

AN URGENT HEALTH AUTHORITY REQUEST

An American biopharmaceutical company had received a health authority request to provide safety narratives for patients meeting elevated laboratory result criteria. This resulted in the need to report several laboratory parameters in both tabular and running-text form across the duration of the study for hundreds of patients, creating for a lengthy template. The Sponsor had no flexibility in timeline.

Upon receipt of the clinical data set, Certara Synchronix quickly mapped and generated the narrative template for all patients meeting criteria. We were able to achieve 100% automation, such that individual narratives did not require manual edits from the narrative writing of QC team. All narratives were delivered to the Sponsor team within 3 business days for final submission efforts to the healthy authority.



The narrative builder features in Synchronix™ Writer enabled us to achieve 100% automation, such that individual narratives did not require manual edits from the narrative writing or QC team.

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.



CONTACT US TO LEARN MORE

[HTTPS://WWW.CERTARA.COM/COMPANY/CONTACT/](https://www.certara.com/company/contact/)