VERISTAT

Successful EU MAA Submission Enabled by U.S.–EU Regulatory Collaboration

On-time submission despite complex data, late-stage document constraints, and late emerging data.

Background

A biopharmaceutical client engaged Veristat in April 2023 to provide regulatory support encompassing marketing authorization preparation and submission for their oncology drug across both U.S. and EU pathways. The client also needed a partner with the capability to act as the EU Marketing Authorization Applicant and provide the necessary regulatory, pharmacovigilance (PV), and quality infrastructure. As part of our global regulatory offering, Veristat is equipped to deliver this support. Veristat's regulatory team guided the preparation, submission, and review of the US NDA, which was FDA-approved in December 2024. Building on this foundation, Veristat's regulatory and medical writing teams integrated the results of the FDA review into the global dossier and prepared the content needed for the EU Marketing Authorization Application (MAA).

This work included adapting materials to meet EMA format and regional expectations, preparing local Module 1 components, integrating emerging data and supporting the client in a pre-submission meeting with EMA, which included preparing the briefing book and the pre-submission interaction package. We also attended the meeting with the client and prepared the draft minutes for rapporteur review.

PROJECT OVERVIEW

SUBMISSION TYPE
- Initial Marketing Authorization Application (MAA), centralized procedure

REGION
- European Union (EMA)

THERAPEUTIC AREA
- Non-small cell lung cancer

SERVICES PROVIDED
- Integration of FDA review outcomes
- Dossier adaptation for EMA
- Acting as Marketing Authorization applicant in the EU
- Medical and regulatory writing
- Module 1 development (labeling, PSMF, administrative content)
- Submission preparation, compilation, and management
- Project Management

Client Challenge

The client needed to submit a complete EU MAA under a fixed, non-movable deadline. (Note: EMA can charge an extra fee if you move your intended MAA submission date under certain conditions. Several challenges were identified during the process:

- Integration of complex FDA review outcomes into the EU dossier
- Adaptation of content to meet EMA and local Module 1 requirements
- Development of EU labeling texts, PSMF components, and other region-specific documents, including the necessary documentation for Veristat to act as EU Marketing Authorization applicant from a regulatory PV and QA perspective.
- Only 60% of final documents were available just weeks before submission

These constraints necessitated exceptional responsiveness, effective communication between client and internal teams, and precise technical execution.

Our Solution

Regulatory & Strategic Adaptation

Veristat incorporated outputs from the FDA review into the EU submission package and aligned content with EMA expectations. This included restructuring and updating narrative components, ensuring consistent messaging, and preparing for a pre-submission meeting with EMA to confirm expectations for the planned MAA.

Medical Writing & Module 1 Development

The medical and regulatory writing teams developed multiple EU-specific deliverables, including:

- EU labeling texts
- PSMF-related materials
- Local administrative and Module 1 components
- Updated dossier content aligned to EMA's format and regional requirements

These updates required close coordination with the client, internal teams and external partners supporting the overall program.

Publishing & Submission Execution

The publishing team delivered substantial volume under tight timelines:

- Rapid QC and integration of late-arriving documents
- Continuous updates during the final weeks, with only ~60% of final documentation available late in the process
- Final compilation, technical validation, and electronic submission
- Ensuring all files met regional technical standards

Cross-Functional Collaboration

Internal communications emphasized:

- Detailed planning and tracing of document development
- Expert input to strategic questions
- "Late evenings" and "incredible teamwork" across contributors
- Team members going "above and beyond" to meet the deadline
- Close coordination between the client, regulatory, medical writing, SME and publishing colleagues
- Flexible, real-time support to address issues as they emerged

Outcome

The EU MAA was successfully submitted by Veristat by the required deadline, and validated by EMA. Veristat continues to support the client and engage with EMA to support the upcoming marketing authorization review and response cycles.

Veristat provides integrated cross-functional support for NDA, BLA, and MAA programs—from early guidance through agency interactions, expert review, documentation updates, and coordinated project management and publishing.

We also adapt documentation for regional needs and can serve as the Marketing Authorization Applicant or Holder in the EU, UK, and Switzerland on your behalf until you have established a local commercial organization.

About Veristat

If you've faced missed deadlines or slow progress, talk to Veristat. We have a proven record of accelerating clinical development programs with the expertise to navigate the complex path to marketing authorization efficiently. Partner with experts who understand the value of speed without compromising quality. From first-time approvals to regional expansions, our cross-functional teams help clients meet regulatory milestones with confidence.

Reach out to us to learn more. veristat.com ›