



> FACT SHEET



VERISTAT

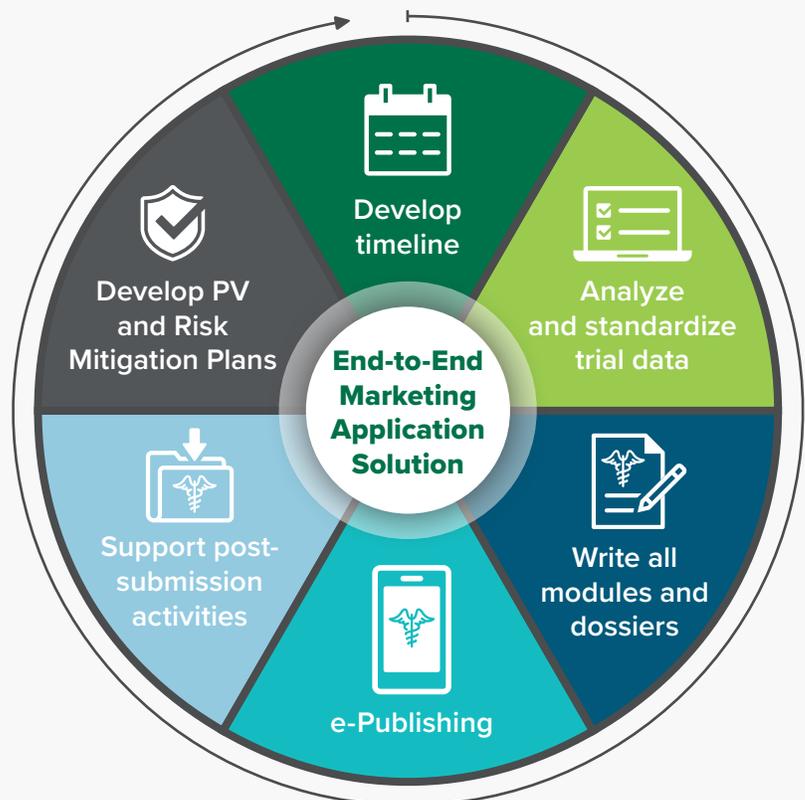
Accelerate Marketing Application Preparation

A marketing application is a critical milestone in your clinical research program. Navigating the global regulatory landscape has become longer and more complex. Sponsors cannot afford mistakes or delays when preparing and submitting marketing applications (NDAs/BLAs, MAAs, etc.) to health authorities.

With a proven record of success, Veristat delivers end-to-end marketing application expertise. Its integrated team of submission experts provides regulatory consulting, biostatistical and programming support, data standardization, medical writing, and publishing services to help you confidently plan and execute your regulatory submissions.



In the past 5 years,
46 approvals
were given for
marketing applications
prepared by Veristat



Marketing Application Success Stories

1 Innovative Data Migration Strategy Enables On-Time NDA Success

A mid-size biopharma company partnered with Veristat to submit an NDA for a groundbreaking rare neurological disorder treatment. Facing a nine-month timeline and a two-month database lock delay, Veristat adopted an unconventional domain-based data migration approach instead of the traditional study-by-study method. This innovative strategy enabled simultaneous work across teams, allowing for parallel processing of 18 legacy studies and two pivotal trials. The submission was completed on time, received priority review, and achieved FDA approval in under six months, becoming the client's first commercial product and the only available treatment for this rare condition. [Learn more >](#)

2 From RTF to FDA Approval: A Data Quality Success Story

A pharmaceutical company's New Drug Application for a pediatric treatment received a Refusal-to-File from the FDA due to incorrect SAS datasets. Veristat was engaged to perform an independent quality review of the pivotal Phase III study data. Our cross-functional team of regulatory, programming and statistical experts conducted comprehensive dataset analysis, improved documentation, and enhanced traceability. Through collaborative efforts with the client, Veristat identified and addressed issues in the ISE datasets, define.xml files, and SDTM/ADaM datasets. The resubmission was completed within seven months, leading to FDA approval. [Learn more >](#)

3 An Agile Approach to Streamlining Complex NDA Documentation

A growing biopharma company partnered with Veristat for medical writing support during their NDA submission for a CNS therapy. Facing an aggressive 5.5-week timeline for the Summary of Clinical Safety, Veristat implemented a three-pronged strategy: comprehensive medical writing expertise, strategic timeline management, and robust governance protocols. By breaking down the SCS into manageable sections and maintaining regular communication touchpoints, Veristat significantly reduced the client's review burden. The collaboration resulted in early delivery of drafts and successful NDA submission one day ahead of schedule. The partnership continues with ongoing FDA information request support and clinical regulatory documentation. [Learn more >](#)

Science-Based Focus That Delivers Results

Veristat is focused, dedicated, and experienced in helping bring new therapies through the clinical development and regulatory submission process for patients with no existing or limited treatment options. Learn more about how Veristat can help streamline your marketing application preparation and submission process.

[veristat.com](https://www.veristat.com)

