# PROTOCOL SYNOPSIS - BMT CTN PROTOCOL 1102

## A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Intermediate-2 and High Risk Myelodysplastic Syndrome

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**Study Design:** This study is designed as a multicenter trial, with biological assignment to one of two study arms; Arm 1: Reduced intensity conditioning allogeneic hematopoietic cell transplantation (RIC-alloHCT), Arm 2: Non-Transplant Therapy/Best Supportive Care.

**Primary Objective:** The primary objective is to compare the three-year overall survival (OS) probabilities between two treatment arms.

**Secondary Objectives:** Patients will also be assessed for the following:

1. Compare leukemia-free survival (LFS) at 3 years from patient consent.
2. Compare Quality of Life (QOL) measures between treatment arms
3. Compare Cost-Effectiveness measures between treatment arms (see Appendix F for ancillary cost-effectiveness protocol)

**Accrual Objective:** The trial will accrue a total of 338 patients if the ratio of HCT vs. nonHCT is 6:4 and 400 patients if the ratio of HCT vs. nonHCT is 7:3.

**Accrual Period:** The estimated accrual period is 2.5-3.5 years.

**Study Duration:** Patients will be followed for three years after biological assignment; total time from start of accrual will be approximately 5.5-6.5 years.

**Eligibility Criteria:** Patients 50-75 years of age with a history of de novo intermediate-2 or high-risk myelodysplastic syndrome (MDS) by the International Prognostic Scoring System (IPSS) with < 20% marrow blasts. MDS must be of an acceptable subtype. Patients must be considered to be suitable RIC alloHCT candidates at the time of initial evaluation based on medical history, physical examination, and available laboratory tests. Specific testing for organ function is not required for eligibility but, if available, these tests should be used to judge eligibility.

Patients and physicians must be willing to comply with treatment assignment:

1. No intent to proceed with alloHCT using donor sources not specified in this protocol, including HLA-mismatched related or unrelated donors (< 6/6 HLA related matched or < 8/8 HLA unrelated matched) or umbilical cord blood unit(s)
2. No intent to use myeloablative conditioning regimens
3. Intent to proceed with RIC alloHCT if a matched sibling or matched unrelated donor is identified. There is no requirement as to the timing of the transplantation.

To be biologically assigned to the alloHCT arm, patients must have either a 6/6 HLA-matched related donor, defined by Class I (HLA-A and -B) intermediate resolution or high resolution DNA-based typing and Class II (HLA-DRBI) at high resolution DNA-based typing OR an 8/8 HLA-A, -B, -C, and -DRB1 at high resolution DNA-based typing unrelated donor identified within 90 days from the date of consent.

## STUDY SCHEMA