

**Invitation to Participate in: *Part I of an Assessment of Stem Cell Transplantation in Medicare Beneficiaries with Myelodysplastic Syndrome and Related Disorders. (10-CMS-MDS-1)***

\*\*\*This invitation is being extended to all US Transplant Centers who wish to provide a mechanism for coverage of allogeneic HCT for patients who are Medicare Beneficiaries and have a diagnosis of MDS and other related disorders.\*\*\*

Transplant center participation in this study is critical to fulfill the requirements necessary for coverage with evidence determination (CED) for Medicare beneficiaries receiving hematopoietic transplantation for Myelodysplastic syndromes and their related subtypes.

**U.S Transplant Center Participation Requirements:**

Retain local IRB approval of the CIBMTR Research Database protocol “Research Database for Hematopoietic Stem Cell Transplantation and Marrow Toxic Injuries” - (NCT 01166009)

- Regardless of existing center preference for forms submission, each U.S transplant center must agree to send Comprehensive Report Forms for any patient who is a Medicare beneficiary, regardless of age, with a diagnosis of MDS and their related subtypes, who wishes to participate in the CED. The center’s preferences for data submission will not otherwise be affected.
- Completion of a one page, simple paper registration form for each participant
- **Complete and return this invitation to verify your centers’ participation (see below).**

**Important Study Information for your Site and Patients:**

**Study Design:**

Eligible patients will be enrolled under the current CIBMTR protocol, *Protocol for a Research Database for Hematopoietic Stem Cell Transplantation and Marrow Toxic Injuries*. This protocol is being used as a means to collect comprehensive outcomes data on all Medicare beneficiaries who receive HCT for the treatment of MDS, and to allow those eligible patients to receive Medicare coverage for the treatment of MDS under the CED mechanism. The accrual goal will be 240 patients who are  $\geq 65$ , over two years. The primary endpoint of the analysis is 100 day mortality. A full protocol and study materials can be found at <http://www.cibmtr.org/HCTforMDS>

**Primary Aim:**

The primary aim of this study is to prospectively examine post- HCT outcomes in CMS beneficiaries with MDS to determine whether these outcomes are similar to those in younger patients.

## Verification of center participation:

### For TED or TED/CRF designated centers:

- Yes, we agree to participate in this study. For all eligible study participants with MDS this center agrees to submit to the CIBMTR the required comprehensive report forms. We understand that our preferences for data submission will not otherwise be changed.
- No, this center will not participate in this study. We understand that by declining participation, CMS beneficiaries with MDS will not have access to transplant coverage through this CED clinical trial.

### For Comprehensive Report Form only designated centers:

- Yes, we agree to participate in this study. We understand that we will continue to submit required forms per usual. This center agrees to submit to the CIBMTR the required comprehensive report forms for all eligible MDS study participants.
- No, this center will not participate in this study. We understand that by declining participation, CMS beneficiaries with MDS will not have access to transplant coverage through this CED clinical trial.

### **SIGNATURE:**

I have indicated above, our centers' participation preference for the 10-CMSMDS-1 study.

**Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_  
**Center Medical Director**

**Center Name:** \_\_\_\_\_

**Center Number** \_\_\_\_\_

Fax or email completed form to:  
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