CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Acute Myelogenous Leukemia (AML) Pre-Infusion Data

Registry Use Only
Sequence Number:

Date Received:

CIBMTR Center Number: ___ ___ ___ ___ ___

CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Event date: __ __ __ __ / __ __ / __ __
YYYY MM DD

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Subsequent Transplant or Cellular Therapy

If this is a report of a second or subsequent transplant or cellular therapy for the same disease subtype and this baseline disease insert has not been completed for the previous transplant (e.g. patient was on TED track for the prior HCT, prior HCT was autologous with no consent, prior cellular therapy was not reported to the CIBMTR), mark "No" and begin the form at question one.

If this is a report of a second or subsequent transplant or cellular therapy for a different disease, mark "no" and begin the form at question one.

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

☐ Yes - ***Go to question 32***

☐ No - ***Go to question 1***

Disease Assessment at Diagnosis

1. Is the disease (AML) therapy related? (not MDS / MPN)

☐ Yes → 2. Specify prior disease:

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

3. Specify other prior disease: _____

4. Date of diagnosis of prior disease

- ☐ Known → 5. Date of diagnosis of prior disease: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ Unknown

Specify therapy for prior disease:

6. Cytotoxic therapy ☐ Yes ☐ No ☐ Unknown
7. Radiation ☐ Yes ☐ No ☐ Unknown
8. Other therapy (e.g. immunotherapy, cellular therapy, etc.)
   - ☐ Yes → 9. Specify other therapy:_____
   - ☐ No
   - ☐ Unknown

☐ No

☐ Unknown

10. Did the recipient have a documented antecedent hematologic disorder (myelodysplastic syndrome or myeloproliferative neoplasm)?

☐ Yes →

11. What was the date of diagnosis of antecedent hematologic disorder? __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

12. What was the classification of the antecedent hematologic disorder at diagnosis?

- ☐ 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)

☐ No

☐ Unknown

☐ 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)

☐ Juvenile myelomonocytic leukemia (JMML, JCML, JCMML) (no evidence of Ph1 or BCR/ABL) (36) **- Also complete CIBMTR Form 2015 - JMML**

☐ Atypical chronic myeloid leukemia, Ph-/bcr/abl- (CML, NOS) (45)

☐ Atypical chronic myeloid leukemia, Ph-/bcr unknown (CML, NOS) (46)

☐ Atypical chronic myeloid leukemia, Ph unknown/bcr - (CML, NOS) (48)

☐ Atypical chronic myeloid leukemia, Ph unknown/bcr unknown (CML, NOS) (49)

☐ Myelodysplastic / myeloproliferative neoplasm, unclassifiable (69) **- Also complete CIBMTR Form 2014 - MDS/MPN**

☐ Aplastic anemia (300) **- Also complete CIBMTR Form 2028 - APL**

☐ Fanconi anemia (311) **- Also complete CIBMTR Form 2029 - FA**

☐ Shwachman-Diamond (305)

☐ Diamond-Blackfan anemia (pure red cell aplasia) (312)

☐ Dyskeratosis congenita (307)

☐ Other antecedent hematologic disorder →

13. Specify other antecedent hematologic disorder: _____

Laboratory Studies at Diagnosis

Report findings at diagnosis of AML, prior to any first treatment:

14. WBC:

☐ Known →

☐ Unknown

15. ___ ___ ___ ___ ___ ___ • ___ ☐ x 10^9/L (x 10^3/mm^3) ☐ x 10^6/L

16. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

17. Blasts in blood:

☐ Known →

☐ Unknown

18. ___ ___ ___ %

19. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

20. Blasts in bone marrow:

☐ Known →

☐ Unknown

21. ___ ___ ___ %

22. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

23. Was extramedullary disease present?
- ☐ Yes →
- ☐ No
- ☐ Unknown

Specify site(s) of disease:

24. Central nervous system
- ☐ Yes →
- ☐ No

25. Cerebrospinal fluid (CSF) ☐ Yes ☐ No

26. Parenchyma (brain) ☐ Yes ☐ No

27. Skin ☐ Yes ☐ No

28. Soft tissue (soft tissue mass / granulocytic sarcoma) ☐ Yes ☐ No

29. Testes / ovaries ☐ Yes ☐ No

30. Other site
- ☐ Yes →
- ☐ No

31. Specify other site: _____

Pre-HCT or Pre-Infusion Therapy

32. Was therapy given?
- ☐ Yes →
- ☐ No

Line of Therapy:

33. Purpose of therapy
☐ Induction ☐ Consolidation ☐ Maintenance ☐ Treatment for disease relapse

34. Intrathecal therapy ☐ Yes ☐ No

35 Systemic therapy
- ☐ Yes →
- ☐ No

36. Date therapy started:
- ☐ Known →
- ☐ Unknown

37. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

38. Date therapy stopped:
- ☐ Known →
- ☐ Unknown

39. Date stopped: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

40. Number of cycles:
- ☐ Known →
- ☐ Unknown
- ☐ Not applicable

41. Number of cycles: ___ ___

42. Specify systemic therapy: (check all that apply for this line of therapy)

- ☐ Azacytidine (Vidaza) ***- Go to question 43***
- ☐ All-trans retinoic acid (Tretinoin)
- ☐ Arsenic
- ☐ Cladribine (2-CDA, Leustatin)
- ☐ Clofarabine
- ☐ Cytarabine (Ara - C) ≤ 10 g/m2/cycle
- ☐ Cytarabine (Ara – C) > 10 g/m2/cycle
- ☐ Daunorubicin (Cerubidine)
- ☐ Decitabine (Dacogen) ***- Go to question 44***
- ☐ Etoposide (VP-16, VePesid)
- ☐ Fludarabine (Fludara)
- ☐ Gemtuzumab (Mylotarg)
- ☐ Idarubicin (Idamycin)
- ☐ Midostaurin
- ☐ Mitoxantrone (Novantrone)
- ☐ Sorafenib ***- Go to question 45***
- ☐ Thioguanine (6-TG)
- ☐ Other systemic therapy ***- Go to question 46***

43. Specify months of therapy:

___ ___ (Azacytidine (Vidaza))

44. Specify months of therapy:

___ ___ (Decitabine (Dacogen))

45. Specify months of therapy:

___ ___ (Sorafenib)

46. Specify other systemic therapy: _____

47. Radiation therapy:

- ☐ Yes →
- ☐ No

48. Date therapy started:

- ☐ Known →
- ☐ Unknown

49. Date started:

__ __ __ __ / __ __ / __ __
YYYY MM DD

50. Date therapy stopped:

- ☐ Known →
- ☐ Unknown

51. Date stopped:

__ __ __ __ / __ __ / __ __
YYYY MM DD

Specify site(s) of radiation therapy:

52. Central nervous system ☐ Yes ☐ No

53. Other site
☐ Yes → 54. Specify other site: _____
☐ No

55. Cellular therapy ☐ Yes ☐ No

56. Best response to line of therapy:
☐ Complete remission (CR) **– All of the following response criteria without progression for at least four weeks: < 5% blasts in the bone marrow, no blasts with Auer rods, no extramedullary disease (e.g., central nervous system or soft tissue involvement), ANC of ≥ 1,000/µL, Platelets ≥ 100,000/µL.**
☐ Complete remission with incomplete hematologic recovery (CRi) **– All CR criteria except for residual neutropenia (<1000/µl) and/or thrombocytopenia (<100,000/µl)**
☐ No complete remission

57. Date assessed: __ __ __ __ / __ __ / __ __
YYYY MM DD

58. Was the recipient MRD negative following this line of therapy? ☐ Yes ☐ No

59. Did the recipient relapse following this line of therapy?
☐ Yes →
☐ No

60. Date of relapse: __ __ __ __ / __ __ / __ __
YYYY MM DD

Specify site(s) of disease relapse:

61. Central nervous system
☐ Yes →
☐ No

62. Cerebrospinal fluid (CSF) ☐ Yes ☐ No

63. Parenchyma (brain) ☐ Yes ☐ No

64. Skin ☐ Yes ☐ No

65. Soft tissue (soft tissue mass / granulocytic sarcoma) ☐ Yes ☐ No

66. Testes / ovaries ☐ Yes ☐ No

67. Other site
☐ Yes → 68. Specify othe site: _____
☐ No

Copy questions 33-68 if needed for multiple lines of therapy.

CIBMTR Center Number: ___ ___ ___ ___ ___ CIBMTR Research ID: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Laboratory Studies At Last Evaluation Prior to the Start of the Preparative Regimen / Infusion

69. WBC:
- ☐ Known →
- ☐ Unknown

70. ___ ___ ___ ___ ___ ___ • ___ ☐ x 10^9/L (x 10^3/mm^3) ☐ x 10^6/L

71. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

72. Blasts in blood:
- ☐ Known →
- ☐ Unknown

73. ___ ___ ___ %

74. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

75. Blasts in bone marrow:
- ☐ Known →
- ☐ Unknown

76. ___ ___ ___ %

77. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

78. Specify method of assessment ☐ Flow cytometry ☐ Morphology

79. Was flow cytometry performed?
- ☐ Yes →
- ☐ No
- ☐ Unknown

Specify tissue and results at last evaluation prior to the start of the preparative regimen / infusion:

80. Blood
- ☐ Yes →
- ☐ No

81. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

82. Was disease detected?
- ☐ yes →
- ☐ No

83. Specify percent disease detected:
___ ___ • ___ ___ ___ %

84. Bone marrow
- ☐ Yes →
- ☐ No

85. Date sample collected: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

86. Was disease detected?
- ☐ yes →
- ☐ No

87. Specify percent disease detected:
___ ___ • ___ ___ ___ %

88. Was extramedullary disease present?

☐ Yes → **Specify site(s) of disease:**

☐ No

☐ Unknown

89. Central nervous system

☐ Yes →

☐ No

90. Cerebrospinal fluid (CSF) ☐ Yes ☐ No

91. Parenchyma (brain) ☐ Yes ☐ No

92. Skin ☐ Yes ☐ No

93. Soft tissue (soft tissue mass / granulocytic sarcoma) ☐ Yes ☐ No

94. Testes / ovaries ☐ Yes ☐ No

95. Other site

☐ Yes →

☐ No - **Go to First Name**

96. Specify other site: _____

First Name: _____

Last Name: _____

E-mail address: _____

Date: __ __ __ __ / __ __ / __ __
YYYY MM DD