

A Medical Writing Essential: Reviewing Statistical Analysis Plans



46th Annual Meeting
Washington, DC - 2010

Anita Frijhoff, PhD, ELS
Medical Writer
Premier Research Group Ltd.



Disclaimer

- The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Drug Information Association, Inc. (“DIA”), its directors, officers, employees, volunteers, members, chapters, councils, Special Interest Area Communities or affiliates, or any organization with which the presenter is employed or affiliated.
- These PowerPoint slides are the intellectual property of the individual presenter and are protected under the copyright laws of the United States of America and other countries. Used by permission. All rights reserved. Drug Information Association, DIA and DIA logo are registered trademarks or trademarks of Drug Information Association Inc. All other trademarks are the property of their respective owners.



Why a SAP Review by Medical Writing?

- Medical writers \neq statistical experts
- Why not just review draft tables, listings, graphs (TLGs) after database lock?



Why? (cont.)

- Goal: clinical study report (CSR)
 - high-quality
 - quick development
- Statistical analysis plan (SAP) review from MW perspective
 - Planned analyses cover study objectives?
 - Revised/additional data presentations needed?



What?

- What is a SAP?
 - SAP: Text & TLG shells
 - Text: Comprehensive and detailed description of the methods
 - TLG shells: Presentation of data analyses proposed for a clinical study
 - ICH guidelines: SAP finalized before database lock to minimize potential for bias and define scope



Agreement on SAP Reviews by MW

- Making the case for SAP reviews by MW
- Review scope
 - **No** editorial review
 - Summaries of data analyses appropriate for CSR?
- Review timeline
 - Time for review by MW
 - Time for revision by Stats before deadline (eg, database lock or delivery of SAP to client)



SAP Review - How?

- Required background
 - Understanding of SAP content (general, phase specific)
 - Knowledge of ICH guidelines & regulatory requirements
- Documents needed
 - Protocol
 - Annotated case report form (CRF)
 - Other pertinent documents



SAP Review - How? *(cont.)*

- And... remember the review scope!



SAP Review – Step 1

- Ensure SAP endpoints and analyses address all study objectives listed in the final version of the protocol



SAP Review – Step 2

- Review the SAP text
 - Comparison vs protocol (objectives, variables, Stats section)
 - Analysis populations
 - Baseline definitions
 - Imputation methods



SAP Review – Step 3

Review of TLG shells

- Listing shells
 - All data points from CRF and external data
 - Column headings vs CRF field labels and external data labels
 - Units
 - Derived variables



SAP Review – Step 3 (cont.)

Review of TLG shells

- Table shells
 - Data summaries per analyses described in the SAP text
 - Column and row headers
 - Analysis population in title
 - Data presentations easy to understand



SAP Review – Step 3 (cont.)

Review of TLG shells

- Graph shells
 - Correct presentation per analysis described in the SAP text (eg, Kaplan-Meier survival curve)
 - Footnotes
 - Legend
 - Legibility



SAP Review – Step 4

- Final evaluation of data presentations (Y/N)
 - Meet ICH guidelines and regulatory requirements
 - Summarize study results appropriately
 - Customized/additional data presentations needed



SAP Reviews by MW - Conclusions

- Require ample practice to become proficient
- Allow for TLG reprogramming early in study
- Efficiencies in other reviews
 - Data listings produced before database lock
 - Draft TLGs created after database lock.



SAP Reviews Are a MW Essential

- SAP reviews:
 - Data presentations required for CSR are present and error-free
- Gains in quality and time for CSR:
 - Use table/figure shells in CSR shell
 - Efficiencies in writing draft CSR

