STATISTICAL TECHNICAL DOCUMENT

Collection of blood samples from patients with relapsing forms of Multiple Sclerosis (RMS) who have developed Immune thrombocytopenic purpura (ITP) after LEMTRADA® treatment

GZ402673-ASY15905

STATISTICIAN: [redacted]

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

HLT:	High Level Terms
MedDRA:	Medical Dictionary for Regulatory Activities
SD:	standard deviation
SOC:	System Organ Classes
WHO-DD:	World Health Organization Drug Dictionary

1 STATISTICAL AND ANALYTICAL PROCEDURES

1.1 INTRODUCTION

The purpose of this document is to provide additional minor details not provided in the protocol.

A comprehensive and detailed description of strategy and statistical technique used to perform the analysis of data was provided in Section 13 of the protocol (Version 1.0, date 31-Aug-2018), amended protocol (Version 1.0, date 24-May-2019).

Adverse events will be coded according to the Medical Dictionary for Regulatory Activities (MedDRA version 22.1).

Previous and concomitant medication records will be coded according to the World Health Organization Drug Dictionary (WHO-DD version September 2019).

1.2 MODIFICATIONS FROM THE STATISTICAL SECTION OF THE PROTOCOL

1.2.1 Modifications to the header of Section 13 “Statistical considerations”

As already mentioned in the Section 13.7 of the amended protocol, the statistical analysis of pharmacogenetics variables will be part of a global biomarker program and is not in the scope of this study. Therefore, data processing, quality control steps or statistical analysis to find predictive biomarkers will not be performed within the ASY15905 study.

1.2.2 Modifications to “13.4 Demographic and baseline characteristics”

The description of the patients will not be limited to the characteristics explicitly mentioned (age, gender, race/ethnicity). All the measured characteristics, including the history of clinical and pathological characteristics, will be summarized by descriptive statistics for the safety population.

Medical history will be summarized by “System Organ Classes” (SOC) and “High Level Terms” (HLT) in the safety population.

The type and the number of samples collected per patient will be also reported.

1.2.3 Modifications to “13.6 Prior/Concomitant medication/therapy”

Prior/Concomitant medication are collected in the study and therefore will be listed and summarized by descriptive statistics.

1.3 DATA HANDLING CONVENTIONS

This section describes the rules and conventions used in the presentation and analysis of data.

In the statistical appendices and in-text tables, the single label "**All**" will be used to define the safety population as no treatment is administered in the study.

All individual data for all subjects who had a blood draw will be presented in data listings.

If not otherwise stated in the statistical section of the protocol:

- Missing data will not be replaced.
- Descriptive statistics for quantitative parameters will be provided using number of observations (N), mean, standard deviation (SD), minimum, maximum and median.
- Descriptive statistics for qualitative parameters will be provided using frequencies (N) and percent (%).

2 SOFTWARE DOCUMENTATION

The analysis of clinical data will be performed under the responsibility of Sanofi Biostatistics Department, using SAS® (SAS Institute, NC USA).