› CASE STUDY

VERISTAT

# Writing Multiple Marketing Applications Simultaneously with Accelerated Timelines

## How an Expert Medical Writing Team Completed Three Submissions Within 6 Weeks of One Another

## Background

A mid-size pharmaceutical company and its development partner, a small biotechnology company, engaged Veristat 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.

## Submission Details

### Indication

- A rare cardiometabolic disorder

### Primary Services Provided

- Project Management
- Medical Writing

### Submission Types

- Marketing Authorization Application (MAA)
- New Drug Application (NDA)
- New Drug Submission (NDS)

## SITUATION

The client's product received Orphan Drug Designation in the United States and Europe, and Priority Review status in Canada. This meant our medical writing team needed to work quickly to complete the submission documents for the MAA, NDA, and NDS.

### Multiple Companies Managing the Submission

The product was 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.

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

Additionally, the 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 resulted in the FDA requesting additional analyses. Ultimately, the submission for the NDA was delayed one month as a result.

## THE SOLUTION

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 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 the client.

## Final Submission Timelines

| JULY | AUGUST | SEPTEMBER |
|---|---|---|
| **MAA submitted** to European Medicines Agency (EMA) | **NDA submitted** to US Food & Drug Administration (FDA) | **NDS submitted** to Health Canada |

## IMPACT

The MAA, NDA and NDS were submitted to the regulatory agencies within six weeks of one another. The MAA was submitted on time and the NDA and NDS submissions were only delayed by one month. So far, our client has received a conditional approval from the EMA and is awaiting approval in the US and Canada.

## The Sheer Volume of the MAA Submission Alone

**1.3 million links**

**346,000 pages**

**856 PDF files**

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