CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

**PHARMACEUTICAL COMPANY: [FULL NAME]**
**CORPORATE [MEMBERSHIP, STUDY, DATASET]: [Assigned number: CMXX-XX, SCXX-XX, or SPXX-XX]**
[If applicable, describe part a/b throughout document sections study population, deliverables, timeline]

**STUDY TITLE:**
[insert text here]

**OBJECTIVE:**
[Short paragraph summarizing objective of study/membership]

**STUDY POPULATION:**
Inclusion Criteria:
- [insert text here]

Exclusion Criteria:
- [insert text here]

**OUTCOMES:**
Primary:
- [insert text here]

Secondary:
- [insert text here]

**VARIABLES TO BE DESCRIBED (bolded variables considered in multivariate analysis):**
Patient-related
- [insert text here]

Disease-related
- [insert text here]

Transplant-related
- [insert text here]

Research-level data (subset of patients only, cRF):
- [insert text here]

**STUDY DESIGN:**
[Paragraph describing study design]

**DELIVERABLES:**
- Table 1. Characteristics of patients: [insert text here]
- Table 2. Univariate outcomes: [insert text here – overall population, and if applicable each sub-population should have its own table] *(will depend on number of evaluable patients and median follow-up of survivors)*
- Table 4. Multivariate analysis of [insert text here – table for each: OS, Rel, DFS etc.]

- Table 5. Causes of death: [insert text here – overall population, and if applicable each sub-population should have its own table]
- Table [last table #]: Required CIBMTR statement

*The CIBMTR collects data at two levels: Transplant Essential Data (TED) level and Comprehensive Report Form (CRF) level. The TED-level data is an internationally accepted standard data set that contains key variables for all consecutive transplant recipients. When a transplant is registered with the CIBMTR, a subset of patients are selected for the CRF level of data collection through a weighted randomization scheme that uses the data submitted on the TED level to identify patients of particular interest for over-sampling. The CRF-level data capture additional patient, disease and treatment-related data. TED- and CRF-level data are collected pre-transplant, 100 days and six months post-transplant, annually until year 6 post-transplant and biannually thereafter until death.

*The rules of the CIBMTR require inclusion of the following statement. "The enclosed data are confidential and represent a preliminary review of information submitted to the CIBMTR. If used publicly, the following statement must be included: 'The data presented here are preliminary and were obtained from the Coordinating Center of the Center for International Blood and Marrow Transplant Research. The analysis has not been reviewed or approved by the Statistical or Scientific Committees of the CIBMTR.' The data may not be published without prior approval of the CIBMTR."*