

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

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Yijin Wang



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