ERROR CORRECTION FORM

Sequence Number: | CIBMTR Recipient ID: | Initials:

Today's Date: Month / Day / 20 Year | Infusion Date: Month / Day / 20 Year | CIBMTR Center Number:

Form 2014 R3.0: Myelodysplasia/Myeloproliferative Neoplasms (MDS/MPN) Pre-HCT Data

Center: CRID:

Key Fields

Sequence Number: _____

Date Received: __ __ __ __ - __ __- __ __

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

Date of HCT for which this form is being completed: __ __ __ __ - __ __- __ __

HCT type: (check all that apply)

- Autologous
- Allogeneic, unrelated
- Allogeneic, related

Product type: (check all that apply)

- Bone marrow
- PBSC
- Single cord blood unit
- Multiple cord blood units
- Other product

Specify: _____

Subsequent Transplant

Is this the report of a second or subsequent transplant for the same disease?

yes no

Disease Assessment at Diagnosis

Questions: 1 - 18

1 What was the date of diagnosis? __ __ __ __ - __ __- __ __

2 What was the MDS / MPN subtype?

_____

3 Was the disease (MDS/MPN) therapy related?

yes no Unknown

4 Specify prior disease

- Breast cancer
- Hodgkin lymphoma
- Non-Hodgkin lymphoma
- Other disease (malignant or nonmalignant)

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Center: CRID:

5 Specify other prior disease: _____

6 Date of diagnosis of prior disease

Known Unknown

7 Date of diagnosis of prior disease: __ __ __ __ - __ __ - __ __

8 Systemic therapy
(chemotherapy)

yes no Unknown

9 Radiation

yes no Unknown

10 Other therapy

yes no Unknown

11 Specify other therapy: _____

12 Did the recipient have a predisposing condition?

yes no Unknown

13 Specify condition

Aplastic Anemia **Also complete CIBMTR form 2028- APL**

Bloom syndrome

Down syndrome

Fanconi anemia **Also complete CIBMTR form 2029- FAN**

Other condition

14 Specify other condition: _____

15 Did the recipient receive any RBC transfusions at the time of diagnosis and/or during the first year post diagnosis?

yes no Unknown

16 Were systemic symptoms (B symptoms) present?
(unexplained fever > 38 C; or night sweats; unexplained weight loss > 10% body weight in six months before diagnosis)

yes no Unknown

17 Did the recipient have splenomegaly (spleen palpable > 3 cm below left costal margin)?

yes no Unknown

18 Did the recipient have hepatomegaly (liver edge palpable > 3 cm below right costal margin)?

yes no Unknown

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Center: CRID:

Laboratory Studies at Diagnosis

Questions: 19 - 39

19 Monocytes

Known Unknown

20 _____ %

21 Date sample collected: __ __ __ __ - __ __- __ __

22 Blasts in blood

Known Unknown

23 _____ %

24 Date sample collected: __ __ __ __ - __ __- __ __

25 Was a bone marrow examination performed?

yes no Unknown

26 Date sample collected: __ __ __ __ - __ __- __ __

27 Cellularity

Decreased (hypocellular)

Normal (normocellular)

Increased (hypercellular)

Unknown

28 Fibrosis

Present Absent Unknown

29 Were tests for molecular markers performed (e.g. PCR)?

yes no Unknown

30 Date sample collected: __ __ __ __ - __ __- __ __

31 ASXL1

Positive Negative Not Done

32 JAK2

(For MPN only)

Positive Negative Not Done

33 ETV6

Positive Negative Not Done

34 EZH2

Positive Negative Not Done

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Center: CRID:

35 P53

Positive Negative Not Done

36 RUNX1

Positive Negative Not Done

Other Molecular Marker (1) **Questions: 37 - 38**

37 Other molecular marker

Positive Negative Not Done

38 Specify other molecular marker: _____

39 Was documentation submitted to the CIBMTR?

yes no

Pre-HCT Therapy

Questions: 40 - 122

40 Was therapy given?

yes no

Line of Therapy (1) **Questions: 41 - 122**

Specify laboratory findings immediately prior to this line of therapy:

41 WBC

Known Unknown

42 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

43 Date sample collected: __ __ __ __ - __ __- __ __

44 Hemoglobin

Known Unknown

45 _____ g/dL g/L mmol/L

46 Date sample collected: __ __ __ __ - __ __- __ __

47 Was RBC transfused < 30 days before date of test?

yes no

48 Platelets

Known Unknown

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Center: CRID:

49 _____ x 10^9/L (x 10^3/mm^3)

x 10^6/L

50 Date sample collected: __ __ __ __ - __ __- __ __

51 Were platelets transfused < 7 days before date of test?

yes no

52 Neutrophils

Known Unknown

53 _____ %

54 Date sample collected: __ __ __ __ - __ __- __ __

55 Blasts in bone marrow

Known Unknown

56 _____ %

57 Date sample collected: __ __ __ __ - __ __- __ __

58 Were cytogenetics tested (conventional or FISH)?

yes no Unknown

59 Date sample collected: __ __ __ __ - __ __- __ __

60 Results of tests

Abnormalities identified

No evaluable metaphases

No abnormalities

Specify abnormalities identified prior to this line of therapy:

61 Specify number of distinct cytogenetic abnormalities

One (1)

Two (2)

Three (3)

Four or more (4 or more)

Monosomy

62 –5

yes no

63 -7

yes no

Form 2014 R3.0: Myelodysplasia/Myeloproliferative Neoplasms (MDS/MPN) Pre-HCT Data

Center: CRID:

64 –13

yes no

65 –20

yes no

66 –Y

yes no

Trisomy

67 +8

yes no

68 +19

yes no

Translocation

69 t(1;3)

yes no

70 t(2;11)

yes no

71 t(3;3)

yes no

72 t(3;21)

yes no

73 t(6;9)

yes no

74 t(11;16)

yes no

Deletion

75 del(3q) / 3q–

yes no

76 del(5q) / 5q-

yes no

77 del(7q) / 7q–

yes no

Form 2014 R3.0: Myelodysplasia/Myeloproliferative Neoplasms (MDS/MPN) Pre-HCT Data

Center: CRID:

78 del(9q) / 9q–

yes no

79 del(11q) / 11q–

yes no

80 del(12p) / 12p–

yes no

81 del(13q) / 13q-

yes no

82 del(20q) / 20q–

yes no

Inversion

83 inv(3)

yes no

Other

84 i17q

yes no

85 Other abnormality

yes no

86 Specify other abnormality: _____

Line of Therapy

87 Systemic therapy

yes no

88 Date therapy started

Known Unknown

89 Date started: __ __ __ __ - __ __- __ __

90 Date therapy stopped

Known Unknown

91 Date stopped: __ __ __ __ - __ __- __ __

92 Androgen

yes no

93 Antithymocyte globulin (ATG)

yes no

Form 2014 R3.0: Myelodysplasia/Myeloproliferative Neoplasms (MDS/MPN) Pre-HCT Data

Center: CRID:

94 Azacytidine (Vidaza)

yes no

95 Bendamustine

yes no

96 Corticosteroids

yes no

97 Cytarabine (Ara-C)

yes no

98 Decitabine (Dacogen)

yes no

99 Deferiprone (Ferriprox)

yes no

100 Deferasirox (Exjade)

yes no

101 Deferoxamine (Desferal)

yes no

102 Erythropoietin (EPO)
(any formulation)

yes no

103 G-CSF
(any formulation)

yes no

104 GM-CSF

yes no

105 Hydroxyurea (Droxia, Hydrea)

yes no

106 Idarubicin (Idamycin)

yes no

107 Lenalidomide (Revlimid)

yes no

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Center: CRID:

108 Ruxolitinib (Jakafi)

yes no

109 Thalidomide (Thalomid)

yes no

110 Tyrosine kinase inhibitor
(e.g. imatinib mesylate)

yes no

111 Other systemic therapy

yes no

112 Specify other systemic therapy: _____

113 Other therapy

yes no

114 Splenic radiation

yes no

115 Splenectomy

yes no

116 Other therapy

yes no

117 Specify other therapy: _____

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Center: CRID:

118 Best response to line of therapy

- Complete remission (CR) - requires all of the following, maintained for ≥ 4 weeks: * bone marrow evaluation: < 5% myeloblasts with normal maturation of all cell lines * peripheral blood evaluation: hemoglobin ≥ 11 g/dL untransfused and without erythropoietin support; ANC ≥ 1000 / mm^3 without myeloid growth factor support; platelets ≥ 100 x 10^9/L without thrombopoietic support; 0% blasts
- Hematologic improvement (HI) - requires one measurement of the following, maintained for ≥ 8 weeks without ongoing cytotoxic therapy; specify which cell line was measured to determine HI response: * HI-E- hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in the previous 8 weeks * HI-P- for pre-treatment platelet count of > 20 x 10^9/L, platelet absolute increase of ≥ 30 x 10^9/L; for pre-treatment platelet count of < 20 x 10^9/L, platelet absolute increase of ≥ 20 x 10^9 /L and ≥100% from pre-treatment level * HI-N- neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500 / mm3
- No response (NR) / stable disease (SD) - does not meet the criteria for at least HI, but no evidence of disease progression
- Progression from hematologic improvement (Prog from HI) - requires at least one of the following, in the absence of another explanation (e.g., infection, bleeding, ongoing chemotherapy, etc.): * ≥ 50% reduction from maximum response levels in granulocytes or platelets * reduction in hemoglobin by ≥ 1.5 g/dL * transfusion dependence
- Relapse from complete remission (Rel from CR) - requires at least one of the following: * return to pre-treatment bone marrow blast percentage * decrease of ≥ 50% from maximum response levels in granulocytes or platelets * transfusion dependence, or hemoglobin level ≥ 1.5 g/dL lower than prior to therapy
- Progression to AML (AML) - ≥ 20% blasts in the bone marrow
- Unknown
- Not assessed

119 Specify the cell line examined to determine HI status

- HI-E - hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in 8 weeks.
- HI-P - for pre-treatment platelet count of > 20x 10^9/L, platelet absolute increase of ≥ 30 x 10^9 /L; for pre-treatment platelet count of < 20 x 10^9/L, platelet absolute increase of ≥ 20 x 10^9/L and ≥ 100% from pre-treatment level
- HI-N - neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500 / mm^3

120 Date assessed: __ __ __ __ - __ __- __ __

121 Did disease relapse/progress following this line of therapy?

yes no

122 Date of relapse/progression: __ __ __ __ - __ __- __ __

Transformation

Questions: 123 - 126

123 Did the recipient progress or transform to a different MDS / MPN subtype between diagnosis and the start of the preparative regimen?

yes no

124 Was a subsequent complete remission achieved?

yes no

125 Specify the date of the most recent transformation: __ __ __ __ - __ __- __ __

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Center: CRID:

126 Specify the MDS / MPN subtype after transformation

- Refractory cytopenia with unilineage dysplasia (RCUD) (includes refractory anemia (RA)) (51)
- Refractory anemia with ringed sideroblasts (RARS) (55)
- Refractory anemia with excess blasts-1 (RAEB-1) (61)
- Refractory anemia with excess blasts-2 (RAEB-2) (62)
- Refractory cytopenia with multilineage dysplasia (RCMD) (64)
- Childhood myelodysplastic syndrome (Refractory cytopenia of childhood (RCC)) (68)
- Myelodysplastic syndrome with isolated del(5q) (5q– syndrome) (66)
- Myelodysplastic syndrome (MDS), unclassifiable (50)
- Chronic neutrophilic leukemia (165)
- Chronic eosinophilic leukemia, NOS (166)
- Essential thrombocythemia (includes primary thrombocytosis, idiopathic thrombocytosis, hemorrhagic thrombocythemia) (58)
- Polycythemia vera (PCV) (57)
- Primary myelofibrosis (includes chronic idiopathic myelofibrosis (CIMF), angiogenic myeloid metaplasia (AMM), myelofibrosis/sclerosis with myeloid metaplasia (MMM), idiopathic myelofibrosis) (167)
- Myeloproliferative neoplasm (MPN), unclassifiable (60)
- Chronic myelomonocytic leukemia (CMMoL) (54)
- Myelodysplastic / myeloproliferative neoplasm, unclassifiable (69)
- Transformed to AML (70) **- Also complete CIBMTR form 2010**

Laboratory Studies at Last Evaluation Prior to the Start of the Preparative Regimen(Conditioning) Questions: 127 - 153

127 Monocytes

Known Unknown

128 _____ %

129 Date sample collected: __ __ __ __ - __ __- __ __

130 Blasts in blood

Known Unknown

131 _____ %

132 Date sample collected: __ __ __ __ - __ __- __ __

133 Was a bone marrow examination performed?

yes no Unknown

134 Date sample collected: __ __ __ __ - __ __- __ __

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Center: CRID:

135 Cellularity

- Decreased (hypocellular)
- Normal (normocellular)
- Increased (hypercellular)
- Unknown

136 Fibrosis

Present Absent Unknown

137 Were tests for molecular markers performed (e.g. PCR)?

yes no Unknown

138 Date sample collected: __ __ __ __ - __ __ - __ __

139 ASXL1

Positive Negative Not Done

140 JAK2
(For MPN only)

Positive Negative Not Done

141 ETV6

Positive Negative Not Done

142 EZH2

Positive Negative Not Done

143 P53

Positive Negative Not Done

144 RUNX1

Positive Negative Not Done

Other Molecular Marker (1) **Questions: 145 - 146**

145 Other molecular marker

Positive Negative Not Done

146 Specify other molecular marker: _____

147 Was flow cytometry performed?

yes no Unknown

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Center: CRID:

Specify tissue and results:

148 Blood

yes no

149 Date sample collected: __ __ __ __ - __ __- __ __

150 Was disease detected?

yes no

151 Bone marrow

yes no

152 Date sample collected: __ __ __ __ - __ __- __ __

153 Was disease detected?

yes no

Disease Assessment at the Last Evaluation Prior to the Preparative Regimen (Conditioning) Questions: 154 - 161

154 Were systemic symptoms (B symptoms) present?
(unexplained fever > 38 C; or night sweats; unexplained weight loss > 10% body weight in six months before last evaluation prior to the start of the preparative regimen)

yes no Unknown

155 Did the recipient have splenomegaly (spleen palpable > 3 cm below left costal margin)?

yes no Unknown

156 Did the recipient have hepatomegaly (liver edge palpable > 3 cm below right costal margin)?

yes no Unknown

157 What was the disease status?

- Complete remission (CR) - requires all of the following, maintained for ≥ 4 weeks: * bone marrow evaluation: < 5% myeloblasts with normal maturation of all cell lines * peripheral blood evaluation: hemoglobin ≥ 11 g/dL untransfused and without erythropoietin support; ANC ≥ 1000 / mm3 without myeloid growth factor support; platelets ≥ 100 x 10^9/L without thrombopoietic support; 0% blasts
- Hematologic improvement (HI) - requires one measurement of the following, maintained for ≥ 8 weeks without ongoing cytotoxic therapy; specify which cell line was measured to determine HI response: * HI-E- hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in the previous 8 weeks * HI-P- for pre-treatment platelet count of > 20 x 10^9/L, platelet absolute increase of ≥ 30 x 10^9/L; for pre-treatment platelet count of < 20 x 10^9/L, platelet absolute increase of ≥ 20 x 10^9/L and ≥ 100% from pre-treatment level * HI-N- neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500 / mm^3
- No response (NR) / stable disease (SD) - does not meet the criteria for at least HI, but no evidence of disease progression
- Progression from hematologic improvement (Prog from HI) - requires at least one of the following, in the absence of another explanation (e.g., infection, bleeding, ongoing chemotherapy, etc.): * ≥ 50% reduction from maximum response levels in granulocytes or platelets * reduction in hemoglobin by ≥ 1.5 g/dL * transfusion dependence
- Relapse from complete remission (Rel from CR) - requires at least one of the following: * return to pre-treatment bone marrow blast percentage * decrease of ≥ 50% from maximum response levels in granulocytes or platelets * transfusion dependence, or hemoglobin level ≥ 1.5 g/dL lower than prior to therapy
- Not assessed

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158 Specify the cell line examined to determine HI status

- HI-E - hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in 8 weeks
- HI-P - for pre-treatment platelet count of > 20 x 10^9/L, platelet absolute increase of ≥ 30 x 10^9 /L; for pre-treatment platelet count of < 20 x 10^9 /L, platelet absolute increase of ≥ 20x 10^9 /L and ≥ 100% from pre-treatment level
- HI-N - neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500 / mm^3

159 Date of progression: __ __ __ __ - __ __- __ __

160 Date of relapse: __ __ __ __ - __ __- __ __

161 Date assessed: __ __ __ __ - __ __- __ __

First Name: _____

Last Name: _____

E-mail address: _____

Date: __ __ __ __ - __ __- __ __

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