

STRATEGIC PLANNING AND TECHNOLOGY TO SUPPORT A ROLLING BLA SUBMISSION UNDER TIGHT TIMELINES

A Tier 3 Sponsor called upon Certara Synchronix to support its rolling BLA submission, the second submission we supported for this Sponsor in the overall partnership. The agile nature of the submission meant the Certara Synchronix team would need to be strategic, flexible, and focused in meeting new milestone deadlines set forth by the FDA in the overall timeline.

The Certara Synchronix team employed strategic planning and resourcing from the start to ensure each milestone deadline would be met or exceeded. The effort set forth came from multiple service lines: the assigned Regulatory Operations team of co-leads and specialists as well as the Document Quality team of editors. We leveraged our global offices to ensure round-the-clock service and our technology to streamline our process, and closely cooperated with the Sponsor every step of the way. Pulling from our GlobalSubmit technology suite: WebReview made it easy for the Sponsor to review the submission quickly and easily; live validation eliminated last-minute validation error remediation; CrossCheck enabled fast but thorough quality control review; and delta publishing allowed for quick turnarounds as reviewed documents came in. Certara's cloud-based publishing software allowed resources to scale up. Thanks to our strategic resourcing and technology, we were able to exceed a deadline by eight calendar days even when the Sponsor requested to bump up the timeline with only 2 weeks advanced notice.



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Certara Synchronix's Regulatory Operations team, paired with GlobalSubmit software, makes rolling submissions achievable no matter how tight the timeline. We are driven by the success of supporting your current submission and building a lasting partnership through your entire drug lifecycle.

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