

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

Key Fields

OMB No: 0915-0310

Expiration Date: 1/31/2017

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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 Recipient 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

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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: _____

What was the prior HSC source(s)?

16 Autologous

yes no

17 Allogeneic, unrelated

yes no

18 Allogeneic, related

yes no

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 for this HCT

Questions: 29 - 62

29 Multiple donors?

yes no

30 Specify number of donors: _____

Donor Information for this HCT (1)

Questions: 31 - 62

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)

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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: _____

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: _____

Questions 52 – 59 are for autologous HCT recipients only. If other than autologous skip to question 60

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

yes no

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

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Specify all agents used in the mobilization events reported above:

54 G-CSF

yes no

55 GM-CSF

yes no

56 Pegylated G-CSF

yes no

57 Plerixafor (Mozobil)

yes no

58 Other CXCR4 inhibitor

yes no

59 Combined with chemotherapy

yes no

60 Was this donor used for any prior HCTs?

yes no

61 Donor CMV-antibodies (IgG or Total)

(Allogeneic HCTs only)

Reactive

Non-reactive

Not done

Not applicable (cord blood unit)

62 Was plerixafor (Mozobil) given at any time prior to the preparative regimen?

(Related HCTs only)

yes no Unknown

Consent

Questions: 63 - 70

63 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

64 Date form was signed: ____ - ____ - ____

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

Yes (patient consented)

No (patient declined)

Not approached

66 Date form was signed: ____ - ____ - ____

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Center:

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67 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)

68 Date form was signed: ____ - ____ - ____

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

(Related donors only)

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

70 Date form was signed: ____ - ____ - ____

Product Processing / Manipulation

Questions: 71 - 89

71 Was the product manipulated prior to infusion?

- yes no

72 Specify portion manipulated

- entire product portion of product

Specify all methods used to manipulate the product:

73 Washed

- yes no

74 Diluted

- yes no

75 Buffy coat enriched
(buffy coat preparation)

- yes no

76 B-cell reduced

- yes no

77 CD8 reduced

- yes no

78 Plasma reduced
(removal)

- yes no

79 RBC reduced

- yes no

80 Cultured
(ex-vivo expansion)

- yes no

81 Genetic manipulation
(gene transfer/transduction)

- yes no

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82 PUVA treated

yes no

83 CD34 enriched (CD34+ selection)

yes no

84 CD133 enriched

yes no

85 Monocyte enriched

yes no

86 Mononuclear cells enriched

yes no

87 T-cell depletion

yes no

88 Other cell manipulation

yes no

89 Specify other cell manipulation: _____

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

Questions: 90 - 93

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

Karnofsky (recipient age ≥ 16 years)

Lansky (recipient age < 16 years)

Performance score prior to the preparative regimen:

91 Karnofsky Scale (recipient age ≥ 16 years) _____

92 Lansky Scale (recipient age < 16 years) _____

93 Recipient CMV-antibodies (IgG or Total)

Reactive Non-reactive Not done

Comorbid Conditions

Questions: 94 - 154

94 Is there a history of mechanical ventilation?

yes no

95 Is there a history of proven invasive fungal infection?

yes no

96 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

97 Arrhythmia

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

yes no Unknown

98 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

99 Cerebrovascular disease

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

yes no Unknown

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100 Diabetes

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

yes no Unknown

101 Heart valve disease

- Except asymptomatic mitral valve prolapse

yes no Unknown

102 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

103 Hepatic, moderate / severe

- Liver cirrhosis, bilirubin > 1.5 × upper limit of normal, or AST/ALT > 2.5 × upper limit of normal

yes no Unknown

104 Infection

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

yes no Unknown

105 Inflammatory bowel disease

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

yes no Unknown

106 Obesity

- Patients with a body mass index > 35 kg/m² at time of transplant

yes no Unknown

107 Peptic ulcer

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

yes no Unknown

108 Psychiatric disturbance

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

yes no Unknown

109 Pulmonary, moderate

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

yes no Unknown

110 Pulmonary, severe

- Corrected diffusion capacity of carbon monoxide and/or FEV1 ≤ 65% or dyspnea at rest or requiring oxygen at transplant

yes no Unknown

111 Renal, moderate / severe

- Serum creatinine > 2 mg/dL or > 177 μmol/L or on dialysis at transplant, OR prior renal transplantation

yes no Unknown

112 Rheumatologic

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

yes no Unknown

113 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

114 Breast cancer

yes no

115 Year of diagnosis: _____

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116 Central nervous system (CNS) malignancy

(glioblastoma, astrocytoma)

yes no

117 Year of diagnosis: _____

118 Gastrointestinal malignancy

(colon, rectum, stomach, pancreas, intestine)

yes no

119 Year of diagnosis: _____

120 Genitourinary malignancy

(kidney, bladder, ovary, testicle, genitalia, uterus, cervix)

yes no

121 Year of diagnosis: _____

122 Lung cancer

yes no

123 Year of diagnosis: _____

124 Melanoma

yes no

125 Year of diagnosis: _____

126 Oropharyngeal cancer

(tongue, buccal mucosa)

yes no

127 Year of diagnosis: _____

128 Sarcoma

yes no

129 Year of diagnosis: _____

130 Thyroid cancer

yes no

131 Year of diagnosis: _____

132 Other co-morbid condition

yes no Unknown

133 Specify other co-morbid condition: _____

134 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:

135 Acute myeloid leukemia (AML / ANLL)

yes no

136 Year of diagnosis: _____

137 Other leukemia, including ALL

yes no

138 Year of diagnosis: _____

139 Specify leukemia: _____

140 Clonal cytogenetic abnormality without leukemia or MDS

yes no

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141 Year of diagnosis: _____

142 Hodgkin disease

yes no

143 Year of diagnosis: _____

144 Lymphoma or lymphoproliferative disease

yes no

145 Year of diagnosis: _____

146 Was the tumor EBV positive?

yes no

147 Other skin malignancy (basal cell, squamous)

yes no

148 Year of diagnosis: _____

149 Specify other skin malignancy: _____

150 Myelodysplasia (MDS) / myeloproliferative (MPN) disorder

yes no

151 Year of diagnosis: _____

152 Other prior malignancy

yes no

153 Year of diagnosis: _____

154 Specify other prior malignancy: _____

Pre-HCT Preparative Regimen (Conditioning)

Questions: 155 - 315

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

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

157 Was a pre-HCT preparative regimen prescribed?

yes no

158 Classify the recipient's prescribed preparative regimen

(Allogeneic HCTs only)

Myeloablative

Non-myeloablative (NST)

Reduced intensity (RIC)

159 Date pre-HCT preparative regimen (irradiation or drugs) began: ____ - ____ - ____

Use earliest date from questions 163 radiation, or 168 – 315 chemotherapy

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

yes no

161 What was the prescribed radiation field?

total body

total body by tomotherapy

total lymphoid or nodal regions

thoracoabdominal region

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

163 Date started: ____ - ____ - ____

164 Was the radiation fractionated?

yes no

165 Prescribed dose per fraction: _____ Gy cGy

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

167 Total number of fractions: _____

Indicate the total prescribed cumulative dose for the preparative regimen:

168 ALG, ALS, ATG, ATS

yes no

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

170 Date started: ____ - ____ - ____

171 Specify source

Horse Rabbit Other

172 Specify other source: _____

173 Anthracycline

yes no

174 Daunorubicin

yes no

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

176 Date started: ____ - ____ - ____

177 Doxorubicin (Adriamycin)

yes no

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

179 Date started: ____ - ____ - ____

180 Idarubicin

yes no

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

182 Date started: ____ - ____ - ____

183 Rubidazole

yes no

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

185 Date started: ____ - ____ - ____

186 Other anthracycline

yes no

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

188 Date started: ____ - ____ - ____

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189 Specify other anthracycline: _____

190 Bleomycin (BLM, Blenoxane)

yes no

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

192 Date started: ____ - ____ - ____

193 Busulfan (Myleran)

yes no

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

195 Date started: ____ - ____ - ____

196 Specify administration

Oral IV Both

197 Carboplatin

yes no

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

199 Date started: ____ - ____ - ____

200 Were pharmacokinetics performed to determine preparative regimen drug dosing?

yes no

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

202 Cisplatin (Platinol, CDDP)

yes no

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

204 Date started: ____ - ____ - ____

205 Cladribine (2-CdA, Leustatin)

yes no

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

207 Date started: ____ - ____ - ____

208 Corticosteroids

(excluding anti-nausea medication)

yes no

209 Methylprednisolone (Solu-Medrol)

yes no

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

211 Date started: ____ - ____ - ____

212 Prednisone

yes no

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

214 Date started: ____ - ____ - ____

215 Dexamethasone

yes no

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

217 Date started: ____ - ____ - ____

218 Other corticosteroid

yes no

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

220 Date started: ____ - ____ - ____

221 Specify other corticosteroid: _____

222 Cyclophosphamide (Cytosan)

yes no

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

224 Date started: ____ - ____ - ____

225 Cytarabine (Ara-C)

yes no

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

227 Date started: ____ - ____ - ____

228 Etoposide (VP-16, VePesid)

yes no

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

230 Date started: ____ - ____ - ____

231 Fludarabine

yes no

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

233 Date started: ____ - ____ - ____

234 Ifosfamide

yes no

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

236 Date started: ____ - ____ - ____

237 Intrathecal therapy

(chemotherapy)

yes no

238 Intrathecal cytarabine (IT Ara-C)

yes no

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Center:

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

240 Date started: ____ - ____ - ____

241 Intrathecal methotrexate (IT MTX)

yes no

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

243 Date started: ____ - ____ - ____

244 Intrathecal thiotepa

yes no

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

246 Date started: ____ - ____ - ____

247 Other intrathecal drug

yes no

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

249 Date started: ____ - ____ - ____

250 Specify other intrathecal drug: _____

251 Melphalan (L-Pam)

yes no

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

253 Date started: ____ - ____ - ____

254 Specify administration

Oral IV Both

255 Mitoxantrone (Novantrone)

yes no

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

257 Date started: ____ - ____ - ____

258 Monoclonal antibody

yes no

259 Radio labeled MAb

yes no

260 Total prescribed dose of radioactive component: _____ mCi MBq

261 Date started: ____ - ____ - ____

Specify radio labeled mAb:

262 Tositumomab (Bexxar)

yes no

263 Ibritumomab tiuxetan (Zevalin)

yes no

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Center:

CRID:

264 Other radio labeled MAb

yes no

265 Specify other radio labeled MAb: _____

266 Alemtuzumab (Campath)

yes no

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

268 Date started: ____ - ____ - ____

269 Rituximab (Rituxan, anti CD20)

yes no

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

271 Date started: ____ - ____ - ____

272 Gemtuzumab (Mylotarg, anti CD33)

yes no

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

274 Date started: ____ - ____ - ____

275 Other MAb

yes no

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

277 Date started: ____ - ____ - ____

278 Specify other MAb: _____

279 Nitrosourea

yes no

280 Carmustine (BCNU)

yes no

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

282 Date started: ____ - ____ - ____

283 CCNU (Lomustine)

yes no

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

285 Date started: ____ - ____ - ____

286 Other nitrosourea

yes no

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

288 Date started: ____ - ____ - ____

289 Specify other nitrosourea: _____

290 Paclitaxel (Taxol, Xyotax)

yes no

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Center:

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

292 Date started: ____-____-____

293 Teniposide (VM26)

yes no

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

295 Date started: ____-____-____

296 Thiotepa

yes no

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

298 Date started: ____-____-____

299 Treosulfan

yes no

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

301 Date started: ____-____-____

302 Tyrosine kinase inhibitors

yes no

303 Dasatinib (Sprycel)

yes no

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

305 Date started: ____-____-____

306 Imatinib mesylate (STI571, Gleevec)

yes no

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

308 Date started: ____-____-____

309 Nilotinib

yes no

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

311 Date started: ____-____-____

312 Other drug

yes no

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

314 Date started: ____-____-____

315 Specify other drug: _____

GVHD Prophylaxis

Questions: 316 - 341

This section is to be completed for allogeneic HCTs only; autologous HCTs continue with question 342.

316 Was GVHD prophylaxis planned / given?

yes no

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Center:

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Specify:

317 ALG, ALS, ATG, ATS

yes no

318 Specify source

Horse Rabbit Other

319 Specify other source: _____

320 Corticosteroids
(systemic)

yes no

321 Cyclosporine (CSA, Neoral, Sandimmune)

yes no

322 Cyclophosphamide (Cytoxan)

yes no

323 Extra-corporeal photopheresis (ECP)

yes no

324 FK 506 (Tacrolimus, Prograf)

yes no

325 In vivo monoclonal antibody

yes no

Specify in vivo monoclonal antibody:

326 Alemtuzumab (Campath)

yes no

327 Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

yes no

328 Specify: _____

329 Etanercept (Enbrel)

yes no

330 Infliximab (Remicade)

yes no

331 Other in vivo monoclonal antibody

yes no

332 Specify antibody: _____

333 In vivo immunotoxin

yes no

334 Specify immunotoxin: _____

335 Methotrexate (MTX) (Amethopterin)

yes no

336 Mycophenolate mofetil (MMF) (CellCept)

yes no

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337 Sirolimus (Rapamycin, Rapamune)

yes no

338 Blinded randomized trial

yes no

339 Specify trial agent: _____

340 Other agent

yes no

341 Specify other agent: _____

Other Toxicity Modifying Regimen

Questions: 342 - 342

Optional for non-U.S. Centers

342 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: 343 - 355

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

yes no

344 Is additional post-HCT therapy planned?

yes no

Questions 345 – 355 are optional for non-U.S. centers

345 Bortezomib (Velcade)

yes no

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

yes no

347 Dexamethasone

yes no

348 Intrathecal therapy
(chemotherapy)

yes no

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

yes no

350 Lenalidomide (Revlimid)

yes no

351 Local radiotherapy

yes no

352 Rituximab (Rituxan, MabThera)

yes no

353 Thalidomide (Thalomid)

yes no

354 Other therapy

yes no

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355 Specify other therapy: _____

Primary Disease for HCT

Questions: 356 - 645

356 Date of diagnosis of primary disease for HCT: ____ - ____ - ____

357 What was the primary disease for which the HCT was performed?

- Acute myelogenous leukemia (AML or ANLL) (10)
- Acute lymphoblastic leukemia (ALL) (20)
- Other acute leukemia (80)
- Chronic myelogenous leukemia (CML) (40)
- Myelodysplastic (MDS) / myeloproliferative (MPN) diseases (50) (Please classify all preleukemias)
- Other leukemia (30) (includes CLL)
- Hodgkin lymphoma (150)
- Non-Hodgkin lymphoma (100)
- Multiple myeloma / plasma cell disorder (PCD) (170)
- Solid tumors (200)
- Severe aplastic anemia (300) (If the recipient developed MDS or AML, indicate MDS or AML as the primary disease)
- Inherited abnormalities of erythrocyte differentiation or function (310)
- Disorders of the immune system (400)
- Inherited abnormalities of platelets (500)
- Inherited disorders of metabolism (520)
- Histiocytic disorders (570)
- autoimmune diseases (600)
- Other disease (900)

Acute Myelogenous Leukemia (AML)

358 Specify the AML classification _____

359 Did AML transform from MDS or MPN?

- yes **Also complete Disease Classification questions 480-527**
- no

360 Is the disease (AML) therapy related?

- yes
- no
- Unknown

361 Did the recipient have a predisposing condition?

- yes
- no
- Unknown

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362 Specify condition

- Bloom syndrome
- Down syndrome
- Fanconi anemia
- Neurofibromatosis type 1
- Other condition

363 Specify other condition: _____

364 Were cytogenetics tested (conventional or FISH)?

- yes no Unknown

365 Results of tests

- Abnormalities identified
- No evaluable metaphases
- No abnormalities

Specify cytogenetic abnormalities identified at any time prior to the start of the preparative regimen:

Monosomy

366 -5

- yes no

367 -7

- yes no

368 -17

- yes no

369 -18

- yes no

370 -X

- yes no

371 -Y

- yes no

Trisomy

372 +4

- yes no

373 +8

- yes no

374 +11

- yes no

375 +13

- yes no

376 +14

- yes no

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Center:

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377 +21

yes no

378 +22

yes no

Translocation

379 t(3;3)

yes no

380 t(6;9)

yes no

381 t(8;21)

yes no

382 t(9;11)

yes no

383 t(9;22)

yes no

384 t(15;17) and variants

yes no

385 t(16;16)

yes no

Deletion

386 del(3q) / 3q-

yes no

387 del(5q) / 5q-

yes no

388 del(7q) / 7q-

yes no

389 del(9q) / 9q-

yes no

390 del(11q) / 11q-

yes no

391 del(16q) / 16q-

yes no

392 del(17q) / 17q-

yes no

393 del(20q) / 20q-

yes no

394 del(21q) / 21q-

yes no

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Center:

CRID:

Inversion

395 inv(3)

yes no

396 inv(16)

yes no

Other

397 (11q23) any abnormality

yes no

398 12p any abnormality

yes no

399 Complex - ≥ 3 distinct abnormalities

yes no

400 Other abnormality

yes no

401 Specify other abnormality: _____

402 Were tests for molecular markers performed (e.g. PCR)?

yes no Unknown

Specify molecular markers identified at any time prior to the start of the preparative regimen.

403 CEBPA

Positive Negative Not Done

404 FLT3 – D835 point mutation

Positive Negative Not Done

405 FLT3 – ITD mutation

Positive Negative Not Done

406 IDH1

Positive Negative Not Done

407 IDH2

Positive Negative Not Done

408 KIT

Positive Negative Not Done

409 NPM1

Positive Negative Not Done

410 Other molecular marker

Positive Negative Not Done

411 Specify other molecular marker: _____

Status at Transplantation

412 What was the disease status (based on hematological test results)? _____

413 How many cycles of induction therapy were required to achieve CR?

1 2 ≥3

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

414 Was the recipient in molecular remission?

Yes No Unknown Not applicable

415 Was the recipient in remission by flow cytometry?

Yes No Unknown Not applicable

416 Was the recipient in cytogenetic remission?

Yes No Unknown Not applicable

417 Date of most recent relapse: ____ - ____ - ____

418 Date assessed: ____ - ____ - ____

Acute Lymphoblastic Leukemia (ALL)

419 Specify ALL classification _____

420 Were tyrosine kinase inhibitors (i.e. imatinib mesylate) given for pre-HCT therapy at any time prior to start of the preparative regimen?

yes no

421 Were cytogenetics tested (conventional or FISH)?

yes no Unknown

422 Results of tests

Abnormalities identified

No evaluable metaphases

No abnormalities

Specify cytogenetic abnormalities identified at any time prior to the start of the preparative regimen.

Monosomy

423 -7

yes no

Trisomy

424 +4

yes no

425 +8

yes no

426 +17

yes no

427 +21

yes no

Translocation

428 t(1;19)

yes no

429 t(2;8)

yes no

430 t(4;11)

yes no

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

431 t(5;14)

yes no

432 t(8;14)

yes no

433 t(8;22)

yes no

434 t(9;22)

yes no

435 t(10;14)

yes no

436 t(11;14)

yes no

437 t(12;21)

yes no

Deletion

438 del(6q) / 6q-

yes no

439 del(9p) / 9p-

yes no

440 del(12p) / 12p-

yes no

Addition

441 add(14q)

yes no

Other

442 (11q23) any abnormality

yes no

443 9p any abnormality

yes no

444 12p any abnormality

yes no

445 Hyperdiploid (>50)

yes no

446 Hypodiploid (<46)

yes no

447 Complex - ≥ 3 distinct abnormalities

yes no

448 Other abnormality

yes no

Form 2400 R4.0: Pre-Transplant Essential Data

Center: _____

CRID: _____

449 Specify other abnormality: _____

450 Were tests for molecular markers performed (e.g. PCR)?

yes no Unknown

Specify molecular markers identified at any time prior to the start of the preparative regimen:

451 BCR / ABL

Positive Negative Not Done

452 TEL-AML / AML1

Positive Negative Not Done

453 Other molecular marker

Positive Negative Not Done

454 Specify other molecular marker: _____

Status at transplantation

455 What was the disease status (based on hematological test results)? _____

456 How many cycles of induction therapy were required to achieve CR?

1 2 ≥3

457 Was the recipient in molecular remission?

Yes No Unknown Not applicable

458 Was the recipient in remission by flow cytometry?

Yes No Unknown Not applicable

459 Was the recipient in cytogenetic remission?

Yes No Unknown Not applicable

460 Date of most recent relapse: ____ - ____ - ____

461 Date assessed: ____ - ____ - ____

Other Acute Leukemia

462 Specify other acute leukemia classification

Acute undifferentiated leukemia (31)

Biphenotypic, bilineage or hybrid leukemia (32)

Acute mast cell leukemia (33)

Other acute leukemia (89)

463 Specify other acute leukemia: _____

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

Status at transplantation

464 What was the disease status (based on hematological test results)?

- Primary induction failure
- 1st complete remission (no previous marrow or extramedullary relapse)
- 2nd complete remission
- ≥3rd complete remission
- 1st relapse
- 2nd relapse
- ≥3rd relapse
- No treatment

465 Date assessed: ____ - ____ - ____

Chronic Myelogenous Leukemia (CML)

Philadelphia chromosome+, Ph+, t(9;22) (q34;q11), or variant OR bcr/abl+

466 Specify CML classification _____

467 Was therapy given prior to this HCT?

- yes no

468 Combination chemotherapy

- yes no

469 Hydroxyurea (Droxia, Hydrea)

- yes no

470 Tyrosine kinase inhibitor

(e.g. imatinib mesylate, dasatinib, nilotinib)

- yes no

471 Interferon-α (Intron, Roferon) (includes PEG)

- yes no

472 Other therapy

- yes no

473 Specify other therapy: _____

474 What was the disease status at last evaluation prior to the start of the preparative regimen? _____

Specify remission:

475 Cytogenetic complete remission (Ph negative)

- yes no Unknown

476 Molecular complete remission (BCR / ABL negative)

- yes no Unknown

477 CML disease status before treatment that achieved this CR

- Chronic phase Accelerated Phase Blast phase

478 Number

- 1st 2nd 3rd or higher

479 Date assessed: ____ - ____ - ____

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

480 What was the MDS / MPN subtype at diagnosis?

-If transformed to AML, indicate AML as primary disease; also complete Disease Classification questions 358-418

481 Was the disease (MDS/MPN) therapy related?

yes no Unknown

482 Did the recipient have a predisposing condition?

yes no Unknown

483 Specify condition

Aplastic Anemia Bloom syndrome Down syndrome Fanconi anemia Other condition

484 Specify other condition: _____

Laboratory Studies at Diagnosis of MDS

485 WBC

Known Unknown

486 _____ x 10⁹/L (x 10³/mm³)

x 10⁶/L

487 Hemoglobin

Known Unknown

488 _____ g/dL g/L mmol/L

489 Was RBC transfused < 30 days before date of test?

yes no

490 Platelets

Known Unknown

491 _____ x 10⁹/L (x 10³/mm³)

x 10⁶/L

492 Were platelets transfused < 7 days before date of test?

yes no

493 Neutrophils

Known Unknown

494 _____ %

495 Blasts in bone marrow

Known Unknown

496 _____ %

497 Were cytogenetics tested (conventional or FISH)?

yes no Unknown

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

498 Results of tests

Abnormalities identified

No evaluable metaphases

No abnormalities

Specify abnormalities identified at diagnosis:

499 Specify number of distinct cytogenetic abnormalities

One (1)

Two (2)

Three (3)

Four or more (4 or more)

Monosomy

500 -5

yes no

501 -7

yes no

502 -13

yes no

503 -20

yes no

504 -Y

yes no

Trisomy

505 +8

yes no

506 +19

yes no

Translocation

507 t(1;3)

yes no

508 t(2;11)

yes no

509 t(3;3)

yes no

510 t(3;21)

yes no

511 t(6;9)

yes no

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

512 t(11;16)

yes no

Deletion

513 del(3q) / 3q-

yes no

514 del(5q) / 5q-

yes no

515 del(7q) / 7q-

yes no

516 del(9q) / 9q-

yes no

517 del(11q) / 11q-

yes no

518 del(12p) / 12p-

yes no

519 del(13q) / 13q-

yes no

520 del(20q) / 20q-

yes no

Inversion

521 inv(3)

yes no

Other

522 i17q

yes no

523 Other abnormality

yes no

524 Specify other abnormality: _____

525 Did the recipient progress or transform to a different MDS / MPN subtype between diagnosis and the start of the preparative regimen?

yes no

526 Specify the date of the most recent transformation: ____ - ____ - ____

527 Specify the MDS / MPN subtype after transformation

Laboratory studies at last evaluation prior to the start of the preparative regimen:

528 WBC

Known Unknown

529 _____ x 10⁹/L (x 10³/mm³)

x 10⁶/L

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

530 Hemoglobin

Known Unknown

531 _____ g/dL g/L mmol/L

532 Was RBC transfused < 30 days before date of test?

yes no

533 Platelets

Known Unknown

534 _____ x 10⁹/L (x 10³/mm³)
 x 10⁶/L

535 Were platelets transfused < 7 days before date of test?

yes no

536 Neutrophils

Known Unknown

537 _____ %

538 Blasts in bone marrow

Known Unknown

539 _____ %

540 Were cytogenetics tested (conventional or FISH)?

yes no Unknown

541 Results of tests

Abnormalities identified

No evaluable metaphases

No abnormalities

Specify cytogenetic abnormalities identified at last evaluation prior to the start of the preparative regimen:

542 Specify number of distinct cytogenetic abnormalities

One (1)

Two (2)

Three (3)

Four or more (4 or more)

Monosomy

543 -5

yes no

544 -7

yes no

545 -13

yes no

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

546 -20

yes no

547 -Y

yes no

Trisomy

548 +8

yes no

549 +19

yes no

Translocation

550 t(1;3)

yes no

551 t(2;11)

yes no

552 t(3;3)

yes no

553 t(3;21)

yes no

554 t(6;9)

yes no

555 t(11;16)

yes no

Deletion

556 del(3q) / 3q-

yes no

557 del(5q) / 5q-

yes no

558 del(7q) / 7q-

yes no

559 del(9q) / 9q-

yes no

560 del(11q) / 11q-

yes no

561 del(12p) / 12p-

yes no

562 del(13q) / 13q-

yes no

563 del(20q) / 20q-

yes no

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

Inversion

564 inv(3)

yes no

Other

565 i17q

yes no

566 Other abnormality

yes no

567 Specify other abnormality: _____

Status at Transplantation

568 What was the disease status?

- Complete remission (CR) – requires all of the following, maintained for ≥ 4 weeks: * bone marrow evaluation: < 5% myeloblasts with normal maturation of all cell lines * peripheral blood evaluation: hemoglobin ≥ 11 g/dL untransfused and without erythropoietin support; ANC ≥ 1000 / mm³ without myeloid growth factor support; platelets ≥ 100 x 10⁹/L without thrombopoietic support; 0% blasts
- Hematologic improvement (HI) – requires one measurement of the following, maintained for ≥ 8 weeks without ongoing cytotoxic therapy; specify which cell line was measured to determine HI response: * HI-E – hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in 8 weeks * HI-P – for pre-treatment platelet count of > 20 x 10⁹ /L, platelet absolute increase of ≥ 30 x 10⁹ /L; for pre-treatment platelet count of < 20 x 10⁹ /L, platelet absolute increase of ≥ 20 x 10⁹ /L and ≥ 100% from pre-treatment level * HI-N – neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500 / mm³
- No response (NR) / stable disease (SD) – does not meet the criteria for at least HI, but no evidence of disease progression
- Progression from hematologic improvement (Prog from HI) – requires at least one of the following, in the absence of another explanation (e.g., infection, bleeding, ongoing chemotherapy, etc.): * ≥ 50% reduction from maximum response levels in granulocytes or platelets * reduction in hemoglobin by ≥ 1.5 g/dL *transfusion dependence
- Relapse from complete remission (Rel from CR) – requires at least one of the following: * return to pre-treatment bone marrow blast percentage * decrease of ≥ 50% from maximum response levels in granulocytes or platelets * transfusion dependence, or hemoglobin level ≥ 1.5 g/dL lower than prior to therapy
- Not assessed

569 Specify the cell line examined to determine HI status

- HI-E – hemoglobin increase of ≥ 1.5 g/dL untransfused; for RBC transfusions performed for Hgb ≤ 9.0, reduction in RBC units transfused in 8 weeks by ≥ 4 units compared to the pre-treatment transfusion number in 8 weeks
- HI-P – for pre-treatment platelet count of > 20 x 10⁹ /L, platelet absolute increase of ≥ 30 x 10⁹ /L; for pre-treatment platelet count of < 20 x 10⁹ /L, platelet absolute increase of ≥ 20 x 10⁹ /L and ≥ 100% from pre-treatment level
- HI-N – neutrophil count increase of ≥ 100% from pre-treatment level and an absolute increase of ≥ 500 / mm³

570 Date of progression: ____ - ____ - ____

571 Date of relapse: ____ - ____ - ____

572 Date assessed: ____ - ____ - ____

Other Leukemia (OL)

573 Specify the other leukemia classification _____

574 Specify other leukemia: _____

575 Was any 17p abnormality detected?

yes no

576 Did a histologic transformation to diffuse large B-cell lymphoma (Richter syndrome) occur at any time after CLL diagnosis?

yes -Also complete Disease Classification questions 583-588

no

Status at transplantation:

577 What was the disease status? _____
(Atypical CML)

578 What was the disease status? _____
(CLL, PLL, Hairy cell Leukemia)

Form 2400 R4.0: Pre-Transplant Essential Data

Center: _____

CRID: _____

579 Date assessed: ____ - ____ - ____

Hodgkin Lymphoma

580 Specify Hodgkin lymphoma classification _____

Status at transplantation:

581 What was the disease status? _____

582 Date assessed: ____ - ____ - ____

Non-Hodgkin Lymphoma

583 Specify Non-Hodgkin lymphoma classification _____

584 Specify other lymphoma: _____

585 Is the non-Hodgkin lymphoma histology reported at diagnosis (question 583) a transformation from CLL?

yes Also complete Disease Classification questions 573-576

no

586 Is the non-Hodgkin lymphoma histology reported (in question 583) a transformation from, or was it diagnosed at the same time as another lymphoma (not CLL)?

yes no

Status at transplantation:

587 What was the disease status? _____

588 Date assessed: ____ - ____ - ____

Multiple Myeloma/Plasma Cell Disorder (PCD)

589 Specify the multiple myeloma/plasma cell disorder (PCD) classification _____

590 Specify other plasma cell disorder: _____

591 Light chain

kappa lambda

592 What was the Durie-Salmon staging?

Stage I (All of the following: Hgb > 10g/dL; serum calcium normal or <10.5 mg/dL; bone x-ray normal bone structure (scale 0), or solitary bone plasmacytoma only; low M-component production rates IgG < 5g/dL, IgA < 3g/dL; urine light change M-component on electrophoresis <4 g/24h)

Stage II (Fitting neither Stage I or III)

Stage III (One or more of the following: Hgb < 8.5 g/dL; serum calcium > 12 mg/dL; advanced lytic bone lesions (scale 3); high M-component production rates IgG > 7g/dL, IgA > 5 g/dL; Bence Jones protein > 12g/24 h)

Unknown

593 What was the Durie-Salmon sub classification?

(at diagnosis)

A -relatively normal renal function (serum creatinine <2.0 mg/dL)

B -abnormal renal function (serum creatinine ≥2.0 mg/dL)

I.S.S.:

594 Serum β2-microglobulin: _____ μg/dL mg/L nmol/L

595 Serum albumin: _____ g/dL g/L

596 Stage

1 (β₂-mic < 3.5, S. albumin >3.5)

2 (β₂-mic <3.5, S. albumin <3.5; β₂-mic 3.5- <5.5, s.albumin-)

3 (β₂-mic ≥ 5.5, S. albumin --)

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

597 Were cytogenetics tested (conventional or FISH)?

yes no Unknown

598 Results of tests

Abnormalities identified

No evaluable metaphases

No abnormalities

Specify cytogenetic abnormalities identified at any time prior to the start of the preparative regimen:

Trisomy

599 +3

yes no

600 +5

yes no

601 +7

yes no

602 +9

yes no

603 +11

yes no

604 +15

yes no

605 +19

yes no

Translocation

606 t(4;14)

yes no

607 t(6;14)

yes no

608 t(11;14)

yes no

609 t(14;16)

yes no

610 t(14;20)

yes no

Deletion

611 del(13q) / 13q-

yes no

612 del (17p) / 17p-

yes no

Form 2400 R4.0: Pre-Transplant Essential Data

Center:

CRID:

Other

613 Hyperdiploid (>50)

yes no

614 Hypodiploid (<46)

yes no

615 Any abnormality at 1q

yes no

616 Any abnormality at 1p

yes no

617 Other abnormality

yes no

618 Specify other abnormality: _____

Status at transplantation:

619 What was the disease status?

- Stringent complete remission (sCR)** — CR as defined, plus: normal free light chain ratio, and absence of clonal cells in the bone marrow by immunohistochemistry of immunofluorescence (confirmation with repeat bone marrow biopsy not needed). (Presence and/or absence of clonal cells is based up on the K/λ ratio. An abnormal K/λ ratio by immunohistochemistry and/or immunofluorescence requires a minimum of 100 plasma cells for analysis. An abnormal ratio reflecting the presence of an abnormal clone is K/λ of <4:1 or <1:2) sCR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy sCR requirements.
- Complete remission (CR)** — negative immunofixation on serum and urine samples, and disappearance of any soft tissue plasmacytomas, and ≤ 5% plasma cells in the bone marrow (confirmation with repeat bone marrow biopsy not needed). CR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy CR requirements.
- Near complete remission (nCR)** — serum & urine M-protein detectable by immunoelectrophoresis (IFE), but not on electrophoresis (negative SPEP & UPEP); ≤ 5% plasma cells in bone marrow. nCR requires two consecutive assessments made at any time before the initiation of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy nCR requirements.
- Very good partial remission (VGPR)** — serum and urine M-protein detectable by immunofixation but not on electrophoresis, or ≥ 90% reduction in serum M-protein and urine M-protein level < 100 mg/24 hours. VGPR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy VGPR requirements.
- Partial remission (PR)** — ≥ 50% reduction in serum M-protein, and reduction in 24-hour urinary M-protein by ≥ 90% or to < 200 mg/24 hours. If the serum and urine M-protein are unmeasurable (i.e., do not meet any of the following criteria: • serum M-protein ≥ 1 g/dL. Urine M-protein ≥ 200 mg/24 hours • serum free light chain assay shows involved level ≥ 10 mg/dL, provided serum free light chain ratio is abnormal), a ≥ 50% decrease in the difference between involved and uninvolved free light chain levels is required in place of the M-protein criteria. If serum and urine M-protein are unmeasurable, and serum free light assay is also unmeasurable, a ≥ 50% reduction in plasma cells is required in place of M-protein, provided the baseline bone marrow plasma cell percentage was ≥ 30%. In addition to the above listed criteria, a ≥ 50% reduction in the size of soft tissue plasmacytomas is also required, if present at baseline. PR requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy PR requirements.
- Stable disease (SD)** — not meeting the criteria for CR, VGPR, PR or PD. SD requires two consecutive assessments made at any time before the institution of any new therapy, and no known evidence of progressive or new bone lesions if radiographic studies were performed; radiographic studies are not required to satisfy SD requirements.
- Progressive disease (PD)** — requires any one or more of the following: Increase of ≥ 25% from baseline in: serum M-component and/or (absolute increase ≥ 0.5 g/dL) (for progressive disease, serum M-component increases of ≥ 1 g/dL are sufficient to define relapse if the starting M-component is ≥ 5 g/dL). Urine M-component and/or (absolute increase ≥ 200 mg/24 hours) for recipients without measurable serum and urine M-protein levels: the difference between involved and uninvolved free light chain levels (absolute increase > 10 mg/dL). Bone marrow plasma cell percentage (absolute percentage ≥ 10%) (relapse from CR has a 5% cutoff vs. 10% for other categories of relapse) definite development of new bone lesions or soft tissue plasmacytomas, or definite increase in the size of any existing bone lesions or soft tissue plasmacytomas. Development of hypercalcemia (corrected serum calcium > 11.5 mg/dL or 2.65 mmol) that can be attributed solely to the plasma cell proliferative disorder PD requires two consecutive assessments made at any time before classification as disease progression, and/or the institution of any new therapy.
- Relapse from CR (Rel) (untreated)** — requires one or more of the following: reappearance of serum or urine M-protein by immunofixation or electrophoresis development of ≥ 5% plasma cells in the bone marrow (relapse from CR has a 5% cutoff vs. 10% for other categories of relapse) appearance of any other sign of progression (e.g., new plasmacytoma, lytic bone lesion, hypercalcemia) Rel requires two consecutive assessments made at any time before classification as relapse, and/or the institution of any new therapy.
- Unknown**
- Not applicable**

620 Date assessed: ____ - ____ - ____

Form 2400 R4.0: Pre-Transplant Essential Data

Center: _____

CRID: _____

Solid Tumors

621 Specify the solid tumor classification _____

Other Disease

622 Specify other solid tumor: _____

Severe Aplastic Anemia

623 Specify the severe aplastic anemia classification _____

624 Specify other acquired cytopenic syndrome: _____

Inherited Abnormalities of Erythrocyte Differentiation or Function

625 Specify the inherited abnormalities of erythrocyte differentiation or function classification _____

626 Specify other constitutional anemia: _____

627 Specify other hemoglobinopathy: _____

Disorders of the immune system

628 Specify disorder of immune system classification _____

629 Specify other SCID: _____

630 Specify other immunodeficiency: _____

Inherited abnormalities of platelets

631 Specify inherited abnormalities of platelets classification

Congenital amegakaryocytosis / congenital thrombocytopenia (501)

Glanzmann thrombasthenia (502)

Other inherited platelet abnormality (509)

632 Specify other inherited platelet abnormality: _____

Inherited Disorders of Metabolism

633 Specify inherited disorders of metabolism classification _____

634 Specify other inherited metabolic disorder: _____

Histiocytic disorders

635 Specify histiocytic disorder classification _____

636 Specify other histiocytic disorder: _____

Autoimmune diseases

637 Specify autoimmune disease classification _____

638 Specify other arthritis:

639 Specify other juvenile idiopathic arthritis (JIA): _____

640 Specify other connective tissue disease: _____

641 Specify other vasculitis: _____

642 Specify other autoimmune neurological disorder: _____

643 Specify other autoimmune cytopenia: _____

644 Specify other autoimmune bowel disorder: _____

Other Disease

645 Specify other disease: _____

First Name: _____

Last Name: _____

E-mail address: _____

Date: ____ - ____ - ____