To View Online:
https://www.certara.com/case-study/scaling-to-support-a-bla-that-grew-8x-larger-than-originally-planned/

CERTARA®
Accelerating Medicines, Together

CASE STUDY

SCALING TO SUPPORT A BLA THAT GREW 8X LARGER THAN ORIGINALLY PLANNED

A commercial stage biopharmaceutical company focused on the development of novel treatments for B-cell diseases was focused on pursuing FDA approval for a recombinant IgG1 chimeric monoclonal antibody, for the treatment of relapsing forms of multiple sclerosis (MS). In 2021, they called upon Certara Synchrogenix to support their BLA submission, which came on the heels of another BLA we submitted for them in March 2021. Work on the BLA began in April 2021. Initially, the BLA was expected to be about 500,000 pages. However, the page count grew exponentially following the FDA's insistence that more Case Report Forms (CRFs) be included in the application.

Despite the massive growth of the application, the sponsor remained committed to completing the BLA submission before the end of Q3. Meeting the aggressive timeline meant that the Certara Synchrogenix publishing team would need to scale and be flexible and focused in completing what had grown to a nearly 4-million-page application.

The Certara Synchrogenix team resourced thirty team members throughout Certara's global locations to meet the challenge. The team worked around the clock with a mission-critical clarity of focus. Despite the application growing to 8x larger than originally planned, the Certara Synchrogenix Regulatory Operations team completed publishing for the application only ten days later than the original submission date, and six days earlier than the absolute deadline.

> "The Certara Synchrogenix team resourced thirty team members throughout Certara's global locations to meet the challenge of completing publishing for an application that had grown to 8x larger than originally planned."

Certara Synchrogenix is capable of seamlessly moving your project forward with round-the-clock publishing support. With global resources in the US, Europe, and Asia, our team can scale up or down as needed to support a submission, making it possible to meet even the most challenging of deadlines.

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