

CHANGING THE NARRATIVE ON NARRATIVES USING TECHNOLOGY-ENABLED AUTHORING

In April 2020, a leading biotechnology company required the authoring of 3,000 narratives in approximately four months across four studies for its BLA. Historically, their statistical programming group had been able to generate the patient index and programmed template output required for drafting the narratives, which the writing vendor's team then used to complete full drafting. This took weeks, even upwards of a month to produce. From the start, they felt the timeline was working against them and nearly impossible to meet.

In response to the challenge, Synchrogenix, a Certara Company, presented Narrative Builder, its technology-enabled authoring solution software for narratives, and pitched taking ownership of the patient index and programmed template generation output.

Synchrogenix worked with the company's mock data to produce the patient index and programmed template outputs in advance of receipt of the final data to ensure alignment and set expectations. This sample generation and template-alignment step enabled Synchrogenix to begin work with the final dataset almost immediately after database lock.

Synchrogenix's efficient and organized technology-enabled authoring process provided peace of mind and trust of quality for the company. Synchrogenix's writing team produced high-quality narratives at an expedited pace while working within its programmed template output. First drafts on approximately 750 narratives for the first study were completed in six weeks, approximately 7.5 weeks in advance of the original timeline. Reviewer comments were limited as programming enabled data consistency and the review team was already aligned on most important template items to focus on from the template-alignment step.

“ The fact you could produce the first drafts so quickly was a key benefit for our timeline. And the fact that the QC review was built in was an additional factor that contributed significantly to meeting our timeline goal. ”

Editor,
Medical Writing

Patient narratives are brief summaries of specific events experienced by patients during the course of a clinical trial. They are a required component of clinical study reports (CSRs) and pharmacovigilance activities and aid in the evaluation of the safety profile of a drug.

“ What made this successful was the approach, a combination of real strategic planning on everyone's part. ”

Associate Director,
Medical Writing

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