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NDA/MAA PREPARATION SURVIVAL GUIDE

Overcoming Data Analysis Hurdles

A biostatisical programming team's ability to strategically migrate and produce clinical trial data outputs in submission-ready format represents a key opportunity to reduce timelines without sacrificing data quality. Well established timelines, technical processes and careful communication are the keys to achieving a shortened timeline while preserving the quality of the marketing application.

Keys to coping with tight submission timelines

- **Involve key reviewers from the start**
- **Develop strategic timeline**
- **Practice with dry runs**
- **Coordinate integrated and CSR analyses**

Carefully construct a strategic timeline

- Prioritize the Statistical Analysis Plan (SAP), which is a key timeline driver because it dictates the analysis requirements, including the approach to data pooling.
- Work backward from the submission deadlines, guided by a clear understanding of the analysis requirements via a well-vetted SAP, to prioritize the appropriate studies and types of data (domains) to facilitate subsequent activities.
- Optimize the prioritization of the study data tabulation model (SDTM); analysis data model (ADaM); and tables, listings, and figures (TLFs) to allow medical writing activities to begin while biostatistics activities continue.
- Be mindful of when data analysis for one or more clinical study reports (CSRs) may be required at the same time as an integrated summary of safety (ISS) or integrated summary of efficacy (ISE).
- Provide final draft SAP(s) to relevant regulatory agencies for early input to avoid late-breaking changes that may require additional time adjustments.

Practice makes perfect

Statistical teams are like sports teams: they need practice. Performing multiple dry runs season the team to work more efficiently when the data are ready, minimizing the chance of issues and delays at critical time points. Set the last practice run close to the final data cut to help identify concerns prior to the official final data release, allowing time for resolution before challenges arise that would impact the timelines at critical milestones.

Bring together integrated analysis and CSR analysis

Integrated analyses are often an amalgamation of various CSR analyses. This makes quality and consistency crucial. Quality outcomes require collaboration between and mutual understanding of both integrated analysis and CSR analysis.

INTEGRATED ANALYSIS	CSR ANALYSIS
• Incorporate statistical review of each CSR in the integrated SAP development process. • Include medical/clinical and medical writing team members in analysis plan reviews.	• Ensure all biostatistics and programming teams understand each CSR analysis. • Proactively execute statistical review checks CSRs vs. integrated analysis.

Overlap communication among the separate statistical teams so they can move in parallel with appropriate cross-team consistency

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CASE STUDY

Adapting Timelines to Complex Restrictions

Scenario: Veristat was engaged for data migration work for 18 legacy studies and two ongoing studies. Sequential study migration would have delayed ISS and ISE development until completion of the final study, which was not practical for the submission timeline.

Solution: The Veristat statistics and programming team batched the data by domain and provided preliminary rolling data outputs to medical writing. Processing by domain allowed analysis of categories of data in parallel across all studies before moving onto other domains, giving useful output for certain sections of the submission documents prior to total migration for even a single study. Even with the database lock delayed by two months, the submission timeline was met. This demonstrated a strategic timeline adaptation driven by key SAP elements.

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Correctly analyzing, standardizing, and reporting your clinical trial data to local and global regulatory agencies is critical to your success. Let us help.

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