



VERISTAT

Different Approaches for Preparing a Marketing Application:

A Review of Successful NDA/MAA Preparation Strategies



Make a
difference.

At Veristat, our work
has profound impact
on the quality of
people's lives.



Webinar Agenda

Operational Complexities of Submissions

Overcoming Data Analysis Challenges

Medical Writing Keys to Success

Question & Answers

Operational Complexities of Submissions



Operational Necessities



1

Establish The Baseline Fundamentals

2

Create The Submission Timeline

3

Be Flexible When The Timeline Shifts

Fundamentals Across All Submissions

- Establish an integrated team-
full collaboration is required
across *all partners*
- Overcommunicate
- Utilize a central repository



Develop An Integrated Timeline

Establish Timeline Ownership And Keep All Partners Updated



Timeline Considerations

- Ensure availability of key decision makers - round table discussions
- Proactively plan for post-submission activities:

- 
- **Agency Rapid Response**
 - **Advisory Committee Meetings**
 - **Safety Updates**

Adapting to Timeline Shifts

- No shortcuts to **QUALITY** – *protect quality review time!*
- **Flexibility** and **creativity** are essential
- One partner makes operational integration smoother



Overcoming Data Analysis Challenges



Common Data Analysis Challenges



1

Short Submission Timeline

2

Timeline Delays | Database Lock

3

Integrated Vs. CSR Analyses

Quality is Key!

Regardless of any and all challenges...

QUALITY

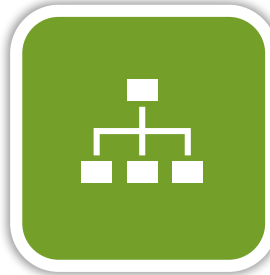
...is of utmost importance in
data analysis



Overcoming Short Timelines

Despite Time Pressures – ***QUALITY Is Vital!***

Team Structure is
Critical



Develop Strategic
Timeline

Involve Key
Reviewers from Start



Include Multiple
Dry Runs - ***Practice!***

Addressing a Database Lock Delay

- Proactive risk mitigation & scenario building
- Utilize independent Unblinding Team
- Automate as much as possible
- Perform a dry run with a close to final data cut
- Rolling deliveries to Medical Writing
- Word Compare Technique - Streamlined process between Biostats & Medical Writing



Integrated Analysis vs. CSR Analysis

Need To
Understand All
CSR Analyses

Overlap
Communications
Between Teams

Quality Requires An Understanding Of Both

Integrated SAP
Development
Is Critical

Statistical Review Of
CSRs Vs. Integrated
Analysis

Medical Writing Keys to Success



Medical Writing Keys to Success



1

Plan Resourcing To Gain Efficiency

2

Establish Document Review Governance

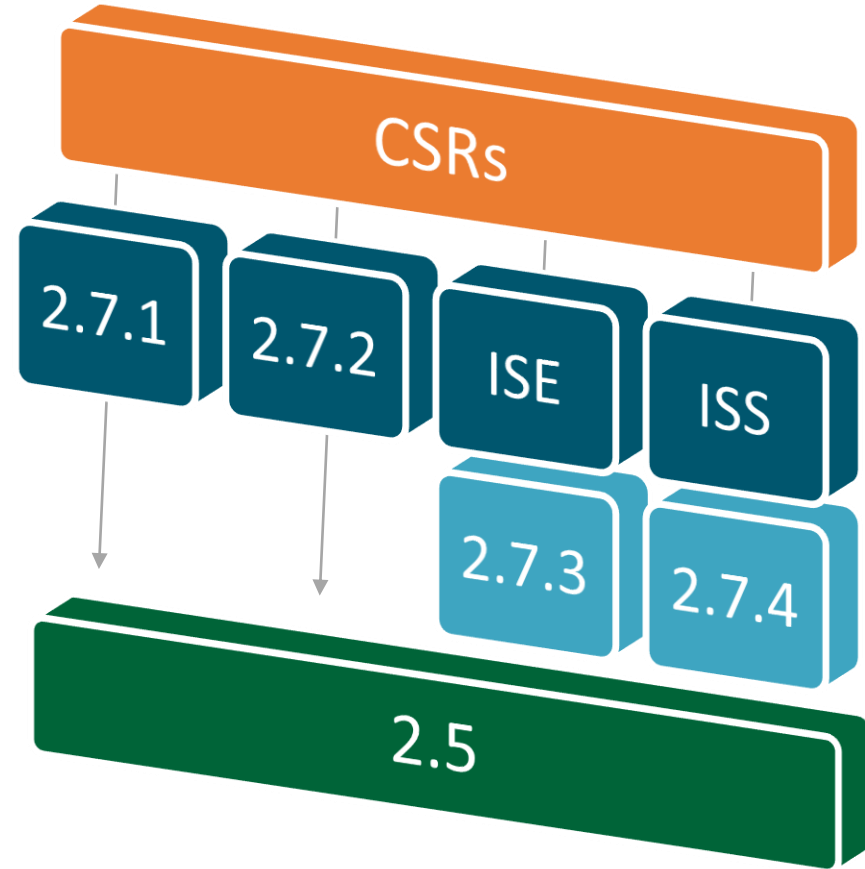
3

Be Strategic In Scheduling Pre-submission Meetings With Regulatory Agencies

Efficient Resource Planning

Smart Resourcing

- Consider how each document is derived
- Leverage writer experience and knowledge of data
- Collaboration is critical



Establish a Document Review Governance



Strategies for Document Review

Involve All Stakeholders & Document Champions



Incorporate “Blocked Reviews” To Review Key Data / Documents On Time



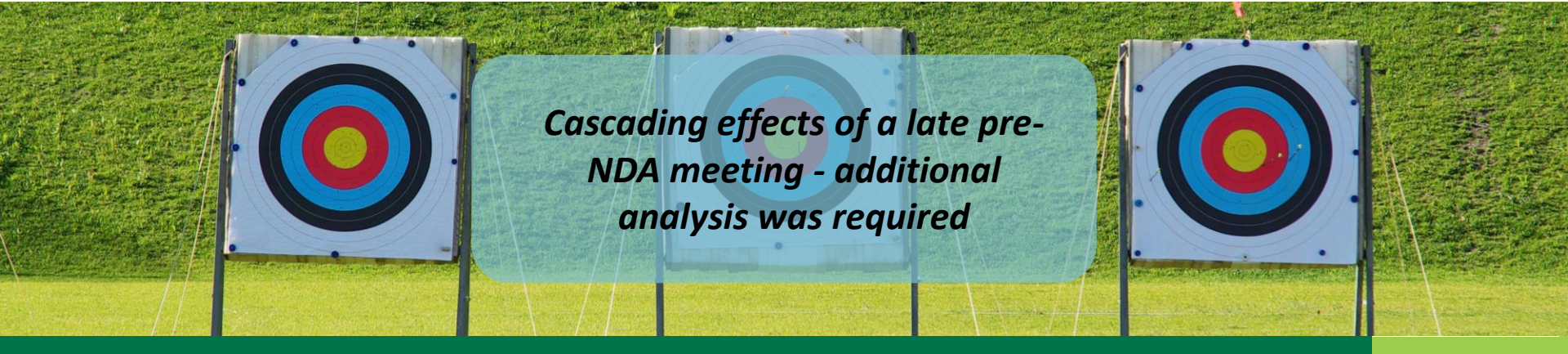
Consider Live-Editing Roundtable Review Meetings



Develop A Submission Style Guide

Timing Your Pre-submission Agency Meeting

- Schedule pre-submission agency meetings prior to finalizing pivotal CSRs
- **Flexibility** required to adjust quickly to agency requests

The image shows three archery targets on a grassy field. A semi-transparent blue box is overlaid on the middle target, containing text. The targets are standard archery targets with concentric rings of black, blue, red, and yellow. The text in the box reads: "Cascading effects of a late pre-NDA meeting - additional analysis was required".

Cascading effects of a late pre-NDA meeting - additional analysis was required

Overall Themes

Integrated Teams

Quality

Flexibility & Creativity



Questions?

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