



BMT CTN PROTOCOL #0303

A Single Arm, Multicenter Phase II Trial of Transplants of HLA-Matched, CD34⁺ Enriched, T cell Depleted Peripheral Blood Stem Cells Isolated by the CliniMACS System in the Treatment of Patients with AML in First or Second Morphologic Complete Remission

Changes to Version 6.0 of the Protocol:

- The first inclusion criterion has been modified as follows. This is reflected in §2.3.1 *Patient Inclusion Criteria*.

Patients with ~~de novo~~ AML, with or without prior history of myelodysplastic syndrome, based on the World Health Organization criteria (see Appendix A) at the following stages:

- First morphologic CR
- Second morphologic CR

The definition of morphologic CR is provided in Section 3.1. Patients with therapy-related AML are also eligible.

- Patients must be less than or equal to 65 years of age, a change from 60 years of age. This is reflected in §2.3.1 *Patient Inclusion Criteria*.
- The following exclusion criterion has been removed: “Patients with any history of cytopenia consistent with diagnoses of myelodysplastic syndrome (MDS) for more than 3 months prior to the diagnosis of AML or patients with treatment-related AML.” This is reflected in §2.3.2 *Patient Exclusion Criteria*.
- The following exclusion criterion has been removed: “Patients with secondary AML.” This is reflected in §2.3.2 *Patient Exclusion Criteria*.