VERISTAT

NDA/MAA PREPARATION SURVIVAL GUIDE

Managing Operational Complexities

While all marketing applications are unique, there is no doubt they share common threads. Understanding each individual project's complexities in advance can help teams create effective approaches for planning, mid-stream adaptation, and final submission.

1. Establish baseline fundamentals

Start by building an organized, effective team and optimized communication plans so the rest of the process can proceed smoothly.

2. Create the submission timeline

Other than the actual submission files, the timeline is the most crucial document for any submission. It serves as a roadmap and organizational tool for every aspect of the process.

3. Be flexible when the timeline shifts

It's not a matter of whether a timeline will change, but how to adapt when it does. Be prepared to respond intelligently and prioritizing ways to maximize efficiency.

1. How do you establish the baseline fundamentals early?

- **Work with an integrated team.**
  All members need to be seen as partners, including vendors, clients and external resources. Keep everyone informed and involved as early in the process as possible, so the team can function cohesively and collaboratively.

- **Get all key members involved early.**
  Sharing critical documents and plans starting with the very first draft can save time by avoiding the need to rework if key decision-makers don't agree with the initial planned strategy.

- **Establish communication practices.**
  Encourage inclusive communication and right from the start. Set up failproof ways to reach the entire team, such as secure chat services and email distribution lists.

- **Keep documents in content repositories.**
  Use a secured file-share service to keep documents centrally organized and easier to share. Send email notifications to make team members aware of updated documents and related details, including review deadlines.

2. How do you build an effective submission timeline?

- **Assign a timeline gatekeeper.**
  Make a single person responsible for managing the updates, distributions, query resolutions and adjustments to the master document containing all components of the submission application on one timeline.

- **Start with submission deadlines and work your way backward.**
  Ensure that you include enough time for publication processes, changes based on agency meetings and any downstream effects of potential revision requests.

- **Embrace roundtable discussions.**
  By getting all team decision-makers together during document development, you can encourage proactive problem-solving and avoid omitting key requirements during the initial draft.

- **Plan for post-submission requirements.**
  Be prepared for agency rapid responses, advisory committee meetings, 60-, 90- or 120-day safety updates, and other possible additions or expectations.

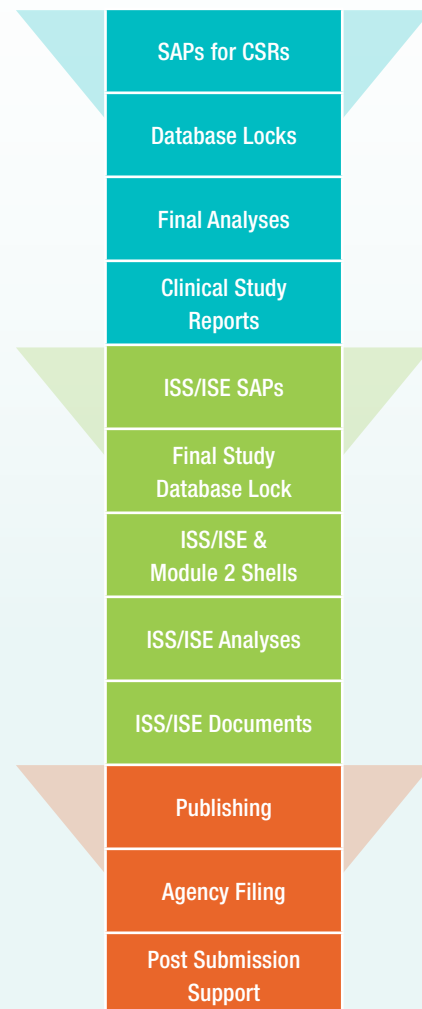## 3. How do you stay flexible when the timeline shifts?

- **Get creative without compromising quality review.**
  Reserving enough time for quality checks is non-negotiable, since skimping on this step only results in delays further down the line. Shave time from other areas or work in parallel when possible to help accommodate inevitable timeline shifts more nimbly.

- **Consider working with a single partner.**
  Not only does consolidation streamline the paperwork, it also smooths communications and keeps everyone on the same page. By putting together a team from a single CRO, you can benefit from more efficient and integrated timeline management, data analysis, medical writing, and publishing, with fewer operational delays.

Develop an Integrated Timeline

- SAPs for CSRs
- Database Locks
- Final Analyses
- Clinical Study Reports
- ISS/ISE SAPs
- Final Study Database Lock
- ISS/ISE & Module 2 Shells
- ISS/ISE Analyses
- ISS/ISE Documents
- Publishing
- Agency Filing
- Post Submission Support

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