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 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: _____

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Retain the original form at the transplant center.

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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

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: _____

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

Center: CRID:

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

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

Center: CRID:

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)

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

Center: CRID:

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

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

Center: CRID:

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

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

Center: CRID:

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

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

Center: CRID:

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

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

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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

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Center: CRID:

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: __ __ __ __ - __ __- __ __

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