ERROR CORRECTION FORM

Sequence Number: | | | | | | | | | | | | | | |

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Initials: | |

Today's Date: Month | | Day | | | 2 0 | | | Year

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CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Chronic Granulomatous Disease (CGD) Pre-HSCT Data

Registry Use Only

Sequence Number:

Date Received:

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Has this patient's data been previously reported to USIDNET?

1 ☐ yes → USIDNET ID: | | | | | | | | | | |
2 ☐ no

Today's Date: Month | | Day | | | 2 0 | | | Year

Date of HSCT for which this form is being completed: 🕮 Month | | Day | | | 2 0 | | | Year

HSCT type: ☐ autologous ☐ allogeneic, unrelated ☐ allogeneic, related ☐ syngeneic (identical twin)

Product type: ☐ marrow ☐ PBSC ☐ cord blood ☐ other product, specify: _____

This form must be accompanied by Form 2000 – Recipient Baseline Data. All information in the box above, including the date, should be identical with the corresponding Form 2000. Information should come from an actual examination by the Transplant Center physician, or the physician who is following the recipient pre-HSCT, or abstraction of the recipient's medical records.

Questions followed by the symbol 🕮 indicate additional information necessary to complete the question is referenced in the forms instruction manual.

If this is a report of a second or subsequent transplant, check here ☐ and continue with question 143.

Disease Assessment at Diagnosis 🕮

Disease assessment at diagnosis includes disease characteristics observed within six weeks of the date of diagnosis.

1. What was the date of diagnosis of Chronic Granulomatous Disease (CGD)? Month | | Day | | | Year
2. What is the pattern of CGD inheritance?
   1 ☐ sporadic (no family history)
   2 ☐ X-linked, documented
   3 ☐ autosomal recessive, documented
   4 ☐ unknown
3. Are the parents of the patient consanguineous (related by blood ancestry)?
   1 ☐ yes
   2 ☐ no
   3 ☐ unknown
4. Are there other blood relatives in the patient's family with immunodeficiency disease?
   1 ☐ yes
   2 ☐ no
   3 ☐ unknown
5. What is the CGD molecular abnormality?
   1 ☐ X-linked (gp91)
   2 ☐ autosomal recessive – $p22^{phox}$
   3 ☐ autosomal recessive – $p47^{phox}$
   4 ☐ autosomal recessive – $p67^{phox}$
   5 ☐ unknown
6. Was a mutated protein / enzyme expressed?
   1 ☐ yes
   2 ☐ no
   3 ☐ unknown

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Fax this form to your designated campus (Milwaukee 414-805-0714 or Minneapolis 612-627-5895).

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Laboratory Studies at Diagnosis

Report findings prior to any first treatment of chronic granulomatous disease.

7. Date CBC tested: Month | | Day | | Year 2 0 | | (testing done within 6 weeks of diagnosis)

8. WBC: | | | | | | | • | | Specify units: 1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L ☐ not tested

9. Lymphocytes: | | % ☐ not tested

10. Eosinophils: | | % ☐ not tested

11. Polymorphonuclear leukocytes (PMN): | | % ☐ not tested

12. Hemoglobin: | | | | • | | 1 ☐ g/dL 2 ☐ g/L 3 ☐ mmol/L ☐ not tested ☐ transfused RBC < 30 days from date of test

13. Platelets: | | | | | | | | 1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L ☐ not tested ☐ transfused platelets < 7 days from date of test

Lymphocyte Analysis

Specify the following lymphocyte analyses performed prior to any disease treatment:

14. Were lymphocyte analyses performed? 🕮
1 ☐ yes → 2 ☐ no

15. Date of most recent testing performed: Month | | Day | | Year | | | |

16. Absolute lymphocyte count: → | | | | | | | | cells / µL (cells / mm^3)

	% of total lymphocytes:		Value:		Specify units:	
17. CD3 (T cells): →		– or –			1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L	☐ not tested
18. CD4 (T helper cells): →		– or –			1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L	☐ not tested
19. CD8 (cytotoxic T cells): →		– or –			1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L	☐ not tested
20. CD20 (B lymphocyte cells): →		– or –			1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L	☐ not tested
21. CD56 (natural killer (NK) cells): →		– or –			1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L	☐ not tested
22. CD4+ / CD45RA+ (naive T cells): →		– or –			1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L	☐ not tested
23. CD4+ / CD45RO+ (memory T cells): →		– or –			1 ☐ x 10^9/L (x 10^3/mm^3) 2 ☐ x 10^6/L	☐ not tested

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WBC Functional Assays

Specify the following WBC functional assays performed prior to any disease treatment:

1 ☐ normal 2 ☐ abnormal 3 ☐ not tested 24. Bacterial susceptibility testing / bacterial killing / drug resistance testing

1 ☐ normal 2 ☐ deficient 3 ☐ not tested 25. Dichlorofluorescein (DCF)

1 ☐ normal 2 ☐ deficient 3 ☐ not tested 26. Dihydrorhodamine oxidation (DHR) ➤ 27. Specify stimulation index: | | | ☐ unknown

1 ☐ normal 2 ☐ absent / decreased 3 ☐ not tested 28. Hydrogen peroxide production

1 ☐ normal 2 ☐ absent 3 ☐ not tested 29. Nitroblue tetrazolium test (NBT) ⟶ 30. Specify method:
1 ☐ slide (histochemical)
2 ☐ quantitative
3 ☐ unknown

1 ☐ normal 2 ☐ absent / decreased 3 ☐ not tested 31. Superoxide production

1 ☐ normal 2 ☐ abnormal 3 ☐ not tested 32. Other lab test result ⟶ 33. Specify other test: _____

Clinical Features Assessed between Diagnosis and the Start of the Preparative Regimen

Infections Identified between Diagnosis and the Start of the Preparative Regimen

Specify the presence of all clinically significant infections identified between diagnosis and the start of the preparative regimen. If any given infection was identified, use the Codes for Commonly Reported Organisms on page 5 to report the organism present. Only report an organism once, even if it was identified at the same site in subsequent infections.

Also report any fungal infections in the Form 2000 – Recipient Baseline Data beginning at question 163.

Copy this chart to report more than three different infections identified at any one site; check here ☐ if additional pages are attached.

Site of infection?	First organism	Second organism	Third organism	Specify other organism
34. 1 ☐ yes 2 ☐ no Adenitis ⟶	35.	36.	37.	38. _____
39. If adenitis was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no				
40. 1 ☐ yes 2 ☐ no Brain abscess ⟶	41.	42.	43.	44. _____
45. If brain abscess was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no				
46. 1 ☐ yes 2 ☐ no Cellulitis ⟶	47.	48.	49.	50. _____
51. If cellulitis was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no				
52. 1 ☐ yes 2 ☐ no Furuncles ⟶	53.	54.	55.	56. _____
57. If furuncles were present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no				
58. 1 ☐ yes 2 ☐ no Genitourinary ⟶	59.	60.	61.	62. _____
63. If genitourinary infection was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no				

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Site of infection?		First organism	Second organism	Third organism	Specify other organism
64. 1 ☐ yes 2 ☐ no	Impetigo → 65.		66.	67.	68. _____
69. If impetigo was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no					
70. 1 ☐ yes 2 ☐ no	Joint → 71.		72.	73.	74. _____
75. If joint infection was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no					
76. 1 ☐ yes 2 ☐ no	Liver abscess → 77.		78.	79.	80. _____
81. If liver abscess was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no					
82. 1 ☐ yes 2 ☐ no	Lung abscess → 83.		84.	85.	86. _____
87. If lung abscess was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no					
88. 1 ☐ yes 2 ☐ no	Lymph nodes abscess → 89.		90.	91.	92. _____
93. If lymph nodes abscess was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no					
94. 1 ☐ yes 2 ☐ no	Meningitis / encephalitis → 95.		96.	97.	98. _____
99. If meningitis or encephalitis was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no					
100. 1 ☐ yes 2 ☐ no	Osteomyelitis → 101.		102.	103.	104. _____
105. If osteomyelitis was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no					
106. 1 ☐ yes 2 ☐ no	Perirectal abscess → 107.		108.	109.	110. _____
111. If perirectal abscess was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no					
112. 1 ☐ yes 2 ☐ no	Pneumonia → 113.		114.	115.	116. _____
117. If pneumonia was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no					
118. 1 ☐ yes 2 ☐ no	Severe or protracted diarrhea → 119.		120.	121.	122. _____
123. If severe or protracted diarrhea was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no					
124. 1 ☐ yes 2 ☐ no	Subcutaneous abscess → 125.		126.	127.	128. _____
129. If subcutaneous abscess was present, was it a prominent feature of CGD? 1 ☐ yes 2 ☐ no					

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Site of infection?

130. 1 ☐ yes 2 ☐ no Systemic infection → 131. | | | | First organism 132. | | | | Second organism 133. | | | | Third organism 134. Specify other organism _____

135. If systemic infection was present, was it a prominent feature of CGD?
1 ☐ yes
2 ☐ no

136. 1 ☐ yes 2 ☐ no Other infection → 137. | | | | 138. | | | | 139. | | | | 140. _____

141. Specify other infection site: _____

142. If other infection was present, was it a prominent feature of CGD?
1 ☐ yes
2 ☐ no

Codes for Commonly Reported Organisms

Bacterial Infections

121 Acinetobacter
122 Actinomyces
123 Bacillus
124 Bacteroides (gracillis, uniformis, vulgaris, other species)
125 Bordetella pertussis (whooping cough)
126 Borrelia (Lyme disease)
127 Branhamella or Moraxella catarrhalis (other species)
128 Campylobacter (all species)
129 Capnocytophaga
171 Chlamydia pneumoniae
172 Other chlamydia, specify
113 Chlamydia, NOS
130 Citrobacter (freundii, other species)
131 Clostridium (all species except difficile)
132 Clostridium difficile
173 Corynebacterium jeikeium
133 Corynebacterium (all non-diptheria species)
101 Coxiella
134 Enterobacter
177 Enterococcus, vancomycin resistant (VRE)
135 Enterococcus (all species)
136 Escherichia (also E. coli)
137 Flavimonas oryzihabitans
138 Flavobacterium
139 Fusobacterium
144 Haemophilus (all species, including influenzae)
145 Helicobacter pylori
146 Klebsiella
147 Lactobacillus (bulgaricus, acidophilus, other species)
102 Legionella
103 Leptospira
148 Leptotrichia buccalis
149 Leuconostoc (all species)
104 Listeria
150 Methylobacterium
151 Micrococcus, NOS
112 Mycobacterium avium–intracellulare (MAC, MAI)
174 Mycobacterium species (cheloneae, fortuitum, haemophilum, kansasii, mucogenicum
110 Mycobacterium tuberculosis (tuberculosis, Koch bacillus)
175 Other mycobacterium, specify
176 Mycobacterium, NOS
105 Mycoplasma
152 Neisseria (gonorrhoea, meningitidis, other species)
106 Nocardia
153 Pasteurella multocida
154 Propionibacterium (acnes, avidum, granulosum, other species)
155 Proteus
156 Pseudomonas (all species except cepacia & maltophilia)
157 Pseudomonas or Burkholderia cepacia
158 Pseudomonas or Stenotrophomonas or Xanthomonas maltophilia
159 Rhodococcus
107 Rickettsia
160 Salmonella (all species)
161 Serratia marcescens
162 Shigella
163 Staphylococcus, coagulase negative (not aureus)
164 Staphylococcus aureus
165 Staphylococcus, NOS
166 Stomatococcus mucilaginosis
167 Streptococcus (all species except Enterococcus)
178 Streptococcus pneumoniae
168 Treponema (syphilis)
169 Vibrio (all species)
197 Multiple bacteria at a single site, specify bacterial codes
198 Other bacteria, specify ‡
501 Suspected atypical bacterial infection
502 Suspected bacterial infection

Fungal Infections

200 Candida, NOS
201 Candida albicans
206 Candida guillermondi
202 Candida krusei
207 Candida lusitaniae
203 Candida parapsilosis
204 Candida tropicalis
205 Candida (Torulopsis) glabrata
209 Other Candida, specify ‡
210 Aspergillus, NOS §
211 Aspergillus flavus §
212 Aspergillus fumigatus §
213 Aspergillus niger §
219 Other Aspergillus, specify ‡ §
220 Cryptococcus species
230 Fusarium species §
261 Histoplasmosis
240 Zygomycetes, NOS §
241 Mucormycosis §
242 Rhizopus §
250 Yeast, NOS
259 Other fungus, specify ‡
260 Pneumocystis (PCP / PJP)
503 Suspected fungal infection

Viral Infections

301 Herpes simplex (HSV1, HSV2)
302 Varicella (herpes zoster, chicken pox)
303 Cytomegalovirus (CMV)
304 Adenovirus
305 Enterovirus (coxsackie, echo, polio)
306 Hepatitis A (HAV)
307 Hepatitis B (HBV, Australian antigen) †
308 Hepatitis C (HCV) †
309 HIV-1 (HTLV-III) ¤
310 Influenza, NOS
323 Influenza A
324 Influenza B
311 Measles (rubeola)
312 Mumps
313 Progressive multifocal leukoencephalopathy (PML)
314 Respiratory syncytial virus (RSV)
315 Rubella (German measles)
316 Parainfluenza
317 Human herpesvirus-6 (HHV-6)
318 Epstein-Barr virus (EBV)
319 Polyoma virus (BK virus, JC virus)
320 Rotavirus
321 Rhinovirus
322 Human papilloma virus (HPV)
329 Other virus, specify ‡
504 Suspected viral infection

Parasitic Infections

402 Toxoplasma
403 Giardia
404 Cryptosporidium
409 Other parasite, specify ‡
505 Suspected parasite infection

Other Infections

509 No organism identified

‡ The codes for "other organism, specify" (codes 198, 209, 219, 259, 329 and 409) should rarely be needed; check with your microbiology lab or HSCT physician before using them.

§ For fungal infections marked with a section symbol (codes 210, 211, 212, 213, 219, 230, 240, 241, and 242), also complete a Fungal Infection (FNG) form.

† For hepatitis infections marked with a dagger symbol (codes 307 and 308), also complete a Hepatitis (HEP) form.

¤ For HIV infections marked with a currency symbol (code 309), also complete an HIV Infection (HIV) form.

* Do not report fever in the absence of infection. Report the most specific site of infection.

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Clinical Status between Diagnosis and the Preparative Regimen

143. Did the recipient experience any of the following clinical features (between diagnosis and prior to the preparative regimen)?

1 ☐ yes → **Complete the table below**

2 ☐ no → **Continue with question 169**

Feature present?		If present, is the feature prominent?	If present, was the feature also present at the time of first treatment for CGD?
144. 1 ☐ yes 2 ☐ no	Autoimmune hemolytic anemia →	145. 1 ☐ yes 2 ☐ no	146. 1 ☐ yes 2 ☐ no
147. 1 ☐ yes 2 ☐ no	Failure to thrive (weight < 5th percentile) →	148. 1 ☐ yes 2 ☐ no	149. 1 ☐ yes 2 ☐ no
150. 1 ☐ yes 2 ☐ no	Gastric outlet obstruction →	151. 1 ☐ yes 2 ☐ no	152. 1 ☐ yes 2 ☐ no
153. 1 ☐ yes 2 ☐ no	Growth retardation (height < 5th percentile) →	154. 1 ☐ yes 2 ☐ no	155. 1 ☐ yes 2 ☐ no
156. 1 ☐ yes 2 ☐ no	Inflammatory bowel disease →	157. 1 ☐ yes 2 ☐ no	158. 1 ☐ yes 2 ☐ no
159. 1 ☐ yes 2 ☐ no	Thrombocytopenia (< 100 x 10^9/L) →	160. 1 ☐ yes 2 ☐ no	161. 1 ☐ yes 2 ☐ no
162. 1 ☐ yes 2 ☐ no	Urinary outlet obstruction →	163. 1 ☐ yes 2 ☐ no	164. 1 ☐ yes 2 ☐ no
165. 1 ☐ yes 2 ☐ no	Other clinical features →	166. 1 ☐ yes 2 ☐ no	167. 1 ☐ yes 2 ☐ no

168. Specify other clinical feature: _____

Pre-HSCT Treatment for Chronic Granulomatous Disease

169. Was treatment given (between diagnosis and prior to the preparative regimen)?

1 ☐ yes → **Complete the table below**

2 ☐ no → **Continue with question 191**

Prophylactic drugs paused for < 1 week should *not* be considered as "Prophylactic Drug Stopped."

Prophylactic Drug Given?	Prophylactic Drug Stopped?	Date Stopped (Month / Day / Year)	
170. Antifungal drug(s) 1 ☐ yes 2 ☐ no →	171. 1 ☐ yes 2 ☐ no → 172.		☐ date estimated ☐ date unknown
173. Co-trimoxazole (Bactrim, Septra) 1 ☐ yes 2 ☐ no →	174. 1 ☐ yes 2 ☐ no → 175.		☐ date estimated ☐ date unknown
176. Interferon-gamma (immune interferon, IFN-g) 1 ☐ yes 2 ☐ no →	177. 1 ☐ yes 2 ☐ no → 178.		☐ date estimated ☐ date unknown

Therapy paused for < 1 week should *not* be considered as "Therapy Stopped."

Therapy Given?	Therapy Stopped?	Date Stopped (Month / Day / Year)	
179. Corticosteroids, systemic 1 ☐ yes 2 ☐ no →	180. 1 ☐ yes 2 ☐ no → 181.		☐ date estimated ☐ date unknown
182. Other immunosuppressive drug 1 ☐ yes 2 ☐ no →	183. 1 ☐ yes 2 ☐ no → 184.		☐ date estimated ☐ date unknown

185. Specify other immunosuppressive drug: _____

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186. Was gene therapy performed (between diagnosis and prior to the preparative regimen)?
1 ☐ yes →
2 ☐ no

187. Specify date of infusion of gene therapy: Month | | Day | | | 2 0 | | | Year

188. Was the recipient considered to have failed gene therapy?
1 ☐ yes
2 ☐ no

189. Did the recipient receive any other significant treatment(s) (between diagnosis and prior to the preparative regimen)?
1 ☐ yes →
2 ☐ no

190. Specify other treatment(s): _____

191. Did the recipient receive parenteral nutrition (between diagnosis and prior to the preparative regimen)?
1 ☐ yes →
2 ☐ no

192. Was parenteral nutrition in use at the time of transplantation?
1 ☐ yes
2 ☐ no

193. Did the recipient receive mechanical ventilation (between diagnosis and prior to the preparative regimen)?
1 ☐ yes →
2 ☐ no

194. Was mechanical ventilation in use at the time of transplantation?
1 ☐ yes
2 ☐ no

195. Were any biologic specimens collected for this recipient (between diagnosis and prior to the preparative regimen)?
1 ☐ yes →
2 ☐ no
3 ☐ unknown

Specify specimen(s) collected and available for future research:

196. 1 ☐ yes 2 ☐ no DNA
197. 1 ☐ yes 2 ☐ no Epstein-Barr virus (EBV)-transformed B-cell line
198. 1 ☐ yes 2 ☐ no Fibroblast cell line
199. 1 ☐ yes 2 ☐ no Herpes virus saimiri-transformed T-cell line
200. 1 ☐ yes 2 ☐ no Other T-cell line
201. 1 ☐ yes 2 ☐ no Pathological specimen → 202. Specify pathological specimen(s): _____
203. 1 ☐ yes 2 ☐ no Peripheral blood mononuclear cells (PBMC), frozen
204. 1 ☐ yes 2 ☐ no RNA → 205. Specify RNA source: _____
206. 1 ☐ yes 2 ☐ no Serum (pre-IVIG)
207. 1 ☐ yes 2 ☐ no Other specimen → 208. Specify other biologic specimen(s): _____

209. Signed: _____
Person completing form

Please print name: _____

Phone: (_____) _____

Fax: (_____) _____

E-mail address: _____

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