Form 4000 R4.0: Cellular Therapy Essential Data Pre-Infusion Form

Center: CRID:

Key Fields

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

Event date: __ __ __ __ - __ __- __ __

Recipient Data

Questions: 1 - 14

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: __ __ __ __ - __ __- __ __

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

○ yes ○ no

Clinical Trials (1)

Questions: 6 - 12

6 Study sponsor

- ○ BMT CTN
- ○ RCI BMT
- ○ USIDNET
- ○ COG
- ○ Corporate / Industry
- ○ EudraCT
- ○ UMIN
- ○ Investigator initiated
- ○ Other

7 Study ID number: _____

8 Specify corporate / industry sponsor name: _____

9 Specify EudraCT number: _____

10 Specify UMIN number: _____

11 Specify other sponsor: _____

12 Specify the ClinicalTrials.gov identification number: _____

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

○ Yes ○ No

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

- ☐ Institutional guidelines / standard treatment
- ☐ Hospital exemption
- ☐ Compassionate use

Form 4000 R4.0: Cellular Therapy Essential Data Pre-Infusion Form

Center: CRID:

Cellular Therapy and HCT History — Questions: 15 - 29

15 Is this the first application of cellular therapy (non-HCT)?

- ○ Yes
- ○ No (recipient has previously been treated using cellular therapy)
- ○ Unknown

16 Were all prior cellular therapies (non-HCT) reported to the CIBMTR?

○ Yes ○ No ○ Unknown

17 Specify the number of prior cellular therapies: _____

Prior Cellular Therapies (1) — Questions: 18 - 23

18 Date of the prior cellular therapy: __ __ __ __ - __ __- __ __ ☐ Date estimated

19 Was the cellular therapy performed at a different institution?

○ Yes ○ No

Specify the institution that performed the prior cellular therapy:

20 Name: _____

City: _____

State: _____

Country: _____

21 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

22 Specify other indication: _____

23 What was the cell source for the prior cellular therapy? (check all that apply)

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related

HCT History

24 Has the recipient ever had a prior HCT?

○ Yes ○ No ○ Unknown

25 Were all prior HCTs reported to the CIBMTR?

○ Yes ○ No ○ Unknown

Prior HCTs (1) — Questions: 26 - 29

26 Date of the prior HCT: __ __ __ __ - __ __- __ __

27 Was the HCT performed at a different institution?

○ Yes ○ No

Specify the institution that performed the prior HCT:

28 Name: _____

City: _____

State: _____

Country: _____

29 Specify the HSC source(s) for the prior HCT (check all that apply)

- ☐ Autologous
- ☐ Allogeneic, unrelated
- ☐ Allogeneic, related

Planned Infusions

Questions: 30 - 38

30 Specify the total number of planned infusions: (per protocol) (as part of this course of cellular therapy) _____

31 Is the product genetically modified?

○ Yes ○ No

Donor Information for this Infusion (1)

Questions: 32 - 35

32 Specify the cell source

- ○ Autologous
- ○ Allogeneic, unrelated
- ○ Allogeneic, related

33 Specify the related donor type

- ○ Syngeneic (monozygotic twin)
- ○ HLA-identical sibling (may include non-monozygotic twin)
- ○ HLA-matched other relative
- ○ HLA-mismatched relative

34 Was this donor used for any prior cellular therapies or HCT? **(for this recipient)**

○ Yes ○ No ○ Unknown

35 Does this product contain cytotoxic T lymphocytes (CTLs)?

○ Yes ○ No

Planned HCT

36 Is a subsequent HCT part of the overall treatment protocol?

○ Yes ○ No

37 Specify the HCT type

○ Autologous ○ Allogeneic

38 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

Questions: 39 - 50

39 What was the indication for performing treatment with cellular therapy?

- 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)
- Malignant hematologic disorder **- Also complete CIBMTR Form 2402**
- Non-malignant disorder **- Also complete CIBMTR Form 2402**
- B cell lymphoproliferative disorder (PTLD, EBV lymphoma)
- Cardiovascular disease
- Musculoskeletal disorder
- Neurologic disease
- Ocular disease
- Pulmonary disease
- Infection treatment
- Infection prophylaxis
- Other indication

40 Date of diagnosis: __ __ __ __ - __ __- __ __

Cardiovascular disease

41 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)
- Limb ischemia (710)
- Thromboangitis obliterans (711)
- Other peripheral vascular disease (719)

42 Specify other cardiovascular disease: _____

43 Specify other peripheral vascular disease: _____

Musculoskeletal

44 Specify musculoskeletal disorder

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

45 Specify other musculoskeletal disorder: _____

Neurologic Disease

46 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)

47 Specify other neurologic disease: _____

Ocular

48 Specify ocular disease: _____

Pulmonary

49 Specify pulmonary disease: _____

Other

50 Specify other indication: _____

Infection

Questions: 51 - 57

Specify organism code(s):

51 _____

52 _____

53 _____

54 _____

55 _____

56 _____

57 Specify other organism: _____

Disease Assessment at Last Evaluation Prior to Cellular Therapy

Questions: 58 - 83

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.

58 Was the disease assessed prior to the cellular therapy?

○ Yes ○ No

59 Was the disease status assessed by molecular testing? (e.g. PCR)

○ Yes ○ No ○ Not Applicable

60 Date sample collected: __ __ __ __ - __ __- __ __

61 Was disease detected?

○ yes ○ no

62 Was the status considered a disease relapse or progression?

○ yes ○ no

63 Was the disease status assessed via flow cytometry? (immunophenotyping)

○ Yes ○ No ○ Not Applicable

64 Date sample collected: __ __ __ __ - __ __- __ __

65 Was disease detected?

○ yes ○ no

66 Was the status considered a disease relapse or progression?

○ yes ○ no

67 Was the disease status assessed by cytogenetic testing? (karyotyping or FISH)

○ Yes ○ No ○ Not Applicable

68 Was the disease status assessed via karyotyping?

○ Yes ○ No ○ Not Applicable

69 Date sample collected: __ __ __ __ - __ __- __ __

70 Was disease detected?

○ yes ○ no

71 Was the status considered a disease relapse or progression?

○ yes ○ no

72 Was the disease status assessed via FISH?

○ Yes ○ No ○ Not Applicable

73 Date sample collected: __ __ __ __ - __ __- __ __

74 Was disease detected?

○ yes ○ no

75 Was the status considered a disease relapse or progression?

○ yes ○ no

76 Was the disease status assessed by radiological assessment? (e.g. PET, MRI, CT)

○ Yes ○ No ○ Not Applicable

77 Date assessed: __ __ __ __ - __ __- __ __

78 Was disease detected?

○ yes ○ no

79 Was the disease status assessed by clinical / hematologic assessment?

○ yes ○ no

80 Date assessed: __ __ __ __ - __ __- __ __

81 Was disease detected?

○ yes ○ no

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

83 Date assessed: __ __ __ __ - __ __- __ __

Systemic Therapy Prior to Cellular Therapy

Questions: 84 - 239

84 Was systemic therapy given immediately prior to cellular therapy as part of the cellular therapy protocol?
- yes
- no

85 Date started: __ __ __ __ - __ __- __ __

86 Specify the reason for which the systemic therapy was given per protocol
- Lympho-depleting therapy
- Reduction of tumor burden
- Other reason

87 Specify other reason: _____

88 ALG, ALS, ATG, ATS
- yes
- no

89 Total dose: _____ mg

90 Date started: __ __ __ __ - __ __- __ __

91 Specify source
- ATGAM (horse)
- ATG - Fresenius (rabbit)
- Thymoglobulin (rabbit)
- Other

92 Specify other source: _____

93 Anthracycline
- Yes
- No

94 Daunorubicin (Cerubidine)
- yes
- no

95 Total dose: _____ mg

96 Date started: __ __ __ __ - __ __- __ __

97 Doxorubicin (Adriamycin)
- yes
- no

98 Total dose: _____ mg

99 Date started: __ __ __ __ - __ __- __ __

100 Idarubicin (Idamycin)
- yes
- no

101 Total dose: _____ mg

102 Date started: __ __ __ __ - __ __- __ __

103 Rubidazone
- Yes
- No

104 Total dose: _____ mg

105 Date started: __ __ __ __ - __ __- __ __

106 Other anthracycline
- Yes
- No

107 Total dose: _____ mg

108 Date started: __ __ __ __ - __ __- __ __

109 Specify other anthracycline: _____

110 Bleomycin (BLM, Blenoxane)
- yes
- no

111 Total dose: _____ mg

112 Date started: __ __ __ __ - __ __- __ __

113 Busulfan (Myleran)
- Yes
- No

114 Total dose: _____ mg

115 Date started: __ __ __ __ - __ __- __ __

116 Specify administration
- Oral
- IV
- Both

117 Carboplatin
- yes
- no

118 Total dose: _____ mg

119 Date started: __ __ __ __ - __ __- __ __

120 Were pharmacokinetics performed to determine drug dosing?
Yes No

121 Specify the target AUC: _____ mg/mL/minute

122 Cisplatin (Platinol, CDDP)
yes no

123 Total dose: _____ mg

124 Date started: __ __ __ __ - __ __- __ __

125 Cladribine (2-CdA, Leustatin)
yes no

126 Total dose: _____ mg

127 Date started: __ __ __ __ - __ __- __ __

128 Corticosteroids
yes no

129 Methylprednisolone (Solu-Medrol)
Yes No

130 Total dose: _____ mg

131 Date started: __ __ __ __ - __ __- __ __

132 Prednisone
Yes No

133 Total dose: _____ mg

134 Date started: __ __ __ __ - __ __- __ __

135 Dexamethasone
yes no

136 Total dose: _____ mg

137 Date started: __ __ __ __ - __ __- __ __

138 Other corticosteroid
Yes No

139 Total dose: _____ mg

140 Date started: __ __ __ __ - __ __- __ __

141 Specify other corticosteroid: _____

142 Cyclophosphamide (Cytoxan)
yes no

143 Total dose: _____ mg

144 Date started: __ __ __ __ - __ __- __ __

145 Cytarabine (Ara-C)
yes no

146 Total dose: _____ mg

147 Date started: __ __ __ __ - __ __- __ __

148 Etoposide (VP-16, VePesid)
yes no

149 Total dose: _____ mg

150 Date started: __ __ __ __ - __ __- __ __

151 Fludarabine (Fludara)
yes no

152 Total dose: _____ mg

153 Date started: __ __ __ __ - __ __- __ __

154 Ifosfamide (Ifex)
yes no

155 Total dose: _____ mg

156 Date started: __ __ __ __ - __ __- __ __

157 Intrathecal therapy (chemotherapy)
yes no

158 Intrathecal cytarabine (IT Ara-C)
Yes No

159 Total dose: _____ mg

160 Date started: __ __ __ __ - __ __- __ __

161 Intrathecal methotrexate (IT MTX)
yes no

162 Total dose: _____ mg

163 Date started: __ __ __ __ - __ __- __ __

164 Intrathecal thiotepa
Yes No

165 Total dose: _____ mg

Center: CRID:

166 Date started: __ __ __ __ - __ __- __ __

167 Other intrathecal drug

Yes No

168 Total dose: _____ mg

169 Date started: __ __ __ __ - __ __- __ __

170 Specify other intrathecal drug: _____

171 Melphalan (L-PAM, Alkeran)

yes no

172 Total dose: _____ mg

173 Date started: __ __ __ __ - __ __- __ __

174 Specify administration

Oral IV Both

175 Mitoxantrone (Novantrone)

yes no

176 Total dose: _____ mg

177 Date started: __ __ __ __ - __ __- __ __

178 Monoclonal antibody (mAb)

Yes No

179 Radio labeled mAb

Yes No

180 Total dose of radioactive component: _____ mCi MBq

181 Date started: __ __ __ __ - __ __- __ __

Specify radio labeled mAb:

182 Tositumomab (Bexxar)

yes no

183 Ibritumomab tiuxetan (Zevalin)

yes no

184 Other radio labeled mAb

Yes No

185 Specify other radio labeled mAb: _____

186 Alemtuzumab (Campath)

yes no

187 Total dose: _____ mg

188 Date started: __ __ __ __ - __ __- __ __

189 Rituximab (Rituxan, anti CD20)

yes no

190 Total dose: _____ mg

191 Date started: __ __ __ __ - __ __- __ __

192 Gemtuzumab (Mylotarg, anti-CD33)

yes no

193 Total dose: _____ mg

194 Date started: __ __ __ __ - __ __- __ __

195 Other mAb

yes no

196 Total dose: _____ mg

197 Date started: __ __ __ __ - __ __- __ __

198 Specify other mAb: _____

199 Nitrosourea

Yes No

200 Carmustine (BCNU, Gliadel)

yes no

201 Total dose: _____ mg

202 Date started: __ __ __ __ - __ __- __ __

203 CCNU (Lomustine)

Yes No

204 Total dose: _____ mg

205 Date started: __ __ __ __ - __ __- __ __

206 Other nitrosourea

Yes No

207 Total dose: _____ mg

208 Date started: __ __ __ __ - __ __- __ __

209 Specify other nitrosourea: _____

210 Paclitaxel (Taxol, Xyotax)
Yes No

211 Total dose: _____ mg
212 Date started: __ __ __ __ - __ __- __ __
213 Teniposide (VM26)
yes no

214 Total dose: _____ mg
215 Date started: __ __ __ __ - __ __- __ __
216 Thiotepa
Yes No

217 Total dose: _____ mg
218 Date started: __ __ __ __ - __ __- __ __
219 Treosulfan
Yes No

220 Total dose: _____ mg
221 Date started: __ __ __ __ - __ __- __ __
222 Tyrosine kinase inhibitors (TKI)
yes no

223 Dasatinib (Sprycel)
yes no

224 Total dose: _____ mg
225 Date started: __ __ __ __ - __ __- __ __
226 Imatinib mesylate (STI571, Gleevec)
yes no

227 Total dose: _____ mg
228 Date started: __ __ __ __ - __ __- __ __
229 Nilotinib (AMN107, Tasigna)
yes no

230 Total dose: _____ mg
231 Date started: __ __ __ __ - __ __- __ __
232 Other tyrosine kinase inhibitor
Yes No

233 Total dose: _____ mg
234 Date started: __ __ __ __ - __ __- __ __
235 Specify other tyrosine kinase inhibitor: _____
236 Other drug
Yes No

237 Total dose: _____ mg
238 Date started: __ __ __ __ - __ __- __ __
239 Specify other drug: _____

Functional Status

Questions: 240 - 242

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

240 What scale was used to determine the recipient's functional status prior to the cellular therapy
Karnofsky (recipient age ≥ 16 years)
Lansky (recipient age ≥ 1 and < 16 years)

241 Karnofsky Scale (recipient age ≥ 16 years) _____
242 Lansky Scale (recipient age ≥ 1 and < 16 years) _____

First Name: _____
Last Name: _____
E-mail address: _____
Date: __ __ __ __ - __ __- __ __