ERROR CORRECTION FORM

Sequence Number: | CIBMTR Recipient ID: | Initials:

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

CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Acute Lymphoblastic Leukemia Pre-HSCT Data

Registry Use Only

Sequence Number:

Date Received:

CIBMTR Center Number:

CIBMTR Recipient ID:

Today's Date: Month / Day / Year 20__

Date of HSCT for which this form is being completed: 📖 Month / Day / Year 20__

HSCT type: ☐ autologous ☐ allogeneic, unrelated ☐ allogeneic, related ☐ syngeneic (identical twin)

Product type: ☐ marrow ☐ PBSC ☐ cord blood ☐ other product, specify: ______

This form must be accompanied by Form 2000 – Recipient Baseline Data. All information in the box above, including the date, should be identical with the corresponding Form 2000. Information should come from an actual examination by the Transplant Center physician, or the physician who is following the recipient pre-HSCT, or abstraction of the recipient's medical records.

Questions followed by the symbol 📖 indicate additional information necessary to complete the question is referenced in the forms instruction manual.

If this is a report of a second or subsequent transplant, check here ☐ and continue with question 121.

Disease Assessment at Diagnosis

1. What was the date of diagnosis of Acute Lymphoblastic Leukemia? Month / Day / Year

2. Did the recipient have a predisposing condition prior to the diagnosis of leukemia?
   - 1 ☐ yes →
   - 2 ☐ no

   3. Specify condition:
      - 1 ☐ aplastic anemia → **Also complete CIBMTR Form 2028 — APL**
      - 2 ☐ Bloom syndrome
      - 3 ☐ Down syndrome
      - 4 ☐ Fanconi anemia → **Also complete CIBMTR Form 2029 — FAN**
      - 5 ☐ other condition → 4. Specify condition: ______

5. Was extramedullary disease present at diagnosis?
   - 1 ☐ yes →
   - 2 ☐ no

   Specify site(s) of disease:

   6. 1 ☐ yes 2 ☐ no Central nervous system (CNS)
   7. 1 ☐ yes 2 ☐ no Mediastinum
   8. 1 ☐ yes 2 ☐ no Testes
   9. 1 ☐ yes 2 ☐ no Other site → 10. Specify site: ______

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Mail this form to your designated campus (Milwaukee or Minneapolis). Retain the original at the transplant center.

Fax this form to your designated campus (Milwaukee 414-456-6165 or Minneapolis 612-627-5895).

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Laboratory Studies at Diagnosis

11. Were cytogenetics tested (conventional or FISH)?
   1 ☐ yes →
   2 ☐ no
   3 ☐ unknown

12. Results of test at diagnosis:
   1 ☐ yes abnormalities identified → **Complete questions 14–38 in the table below**
   2 ☐ no evaluable metaphases
   3 ☐ no abnormalities

13. Results of tests after diagnosis to prior to the preparative regimen:
   1 ☐ yes abnormalities identified → **Complete questions 39–63 in the table below**
   2 ☐ no evaluable metaphases on any tests
   3 ☐ no abnormalities on any tests after diagnosis and before the preparative regimen

Specify abnormalities identified:

Cytogenetic abnormality	**At diagnosis**	**Any test result between diagnosis and preparative regimen**
Monosomy		
–7	14. 1 ☐ yes 2 ☐ no	39. 1 ☐ yes 2 ☐ no
Trisomy		
+4	15. 1 ☐ yes 2 ☐ no	40. 1 ☐ yes 2 ☐ no
+8	16. 1 ☐ yes 2 ☐ no	41. 1 ☐ yes 2 ☐ no
+17	17. 1 ☐ yes 2 ☐ no	42. 1 ☐ yes 2 ☐ no
+21	18. 1 ☐ yes 2 ☐ no	43. 1 ☐ yes 2 ☐ no
Translocation		
t(1;19)	19. 1 ☐ yes 2 ☐ no	44. 1 ☐ yes 2 ☐ no
t(4;11)	20. 1 ☐ yes 2 ☐ no	45. 1 ☐ yes 2 ☐ no
t(5;17)	21. 1 ☐ yes 2 ☐ no	46. 1 ☐ yes 2 ☐ no
t(8;14)	22. 1 ☐ yes 2 ☐ no	47. 1 ☐ yes 2 ☐ no
t(9;22)	23. 1 ☐ yes 2 ☐ no	48. 1 ☐ yes 2 ☐ no
translocation 9p	24. 1 ☐ yes 2 ☐ no	49. 1 ☐ yes 2 ☐ no
t(10;14)	25. 1 ☐ yes 2 ☐ no	50. 1 ☐ yes 2 ☐ no
t(11;14)	26. 1 ☐ yes 2 ☐ no	51. 1 ☐ yes 2 ☐ no
t(v;11q23)	27. 1 ☐ yes 2 ☐ no	52. 1 ☐ yes 2 ☐ no
t(12;21)	28. 1 ☐ yes 2 ☐ no	53. 1 ☐ yes 2 ☐ no
translocation 12p	29. 1 ☐ yes 2 ☐ no	54. 1 ☐ yes 2 ☐ no
Deletion		
del(6q) / 6q–	30. 1 ☐ yes 2 ☐ no	55. 1 ☐ yes 2 ☐ no
del(9p) / 9p–	31. 1 ☐ yes 2 ☐ no	56. 1 ☐ yes 2 ☐ no
del(12p) / 12p–	32. 1 ☐ yes 2 ☐ no	57. 1 ☐ yes 2 ☐ no
Addition		
add(14q)	33. 1 ☐ yes 2 ☐ no	58. 1 ☐ yes 2 ☐ no
Other		
hyperdiploid (> 50)	34. 1 ☐ yes 2 ☐ no	59. 1 ☐ yes 2 ☐ no
hypodiploid (< 46)	35. 1 ☐ yes 2 ☐ no	60. 1 ☐ yes 2 ☐ no
complex (≥ 3 distinct abnormalities)	36. 1 ☐ yes 2 ☐ no	61. 1 ☐ yes 2 ☐ no
other abnormality	37. 1 ☐ yes 2 ☐ no	62. 1 ☐ yes 2 ☐ no
specify other abnormality:	38. ____________	63. ____________

64. Is a copy of the cytogenetic or FISH report attached?
   1 ☐ yes
   2 ☐ no

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Pre-HSCT Treatment for Acute Lymphoblastic Leukemia

65. Was central nervous system prophylaxis given at any time prior to the preparative regimen?
 1 ☐ yes →
 2 ☐ no

Specify prophylaxis:

66. 1 ☐ yes 2 ☐ no Cranial irradiation
67. 1 ☐ yes 2 ☐ no High-dose cytarabine
68. 1 ☐ yes 2 ☐ no Intrathecal chemotherapy
69. 1 ☐ yes 2 ☐ no Spinal irradiation
70. 1 ☐ yes 2 ☐ no Other prophylaxis → 71. Specify prophylaxis: ____________

72. Was therapy given between diagnosis and the start of the preparative regimen? 📖
 1 ☐ yes →
 2 ☐ no

Line of Therapy:	1st Line of Therapy	2nd Line of Therapy
Purpose of therapy:	73. 1 ☐ induction 2 ☐ consolidation 3 ☐ maintenance 4 ☐ treatment for relapse	97. 1 ☐ induction 2 ☐ consolidation 3 ☐ maintenance 4 ☐ treatment for relapse
Systemic / Intrathecal Therapy:	74. 1 ☐ yes 2 ☐ no → cont. with q. 87	98. 1 ☐ yes 2 ☐ no → cont. with q. 111
Date therapy started:	75. ☐☐ Month ☐☐ Day ☐☐☐☐ Year	99. ☐☐ Month ☐☐ Day ☐☐☐☐ Year
Date therapy stopped:	76. ☐☐ Month ☐☐ Day ☐☐☐☐ Year	100. ☐☐ Month ☐☐ Day ☐☐☐☐ Year
Number of cycles:	77. ☐☐ ☐ unknown/not applicable	101. ☐☐ ☐ unknown/not applicable
aldesleukin (IL-2)	78. 1 ☐ yes 2 ☐ no	102. 1 ☐ yes 2 ☐ no
chemotherapy	79. 1 ☐ yes 2 ☐ no	103. 1 ☐ yes 2 ☐ no
dasatinib (Sprycel)	80. 1 ☐ yes 2 ☐ no	104. 1 ☐ yes 2 ☐ no
imatinib (Gleevec)	81. 1 ☐ yes 2 ☐ no	105. 1 ☐ yes 2 ☐ no
interferon-α (Referon-α)	82. 1 ☐ yes 2 ☐ no	106. 1 ☐ yes 2 ☐ no
intrathecal drugs	83. 1 ☐ yes 2 ☐ no	107. 1 ☐ yes 2 ☐ no
nilotinib (AMN107, Tasigna)	84. 1 ☐ yes 2 ☐ no	108. 1 ☐ yes 2 ☐ no
other therapy	85. 1 ☐ yes 2 ☐ no	109. 1 ☐ yes 2 ☐ no
specify other therapy	86. ____________	110. ____________
Radiation Therapy:	87. 1 ☐ yes 2 ☐ no → cont. with q. 93	111. 1 ☐ yes 2 ☐ no → cont. with q. 117
Date therapy started:	88. ☐☐ Month ☐☐ Day ☐☐☐☐ Year	112. ☐☐ Month ☐☐ Day ☐☐☐☐ Year
Date therapy stopped:	89. ☐☐ Month ☐☐ Day ☐☐☐☐ Year	113. ☐☐ Month ☐☐ Day ☐☐☐☐ Year
central nervous system	90. 1 ☐ yes 2 ☐ no	114. 1 ☐ yes 2 ☐ no
other site	91. 1 ☐ yes 2 ☐ no	115. 1 ☐ yes 2 ☐ no
specify other site	92. ____________	116. ____________
Best Response to Line of Therapy:	93. 1 ☐ complete response 2 ☐ no complete response	117. 1 ☐ continuous complete response 2 ☐ complete response 3 ☐ no complete response
Date response established:	94. ☐☐ Month ☐☐ Day ☐☐☐☐ Year	118. ☐☐ Month ☐☐ Day ☐☐☐☐ Year
Did the recipient relapse following this line of therapy?	95. 1 ☐ yes 2 ☐ no	119. 1 ☐ yes 2 ☐ no
Date of relapse:	96. ☐☐ Month ☐☐ Day ☐☐☐☐ Year	120. ☐☐ Month ☐☐ Day ☐☐☐☐ Year

Copy this page to report more than 2 lines of therapy; check here ☐ if additional pages are attached.

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Infusion Date: Month __ Day __ Year 2 0 __ __

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Laboratory Studies Prior to the Start of the Preparative Regimen

Report findings prior to any first treatment of the primary disease for which the HSCT is being performed.

121. WBC:
- 1 ☐ known → ______ . __
- 2 ☐ not known

Specify units:
- 1 ☐ x 10^9/L (x 10^3/mm^3)
- 2 ☐ x 10^6/L

122. Blasts in blood:
- 1 ☐ known → ___ %
- 2 ☐ not known

123. Blasts in bone marrow:
- 1 ☐ known → ___ % → 124. Date of bone marrow examination: Month __ Day __ Year 2 0 __ __
- 2 ☐ not known

125. Were tests for BCR / ABL or other molecular markers performed at any time prior to the preparative regimen?
- 1 ☐ yes →
- 2 ☐ no

126. Was BCR / ABL testing performed?
- 1 ☐ yes →
- 2 ☐ no

127. Specify results:
- 1 ☐ positive
- 2 ☐ negative

128. Was TEL / AML / AML-1 testing performed?
- 1 ☐ yes →
- 2 ☐ no

129. Specify results:
- 1 ☐ positive
- 2 ☐ negative

130. Was any other molecular testing performed?
- 1 ☐ yes →
- 2 ☐ no

131. Specify test: ______________

132. Specify results:
- 1 ☐ positive
- 2 ☐ negative

133. Did the recipient have central nervous system leukemia at any time or immediately prior to the preparative regimen?
- 1 ☐ yes →
- 2 ☐ no
- 3 ☐ unknown

Specify treatment(s) given:

134. 1 ☐ yes 2 ☐ no No treatment

135. 1 ☐ yes 2 ☐ no Cranial irradiation

136. 1 ☐ yes 2 ☐ no High-dose cytarabine

137. 1 ☐ yes 2 ☐ no Intrathecal chemotherapy

138. 1 ☐ yes 2 ☐ no Spinal irradiation

139. 1 ☐ yes 2 ☐ no Other treatment → 140. Specify treatment: ______________

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Infusion Date: __ __ (Month) __ __ (Day) 2 0 __ __ (Year)

CIBMTR Center Number: ______

CIBMTR Center Number: ______ CIBMTR Recipient ID: ______________

Disease Status at the Last Assessment Prior to the Preparative Regimen

141. What was the status of ALL (based on hematological test results) at the last evaluation prior to the preparative regimen?

1 ☐ 1st complete remission (no previous marrow or extramedullary relapse) →
2 ☐ 2nd complete remission →
3 ☐ ≥ 3rd complete remission →

> 142. Was the recipient in cytogenetic remission?
> 1 ☐ yes
> 2 ☐ no
> 3 ☐ unknown
>
> 143. Was the recipient in molecular remission?
> 1 ☐ yes
> 2 ☐ no
> 3 ☐ unknown

4 ☐ primary induction failure →
5 ☐ 1st relapse →
6 ☐ 2nd relapse →
7 ☐ ≥ 3rd relapse →
8 ☐ no treatment

> Specify site(s) of active leukemia immediately prior to the preparative regimen:
>
> 144. 1 ☐ yes 2 ☐ no Bone marrow
> 145. 1 ☐ yes 2 ☐ no Central nervous system
> 146. 1 ☐ yes 2 ☐ no Cytogenetic / FISH test results
> 147. 1 ☐ yes 2 ☐ no Molecular test results
> 148. 1 ☐ yes 2 ☐ no Testes
> 149. 1 ☐ yes 2 ☐ no Other site → 150. Specify site: ______________

151. Date of the most recent assessment for disease status prior to the preparative regimen: __ __ (Month) __ __ (Day) 2 0 __ __ (Year)

152. Signed: ______________________________

Person completing form

Please print name: ______________________________

Phone: (________) ______________________________

Fax: (________) ______________________________

E-mail address: ______________________________

CIBMTR Form 2011 (ALL) v1.0 (5–5) July 2007

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