CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Cellular Therapy Essential Data Pre-Infusion Form

Registry Use Only
Sequence Number:

Date Received:

CIBMTR Center Number: ___ ___ ___ ___ ___

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

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

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

Recipient Data

This form must be completed for all recipients of non-HCT cellular products. For recipients of hematopoietic cell transplants, complete a form 2400 – Pre-Transplant Essential Data.

This form reflects baseline recipient data for one course of cellular therapy.

1. Ethnicity

☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Not applicable (not a resident of the USA) ☐ Unknown

2. Race : (check all that apply)

☐ White ☐ Black or African American ☐ Asian ☐ American Indian or Alaska Native

☐ Native Hawaiian or Other Pacific Islander ☐ Not reported ☐ Unknown

3. Has the recipient signed an IRB / Ethics Committee-approved consent form for submitting research data to the CIBMTR?

☐ Yes (patient consented) →

☐ No (patient declined)

☐ Not approached

☐ Not applicable

4. Date form was signed: __ __ __ __ / __ __ / __ __
YYYY MM DD

5. Is the recipient participating in a cellular therapy clinical trial?

☐ Yes →

☐ No

Copy and complete questions 6-11 to report participation in more than one clinical trial

6. Study sponsor:

☐ BMT CTN ***- Go to question 11***

☐ COG ***- Go to question 11***

☐ Corporate / Industry ***- Go to question 7***

☐ EudraCT ***- Go to question 8***

☐ Investigator initiated ***- Go to question 11***

☐ RCI BMT ***- Go to question 11***

☐ USIDNET ***- Go to question 11***

☐ UMIN ***- Go to question 9***

☐ Other ***- Go to question 10***

7. Specify corporate / industry sponsor name: _____ ***- Go to question 11***

8. Specify EudraCT number: _____ ***- Go to question 12***

9. Specify UMIN number: _____ ***- Go to question 12***

10. Specify other sponsor: _____ ***- Go to question 11***

11. Specify the ClinicalTrials.gov identification number: _____ ***- Go to question 14***

12. Is the recipient receiving cellular therapy outside the context of a clinical trial?

☐ Yes →

☐ No

13. Specify the reason for not being on a clinical trial (check all that apply)

☐ Institutional guidelines / standard treatment

☐ Hospital exemption

☐ Compassionate use

Cellular Therapy and HCT History

14. Is this the first application of cellular therapy (non-HCT)?
- ☐ Yes
- ☐ No (recipient has previously been treated using cellular therapy) →
- ☐ Unknown

15. Were all prior cellular therapies (non-HCT) reported to the CIBMTR?
- ☐ Yes
- ☐ No →
- ☐ Unknown

16. Specify the number of prior cellular therapies: ___ ___

Copy and complete questions 17-22 to report all prior cellular therapies that have not yet been reported to the CIBMTR

17. Date of the prior cellular therapy: __ __ __ __ / __ __ / __ __ ☐ Date estimated
YYYY MM DD

18. Was the cellular therapy performed at a different institution?
- ☐ Yes →
- ☐ No

Specify the institution that performed the prior cellular therapy:

19. Name: _____

City: _____

State: _____

Country: _____

20. Specify the indication for the prior cellular therapy
- ☐ Promote stem cell engraftment (e.g. co-infusion with HCT)
- ☐ Suboptimal donor chimerism (post-HCT)
- ☐ Immune reconstitution (post-HCT)
- ☐ GVHD prophylaxis (with HCT)
- ☐ GVHD treatment (post-HCT)
- ☐ Prevent disease relapse (post-HCT)
- ☐ Relapsed, persistent or progressive disease (post-HCT)
- ☐ Infection treatment
- ☐ Infection prophylaxis
- ☐ B cell lymphoproliferative disorder (PTLD, EBV lymphoma)
- ☐ Autoimmune disease
- ☐ Cardiovascular disease
- ☐ Musculoskeletal disorder
- ☐ Neurologic disease
- ☐ Ocular disease
- ☐ Pulmonary disease
- ☐ Solid tumor
- ☐ Malignant hematologic disorder
- ☐ Non-malignant disorder
- ☐ Unknown
- ☐ Other indication ***- Go to question 21***

21. Specify other indication: _____

22. What was the cell source for the prior cellular therapy? (check all that apply)
☐ Autologous ☐ Allogeneic, unrelated ☐ Allogeneic, related

HCT History

23. Has the recipient ever had a prior HCT?
☐ Yes →
☐ No
☐ Unknown

24. Were all prior HCTs reported to the CIBMTR?
☐ Yes
☐ No →
☐ Unknown

Copy and complete questions 25-28 to report all prior HCTs that have not yet been reported to the CIBMTR:

25. Date of the prior HCT: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

26. Was the HCT performed at a different institution?
☐ Yes →
☐ No

Specify the institution that performed the prior HCT:

27. Name: _____
City: _____
State: _____
Country: _____

28. What was the cell source for the prior cellular therapy? (check all that apply)
☐ Autologous ☐ Allogeneic, unrelated ☐ Allogeneic, related

Product Identification

29. Specify the total number of products: __ __ (per protocol) (as part of this course of cellular therapy)

30. Is the product genetically modified? ☐ Yes ☐ No

Copy and complete questions 31-43 to report all donors used for these infusions:

31. Specify the cell source
☐ Autologous ***- Go to question 34***
☐ Allogeneic, unrelated ***- Go to question 33***
☐ Allogeneic, related ***- Go to question 32***

32. Specify the related donor type
- ☐ Syngeneic (monozygotic twin)
- ☐ HLA-identical sibling (may include non-monozygotic twin)
- ☐ HLA-matched other relative
- ☐ HLA-mismatched relative

33. Was this donor used for any prior cellular therapies or HCT? (for this recipient)
- ☐ Yes ☐ No ☐ Unknown

34. What is the tissue source of the cellular product? (check all that apply)
- ☐ Bone marrow
- ☐ Cord blood unit
- ☐ Peripheral blood
- ☐ Adipose tissue
- ☐ Amniotic fluid
- ☐ Cardiac tissue
- ☐ Hepatic tissue
- ☐ Neuronal tissue
- ☐ Ophthalmic tissue
- ☐ Pancreatic tissue
- ☐ Placenta
- ☐ Tumor
- ☐ Umbilical cord
- ☐ Other tissue source → 35. Specify other tissue source:_____
- ☐ Unknown

36. What is the cell type? (check all that apply)
- ☐ Lymphocytes (unselected)
- ☐ CD4+ lymphocytes
- ☐ CD8+ lymphocytes
- ☐ Cytotoxic T lymphocytes (CTLs)
- ☐ Natural killer cells (NK cells)
- ☐ Dendritic cells / tumor cell hybridomas (tumor vaccines)
- ☐ Mesenchymal stromal stem cells (MSCs)
- ☐ Unspecified mononuclear cells
- ☐ Endothelial progenitor cells
- ☐ Human umbilical cord perivascular (HUCPV) cells
- ☐ Cardiac progenitor cells
- ☐ Islet cells
- ☐ Oligodendrocytes
- ☐ Other cell type → 37. Specify other cell type:_____

38. Where was the cellular therapy product manufactured / processed?

- ☐ Pharmaceutical / biotech company ***- Go to question 40***
- ☐ Cell processing laboratory off site ***- Go to question 41***
- ☐ Cell processing laboratory at the same center as the product is being infused ***- Go to question 44***
- ☐ Other site ***- Go to question 39***

39. Specify other site: _____ ***- Go to question 41***

40. Specify pharmaceutical / biotech company

- ☐ Atara Biotherapeutics ***- Go to question 44***
- ☐ Bellicum Pharmaceuticals ***- Go to question 44***
- ☐ Bluebird Bio ***- Go to question 42***
- ☐ Celgene ***- Go to question 42***
- ☐ Juno Therapeutics ***- Go to question 42***
- ☐ Kite Pharma ***- Go to question 42***
- ☐ Mesoblast ***- Go to question 44***
- ☐ Novartis ***- Go to question 42***
- ☐ Other pharmaceutical company →

Specify the institution / company where the cellular product was manufactured:

41. Name: _____
City: _____
State: _____
Country: _____
- Go to question 44

42. Name of product

- ☐ Tisagenlecleucel (Kymriah®)
- ☐ Axicabtagene Ciloleucel (Yescarta®)
- ☐ Other product →

43. Specify other product: _____

Planned HCT

44. Is a subsequent HCT part of the overall treatment protocol?

- ☐ Yes →
- ☐ No

45. Specify the HCT type ☐ Autologous ☐ Allogeneic

46. Specify the circumstances in which the subsequent HCT will be performed

- ☐ Regardless of response to cellular therapy
- ☐ Only if the patient responds to cellular therapy
- ☐ Only if the patient fails to respond or has an incomplete response

Indication for Cellular Therapy

47. Is the cellular therapy being given for prevention?

☐ Yes →
☐ No

48. Reason for prevention
- ☐ GVHD prophylaxis (with HCT) ***- Go to question 94***
- ☐ Prevent disease relapse (post-HCT) ***- Go to question 94***
- ☐ Infection prophylaxis ***- Go to question 61***

49. What was the indication for performing treatment with cellular therapy?
- ☐ Suboptimal donor chimerism (post-HCT) ***- Go to question 94***
- ☐ Immune reconstitution (post-HCT) ***- Go to question 94***
- ☐ GVHD treatment (post-HCT) ***- Go to question 94***
- ☐ Malignant hematologic disorder **– Also complete CIBMTR Form 2402** ***- Go to question 68***
- ☐ Non-malignant disorder **– Also complete CIBMTR Form 2402*** ***- Go to question 94***
- ☐ Solid tumor **- Also complete CIBMTR Form 2402** ***- Go to question 94***
- ☐ Cardiovascular disease ***- Go to question 50***
- ☐ Musculoskeletal disorder ***- Go to question 50***
- ☐ Neurologic disease ***- Go to question 50***
- ☐ Ocular disease ***- Go to question 50***
- ☐ Pulmonary disease ***- Go to question 50***
- ☐ Infection treatment ***- Go to question 50***
- ☐ Other indication ***- Go to question 50***

50. Date of diagnosis: __ __ __ __ / __ __ / __ __
YYYY MM DD

Infection treatment - Go to question 61
Cardiovascular disease - Go to question 51
Musculoskeletal disorder - Go to question 54
Neurologic disease - Go to question 56
Ocular disease - Go to question 58
Pulmonary disease - Go to question 59
Other disease - Go to question 60

Cardiovascular disease

51. Specify cardiovascular disease
- ☐ AMI, acute myocardial infarction (701)
- ☐ Chronic coronary artery disease (ischemic, cardiomyopathy) (702)
- ☐ Heart failure (non-ischemic etiology) (703)
- ☐ Other cardiovascular disease (709)

→ 52. Specify other cardiovascular disease: _____
- Go to questions 94

- ☐ Limb ischemia (710)
- ☐ Thromboangitis obliterans (711)
- ☐ Other peripheral vascular disease (719)

→ 53. Specify other peripheral vascular disease: _____
- Go to questions 94

Musculoskeletal

54. Specify musculoskeletal disorder

- ☐ Avascular necrosis of femoral head (721)
- ☐ Osteoarthritis (722)
- ☐ Osteogenesis imperfecta (723)
- ☐ Traumatic joint injury (724)
- ☐ Other musculoskeletal disorder (729)

→ 55. Specify other musculoskeletal disorder: _____
- Go to questions 94

Neurologic Disease

56. Specify neurologic disease

- ☐ Acute cerebral vascular ischemia (731)
- ☐ ALS, amiotrophic lateral sclerosis (732)
- ☐ Parkinson disease (733)
- ☐ Spinal cord injury (734)
- ☐ Cerebral palsy (753)
- ☐ Congenital hydrocephalus (754)
- ☐ Myasthenia gravis (601)
- ☐ Duchenne muscular dystrophy (735)
- ☐ Other neurologic disease (749)

→ 57. Specify other neurologic disease: _____
- Go to questions 94

Ocular

58. Specify ocular disease:_____ ***- Go to question 94***

Pulmonary

59. Specify pulmonary disease: _____ ***- Go to question 94***

Other

60. Specify other indication: _____ ***- Go to question 94***

Infection

Specify organism code(s):

61. ___ ___ ___
62. ___ ___ ___
63. ___ ___ ___
64. ___ ___ ___
65. ___ ___ ___
66. ___ ___ ___
67. Specify other organism: _____ ***- Go to question 94***

Disease Assessment at Last Evaluation Prior to Cellular Therapy

Specify the method(s) of disease detection below. For each method used, if the result was positive report the first date the disease was detected; if the result was negative report the last date the method was used prior to cellular therapy.

68. Was the disease assessed prior to the cellular therapy?
- ☐ Yes →
- ☐ No

69. Was the disease status assessed by molecular testing (e.g. PCR)?
- ☐ Yes →
- ☐ No
- ☐ Not applicable

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

71. Was disease detected?
- ☐ Yes →
- ☐ No

72. Was the status considered a disease relapse or progression?
☐ Yes ☐ No

73. Was the disease status assessed via flow cytometry? (immunophenotyping)
- ☐ Yes →
- ☐ No
- ☐ Not applicable

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

75. Was disease detected?
- ☐ Yes →
- ☐ No

76. Was the status considered a disease relapse or progression?
☐ Yes ☐ No

77. Was the disease status assessed by cytogenetic testing (karyotyping or FISH)?
- ☐ Yes →
- ☐ No
- ☐ Not applicable

78. Was the disease status assessed via karyotyping?
- ☐ Yes →
- ☐ No
- ☐ Not applicable

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

80. Was disease detected?
- ☐ Yes →
- ☐ No

81. Was the status considered a disease relapse or progression?
☐ Yes ☐ No

82. Was the disease status assessed via FISH?
- ☐ Yes →
- ☐ No
- ☐ Not applicable

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

84. Was disease detected?
- ☐ Yes →
- ☐ No

85. Was the status considered a disease relapse or progression?
☐ Yes ☐ No

86. Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)
- ☐ Yes →
- ☐ No
- ☐ Not applicable

87. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

88. Was disease detected? ☐ Yes ☐ No

89. Was the disease status assessed by clinical / hematologic assessment?
- ☐ Yes →
- ☐ No

90. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

91. Was disease detected? ☐ Yes ☐ No

92. What was the recipient's disease status immediately prior to the cellular therapy?
☐ Complete remission (CR) ☐ Not in complete remission

93. Date assessed: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)

Systemic Therapy Prior to Cellular Therapy

94. Was systemic therapy given immediately prior to cellular therapy as part of the cellular therapy protocol?
- ☐ Yes →
- ☐ No

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

96. Specify the reason for which the systemic therapy was given per protocol
- ☐ Lympho-depleting therapy
- ☐ Reduction of tumor burden
- ☐ Other reason →

97. Specify other reason: _____

98. ALG, ALS, ATG, ATS
- ☐ Yes →
  - 99. Total dose ___ ___ ___ ___ mg
  - 100. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
  - 101. Specify source
    - ☐ ATGAM (horse)
    - ☐ ATG – Fresenius (rabbit)
    - ☐ Thymoglobulin (rabbit)
    - ☐ Other →
      - 102. Specify other source: _____
- ☐ No

103. Anthracycline
- ☐ Yes →
  - 104. Daunorubicin (Cerubidine)
    - ☐ Yes →
      - 105. Total dose ___ ___ ___ ___ mg
      - 106. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
    - ☐ No
  - 107. Doxorubicin (Adriamycin)
    - ☐ Yes →
      - 108. Total dose ___ ___ ___ ___ mg
      - 109. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
    - ☐ No
  - 110. Idarubicin (Idamycin)
    - ☐ Yes →
      - 111. Total dose ___ ___ ___ ___ mg
      - 112. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
    - ☐ No
  - 113. Rubidazone
    - ☐ Yes →
      - 114. Total dose ___ ___ ___ ___ mg
      - 115. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
    - ☐ No
  - 116. Other anthracycline
    - ☐ Yes →
      - 117. Specify other anthracycline: _____
      - 118. Total dose ___ ___ ___ ___ mg
      - 119. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
    - ☐ No
- ☐ No

120. Bleomycin (BLM, Blenoxane)

☐ Yes → 121. Total dose ___ ___ ___ ___ mg

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

☐ No

123. Busulfan (Myleran)

☐ Yes → 124. Total dose ___ ___ ___ ___ mg

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

126. Specify administration: ☐ Oral ☐ IV ☐ Both

☐ No

127. Carboplatin

☐ Yes → 128. Total dose ___ ___ ___ ___ mg

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

130. Were pharmacokinetics performed to determine drug dosing?

☐ Yes → 131. Specify the target AUC: ___ ___ ___mg/mL/minute

☐ No

☐ No

132. Cisplatin (Platinol, CDDP)

☐ Yes → 133. Total dose ___ ___ ___ ___ mg

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

☐ No

135. Cladribine (2-CdA, Leustatin)

☐ Yes → 136. Total dose ___ ___ ___ ___ mg

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

☐ No

138. Corticosteroids

☐ Yes →

139. Methylprednisolone (Solu-Medrol)

☐ Yes → 140. Total dose ___ ___ ___ ___ mg

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

☐ No

142. Prednisone

☐ Yes → 143. Total dose ___ ___ ___ ___ mg

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

☐ No

☐ No

145. Dexamethasone

☐ Yes →
☐ No

146. Total dose ___ ___ ___ ___ mg

147. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

148. Other corticosteroid

☐ Yes →
☐ No

149. Specify other corticosteroid: _____

150. Total dose ___ ___ ___ ___ mg

151. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

152. Cyclophosphamide (Cytoxan)

☐ Yes →
☐ No

153. Total dose ___ ___ ___ ___ mg

154. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

155. Cytarabine (Ara-C)

☐ Yes →
☐ No

156. Total dose ___ ___ ___ ___ mg

157. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

158. Etoposide (VP-16, VePesid)

☐ Yes →
☐ No

159. Total dose ___ ___ ___ ___ mg

160. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

161. Fludarabine (Fludara)

☐ Yes →
☐ No

162. Total dose ___ ___ ___ ___ mg

163. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

164. Ifosfamide (Ifex)

☐ Yes →
☐ No

165. Total dose ___ ___ ___ ___ mg

166. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

167. Intrathecal therapy (chemotherapy)
☐ Yes →
☐ No

168. Intrathecal cytarabine (IT Ara-C)
☐ Yes →
☐ No

169. Total dose ___ ___ ___ ___ mg

170. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

171. Intrathecal methotrexate (IT MTX)
☐ Yes →
☐ No

172. Total dose ___ ___ ___ ___ mg

173. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

174. Intrathecal thiotepa
☐ Yes →
☐ No

175. Total dose ___ ___ ___ ___ mg

176. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

177. Other intrathecal drug
☐ Yes →
☐ No

178. Specify other intrathecal drug: _____

179. Total dose ___ ___ ___ ___ mg

180. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

181. Melphalan (L-Pam, Alkeran)
☐ Yes →
☐ No

182. Total dose ___ ___ ___ ___ mg

183. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

184. Specify administration: ☐ Oral ☐ IV ☐ Both

185. Mitoxantrone (Novantrone)
☐ Yes →
☐ No

186. Total dose ___ ___ ___ ___ mg

187. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

188. Monoclonal antibody (mAb)
☐ Yes →
☐ No

189. Radio labeled mAb
☐ Yes →
☐ No

190. Total dose of radioactive component: ___ ___ ___ ___ • ___
☐ mCi ☐ MBq

191. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

Specify radio labeled mAb:

192. Tositumomab (Bexxar) ☐ Yes ☐ No

193. Ibritumomab tiuxetan (Zevalin) ☐ Yes ☐ No

194. Other radio labeled mAb
☐ Yes → 195. Specify other radio labeled mAb: _____
☐ No

196. Alemtuzumab (Campath)
☐ Yes →
☐ No

197. Total dose ___ ___ ___ ___ mg

198. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

199. Rituximab (Rituxan, anti CD20)
☐ Yes →
☐ No

200. Total dose ___ ___ ___ ___ mg

201. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

202. Gemtuzumab (Mylotarg, anti CD-33)
☐ Yes →
☐ No

203. Total dose ___ ___ ___ ___ mg

204. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

205. Other mAb
☐ Yes →
☐ No

206. Specify other mAb: _____

207. Total dose ___ ___ ___ ___ mg

208. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

209. Nitrosourea
☐ Yes →
☐ No

210. Carmustine (BCNU, Gliadel)
☐ Yes →
☐ No

211. Total dose ___ ___ ___ ___ mg

212. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

213. CCNU (Lomustine)
☐ Yes →
☐ No

214. Total dose ___ ___ ___ ___ mg

215. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

216. Other nitrosourea
☐ Yes →
☐ No

217. Specify other nitrosourea: _____

218. Total dose ___ ___ ___ ___ mg

219. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

220. Paclitaxel (Taxol, Xyotax)
☐ Yes →
☐ No

221. Total dose ___ ___ ___ ___ mg

222. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

223. Teniposide (VM26)
☐ Yes →
☐ No

224. Total dose ___ ___ ___ ___ mg

225. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

226. Thiotepa
☐ Yes →
☐ No

227. Total dose ___ ___ ___ ___ mg

228. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

229. Treosulfan
☐ Yes →
☐ No

230. Total dose ___ ___ ___ ___ mg

231. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

232. Tyrosine kinase inhibitors (TKI)
☐ Yes →
☐ No

233. Dasatinib (Sprycel)
☐ Yes →
☐ No

234. Total dose ___ ___ ___ ___ mg

235. Date started: __ __ __ __ / __ __ / __ __
YYYY MM DD

236. Imatinib mesylate (STI571, Gleevec)
- ☐ Yes →
  - 237. Total dose ___ ___ ___ ___ mg
  - 238. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ No

239. Nilotinib (AMN107, Tasigna)
- ☐ Yes →
  - 240. Total dose ___ ___ ___ ___ mg
  - 241. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ No

242. Other tyrosine kinase inhibitor
- ☐ Yes →
  - 243. Specify other tyrosine kinase inhibitor: _____
  - 244. Total dose ___ ___ ___ ___ mg
  - 245. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ No

246. Other drug
- ☐ Yes →
  - 247. Specify other drug: _____
  - 248. Total dose ___ ___ ___ ___ mg
  - 249. Date started: __ __ __ __ / __ __ / __ __ (YYYY / MM / DD)
- ☐ No

Functional Status

Specify the functional status of the recipient immediately prior to the cellular therapy:

250. What scale was used to determine the recipient's functional status prior to the cellular therapy
- ☐ Karnofsky (recipient age ≥ 16 years) ***- Go to question 251***
- ☐ Lansky (recipient age ≥1 and < 16 years) ***- Go to question 252***

251. Karnofsky Scale (recipient age ≥ 16 years)

- ☐ 100 Normal; no complaints; no evidence of disease
- ☐ 90 Able to carry on normal activity
- ☐ 80 Normal activity with effort
- ☐ 70 Cares for self; unable to carry on normal activity or to do active work
- ☐ 60 Requires occasional assistance but is able to care for most needs
- ☐ 50 Requires considerable assistance and frequent medical care
- ☐ 40 Disabled; requires special care and assistance
- ☐ 30 Severely disabled; hospitalization indicated, although death not imminent
- ☐ 20 Very sick; hospitalization necessary
- ☐ 10 Moribund; fatal process progressing rapidly

- Go to question 253

252. Lansky Scale (recipient age ≥ 1 and < 16 years)

- ☐ 100 Fully active
- ☐ 90 Minor restriction in physically strenuous play
- ☐ 80 Restricted in strenuous play, tires more easily, otherwise active
- ☐ 70 Both greater restrictions of, and less time spent in, active play
- ☐ 60 Ambulatory up to 50% of time, limited active play with assistance / supervision
- ☐ 50 Considerable assistance required for any active play; fully able to engage in quiet play
- ☐ 40 Able to initiate quiet activities
- ☐ 30 Needs considerable assistance for quiet activity
- ☐ 20 Limited to very passive activity initiated by others (e.g., TV)
- ☐ 10 Completely disabled, not even passive play

Co-morbid Conditions

This section to be completed for malignant hematologic disorders and solid tumor indications

253. Were there ***clinically significant*** co-existing diseases or organ impairment at time of patient assessment prior to preparative regimen?
Source: Blood, 2005 Oct 15;106(8):2912-2919

- ☐ Yes →
- ☐ No

254. Arrhythmia **- For example, any history of atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias requiring treatment**

☐ Yes ☐ No ☐ Unknown

255. Cardiac **- Any history of coronary artery disease (one or more vessel-coronary artery stenosis requiring medical treatment, stent, or bypass graft), congestive heart failure, myocardial infarction, OR ejection fraction ≤ 50% on the most recent test**

☐ Yes ☐ No ☐ Unknown

256. Cerebrovascular disease **- Any history of transient ischemic attack, subarachnoid hemorrhage or cerebrovascular accident**

☐ Yes ☐ No ☐ Unknown

257. Diabetes **- Requiring treatment with insulin or oral hypoglycemics in the last 4 weeks but not diet alone**

☐ Yes ☐ No ☐ Unknown

258. Heart valve disease **- Except asymptomatic mitral valve prolapse**

☐ Yes ☐ No ☐ Unknown

259. Hepatic, mild **- Chronic hepatitis, bilirubin > upper limit of normal to 1.5 × upper limit of normal, or AST/ALT > upper limit of normal to 2.5 × upper limit of normal at the time of transplant OR any history of hepatitis B or hepatitis C infection**

☐ Yes ☐ No ☐ Unknown

260. Hepatic, moderate / severe **- Liver cirrhosis, bilirubin > 1.5 × upper limit of normal, or AST/ALT > 2.5 × upper limit of normal**

☐ Yes ☐ No ☐ Unknown

261. Infection **- For example, documented infection, fever of unknown origin, or pulmonary nodules requiring continuation of antimicrobial treatment after day 0**

☐ Yes ☐ No ☐ Unknown

262. Inflammatory bowel disease **- Any history of Crohn's disease or ulcerative colitis requiring treatment**

☐ Yes ☐ No ☐ Unknown

263. Obesity **- Patients with a body mass index > 35 kg/m^2 prior to the start of conditioning**

☐ Yes ☐ No ☐ Unknown

264. Peptic ulcer **- Any history of peptic ulcer confirmed by endoscopy and requiring treatment**

☐ Yes ☐ No ☐ Unknown

265. Psychiatric disturbance **- For example, depression, anxiety, bipolar disorder or schizophrenia requiring psychiatric consult or treatment in the last 4 weeks**

☐ Yes ☐ No ☐ Unknown

266. Pulmonary, moderate **- Corrected diffusion capacity of carbon monoxide and/or FEV$_1$ 66-80% or dyspnea on slight activity at transplant**

☐ Yes ☐ No ☐ Unknown

267. Pulmonary, severe **- Corrected diffusion capacity of carbon monoxide and/or FEV$_1$ ≤ 65% or dyspnea at rest or requiring oxygen at transplant**

☐ Yes ☐ No ☐ Unknown

268. Renal, moderate/severe **- Serum creatinine > 2 mg/dL or > 177 µmol/L or on dialysis at transplant, OR prior renal transplantation**

☐ Yes ☐ No ☐ Unknown

269. Rheumatologic **- For example, any history of systemic lupus erythmatosis, rheumatoid arthritis, polymyositis, mixed connective tissue disease, or polymyalgia rheumatica requiring treatment (do NOT include degenerative joint disease, osteoarthritis)**

☐ Yes ☐ No ☐ Unknown

270. Solid tumor, prior **- Treated at any time point in the patient's past history, excluding non-melanoma skin cancer, leukemia, lymphoma or multiple myeloma**

☐ Yes → ☐ No ☐ Unknown

271. Breast cancer

☐ Yes → ☐ No

272. Year of diagnosis: ___ ___ ___ ___

273. Central nervous system (CNS) malignancy (glioblastoma, astrocytoma)

☐ Yes → ☐ No

274. Year of diagnosis: ___ ___ ___ ___

275. Gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine)

☐ Yes → ☐ No

276. Year of diagnosis: ___ ___ ___ ___

277. Genitourinary malignancy (kidney, bladder, ovary, testicle, genitalia, uterus, cervix)
☐ Yes → 278. Year of diagnosis: ___ ___ ___ ___
☐ No

279. Lung cancer
☐ Yes → 280. Year of diagnosis: ___ ___ ___ ___
☐ No

281. Melanoma
☐ Yes → 282. Year of diagnosis: ___ ___ ___ ___
☐ No

283. Oropharyngeal cancer (tongue, buccal mucosa)
☐ Yes → 284. Year of diagnosis: ___ ___ ___ ___
☐ No

285. Sarcoma
☐ Yes → 286. Year of diagnosis: ___ ___ ___ ___
☐ No

287. Thyroid cancer
☐ Yes → 288. Year of diagnosis: ___ ___ ___ ___
☐ No

289. Other co-morbid condition
☐ Yes → 290. Specify other co-morbid condition: _____
☐ No
☐ Unknown

291. Was there a history of malignancy (hematologic or non-melanoma skin cancer) other than the primary disease for which this infusion is being performed?
☐ Yes →
☐ No

Specify which malignancy(ies) occurred:

292. Acute myeloid leukemia (AML / ANLL)
☐ Yes → 293. Year of diagnosis: ___ ___ ___ ___
☐ No

294. Other leukemia, including ALL
☐ Yes → 295. Year of diagnosis: ___ ___ ___ ___
☐ No 296. Specify leukemia: _____

297. Clonal cytogenetic abnormality without leukemia or MDS
☐ Yes → 298. Year of diagnosis: ___ ___ ___ ___
☐ No

299. Hodgkin disease
☐ Yes → 300. Year of diagnosis: ___ ___ ___ ___
☐ No

301. Lymphoma or lymphoproliferative disease

☐ Yes →
☐ No

302. Year of diagnosis: ___ ___ ___ ___

303. Was the tumor EBV positive? ☐ Yes ☐ No

304. Other skin malignancy (basal cell, squamous)

☐ Yes →
☐ No

305. Year of diagnosis: ___ ___ ___ ___

306. Specify other skin malignancy: _____

307. Myelodysplasia (MDS) / myeloproliferative (MPN) disorder

☐ Yes →
☐ No

308. Year of diagnosis: ___ ___ ___ ___

309. Other prior malignancy

☐ Yes →
☐ No

310. Year of diagnosis: ___ ___ ___ ___

311. Specify other skin malignancy: _____

First Name: _____

Last Name:_____

E-mail address: _____

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