STATISTICAL ANALYSIS PLAN SAMPLE TEMPLATE

FOR CLINICAL TRIAL DISCLOSURE PROJECTS

Statistical Analysis Plan
(SAP)

Version: <1,2,3…>

Author: < > (<Title, Institution>)

Date: DD-MMM-YYYY

CONTENTS

7.1 STATISTICAL PROCEDURES

Provide here the types of statistical tests to be used, with methods of stratification, types of sums of squares (if applicable), etc. If a formal meta-analysis is to be performed, then the model should be specified, including which terms are to be considered as fixed effects and which are to be considered as random effects. Sub-structure may be added in this section to break out methods, for example, by parametric/non-parametric/binary endpoints, or by continuous/categorical/binary data.

7.2 MEASURES TO ADJUST FOR MULTIPLICITY, CONFOUNDERS, HETEROGENEITY, ETC.

Briefly describe and justify these measures if applicable. For example, in the setting of observational data analyses, one possible adjustment measure might be propensity scoring.

8 SENSITIVITY ANALYSES

If any sensitivity analyses are planned, using for example different analysis sets, covariates, methods/models etc, then these analyses should be described and briefly justified here.

9 RATIONALE FOR ANY DEVIATION FROM PRE-SPECIFIED ANALYSIS PLAN PERFORMED BY PFIZER

If these analyses differ from those that were already performed, provide brief rationale for the change in approach.

10 QC PLANS

Provide a brief description of the QC Plan.

11 PROGRAMMING PLANS

Provide algorithms for generating tables and results to be executed by a Statistician.

12 REFERENCES

13 APPENDICES

If applicable, provide the following in the appendix:

- Definition and use of visit windows in reporting
- Definition of Analysis Populations/Sets
- Further Definition of Endpoints
- Statistical Methodology Details