PROGRAMMED NARRATIVES: WORKING SMARTER NOT HARDER

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THE PROBLEM WITH SAFETY NARRATIVE WRITING

The typical process for writing safety narratives requires a writer to create a clear and concise account of the events and clinical data surrounding a particular adverse event. Usually, to do so, the writer must pull individual data points from multiple data listings and manually insert them into a narrative template document. This is time consuming and labor intensive. By necessity, the process involves a tremendous amount of data transcription, and can also require manual calculation (eg, event durations, time from event to treatment) and manual tabulation (eg, relevant laboratory results). As such, the process is inherently error prone. A high-quality deliverable requires a substantial investment in time and labor – not only for the writer who prepares the narratives, but for the clinical staff who review the summaries, and the quality control staff who verify each data point in the document.

THE SOLUTION

Let's work smarter, not harder! By working together with biostatisticians and programmers, the medical writer can use programming capabilities to pre-populate the safety narrative template with common data elements and automate many of the data entry tasks of narrative writing. With the data entry tasks out of the way, medical writers can focus their time and effort on filling in unique details from sources like the safety report forms for a given subject. This automated process also eases the time and effort needed for quality control review because the programming undergoes its own quality control review, which provides assurance that the data is being populated correctly.



HOW DOES IT WORK?

ESTABLISH THE TEAM

Medical writer reaches out to the client to determine who the decision makers and reviewers will be.

Medical writer also reaches out to the biostatistics and programming department to determine who has been assigned to the study the narratives are being written for.

ANNOTATE

TEMPLATE

Medical writer and programmer

exact source of each data point

(eg, what data set, what variable).

They also determine any required

calculations (durations, study day,

annotate the template to reflect the

THE NARRATIVE

04

age, etc).

Medical writer works with the client to determine the details of the narrative template.

They discuss and decide early on conventions for each required element.

05 Programmer runs the automated

output.

Medical writer performs a quality control review of the outputs.

A sample of programmed outputs is forwarded to the client for approval.

GENERATE REMAINING NARRATIVES

Medical writing team completes, peer reviews, and QCs remaining narratives.

Client reviews narratives at agreed upon timepoints in the process.

CREATE THE NARRATIVE TEMPLATE

HOST A KICK 00 OFF MEETING

Medical writer(s) and client stakeholders confirm that the variables being pulled into the narrative template meet the client expectations.

They review the narrative review cycle and timelines.

This step is particularly important for large or complex narrative projects.

RUN AND QC PROGRAMMED NARRATIVES

WRITE SAMPLE NARRATIVES

Medical writer tests the template by completing the non-programmed portion of a sample of narratives to ensure the template "works" for the writer.

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Sample narratives are forwarded to the client for review and to confirm the completed narratives meet the client's expectations.

Template and/or annotations are revised if needed.

COMPLETE **PROJECT ON** TIME AND ON BUDGET

BENEFITS OF THE AUTOMATED PROCESS

It's Faster

Common elements (ID, age, gender, race, diagnosis, treatment assignment, medical history, concomitant medications, event start/stop dates, etc.) are pre-populated reducing data entry and QC time.

It's Less Labor Intensive

SECRETS TO SUCCESS

Programming safety narrative information is a smart way to reduce workload. Medical writers who implement this strategy successfully do the following:





It's More Accurate and Consistent

- Data is pulled directly from the data source.
- Document formatting and repeated language are programmed into each narrative.

Fewer people are needed to complete the work.

- Communicate with client stakeholders early and often and ask clarifying questions to ensure full understanding of the client's expectations.
- Be transparent with all client, medical writing, and programming team members about changes to the narrative language or programming details.
- Raise a red flag as soon as data issues or inconsistencies between the narrative template and programmed information are noticed.
- Keep an immaculate tracking system by continuously updating a narrative tracker and moving narratives through a folder system.
- Leave plenty of time for the QC Review, and if timelines shift, maintain an appropriate amount of time for QC review.