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CERTARA®
Accerlating Medicines, Together

CASE STUDY

A HIGH-VOLUME SUBMISSION WITH CONCERNS OVER QUALITY

An American biotechnology company had an extensive requirement for narratives based on an unanticipated number of patients who met criteria (~2,000) across several clinical study reports (CSRs) for an upcoming NDA submission. With only a few months to review and finalize all narratives, the Sponsor was concerned over the speed and quality of production.

Certara Synchrogenix worked with the Sponsor to align on the template, implemented the narrative builder features in Synchrogenix™ Writer, resourced a global team, and provided narratives for review on a rolling basis often weeks ahead of schedule. Automation enabled the high volume of narratives to be drafted more quickly utilizing fewer resources but with greater consistency standards than thought possible. The Sponsor was relieved that what was anticipated as the most complicated piece of the NDA was expertly managed and efficiently completed before deadline by Certara Synchrogenix.

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Using the narrative builder features in Synchrogenix™ 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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