



Addendum to Statistical Analysis Plan Study Part 2

PROTOCOL TITLE: A PHASE 2 STUDY OF THE SAFETY, EFFICACY, AND PHARMACODYNAMICS OF **RTA 408 IN THE TREATMENT OF** FRIEDREICH'S ATAXIA **PROTOCOL ID:** 408-C-1402 **PRODUCT NAME: RTA 408 SPONSOR NAME:** Reata Pharmaceuticals, Inc. **SPONSOR ADDRESS:** 2801 Gateway Drive, Suite 150 **Irving, TX 75063** PROTOCOL VERSION: 9.0 SAP VERSION: 2.0

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VP, Product Development

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This document describes the changes in the programs specified in the 408-C-1402 Part 2 statistical analysis plan (SAP) for sensitivity analyses using multiple imputation due to patient number sparseness at sites. This document is prepared prior to unblinding of the clinical and programing team and is considered to be a pre-specified, blinded modification algorithm in case programs fail to execute after unblinding due to sparse data at some sites.

The SAS procedure PROC MI may fail to impute if some sites have too few patients. However, it is possible that sparseness at site may lead to lack of convergence in other analyses. In the event data by site is too sparse for a given analysis to execute, the following covariates will be used in the order listed in place of site:

- 1. Region (USA/Non-USA) will be used instead of site.
- 2. If analyses will not execute with region (USA/Non-USA) then no covariates will be used to replace site.

For pes cavus population, no site or region will be included because there are fewer patients and few missing values.