Regulatory Matters

Using technology to reduce the time it takes to generate patient narratives

SECTION EDITOR

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Problem statement

Writing patient narratives using clinical study data is often a manual, tedious, and time-consuming task for medical writers and/or safety specialists. A narrative must be developed to describe each death, each other serious adverse event, and other significant adverse events experienced by a patient during a clinical study.[1] Narratives typically report summary information, including:

- Patient demographics, baseline characteristics, and medical history;
- Adverse events (AEs) and serious adverse events (SAEs); and
- Laboratory values.

These data are provided in statistical outputs (e.g., tables and listings), which typically are manually copied and pasted into the narratives. In addition, identification of which patients require a narrative can be challenging because the study team must manually review the outputs to determine which patients meet the predefined, study-specific criteria. Altogether, this results in additional costs, resources, and project time to develop the narratives and then verify their data via quality check (QC) review.

How technology can help

A software utility can be used to automatically generate patient narratives in Microsoft Word, which supports the following:

- The ability to predefine the study-specific criteria (e.g., adverse event of special interest) that would determine which patients will require a narrative.
  - The author does not need to manually review adverse event listings to detect which patients will need a narrative.
- The ability to have predefined data points, such as baseline information, autopopulated into each patient's narrative "template" from the statistical outputs; the order and layout of data in the template can be predefined and configured on a per-study basis.
  - The author can focus on the descriptive text instead of having to manually copy/paste data from the outputs.
  - QC reviewers do not need to verify all data points in the narrative.

By using a narrative-generation utility, the following benefits may be realised:

- Significant time savings and improved quality.
  - Determination of which patients qualify for a narrative is automated based on configurable, study-specific criteria, rather than manual review of outputs, resulting in a list of patient narratives that ensures no qualifying patients are missed.
  - The author does not need to spend time manually searching the statistical outputs for the relevant data points and then copy/paste them into the narrative.
  - QC review time is reduced because sections of the narrative are automatically populated from validated data, reducing human error.
  - All narratives for a study can be automatically compiled into a single submission-ready document based on the list of patient narratives.
- Regeneration of narratives can be conducted for a study in a consistent manner.
  - For post–database lock updates, the utility can be re-run and the newly generated narratives easily compared to the original narratives, with any differences highlighted for the author to accept/reject, as needed.

Implementing a narrative-generation utility can result in significant time savings and improved quality. In addition, reducing the burden of manually generating narratives allows the authors and QC reviewers to focus their efforts on their areas of expertise, rather than mundane tasks, perhaps even resulting in a happier workplace environment!

Reference

1. ICH Harmonised Tripartite Guideline. Structure and Content of Clinical Study Reports E3. Current Step 4 version dated 30 November 1995 [cited 2019 Sep 23]. Available from: https://database.ich.org/sites/default/files/E3_Guideline.pdf

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