspective exploration of the book is key styles, dissect their captivating writing model, and immerse ourselves in the indelible impression it leaves upon the depths of readers souls.

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