Form 5000 R1.0: RITN Baseline Form

Center: CRID:

Key Fields

Sequence Number: _____

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

CIBMTR Center Number: _____

CIBMTR Research ID: _____

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

Patient Information

Questions: 1 - 9

1 Date of arrival at RITN center: __ __ __ __ - __ __- __ __

Specify patient height and weight at time of arrival to RITN center:

2 Height: _____ ○ inches ○ centimeters

3 Weight: _____ ○ pounds ○ kilograms

4 Ethnicity

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

Race (1)

Questions: 5 - 6

5 Race _____

6 Race detail _____

7 What scale was used to determine the patient's functional status?

○ Karnofsky ○ Lansky

Performance score at time of evaluation:

8 Karnofsky scale (patient age ≥ 16 years) _____

9 Lansky scale (patient age < 16 years) _____

Consent

Questions: 10 - 13

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

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

11 Date form was signed: __ __ __ __ - __ __- __ __

12 Has the patient 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)

13 Date form was signed: __ __ __ __ - __ __- __ __

Co-morbid Conditions

Questions: 14 - 76

14 Were there clinically significant co-existing diseases or organ impairment at time of evaluation?
Source: Blood, 2005 Oct 15;106(8):2912-2919

○ yes ○ no

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

○ yes ○ no ○ Unknown

16 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

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

○ yes ○ no ○ Unknown

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

○ yes ○ no ○ Unknown

19 Heart valve disease - Except asymptomatic mitral valve prolapse

○ yes ○ no ○ Unknown

20 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

21 Hepatic, moderate / severe - Liver cirrhosis, bilirubin > 1.5 × upper limit of normal, or AST/ALT > 2.5 × upper limit of normal
yes no Unknown

22 Infection - For example, documented infection, fever of unknown origin, or pulmonary nodules requiring continuation of antimicrobial treatment after evaluation
yes no Unknown

23 Inflammatory bowel disease - Any history of Crohn's disease or ulcerative colitis requiring treatment
yes no Unknown

24 Obesity - Patients with a body mass index > 35 kg/m2 at time of evaluation
yes no Unknown

25 Peptic ulcer - Any history of peptic ulcer confirmed by endoscopy and requiring treatment
yes no Unknown

26 Psychiatric disturbance - For example, depression, anxiety, bipolar disorder or schizophrenia requiring psychiatric consult or treatment in the last 4 weeks
yes no Unknown

27 Pulmonary, moderate - Corrected diffusion capacity of carbon monoxide and/or FEV1 66-80% or dyspnea on slight activity at transplant
yes no Unknown

28 Pulmonary, severe - Corrected diffusion capacity of carbon monoxide and/or FEV1 ≤ 65% or dyspnea at rest or requiring oxygen at evaluation
yes no Unknown

29 Renal, moderate / severe - Serum creatinine > 2 mg/dL or > 177 µmol/L or on dialysis at transplant, OR prior renal transplantation
yes no Unknown

30 Rheumatologic - For example, any history of systemic lupus erythmatosis, rheumatoid arthritis, polymyositis, mixed connective tissue disease, or polymyalgia rheumatica requiring treatment (do NOT include degenerative joint disease, osteoarthritis)
yes no Unknown

31 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

32 Breast cancer
yes no

33 Year of diagnosis: _____

34 Central nervous system (CNS) malignancy
(e.g. glioblastoma, astrocytoma)
yes no

35 Year of diagnosis: _____

36 Gastrointestinal malignancy
(e.g. colon, rectum, stomach, pancreas, intestine)
yes no

37 Year of diagnosis: _____

38 Genitourinary malignancy
(e.g. kidney, bladder, ovary, testicle, genitalia, uterus, cervix)
yes no

39 Year of diagnosis: _____

40 Lung cancer
yes no

41 Year of diagnosis: _____

42 Melanoma
yes no

43 Year of diagnosis: _____

44 Oropharyngeal cancer
(e.g. tongue, buccal mucosa)
yes no

45 Year of diagnosis: _____

46 Sarcoma
yes no

47 Year of diagnosis: _____

48 Thyroid cancer
yes no

49 Year of diagnosis: _____

50 Other co-morbid condition
yes no Unknown

51 Specify other co-morbid condition: _____

History of Malignancy (Hematologic or Non-Melanoma Skin Cancer)

52 Was there a history of malignancy (hematologic or non-melanoma skin cancer)?
yes no

Specify which malignancy(ies) occurred:

53 Acute myeloid leukemia (AML / ANLL)
yes no

54 Year of diagnosis: _____

55 Other leukemia, including ALL
yes no

56 Year of diagnosis: _____

57 Specify leukemia: _____

58 Clonal cytogenetic abnormality without leukemia or MDS
yes no

59 Year of diagnosis: _____

60 Hodgkin disease
yes no

61 Year of diagnosis: _____

62 Lymphoma or lymphoproliferative disease
yes no

63 Year of diagnosis: _____

64 Was the tumor EBV positive?
yes no

65 Other skin malignancy (basal cell, squamous)
yes no

66 Year of diagnosis: _____

67 Specify other skin malignancy: _____

68 Myelodysplasia (MDS) / myeloproliferative (MPN) disorder
yes no

69 Year of diagnosis: _____

70 Other prior malignancy
yes no

71 Year of diagnosis: _____

72 Specify other prior malignancy: _____

73 Has the patient received radiation therapy at any time?
yes no

74 Was the patient receiving radiation therapy at the time of exposure?
Yes No

75 Has the patient received chemotherapy at any time?
yes no

76 Was the patient receiving chemotherapy at the time of exposure?
Yes No

Patient Exposure

Questions: 77 - 87

77 What was the marrow toxic incident type?
- Improvised nuclear device (IND) / military nuclear weapon
- Radiological exposure device (RED) (e.g. Open source)
- Radiological dispersal device (RDD) (e.g. Dirty bomb)
- Nuclear power plant accident
- Industrial / workplace accident
- Chemical (e.g. Mustard agent)
- Unknown

78 Was the patient pregnant at the time of exposure?
(Female only)
Yes No Unknown

79 Did the patient have internal contamination?
- Yes
- No
- Not Applicable (e.g. RED)
- Unknown

80 Was external dose estimation from exposure done?

- Yes
- No
- Not Applicable (chemical)
- Unknown

External Dose Estimation (1) — Questions: 81 - 86

81 Was external dose estimation given as a specific value?

Yes No

82 _____ Sv Gy cGy

83 Was external dose estimation given as a range?

Yes No

84 _____ - _____ Sv Gy cGy

85 Specify method used to estimate external dose from exposure

- Lymphocyte depletion kinetics
- Time to onset of vomiting
- Prodromal symptoms
- Chromosome analysis (dicentrics)
- Other method

86 Specify other method: _____

87 Was documentation submitted to the CIBMTR?
(e.g. dosimetry evaluation/report)

Yes No

Patient Trauma / Illness — Questions: 88 - 132

88 Did the patient experience any trauma / injuries as a result of the radiation incident?

Yes No

89 Head
(include brain)

Yes No

90 Specify severity

- Minor
- Moderate (potentially life threatening without appropriate treatment)
- Severe (potentially life threatening even with treatment)
- Unknown

91 Abdomen

Yes No

92 Specify severity

- Minor
- Moderate (potentially life threatening without appropriate treatment)
- Severe (potentially life threatening even with treatment)
- Unknown

93 Pelvis

Yes No

94 Specify severity

- Minor
- Moderate (potentially life threatening without appropriate treatment) (includes parapelegia)
- Severe (potentially life threatening even with treatment) (includes greater paralysis)
- Unknown

95 Spine
(include spinal cord)

Yes No

96 Specify severity

- Minor
- Moderate (potentially life threatening without appropriate treatment) (includes parapelegia)
- Severe (potentially life threatening even with treatment) (includes greater paralysis)
- Unknown

97 Cardiothoracic
(including central vessels)

Yes No

98 Specify severity

- Minor
- Moderate (potentially life threatening without appropriate treatment)
- Severe (potentially life threatening even with treatment)
- Unknown

99 Extremities
(including extremity vascular)

Yes No

100 Specify severity

- Minor
- Moderate (potentially life threatening without appropriate treatment)
- Severe (potentially life threatening even with treatment)
- Unknown

101 Burns
(2^{nd} or 3^{rd} degree)

Yes No

102 Specify percent of body surface area affected: _____ %

103 Did the patient experience any symptoms following exposure?

Yes No Unknown

Specify symptoms:

104 Nausea
(without vomiting)

Yes No

105 Specify intensity

Mild Tolerable Intense Intolerable Unknown

106 Time of onset of nausea

<1 hour 1 - 2 hours >2 - 6 hours >6 hours Unknown

107 Vomiting

Yes No

108 Specify frequency of vomiting

- Occasional (1 time per day)
- Intermittent (2-5 times per day)
- Persistent (6-10 times per day)
- Refractory (>10 times per day or parenteral nutrition)
- Unknown

109 Time of onset of vomiting

<1 hour 1 - 2 hours >2 - 6 hours >6 hours Unknown

110 Anorexia

Yes No

111 Specify degree of anorexia

- Able to eat and drink; reasonable intake
- Significantly decreased intake, but able to eat
- No significant intake
- Parenteral nutrition
- Unknown

112 Diarrhea

Yes No

113 Specify degree of diarrhea
- 2 - 3 stools per day
- 4 - 6 stools per day
- 7 - 9 stools per day
- ≥ 10 stools per day
- Unknown

114 Time of onset of diarrhea
<1 hour | 1 - 3 hours | >3 - 8 hours | >8 hours | Unknown

115 Gastrointestinal (GI) bleeding
Yes | No

116 Fatigue
Yes | No

117 Specify degree of fatigue
- Able to work or perform normal activity
- Needs assistance for self-care
- Unknown

118 Fever
Yes | No

119 Specify fever
- < 38° C / < 100.4° F
- 38° C - 40° C / 100.4° F - 104° F
- > 40° C / > 104° F for less than 24 hours
- > 40° C / > 104° F for more than 24 hours
- Unknown

120 Time of onset of fever
<1 hour | 1 - 2 hours | >2 - 3 hours | >3 hours | Unknown

121 Headache
Yes | No

122 Specify intensity
Minimal | Moderate | Intense | Unknown

123 Time of onset of headache
<1 hour | 1 - 2 hours | >2 - 4 hours | >4 - 24 hours | >24 hours | Unknown

124 Confusion / cognitive deficits
Yes | No

125 Loss of consciousness
Yes | No

126 Neurological deficits
Yes | No

127 Specify degree of neurological deficits
- Mild, no significant interference with normal activity
- Prominent, significant interference with normal activity
- Life threatening

128 Hypotension
Yes | No

129 Other symptom
Yes | No

Other Symptoms (1) — Questions: 130 - 132

130 Specify other symptom: _____

131 Specify intensity
Minimal | Moderate | Intense | Unknown

132 Time of onset of other symptom
≤30 minutes | >30 minutes - 1 hour | >1 - 1.5 hours | >1.5 - 2 hours | >2 - 3 hours | >3 - 4 hours | >4 - 5 hours | >5 hours
- Unknown

Organ Function — Questions: 133 - 167

133 AST (SGOT)
○ Known ○ Unknown

134 _____ ○ U/L ○ µkat/L

135 Date sample collected: __ __ __ __ - __ __- __ __

136 Upper limit of normal for your institution: _____ ○ U/L ○ µkat/L

137 ALT (SGPT)
○ Known ○ Unknown

138 _____ ○ U/L ○ µkat/L

139 Date sample collected: __ __ __ __ - __ __- __ __

140 Upper limit of normal for your institution: _____ ○ U/L ○ µkat/L

141 Total serum bilirubin
○ Known ○ Unknown

142 _____ ○ mg/dL ○ µmol/L

143 Date sample collected: __ __ __ __ - __ __- __ __

144 Upper limit of normal for your institution: _____ ○ mg/dL ○ µmol/L

145 Serum creatinine
○ Known ○ Unknown

146 _____ ○ mg/dL ○ mmol/L ○ µmol/L

147 Date sample collected: __ __ __ __ - __ __- __ __

148 Upper limit of normal for your institution: _____ ○ mg/dL ○ mmol/L ○ µmol/L

149 Serum albumin
○ Known ○ Unknown

150 _____ ○ g/dL ○ g/L

151 Date sample collected: __ __ __ __ - __ __- __ __

152 Upper limit of normal for your institution: _____ ○ g/dL ○ g/L

153 Amylase
○ Known ○ Unknown

154 _____

155 Were amylase isoenzymes obtained?
○ Known ○ Unknown

156 Pancreatic amylase
○ Known ○ Unknown

157 _____ U/L

158 Salivary amylase
○ Known ○ Unknown

159 _____ U/L

160 International normalized ratio (INR)
○ Known ○ Unknown

161 _____

162 Partial thromboplastin time (PTT)
○ Known ○ Unknown

163 _____ seconds

164 Reticulocytes (uncorrected)
○ Known ○ Unknown

165 _____ x 10^9/L

166 Was a bone marrow examination performed?
○ yes ○ no ○ Unknown

167 Date sample collected: __ __ __ __ - __ __- __ __

Complete Blood Count

Questions: 168 - 183

168 Date sample collected: __ __ __ __ - __ __- __ __

169 WBC
○ Known ○ Unknown

170 _____ ○ x 10^9/L (x 10^3/mm^3)
○ x 10^6/L

171 Was G-CSF given ≤ 7 days before date of test?
○ Yes ○ No

172 Neutrophils
○ Known ○ Unknown

173 _____ %

174 Lymphocytes
○ Known ○ Unknown

175 _____ %

176 Hemoglobin
○ Known ○ Unknown

177 _____ ○ g/dL ○ g/L ○ mmol/L

178 Was RBC transfused < 30 days before date of test?
○ yes ○ no

179 Hematocrit
○ Known ○ Unknown

180 _____ %

181 Platelets
○ Known ○ Unknown

182 _____ ○ x 10^9/L (x 10^3/mm^3)
○ x 10^6/L

183 Were platelets transfused ≤ 7 days before date of test?
○ Yes ○ No

Lymphocyte Analyses
Questions: 184 - 198

184 Were lymphocyte analyses performed?
○ yes ○ no

Lymphocyte Analyses (1)
Questions: 185 - 198

185 Date sample collected: __ __ __ __ - __ __ - __ __

186 Time: _____ ○ Standard time
○ Daylight savings time

187 CD3 (T cells)
○ Known ○ Unknown

188 _____ ○ x 10^9/L (x 10^3/mm^3)
○ x 10^6/L

189 CD4 (T helper cells)
○ Known ○ Unknown

190 _____ ○ x 10^9/L (x 10^3/mm^3)
○ x 10^6/L

191 CD8 (cytotoxic T cells)
○ Known ○ Unknown

192 _____ ○ x 10^9/L (x 10^3/mm^3)
○ x 10^6/L

193 CD19
○ Known ○ Unknown

194 _____ ○ x 10^9/L (x 10^3/mm^3)
○ x 10^6/L

195 CD20 (B lymphocyte cells)
○ Known ○ Unknown

196 _____ ○ x 10^9/L (x 10^3/mm^3)
○ x 10^6/L

197 CD56 (natural killer (NK) cells)
○ Known ○ Unknown

198 _____ ○ x 10^9/L (x 10^3/mm^3)
○ x 10^6/L

Therapy and Infection Prophylaxis
Questions: 199 - 263

199 Was therapy given?
(Includes therapy and infection prophylaxis)
○ yes ○ no

Therapy and Infection Prophylaxis (1) **Questions: 200 - 263**

200 Specify time point when drugs were given
○ Since exposure but prior to evaluation (at RITN center)
○ During or after evaluation (at RITN center)

201 Indication for which drugs were given
○ Therapy ○ Infection prophylaxis

Specify drugs given:

202 Systemic antibacterial antibiotics
○ Yes ○ No ○ Unknown

203 Non-absorbable oral antibiotics
○ Yes ○ No ○ Unknown

204 Systemic antifungal drugs
○ Yes ○ No ○ Unknown

205 Amphotericin
(Fungizone) *(non-lipid formulation)*
○ Yes ○ No

206 Amphotericin
(e.g. Abelcet, AmBisome, Amphotec) *(lipid formulation)*
○ Yes ○ No

207 Caspofungin
○ Yes ○ No

208 Fluconazole
○ Yes ○ No

209 Isavuconazole
○ Yes ○ No

210 Itraconazole
○ Yes ○ No

211 Micafungin
○ Yes ○ No

212 Posaconazole
○ Yes ○ No

213 Ravuconazole
○ Yes ○ No

214 Voriconazole
○ Yes ○ No

215 Other systemic antifungal drug
○ Yes ○ No

216 Specify other systemic antifungal drug: _____

217 Antiviral drugs
○ Yes ○ No ○ Unknown

218 Acyclovir
○ yes ○ no

219 Foscarnet
○ Yes ○ No

220 Ganciclovir (DHPG)
○ yes ○ no

221 Valganciclovir (Valcyte)
○ Yes ○ No

222 Valacyclovir
○ Yes ○ No

223 Other antiviral drug
○ Yes ○ No

224 Specify other antiviral drug: _____

225 Growth factors
○ Yes ○ No ○ Unknown

226 G-CSF
yes no

227 GM-CSF
yes no

228 Pegylated G-CSF
yes no

229 TBO-filgrastim (Granix, Teva)
Yes No

230 Other growth factor
yes no

231 Specify other growth factor: _____

232 Corticosteroids
Yes No Unknown

233 Decorporation drugs
Yes No Unknown

234 Aluminum carbonate
Yes No

235 Aluminum hydroxide
Yes No

236 Barium sulfate
Yes No

237 Calcium carbonate
Yes No

238 Calcium gluconate
Yes No

239 Calcium phosphate
Yes No

240 Deferoxamine (Desferal)
yes no

241 Calcium DTPA IV
Yes No

242 Calcium DTPA by nebulizer
Yes No

243 Zinc DTPA IV
Yes No

244 Dimercaprol (BAL)
Yes No

245 Calcium disodium EDTA
Yes No

246 D-Penicillamine
Yes No

247 Potassium iodide (KI)
Yes No

248 Potassium phosphate
Yes No

249 Potassium phosphate, dibasic
Yes No

250 Propylthiouracil
Yes No

251 Prussian blue, insoluble
Yes No

252 Sevelamer
Yes No

253 Sodium alginate
Yes No

254 Sodium bicarbonate
Yes No

255 Sodium glycerophosphate
Yes No

256 Sodium phosphate
Yes No

257 Succimer (DMSA)
Yes No

258 Other decorporation drug
Yes No

259 Specify other decorporation drug: _____

260 RBC transfusion
Yes No

261 Platelet transfusion
Yes No

262 Other therapy
yes no

263 Specify other therapy: _____

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