

Form 2400 R5.0: Pre-Transplant Essential Data

Center: _____

CRID: _____

Key Fields

OMB No: 0915-0310

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Sequence Number: _____

Date Received: ____-____-____

Center Identification

CIBMTR Center Number: _____

EBMT Code (CIC): _____

Hospital: _____

Unit (check only one)

Adult Pediatric

Recipient Identification

CIBMTR Research ID: (CRID) _____

Recipient Data

Questions: 1 - 10

1 Date of birth: ____-____-____

2 Sex

male female

3 Ethnicity

Hispanic or Latino

Not Hispanic or Latino

Not applicable (not a resident of the USA)

Unknown

Race (1)

Questions: 4 - 4

4 Race _____

5 Zip or postal code for place of recipient's residence: (USA recipients only) _____

6 Is the recipient participating in a clinical trial?

yes no

Clinical Trials (1)

Questions: 7 - 10

7 Study Sponsor _____

8 Specify other sponsor: _____

9 Study ID Number _____

10 Subject ID: _____

Hematopoietic Cellular Transplant (HCT)

Questions: 11 - 28

11 Date of this HCT: ____-____-____

12 Was this the first HCT for this recipient?

yes no

13 Is a subsequent HCT planned as part of the overall treatment protocol (not as a reaction to post-HCT disease assessment)? (For autologous HCTs only)

yes no

14 Specify subsequent HCT planned

Autologous Allogeneic

15 Specify the number of prior HCTs: _____

Specify the HSC source(s) for all prior HCTs:

16 Autologous

yes no

17 Allogeneic, unrelated

yes no

18 Allogeneic, related

yes no

Form 2400 R5.0: Pre-Transplant Essential Data

Center: _____

CRID: _____

19 Syngeneic

yes no

20 Date of the last HCT: (just before current HCT) _____ - _____ - _____

21 Was the last HCT performed at a different institution?

yes no

Specify the institution that performed the last HCT:

22 Name: _____

City: _____

State: _____

Country: _____

23 What was the HSC source for the last HCT?

- Autologous
 Allogeneic, unrelated donor
 Allogeneic, related donor

24 Reason for current HCT _____

25 Date of graft failure / rejection: _____ - _____ - _____

26 Date of relapse: _____ - _____ - _____

27 Date of secondary malignancy: _____ - _____ - _____

28 Specify other reason: _____

Donor Information

Questions: 29 - 63

29 Multiple donors?

yes no

30 Specify number of donors: _____

Donor Information for this HCT (1)

Questions: 31 - 63

31 Specify donor _____

32 NMDP cord blood unit ID: _____

33 NMDP donor ID: _____

34 Non-NMDP unrelated donor ID: (not applicable for related donors) _____

35 Non-NMDP cord blood unit ID: (include related and autologous CBUs) _____

36 Is the CBU ID also the ISBT DIN number?

yes no

37 Specify the ISBT DIN number: _____

38 Registry or UCB Bank ID _____

39 Specify other Registry or UCB Bank: _____

40 Specify the related donor type

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

41 Date of birth (donor / infant)

Known Unknown

42 Date of birth: (donor / infant) _____ - _____ - _____

43 Age (donor / infant)

Known Unknown

44 Age: (donor / infant) _____ Months (use only if less than 1 year old)
 years

45 Sex (donor / infant)

male female

Specify product type:

46 Bone marrow

yes no

47 PBSC

yes no

48 Single cord blood unit

yes no

49 Other product

yes no

50 Specify other product type: _____

Form 2400 R5.0: Pre-Transplant Essential Data

Center:

CRID:

A series of collections should be considered a **single product** when they are all from the same donor and use the same collection method and technique (and mobilization, if applicable), even if the collections are performed on different days.

51 Specify number of products infused from this donor: _____

52 Specify the number of these products intended to achieve hematopoietic engraftment: _____

Questions 53 – 60 are for autologous HCT recipients only. If other than autologous skip to question 61

53 Did the recipient have more than one mobilization event to acquire cells for HCT?

yes no

54 Specify the total number of mobilization events performed for this HCT: (regardless of the number of collections or which collections were used for this HCT) _____

Specify all agents used in the mobilization events reported above:

55 G-CSF

yes no

56 GM-CSF

yes no

57 Pegylated G-CSF

yes no

58 Plerixafor (Mozobil)

yes no

59 Other CXCR4 inhibitor

yes no

60 Combined with chemotherapy

yes no

61 Was this donor used for any prior HCTs?

yes no

62 Donor CMV-antibodies (IgG or Total) (**Allogeneic HCTs only**)

- Reactive
 Non-reactive
 Not done
 Not applicable (cord blood unit)

63 Was plerixafor (Mozobil) given at any time prior to the preparative regimen? (**Related HCTs only**)

yes no Unknown

Consent

Questions: 64 - 71

64 Has the recipient signed an IRB-approved consent form for submitting research data to the NMDP / CIBMTR?

- Yes (patient consented)
 No (patient declined)
 Not approached

65 Date form was signed: ____ - ____ - ____

66 Did the recipient give permission to be directly contacted for future research?

- Yes (patient provided permission)
 No (patient declined)
 Not approached

67 Date form was signed: ____ - ____ - ____

68 Has the recipient signed an IRB-approved consent form to donate research blood samples to the NMDP / CIBMTR?

- Yes (patient consented)
 No (patient declined)
 Not approached
 Not applicable (center not participating)

69 Date form was signed: ____ - ____ - ____

70 Has the donor signed an IRB-approved consent form to donate research blood samples to the NMDP / CIBMTR? (**Allogeneic donors only**)

- Yes (donor consented)
 No (donor declined)
 Not approached
 Not applicable (center not participating)

71 Date form was signed: ____ - ____ - ____

Product Processing / Manipulation

Questions: 72 - 90

Form 2400 R5.0: Pre-Transplant Essential Data

Center:

CRID:

72 Was the product manipulated prior to infusion?

yes no

73 Specify portion manipulated

entire product portion of product

Specify all methods used to manipulate the product:

74 Washed

yes no

75 Diluted

yes no

76 Buffy coat enriched (buffy coat preparation)

yes no

77 B-cell reduced

yes no

78 CD8 reduced

yes no

79 Plasma reduced (removal)

yes no

80 RBC reduced

yes no

81 Cultured (ex-vivo expansion)

yes no

82 Genetic manipulation (gene transfer / transduction)

yes no

83 PUVA treated

yes no

84 CD34 enriched (CD34+ selection)

yes no

85 CD133 enriched

yes no

86 Monocyte enriched

yes no

87 Mononuclear cells enriched

yes no

88 T-cell depletion

yes no

89 Other cell manipulation

yes no

90 Specify other cell manipulation: _____

Clinical Status of Recipient Prior to the Preparative Regimen (Conditioning)

Questions: 91 - 94

91 What scale was used to determine the recipient's functional status?

Karnofsky (recipient age \geq 16 years)

Lansky (recipient age < 16 years)

Performance score prior to the preparative regimen:

92 Karnofsky Scale (recipient age \geq 16 years) _____

93 Lansky Scale (recipient age < 16 years) _____

94 Recipient CMV-antibodies (IgG or Total)

Reactive Non-reactive Not done

Comorbid Conditions

Questions: 95 - 155

95 Is there a history of mechanical ventilation?

yes no

96 Is there a history of proven invasive fungal infection?

yes no

97 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

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

yes no Unknown

Form 2400 R5.0: Pre-Transplant Essential Data

Center:

CRID:

99 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 \leq 50% on the most recent test

yes no Unknown

100 Cerebrovascular disease - Any history of transient ischemic attack, subarachnoid hemorrhage or cerebrovascular accident

yes no Unknown

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

yes no Unknown

102 Heart valve disease - Except asymptomatic mitral valve prolapse

yes no Unknown

103 Hepatic, mild - Chronic hepatitis, bilirubin $>$ upper limit of normal to $1.5 \times$ upper limit of normal, or AST/ALT $>$ upper limit of normal to $2.5 \times$ upper limit of normal at the time of transplant OR any history of hepatitis B or hepatitis C infection

yes no Unknown

104 Hepatic, moderate / severe - Liver cirrhosis, bilirubin $>$ $1.5 \times$ upper limit of normal, or AST/ALT $>$ $2.5 \times$ upper limit of normal

yes no Unknown

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

yes no Unknown

106 Inflammatory bowel disease - Any history of Crohn's disease or ulcerative colitis requiring treatment

yes no Unknown

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

yes no Unknown

108 Peptic ulcer - Any history of peptic ulcer confirmed by endoscopy and requiring treatment

yes no Unknown

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

yes no Unknown

110 Pulmonary, moderate - Corrected diffusion capacity of carbon monoxide and/or FEV₁ 66-80% or dyspnea on slight activity at transplant

yes no Unknown

111 Pulmonary, severe - Corrected diffusion capacity of carbon monoxide and/or FEV₁ \leq 65% or dyspnea at rest or requiring oxygen at transplant

yes no Unknown

112 Renal, moderate / severe - Serum creatinine $>$ 2 mg/dL or $>$ 177 $\mu\text{mol/L}$ or on dialysis at transplant, OR prior renal transplantation

yes no Unknown

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

yes no Unknown

114 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

115 Breast cancer

yes no

116 Year of diagnosis: _____

117 Central nervous system (CNS) malignancy (glioblastoma, astrocytoma)

yes no

118 Year of diagnosis: _____

119 Gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine)

yes no

120 Year of diagnosis: _____

121 Genitourinary malignancy (kidney, bladder, ovary, testicle, genitalia, uterus, cervix)

yes no

122 Year of diagnosis: _____

123 Lung cancer

yes no

124 Year of diagnosis: _____

125 Melanoma

yes no

126 Year of diagnosis: _____

127 Oropharyngeal cancer (tongue, buccal mucosa)

yes no

128 Year of diagnosis: _____

129 Sarcoma

yes no

130 Year of diagnosis: _____

Form 2400 R5.0: Pre-Transplant Essential Data

Center: _____

CRID: _____

131 Thyroid cancer

yes no

132 Year of diagnosis: _____

133 Other co-morbid condition

yes no Unknown

134 Specify other co-morbid condition: _____

135 Was there a history of malignancy (hematologic or non-melanoma skin cancer) other than the primary disease for which this HCT is being performed?

yes no

Specify which malignancy(ies) occurred:

136 Acute myeloid leukemia (AML / ANLL)

yes no

137 Year of diagnosis: _____

138 Other leukemia, including ALL

yes no

139 Year of diagnosis: _____

140 Specify leukemia: _____

141 Clonal cytogenetic abnormality without leukemia or MDS

yes no

142 Year of diagnosis: _____

143 Hodgkin disease

yes no

144 Year of diagnosis: _____

145 Lymphoma or lymphoproliferative disease

yes no

146 Year of diagnosis: _____

147 Was the tumor EBV positive?

yes no

148 Other skin malignancy (basal cell, squamous)

yes no

149 Year of diagnosis: _____

150 Specify other skin malignancy: _____

151 Myelodysplasia (MDS) / myeloproliferative (MPN) disorder

yes no

152 Year of diagnosis: _____

153 Other prior malignancy

yes no

154 Year of diagnosis: _____

155 Specify other prior malignancy: _____

Pre-HCT Preparative Regimen (Conditioning)

Questions: 156 - 316

156 Height at initiation of pre-HCT preparative regimen: _____ inches centimeters

157 Actual weight at initiation of pre-HCT preparative regimen: _____ pounds kilograms

158 Was a pre-HCT preparative regimen prescribed?

yes no

159 Classify the recipient's prescribed preparative regimen (**Allogeneic HCTs only**)

- Myeloablative
 Non-myeloablative (NST)
 Reduced intensity (RIC)

160 Date pre-HCT preparative regimen began: (irradiation or drugs) ____ - ____ - ____ (Use earliest date from question 164 radiation, or 169 - 316 chemotherapy)

161 Was irradiation planned as part of the pre-HCT preparative regimen?

yes no

162 What was the prescribed radiation field?

- Total body
 Total body by intensity-modulated radiation therapy (IMRT)
 Total lymphoid or nodal regions
 Thoracoabdominal region

163 Total prescribed dose: (dose per fraction x total number of fractions) _____ Gy cGy

164 Date started: ____ - ____ - ____

165 Was the radiation fractionated?

yes no

Form 2400 R5.0: Pre-Transplant Essential Data

Center: _____

CRID: _____

166 Prescribed dose per fraction: _____ Gy cGy

167 Number of days: (include "rest" days) _____

168 Total number of fractions: _____

Indicate the total prescribed cumulative dose for the preparative regimen:

169 ALG, ALS, ATG, ATS

yes no

170 Total prescribed dose: _____ mg/kg

171 Date started: ____ - ____ - ____

172 Specify source

- ATGAM (horse)
 ATG - Fresenius (rabbit)
 Thymoglobulin (rabbit)
 Other

173 Specify other source: _____

174 Anthracycline

yes no

175 Daunorubicin

yes no

176 Total prescribed dose : _____ mg/m² mg/kg

177 Date started: ____ - ____ - ____

178 Doxorubicin (Adriamycin)

yes no

179 Total prescribed dose : _____ mg/m² mg/kg

180 Date started: ____ - ____ - ____

181 Idarubicin

yes no

182 Total prescribed dose : _____ mg/m² mg/kg

183 Date started: ____ - ____ - ____

184 Rubidazole

yes no

185 Total prescribed dose : _____ mg/m² mg/kg

186 Date started: ____ - ____ - ____

187 Other anthracycline

yes no

188 Total prescribed dose : _____ mg/m² mg/kg

189 Date started: ____ - ____ - ____

190 Specify other anthracycline: _____

191 Bleomycin (BLM, Blenoxane)

yes no

192 Total prescribed dose : _____ mg/m² mg/kg

193 Date started: ____ - ____ - ____

194 Busulfan (Myleran)

yes no

195 Total prescribed dose : _____ mg/m²
 mg/kg
 Target total AUC (µmol x min/L)

196 Date started: ____ - ____ - ____

197 Specify administration

Oral IV Both

198 Carboplatin

yes no

199 Total prescribed dose : _____ mg/m² mg/kg

200 Date started: ____ - ____ - ____

201 Were pharmacokinetics performed to determine preparative regimen drug dosing?

yes no

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

203 Cisplatin (Platinol, CDDP)

yes no

204 Total prescribed dose : _____ mg/m² mg/kg

Form 2400 R5.0: Pre-Transplant Essential Data

Center: _____

CRID: _____

205 Date started: ____-____-____

206 Cladribine (2-CdA, Leustatin)

yes no

207 Total prescribed dose : _____ mg/m² mg/kg

208 Date started: ____-____-____

209 Corticosteroids (excluding anti-nausea medication)

yes no

210 Methylprednisolone (Solu-Medrol)

yes no

211 Total prescribed dose : _____ mg/m² mg/kg

212 Date started: ____-____-____

213 Prednisone

yes no

214 Total prescribed dose : _____ mg/m² mg/kg

215 Date started: ____-____-____

216 Dexamethasone

yes no

217 Total prescribed dose : _____ mg/m² mg/kg

218 Date started: ____-____-____

219 Other corticosteroid

yes no

220 Total prescribed dose : _____ mg/m² mg/kg

221 Date started: ____-____-____

222 Specify other corticosteroid: _____

223 Cyclophosphamide (Cytoxan)

yes no

224 Total prescribed dose : _____ mg/m² mg/kg

225 Date started: ____-____-____

226 Cytarabine (Ara-C)

yes no

227 Total prescribed dose : _____ mg/m² mg/kg

228 Date started: ____-____-____

229 Etoposide (VP-16, VePesid)

yes no

230 Total prescribed dose : _____ mg/m² mg/kg

231 Date started: ____-____-____

232 Fludarabine

yes no

233 Total prescribed dose : _____ mg/m² mg/kg

234 Date started: ____-____-____

235 Ifosfamide

yes no

236 Total prescribed dose : _____ mg/m² mg/kg

237 Date started: ____-____-____

238 Intrathecal therapy (chemotherapy)

yes no

239 Intrathecal cytarabine (IT Ara-C)

yes no

240 Total prescribed dose : _____ mg/m² mg/kg

241 Date started: ____-____-____

242 Intrathecal methotrexate (IT MTX)

yes no

243 Total prescribed dose : _____ mg/m² mg/kg

244 Date started: ____-____-____

245 Intrathecal thiotepa

yes no

246 Total prescribed dose : _____ mg/m² mg/kg

247 Date started: ____-____-____

Form 2400 R5.0: Pre-Transplant Essential Data

Center: _____

CRID: _____

248 Other intrathecal drug

yes no

249 Total prescribed dose : _____ mg/m² mg/kg

250 Date started: _____ - _____ - _____

251 Specify other intrathecal drug: _____

252 Melphalan (L-Pam)

yes no

253 Total prescribed dose : _____ mg/m² mg/kg

254 Date started: _____ - _____ - _____

255 Specify administration

Oral IV Both

256 Mitoxantrone (Novantrone)

yes no

257 Total prescribed dose : _____ mg/m² mg/kg

258 Date started: _____ - _____ - _____

259 Monoclonal antibody

yes no

260 Radio labeled mAb

yes no

261 Total prescribed dose of radioactive component: _____ mCi MBq

262 Date started: _____ - _____ - _____

Specify radio labeled mAb:

263 Tositumomab (Bexxar)

yes no

264 Ibritumomab tiuxetan (Zevalin)

yes no

265 Other radio labeled mAb

yes no

266 Specify other radio labeled mAb: _____

267 Alemtuzumab (Campath)

yes no

268 Total prescribed dose : _____ mg/m² mg/kg

269 Date started: _____ - _____ - _____

270 Rituximab (Rituxan, anti CD20)

yes no

271 Total prescribed dose : _____ mg/m² mg/kg

272 Date started: _____ - _____ - _____

273 Gemtuzumab (Mylotarg, anti CD33)

yes no

274 Total prescribed dose : _____ mg/m² mg/kg

275 Date started: _____ - _____ - _____

276 Other mAb

yes no

277 Total prescribed dose : _____ mg/m² mg/kg

278 Date started: _____ - _____ - _____

279 Specify other mAb: _____

280 Nitrosourea

yes no

281 Carmustine (BCNU)

yes no

282 Total prescribed dose : _____ mg/m² mg/kg

283 Date started: _____ - _____ - _____

284 CCNU (Lomustine)

yes no

285 Total prescribed dose : _____ mg/m² mg/kg

286 Date started: _____ - _____ - _____

287 Other nitrosourea

yes no

Form 2400 R5.0: Pre-Transplant Essential Data

Center: _____

CRID: _____

288 Total prescribed dose : _____ mg/m² mg/kg

289 Date started: _____ - _____ - _____

290 Specify other nitrosourea: _____

291 Paclitaxel (Taxol, Xyotax)

yes no

292 Total prescribed dose : _____ mg/m² mg/kg

293 Date started: _____ - _____ - _____

294 Teniposide (VM26)

yes no

295 Total prescribed dose : _____ mg/m² mg/kg

296 Date started: _____ - _____ - _____

297 Thiotepa

yes no

298 Total prescribed dose : _____ mg/m² mg/kg

299 Date started: _____ - _____ - _____

300 Treosulfan

yes no

301 Total prescribed dose : _____ mg/m² mg/kg

302 Date started: _____ - _____ - _____

303 Tyrosine kinase inhibitors

yes no

304 Dasatinib (Sprycel)

yes no

305 Total prescribed dose : _____ mg/m² mg/kg

306 Date started: _____ - _____ - _____

307 Imatinib mesylate (STI571, Gleevec)

yes no

308 Total prescribed dose : _____ mg/m² mg/kg

309 Date started: _____ - _____ - _____

310 Nilotinib

yes no

311 Total prescribed dose : _____ mg/m² mg/kg

312 Date started: _____ - _____ - _____

313 Other drug

yes no

314 Total prescribed dose : _____ mg/m² mg/kg

315 Date started: _____ - _____ - _____

316 Specify other drug: _____

GVHD Prophylaxis

Questions: 317 - 343

This section is to be completed for allogeneic HCTs only; autologous HCTs continue with question 344.

317 Was GVHD prophylaxis planned / given?

yes no

Specify:

318 ALG, ALS, ATG, ATS

yes no

319 Total dose: _____ mg/kg

320 Specify source

- ATGAM (horse)
- ATG - Fresenius (rabbit)
- Thymoglobulin (rabbit)
- Other

321 Specify other source: _____

322 Corticosteroids (systemic)

yes no

323 Cyclosporine (CSA, Neoral, Sandimmune)

yes no

324 Cyclophosphamide (Cytoxan)

yes no

Form 2400 R5.0: Pre-Transplant Essential Data

Center:

CRID:

325 Extra-corporeal photopheresis (ECP)

yes no

326 FK 506 (Tacrolimus, Prograf)

yes no

327 In vivo monoclonal antibody

yes no

Specify in vivo monoclonal antibody:

328 Alemtuzumab (Campath)

yes no

329 Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

yes no

330 Specify: _____

331 Etanercept (Enbrel)

yes no

332 Infliximab (Remicade)

yes no

333 Other in vivo monoclonal antibody

yes no

334 Specify antibody: _____

335 In vivo immunotoxin

yes no

336 Specify immunotoxin: _____

337 Methotrexate (MTX) (Amethopterin)

yes no

338 Mycophenolate mofetil (MMF) (CellCept)

yes no

339 Sirolimus (Rapamycin, Rapamune)

yes no

340 Blinded randomized trial

yes no

341 Specify trial agent: _____

342 Other agent

yes no

343 Specify other agent: _____

Other Toxicity Modifying Regimen

Questions: 344 - 344

Optional for non-U.S. Centers

344 Was KGF (palifermin, Kevivance) started or is there a plan to use it?

Yes No masked trial

Post-HCT Disease Therapy Planned as of Day 0

Questions: 345 - 357

345 Is this HCT part of a planned multiple (sequential) graft / HCT protocol?

yes no

346 Is additional post-HCT therapy planned?

yes no

Questions 347 – 357 are optional for non-U.S. centers

347 Bortezomib (Velcade)

yes no

348 Cellular therapy (e.g. DCI, DLI)

yes no

349 Dexamethasone

yes no

350 Intrathecal therapy (chemotherapy)

yes no

351 Tyrosine kinase inhibitor (e.g. imatinib mesylate)

yes no

352 Lenalidomide (Revlimid)

yes no

Form 2400 R5.0: Pre-Transplant Essential Data

Center: _____

CRID: _____

353 Local radiotherapy

yes no

354 Rituximab (Rituxan, MabThera)

yes no

355 Thalidomide (Thalomid)

yes no

356 Other therapy

yes no

357 Specify other therapy: _____

First Name: _____

Last Name: _____

E-mail address: _____

Date: ____ - ____ - ____