VERISTAT

Regulatory Publishing Expertise Across the Entire Development Journey

In the past 3 years, Veristat publishers have supported more than

140 sponsors with

200+ publishing projects

Client Success Stories

1. Expert Support for an Understaffed Regulatory Team Leads to Flawless IND Submission

Development Phase: Pre-IND, Phase I, Phase II submissions to FDA

Veristat began working with a sponsor to help support its lean regulatory affairs team in filing high-quality IND submissions and its CSR publishing. Our collaboration initiated at a pre-IND phase and continued through Phase I and Phase II studies, providing the sponsor with regulatory publishing and project management expertise. Despite working under stringent timelines, many of which had 2- to 3-day turnarounds, and with minimal client involvement, Veristat executed several flawless submissions in varying formats with zero error notices from the FDA. While we served as an extension of the sponsor's regulatory team, the client was able to stay focused on pressing business matters by relying on our teams to successfully satisfy all publishing requirements.

2. Successful Submission of a Marketing Authorization Application (MAA)

Lifecycle Phase: Registration submission to European Medicines Agency (EMA)

A clinical-stage European biopharmaceutical company developing a biosimilar and medical device engaged Veristat to support publishing their first MAA. Although there were quality issues and delays on the sponsor's end, Veristat accommodated the client's tight deadlines and was able to successfully meet the submission timeline. Our team continues to support the client throughout the technical and content validation of the dossier.

3. The Power of Publishing for an Efficient NDA Submission Process

Lifecycle Phase: Registration submission to FDA

A commercial-stage sponsor sought out Veristat for support of their NDA submissions, amendments to documents, and ad promo submissions. The project was transferred to Veristat from another vendor, and all the content provided needed comprehensive modification to meet FDA data submission requirements and specifications. Veristat's publishing lead and project manager worked closely with the sponsor to construct a process roadmap and timeline that targeted an NDA submission for the same year. Armed with a team of in-house regulatory strategists, medical writers, and biometrics experts, we submitted a flawless NDA to FDA, and approval was achieved.

PUBLISHING BEST PRACTICES FOR NDAs, BLAs & MAAs

Effectively managing the publishing of documents required for a regulatory registration submission can help accelerate the time it takes to bring your product to market. Veristat's publishing experts recommend following these best practices as you prepare for your submission:

1. Schedule a kickoff meeting sooner rather than later

A publishing-specific kickoff meeting should happen at least a year out from the target submission date and include all key stakeholders from clinical, CMC, and relevant non-clinical functions involved.

2. Facilitate ongoing communication

Effective communication is crucial for effective publishing management and the backbone of a successful submission. Reviewers with decision-making authority should be identified early on, and one single point of contact should serve as the day-to-day interface with Veristat's publishing lead for optimal collaboration.

3. Prepare for unexpected program delays

Challenges that delays can impose on the submission schedule are impossible to predict. Work closely and consistently with publishing, regulatory, and biometric experts to ensure your final submission stays on track.

Contact Our Trusted Regulatory Publishing Experts

At Veristat, we understand the critical nature of publishing and submitting your marketing application to health authorities. Learn how our regulatory publishing experts can help you establish realistic timelines and best practices for publishing your applications, amendments, supplements, and reports to FDA, EMA, and global health authorities.

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