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CASE STUDY

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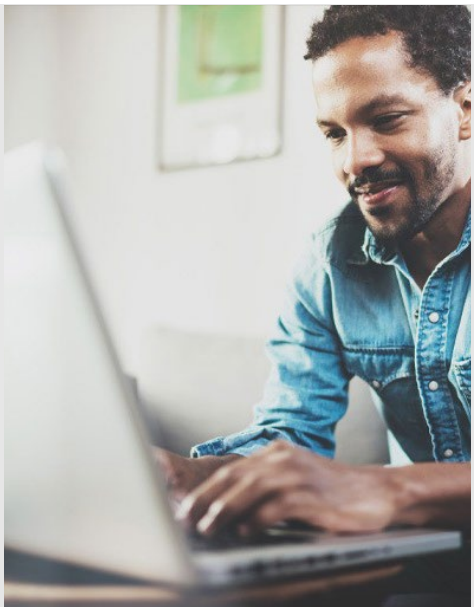
REGULATORY WRITING EXPERTISE FOR PIVOTAL CLINICAL STUDY REPORTS

Gene therapy developers often have technical expertise when it comes to their product but may not have a full understanding of regulatory writing requirements for specific document content.

Two gene therapy companies were in need of regulatory writing support for pivotal clinical study reports (CSRs). They engaged with Certara's Cell & Gene Therapy practice because of its proven regulatory and medical writing expertise across therapeutic areas.

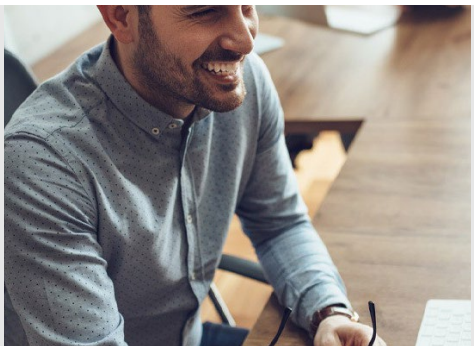
One developer needed several CSRs written, but had poor source materials. The company relied on Synchrogenix, Certara's Regulatory Science Division for regulatory writing, to develop CSRs that presented a cohesive, compelling, and concise story around their drug, which had shown amazing results.

Another developer engaged Synchrogenix to drive the CSR writing process fully and to completion. Synchrogenix's experts provided a convincing framing of the key data and conclusions in support of regulatory requirements.



Synchrogenix's regulatory writers have authored over 200 CMC, 350 nonclinical, and nearly 5,000 clinical documents for sponsors over the past 5 years.

Clinical study reports are a comprehensive look at all the data produced in a clinical study, presented in text, tables, and figure formats. They often include discussions and conclusions that provide context to the findings regarding the drug, device, or any other type of therapeutic product or practice under study and where it may contribute to an improvement on the state of the art for treating or preventing a particular health condition.



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