

A NEW SPONSOR TEAM WITH FEW PROCESSES AND LITTLE PROJECT EXPERIENCE IN PLACE

A commercial-stage biopharmaceutical company recently employed new team members to support the production of patient safety narratives across the primary and extension Clinical Study Reports (CSR)s. The Sponsor team had not worked with a narrative vendor in the past and was not very familiar with the narrative process overall and how it fit into the overall CSR process. The Sponsor was not sure what source data would be available for the Certara Synchronix team to work with, and how to best write to the existing template.

We introduced the narrative builder features within Synchronix™ Writer to the Sponsor, explained the data mapping process, and highlighted our writers' and QCers' ability to work with the clinical dataset directly. We worked with the Sponsor's existing template and identified areas for improvement based on the specific study data sets. The Certara Synchronix team was able to deliver draft narratives for Sponsor review ahead of schedule while providing the flexibility and support to address any of the Sponsor's questions along the way. The Sponsor had a very pleasant first narrative experience, and will be working with Certara Synchronix on narrative projects in the pipeline.



Certara Synchronix worked with the Sponsor's existing template in one therapeutic area and standardized it to the Sponsor's unique Style Guide.

Using the narrative builder features in Synchronix™ Writer, we can support your high-volume submission with confidence, while ensuring the same quality and consistency standards we stand by.



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