VERISTAT

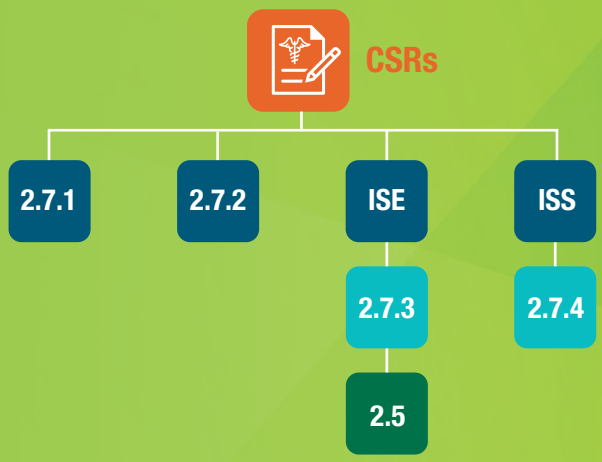
NDA/MAA PREPARATION SURVIVAL GUIDE

Successful Medical Writing Strategies

Careful planning and an optimized timeline can shorten the time required to produce effective, consistent marketing application documents. Ongoing, open communication is critical for strategic thinking among assigned medical writers, enabling unoccupied writers to step in and offer support to colleagues on other sections.

Turn reporting redundancy to your advantage

The clinical study report (CSR) serves as the basis for deriving marketing applications' clinical modules. Once CSRs are final, medical writers can strategically piece together required components in a specific order, from documents requiring the greatest level of detail down to those requiring the least, to avoid rework.



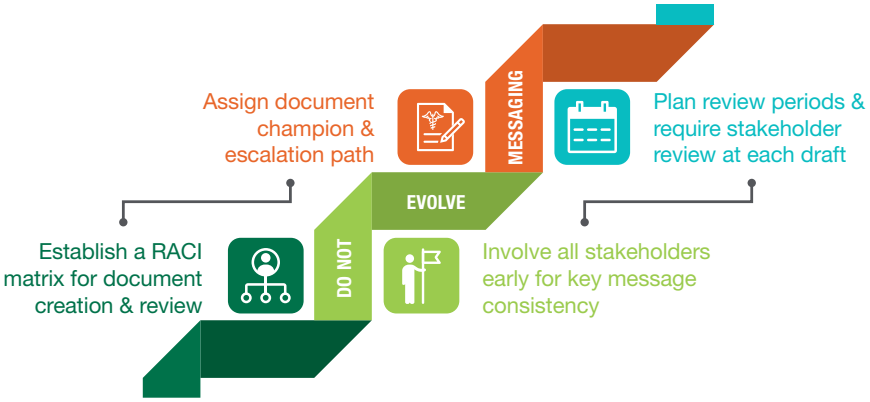
- When time permits, use the same group of medical writers for key CSR sections as for the submission document modules.
- Assign one writer each, when feasible, to modules 2.7.1, 2.7.2, efficacy (ISE plus 2.7.3), and safety (ISS plus 2.7.4).
- Extract the relevant ISE and ISS sections verbatim to modules 2.7.3 and 2.7.4 when possible.
- Assign one writer, typically the efficacy writer (ISE plus 2.7.3), to produce module 2.5.

Strategically schedule pre-submission meetings

Timing your pre-submission agency meeting prior to finalizing pivotal CSRs can have a huge impact on the scope of work and attainable filing date. Agency meetings held closer to submission could lead to delays in filing, if requests for additional analyses have a cascading impact on submission materials.

Reclaim time by reinventing document review

Creative planning for the document review process allows teams on tight timelines to avoid unproductive revision repetition, minimize the opportunity for misinterpretation, and speed up the review periods required for document advancement.



- **Designate a document champion**
  This individual will take ownership of resolving conflicting comments, protect consistent messaging, and manage version integrity.
- **Establish a RACI matrix**
  A responsibility assignment (Responsible, Accountable, Consulted, and Informed, or RACI) matrix establishes reviewers and key decision-makers for each document.
- **Develop a submission-specific style guide**
  This reference will provide a concrete reminder to all reviewers regarding messaging, style, nomenclature and approved brand or product stylistic preferences.
- **Schedule blocks of review time**
  Work with the project manager or document champion to reserve time for your submission document on reviewers' calendars.
- **Conduct roundtable live editing**
  Bring key reviewers together for a group editing session to solicit feedback on key concerns and resolve conflicting advice.

CASE STUDY

Simultaneous Submissions with Accelerated Timelines

Situation: A mid-size pharmaceutical company engaged Veristat to complete an MAA, NDA, and New Drug Submission (NDS) with similar submission dates. The pre-NDA meeting was scheduled just two months prior to target NDA filing date. The FDA requested multiple additional analyses, affecting five finalized CSRs, modules 2.5 and 2.7 clinical summaries, and the ISS.

Solution: Veristat's project manager and medical writing team developed a collaborative plan to bring in more resources. Each amended submission document had a single champion to resolve conflicting feedback and facilitate communication and consistency. Document authoring and eCTD-compliant electronic publishing at Veristat streamlined the completion process. End result: a final delay of only one month for the NDA and NDS submissions and on-time MAA submission, all submitted within a six-week timeframe.

Contact Veristat Today

Ensure a streamlined medical writing process for your marketing application. Learn how Veristat can help.

www.veristat.com

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