

**CASE STUDY** 

## COMPLEX PATIENT PROFILE AND NARRATIVE TEMPLATE NEEDS

A global pharmaceutical company came to Certara Synchrogenix to generate both patient profile (PPL) and narrative templates for one of its most complex studies. Historically, the Sponsor's statistical programming team had generated the PPLs as a resource for reviewers to use during their review cycle but would be unable to do so moving forward. The Sponsor team was seeking a way to make the fully written narrative template easier to write and present to reviewers.

Certara Synchrogenix employed the narrative builder features in Synchrogenix™ Writer to build out the PPL template for all subjects. We automated complex narrative template sections through advanced software features, pulling from multiple data domains and adding logic and calculations. The PPL and narrative templates were merged and both were delivered as one cohesive document to the Sponsor team during the review cycle. This resulted in an efficient and streamlined review process of complex data.



The narrative builder features in Synchrogenix™ Writer enabled us to automate complex narrative template sections through advanced software features, pulling from multiple data domains and adding logic and calculations.

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.

