

**STATISTICAL ANALYSIS PLAN SAMPLE
TEMPLATE
FOR CLINICAL TRIAL DISCLOSURE PROJECTS**

Statistical Analysis Plan (SAP)

Version: <1,2,3...>

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Date: DD-MMM-YYYY

CONTENTS

1 INTRODUCTION

2 DATA SOURCE

In this section, describe the data sets to be analyzed.

3 ANALYSIS OBJECTIVES

Briefly state the overall scientific objectives of the analyses, including the key unanswered questions that these analyses are designed to address. If necessary, provide additional detail to formulate the objectives in statistical terms. Include a brief summary of how each objective will be addressed in the analyses.

4 ANALYSIS SETS/ POPULATIONS/SUBGROUPS

Include a brief definition of analysis sets/populations to be used including criteria for inclusion/exclusion for the population.

Subgroups/subsets should be clearly defined and related back to the objectives stated above.

5 ENDPOINTS AND COVARIATES

Provide a brief definition of each type of endpoint, if different from those defined in the original protocol(s), indicating any use of visit windows and definition of baseline, as appropriate. In general, an endpoint should be defined by both a variable and a time point (eg, HIV-RNA viral load, change from baseline to week 24).

If covariates are to be included in the statistical analyses, provide brief definitions/derivation rules.

6 HANDLING OF MISSING VALUES AND OTHER DATA CONVENTIONS

Describe how missing values will be handled in the statistical analyses, and justify the methods used.

7 STATISTICAL METHODOLOGY

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