VERISTAT

Writing Multiple Marketing Applications With Accelerated Timelines At The Same Time

How An Experienced and Flexible Medical Writing Team Completed Three Submissions Within 6 Weeks Of Each Other

Background

A mid-size pharmaceutical company and its development partner, a small biotechnology company engaged Veristat in 2016 to complete the medical writing for their product's Marketing Authorization Application (MAA), New Drug Application (NDA), and New Drug Submission (NDS).

All three submissions were being written at the same time; however, our client intentionally scheduled a staggered submission timeline.

Study Demographics

INDICATION:

A Rare Cardiometabolic Disorder

PRIMARY SERVICES PROVIDED:

- Project Management
- Medical Writing

SUBMISSION TYPES

- MAA
- NDA
- NDS

Final Submission Timelines

JUL

MAA submitted to European Medicines Agency (EMA)

AUG

NDA submitted to US Food & Drug Administration (FDA)

SEP

NDS submitted to Health Canada

GOAL

Our client needed Veristat's medical writing team to quickly complete the submission documents for the MAA, NDA, and NDS in an accelerated timeline because the product received Orphan Drug Designation in the United States and Europe and Priority Review status in Canada.

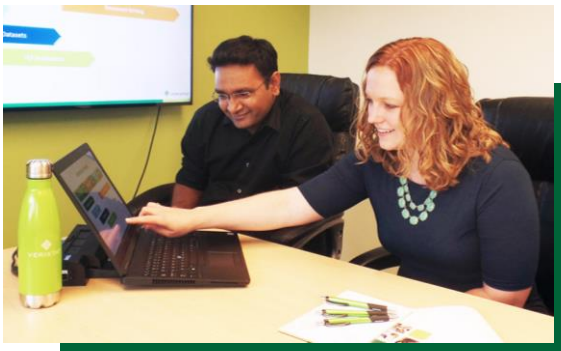
THE CHALLENGES

Multiple Companies Managing The Submission

The product is being co-developed by two biopharmaceutical firms, and both companies had their teams involved in the submission project. At times, the representatives at each company did not agree on the writing strategy or would give conflicting reviews of the documents being reviewed.

A Late Pre-NDA Meeting | Additional Analyses Requested by FDA

Another complication to the submission timeline is that our client scheduled their Pre-NDA meeting with the FDA late in the process. The meeting was held two months prior to the NDA submission date goal, and the outcome of the meeting was that FDA requested additional analyses. Ultimately, the submission for the NDA was delayed one month as a result.



THE SOLUTIONS

Once we learned of the FDA's additional requests, Veristat's submission project manager and the medical writing team developed a plan to bring in more resources to keep the NDA and NDS submission timelines moving forward. As a result of the agency's feedback, our medical writers had to produce addendums for five clinical study reports (CSRs) included in the submission (including the pivotal CSR).

We had already completed the ISS, so considerable rework had to be done to add in the new analyses. Additionally, the final M2.5, M2.7.3, and M2.7.4 sections submitted with the MAA had to be revised based on FDA's feedback.

Each CSR addendum and submission document had a different document owner (or document "champion") from one of the two partnering client companies. Sometimes this was challenging as there were many different tiers of review; however, it worked out well to have a single document owner, particularly when there was conflicting feedback from multiple reviewers, as the document owner's feedback took priority.

The Veristat medical writing team demonstrated exemplary communication skills to ensure consistent messaging across the various documents that were being authored simultaneously. This is only possible with a nimble, integrated team that is experienced in working collaboratively on large and complex submission projects. Additionally, document authoring followed by eCTD-compliant electronic publishing at Veristat allowed us to further streamline the timeline at critical milestones, ultimately resulting in on-time submission of the MAA, NDA, and NDS by our client.

RESULTS

The MAA, NDA and NDS were submitted to the regulatory agencies over the summer of 2017 within 6 weeks of one another. The MAA was submitted on time, and the NDA and NDS submissions were only delayed by 1 month. Our client is planning a potential global commercial launch of the product in 2018, pending regulatory approvals.

THE SHEER VOLUME OF THE MAA SUBMISSION ALONE

1.3 million links

346,000 pages

856 PDF files

It is estimated that if the MAA were printed out on paper, the paper stack would stand

12 feet tall!

Contact Veristat Today

To learn more about Veristat and how our medical writing team can help you achieve success with your trial or development program and regulatory submission, reach out to us today.

+1 508.429.7340 marketing@veristat.com