

Narrative writing process:

- Medical Writer prepares a narrative template using various data sources like CRF pages, analysis datasets, pharmacovigilance database, clinical database listings
- Peer and scientific review by the CRD project lead to check the document is accurate, complete, and consistent with requirements.
- Clinical review of draft narrative by the Sponsor, Stakeholders.
- Re drafting narrative after clinical review comments: If the writer does not agree with clinical review comments, when the review comments are unclear, a conflict with the evidence, these should be discussed with the Sponsors or other stakeholders and duly noted and filed.
- Quality control (QC) review is based on final patient data.
- Due to the large number of narratives required for individual studies and small size of each document relative to the CSR, it is recommended that a single QC review be performed toward the end of the process, rather than QC review of the first draft and final deliverable.
- Approval by the Sponsor after a final review.

Narrative Writing In Pharmacovigilance

Menghis Bairu, Richard Chin



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