



## NDA/MAA PREPARATION SURVIVAL GUIDE

# Three Guiding Principles

No two marketing application (NDA, BLA, MAA, NDS, jNDA, etc.) projects are ever the same. From our years of experience preparing more than 120 marketing applications, Veristat has learned there are three constants you can count on, and we have adopted these as guiding principles to ensure success:



**Integrated teams  
are essential.**



**Creativity and flexibility  
are vital.**



**Quality is always  
paramount.**

## Start with a tightly integrated team

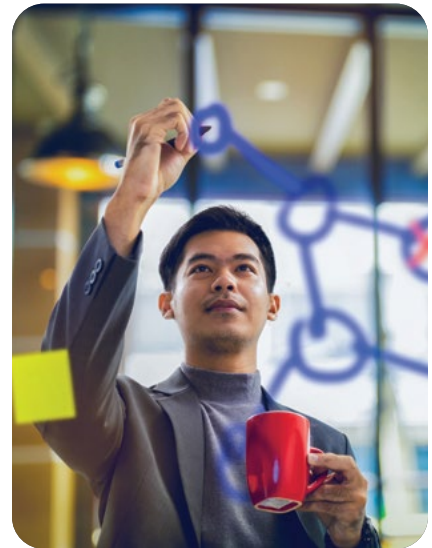
If you can't engage one single vendor to manage your marketing application preparation, take the right steps to build a cohesive and communicative team of multiple parties. Your team requires expertise from multiple disciplines including biostatisticians, statistical programmers, project managers, medical writers, regulatory consultants, and regulatory publishers.

- **Overcommunicate.**  
Loop in everyone to avoid siloed communication, delays in feedback, and errors in assumption.
- **Perfect the art of the roundtable meeting.**  
Bring all key stakeholders together, early and often, for key strategic planning, reviews and data analysis planning.
- **Assign ownership and accountability.**  
Designate champions and decision-makers responsible for moving each part of the project forward.

## Embrace creative thinking

It's not a matter of whether your timeline will shift, but how and when. Stay prepared with agile strategies to adapt and adjust.

- **Thoughtfully build your submission timeline.**  
Serving as the project roadmap for all teams, the timeline is the most critical working document.
- **Make sure everyone is on the same page.**  
Keeping large teams aware and informed can ease timeline crunches and avoid inconsistency.
- **Think outside the box.**  
Uncover trouble spots with dry runs for data analysis. Enable earlier starts with rolling delivery of data to medical writers. Creatively divide and conquer workload.



## Protect quality above all else

The fastest submission project in the world is worthless if the quality is sub-par. Make sure you don't let tight timelines encroach on your performance.

- **Never sacrifice quality review time.**  
Even under the worst time crunch, always allot the attention and resources necessary for an effective, thorough quality review, so your submission won't pay the price later.
- **Plan effectively to avoid quality compromises.**  
Stay proactive to facilitate time savings that don't just protect quality review time — they enhance it.

By thinking through these practices in planning your next complex NDA or MAA submission project, you can be confident in streamlining your processes and optimizing performance. While each submission will always present its unique challenges, these guiding principles can keep your team ready and able to meet them.



## Contact Veristat Today

To learn more about Veristat or how we can assist you with your clinical trial design, execution and regulatory submissions, reach out to us today.

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