# Form 2100 R3.0: 100 Days Post-HSCT Data

Center: CRID:

## Key Fields

Sequence Number _____

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

CIBMTR Center Number: _____

CIBMTR Recipient ID: _____

Today's Date: __ __ __ __ - __ __- __ __

Date of HSCT for which this form is being completed: __ __ __ __ - __ __- __ __

**HSCT type (check all that apply):**

- Autologous
- Allogeneic, unrelated
- Allogeneic, related
- Syngeneic (identical twin)

**Product type (check all that apply):**

- Marrow
- PBSC
- Cord blood
- multiple cord blood units infused
- Other product

Specify: _____

## Vital Status

**Questions: 1 - 7**

**1** Date of actual contact with the recipient to determine medical status for this follow-up report: __ __ __ __ - __ __- __ __

**2** Did this patient receive the scheduled HSCT?

yes no

**3** Reason:

- patient died between start of preparative regimen and HSCT
- HSCT was canceled, but patient is alive

**4** Reason for cancellation: _____

**5** Did recipient receive a subsequent HSCT (bone marrow, mobilized peripheral blood stem cells, cord blood) prior to day 100 after the HSCT for which this form is being completed?

yes no

**6** Specify the recipient's survival status at the date of actual contact:

Alive Dead

**7** Has the recipient received a donor cellular infusion (DCI)?

yes no

## Hematopoietic Reconstitution Post-HSCT

**Questions: 8 - 33**

**8** Did the recipient receive hematopoietic, lymphoid growth factors or cytokines after the start of the preparatory regimen?

yes no

**Specify agents and provide dates for the first course of each agent given in this reporting period.**

**9** G-CSF

yes no

**10** Date G-CSF therapy started: __ __ __ __ - __ __- __ __

**11** Therapy: _____

**12** Specify drug given:

Neupogen Neulasta Lenograstim

**13** GM-CSF

yes no

**14** Date GM-CSF therapy started: __ __ __ __ - __ __- __ __

**15** Therapy: _____

**16** Erythropoietin

yes no

**17** Date therapy started: __ __ __ __ - __ __- __ __

**18** Therapy: _____

**19** Specify drug given:

Epogen

Aranesp (darbepoetin alfa)

**20** KGF (palifermin, Kepivance)
*(If used for GVHD prophylaxis, report at question 118.)*

yes no

**21** Date KGF therapy started: __ __ __ __ - __ __- __ __

**22** Therapy: _____

**23** Velafermin
*(If used for GVHD prophylaxis, report at question 120).)*

yes no

**24** Date velafermin therapy started: __ __ __ __ - __ __- __ __

**25** Therapy: _____

**26** Blinded growth factor or cytokine trial

yes no

**27** Specify study agent: _____

**28** Date therapy started: __ __ __ __ - __ __- __ __

**29** Therapy: _____

**30** Other agent:

yes no

**31** Specify other agent: _____

**32** Date other therapy started: __ __ __ __ - __ __- __ __

**33** Therapy: _____

## Granulopoiesis/Neutrophil Recovery

**Questions: 34 - 43**

***To report dates in this section, use the first of 3 consecutive laboratory values obtained on different days.**

**34** Is (was) there evidence of hematopoietic recovery following the initial HSCT? *(check only one)*

Yes, ANC >= 500/mm$^3$ achieved and sustained for 3 lab values * with no subsequent decline

Yes, ANC >= 500/mm$^3$ for 3 lab values * with subsequent decline in ANC to < 500/mm$^3$ for >= 3 days

No, ANC >= 500/mm$^3$ was not achieved * and there was no evidence of recurrent disease in the bone marrow

No, ANC >= 500/mm$^3$ was not achieved * and there was documented persistent disease in the bone marrow post-HSCT

ANC never dropped below 500/mm$^3$ at any time after the start of the preparative regimen

**35** Date ANC >= 500/mm$^3$ (first of 3 lab values): * __ __ __ __ - __ __- __ __

**36** Date ANC >= 500/mm$^3$ (first of 3 lab values): * __ __ __ __ - __ __- __ __

**37** Date of decline in ANC to < 500/mm$^3$ for >= 3 days (first of 3 days that the ANC declined): * __ __ __ __ - __ __- __ __

**38** WBC: _____ x 10$^9$/L (x 10$^3$/mm$^3$)

x 10$^6$/L

**39** Neutrophils: _____ **%**

**40** Did recipient recover and maintain ANC >= 500/mm$^3$ * following the decline?

yes no

**41** Date of ANC recovery: __ __ __ __ - __ __- __ __ Date of ANC recovery unknown

**CBC on first day of recovery:**

**42** WBC: _____ x 10$^9$/L (x 10$^3$/mm$^3$)

x 10$^6$/L

**43** Neutrophils: _____ **%**

## Megakaryopoiesis/Platelet Recovery

**Questions: 44 - 47**

**44** Was an initial platelet count >= 20 x 10$^9$/L achieved?

Yes

No

platelet count never dropped below 20 x 10$^9$/L

**45** Date platelets >= 20 x 10$^9$/L: * __ __ __ __ - __ __- __ __ date estimated Date unknown

**46** Was an initial platelet count >= 50 x 10$^9$/L achieved?

Yes

No

platelet count never dropped below 50 x 10$^9$/L

**47** Date platelets >= 50 x 10$^9$/L: * __ __ __ __ - __ __- __ __ date estimated Date unknown

## Current Hematologic Findings

**Questions: 48 - 54**

**48** Date of most recent hematologic testing: __ __ __ __ - __ __- __ __

**49** WBC: _____ x 10$^9$/L (x 10$^3$/mm$^3$)

x 10$^6$/L

WBC not tested

**50** Neutrophils: _____ **%** Neutrophils not tested

**51** Lymphocytes: _____ **%** Lymphocytes not tested

**52** Hemoglobin: _____ g/dL g/L mmol/L

Hemoglobin not tested

transfused RBS ≤ 30 days from date of most current testing

**53** Hematocrit: _____ **%** Not tested

transfused RBS ≤ 30 days from date of most current testing

**54** Platelets: _____ ☐ x $10^9$/L (x $10^3$/$mm^3$)

☐ x $10^6$/L

☐ Platelets not tested

☐ transfused platelets ≤ 7 days from date of most current testing

## Immune Reconstitution

**Questions: 55 - 76**

**Specify the immunoglobulin values from the most recent testing:**

**55** IgG: _____ ☐ mg/dL ☐ g/dL ☐ g/L

☐ IgG not tested

**56** Date tested: __ __ __ __ - __ __- __ __

**57** IgM: _____ ☐ mg/dL ☐ g/dL ☐ g/L

☐ IgM not tested

**58** Date tested: __ __ __ __ - __ __- __ __

**59** IgA: _____ ☐ mg/dL ☐ g/dL ☐ g/L

☐ IgA not tested

**60** Date tested: __ __ __ __ - __ __- __ __

**61** Did the recipient receive supplemental intravenous immunoglobulins (IVIG)?

☐ yes ☐ no

**62** Was therapy ongoing within one month of immunoglobulin testing?

☐ yes ☐ no

**Indication(s) for use:**

**63** Prophylaxis for low IgG with no active infection (polyclonal IV gamma globulin / IVIG)

☐ yes ☐ no

**64** Prophylaxis for cytomegalovirus (CMV) infection (CMV / hyperimmune gamma globulin)

☐ yes ☐ no

**65** Treatment for CMV infection

☐ yes ☐ no

**66** Treatment for respiratory syncytial virus (RSV) infection

☐ yes ☐ no

**67** Treatment for infection with low IgG (not CMV or RSV)

☐ yes ☐ no

**68** Other indication

☐ yes ☐ no

**69** Specify other indication: _____

**70** Were lymphocyte analyses performed?

☐ yes ☐ no

**71** Date of most recent testing performed: __ __ __ __ - __ __- __ __

**72** CD3 _____ x $10^9$/L (x $10^3$/$mm^3$)
x $10^6$/L
CD3 not tested

**73** CD4 _____ x $10^9$/L (x $10^3$/$mm^3$)
x $10^6$/L
CD4 not tested

**74** CD8 _____ x $10^9$/L (x $10^3$/$mm^3$)
x $10^6$/L
CD8 not tested

**75** CD20 _____ x $10^9$/L (x $10^3$/$mm^3$)
x $10^6$/L
CD20 not tested

**76** CD56 _____ x $10^9$/L (x $10^3$/$mm^3$)
x $10^6$/L
CD56 not tested

## Chimerism Studies — Questions: 77 - 102

**77** *Allogeneic HSCTs only:* Were chimerism studies performed post-HSCT?
yes no

**78** Are chimerism laboratory reports attached to this form?
yes no

**79** Were infusions from more than one donor given?
yes no

**80** Specify donor gender:
male female

## Single Donor (1) — Questions: 81 - 90

Provide date(s), method(s) and other information for all chimerism studies performed prior to date of contact (question 1).

**81** Date __ __ __ __ - __ __- __ __

**82** Method _____

**83** Specify: _____

**84** Cell type _____

**85** Specify: _____

**86** Total cells examined _____

**87** Number of donor cells _____

**88** Number of host cells _____

**89** Percent donor cells, quantitative method _____ Presence of donor cells was detected by non-quantitative method

**90** Percent host cells, quantitative method _____ Presence of host cells was detected by non-quantitative method

## Multiple Donors (1) — Questions: 91 - 102

**91** NMDP Donor ID: _____

-or-

Donor's / infant's date of birth: __ __ __ __ - __ __- __ __

-or-

NMDP cord blood unit ID _____

-or-

Non-NMDP unrelated donor ID: _____

-or-

Non-NMDP cord blood unit ID: _____

**92** Donor's / infant's gender:

male female

**93** Date __ __ __ __ - __ __- __ __

**94** Method _____

**95** Specify: _____

**96** Cell type _____

**97** Specify: _____

**98** Total cells examined _____

**99** Number of donor cells _____

**100** Number of host cells _____

**101** Percent donor cells, quantitative method _____ Presence of donor cells was detected by non-quantitative method

**102** Percent host cells, quantitative method _____ Presence of host cells was detected by non-quantitative method

## Engraftment Syndrome — Questions: 103 - 109

**103** Did engraftment syndrome occur?

yes no

**104** Date of onset: __ __ __ __ - __ __- __ __

**Specify the symptoms of engraftment syndrome:**

**105** Capillary leak syndrome

yes no

**106** Fever

yes no

**107** Skin rash

yes no

**108** Specify amount of body surface area affected: _____ **%**

**109** Was engraftment syndrome treated with corticosteriods?

yes no

## Acute Graft vs. Host Disease (GVHD) — Questions: 110 - 187

**110** Was specific therapy used after the start of the preparative regimen to prevent acute GVHD or graft rejection *(note: do not include growth factors reported in question 8, or ex vivo T-cell depletion reported on the Product Insert),* or for autologous HSCT to induce acute GVHD?

yes no

**111** ALS, ALG, ATS, ATG

yes no

**112** Specify source:

Horse Rabbit Other

**113** Specify source: _____

**114** Corticosteroids (systemic)

yes no

**115** Cyclosporine (CSA) (Sandimmune, Neoral)

yes no

**116** ECP (extra-corporeal photopheresis)

yes no

**117** FK 506 (Tacrolimus, Prograf)

yes no

**118** KGF (palifermin, Kepivance) *(if used to prevent mucositis, report at question 20.)*

yes no

**119** Specify date started: __ __ __ __ - __ __- __ __

**120** Velafermin (If used to prevent mucositis, report at question 23.)

yes no

**121** Specify date started: __ __ __ __ - __ __- __ __

**122** In vivo monoclonal antibody

yes no

**Specify in vivo monoclonal antibody:**

**123** Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

yes no

**124** Specify: _____

**125** Campath

yes no

**126** Etanercept (Enbrel)

yes no

**127** Infliximab (Remicade)

yes no

**128** Other in vivo monoclonal antibody

yes no

**129** Specify antibody: _____

**130** In vivo immunotoxin

yes no

**131** Specify: _____

**132** Methotrexate (MTX) (Amethopterin)

yes no

**133** Mycophenolate mofetil (MMF) (CellCept)

yes no

**134** Sirolimus (Rapamycin, Rapamune)

yes no

**135** Ursodiol

yes no

**136** Blinded randomized trial

yes no

**137** Specify trial agent: _____

**138** Other agent

yes no

**139** Specify other agent: _____

**140** Did acute GVHD occur?

Yes

acute GVHD persists from prior HSCT / DCI

No

Unknown

**141** Date of acute GVHD diagnosis: __ __ __ __ - __ __- __ __ Date is greater than 100 days; date is correct

**142** Was the diagnosis based on evidence from a biopsy (histology)?

yes no

**Specify result(s):**

**143** gastrointestinal (GI)

Positive Negative Inconclusive Not tested

**144** Liver

Positive Negative Inconclusive Not tested

**145** Lung

Positive Negative Inconclusive Not tested

**146** Skin

Positive Negative Inconclusive Not tested

**147** Other site

Positive Negative Inconclusive Not tested

**148** Specify other site: _____

**149** Is a copy of the pathology report attached?

yes no

**150** Was the diagnosis based on clinical evidence?

yes no

**151** Maximum overall grade of acute GVHD:

I II III IV

**152** Is acute GVHD still present at the date of contact for this report (question 1)?

- Yes
- No
- progressed to chronic GVHD
- Unknown

**List the maximum severity of organ involvement:**

**153** Skin

- no skin acute GVHD / rash not attributable to acute GVHD
- stage 0 – no rash
- stage 1 – maculopapular rash, < 25% of body surface
- stage 2 – maculopapular rash, 25–50% of body surface
- stage 3 – generalized erythroderma
- stage 4 – generalized erythroderma with bullae formation and desquamation

**154** Lower intestinal tract: (use mL/day for adult recipients and mL/$m^2$/day for pediatric recipients)

- no gut acute GVHD / diarrhea not attributable to acute GVHD
- Stage 0 – no diarrhea
- stage 0 – diarrhea <= 500 mL/day or < 280 mL/$m^2$/day
- stage 1 – diarrhea > 500 but <= 1000 mL/day or 280-555 mL/$m^2$/day
- stage 2 – diarrhea > 1000 but <= 1500 mL/day or 556-833 mL/$m^2$/day
- stage 3 – diarrhea > 1500 mL/day or > 833 mL/$m^2$/day
- stage 4 – severe abdominal pain, with or without ileus

**155** Upper intestinal tract:

- stage 0 - no persistant nausea or vomiting
- stage 1 - persistant nausea or vomiting

**156** Liver

- no liver acute GVHD / bilirubin level not attributable to acute GVHD
- stage 0 – bilirubin < 2.0 mg/dL (< 34 µmol/L)
- stage 1 – bilirubin 2.0–3.0 mg/dL (34–52 µmol/L)
- stage 2 – bilirubin 3.1–6.0 mg/dL (53–103 µmol/L)
- stage 3 – bilirubin 6.1–15.0 mg/dL (104–256 µmol/L)
- stage 4 – bilirubin > 15.0 mg/dL (> 256 µmol/L)

**157** Other clinical organ involvement?

- yes
- no

**Specify site:**

**158** Lung

yes no

**159** Other site:

yes no

**160** Specify other site: _____

**161** Was specific therapy used to treat acute GVHD?

yes no

**162** ALS, ALG, ATS, ATG

yes no

**163** Specify source:

Horse Rabbit Other

**164** Specify source: _____

**165** Corticosteroids (systemic)

yes no

**166** Corticosteriods (topical)

yes no

**167** Cyclosporine (CSA) (Sandimmune, Neoral)

yes no

**168** ECP (extra-corporeal photopheresis)

yes no

**169** FK 506 (Tacrolimus, Prograf)

yes no

**170** In vivo monoclonal antibody

yes no

**Specify in vivo monoclonal antibody:**

**171** Anti CD25 (Zenapax, Daclizumab, AntiTAC)

yes no

**172** Specify anti CD25: _____

**173** Campath

yes no

**174** Etanercept (Enbrel)

yes no

**175** Infliximab (Remicade)

yes no

**176** Other in vivo monoclonal antibody

yes no

**177** Specify antibody: _____

**178** In vivo immunotoxin

yes no

**179** Specify immunotoxin: _____

**180** Methotrexate (MTX) (Amethopterin)

yes no

**181** Mycophenolate mofetil (MMF) (CellCept)

yes no

**182** Sirolimus (Rapamycin, Rapamune)

yes no

**183** Ursodiol

yes no

**184** Blinded randomized trial

yes no

**185** Specify trial agent: _____

**186** Other agent

yes no

**187** Specify other agent: _____

## Chronic Graft vs. Host Disease (GVHD)

**Questions: 188 - 259**

**188** Has recipient developed clinical chronic GVHD?

Yes

chronic GVHD persists from prior HSCT / DCI

No

Unknown

**189** Date of chronic GVHD diagnosis: __ __ __ __ - __ __- __ __ Date is less than 100 days; date is correct

**190** Onset of chronic GVHD was:

Progressive (acute GVHD progressed directly to chronic GVHD)

Interrupted (acute GVHD resolved, then chronic GVHD developed)

De novo (acute GVHD never developed)

chronic GHVD flare (symptoms reactivated within 30 days of drug tapering or discontinuation)

**If the recipient is 16 years of age or older, complete the Karnofsky Scale. If the recipient is younger than 16 years of age, complete the Lansky Scale.**

**191** Karnofsky / Lansky score at diagnosis of chronic GVHD: _____

**192** Platelet count at diagnosis of chronic GVHD: _____ x $10^9$/L (x $10^3$/$mm^3$)

x $10^6$/L

**193** Diagnosis was based on:

histologic evidence / biopsy proven

Clinical evidence

Both

Unknown

**194** Maximum grade of chronic GVHD:

- limited – localized skin involvement and/or hepatic dysfunction due to chronic GVHD
- extensive -one or more of the following:

  generalized skin involvement; or,
  liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,
  involvement of eye: Schirmer's test with < 5 mm wetting; or
  involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or
  involvement of any other target organ

**195** Overall severity of chronic GVHD:

- mild – signs and symptoms of chronic GVHD do not interfere substantially with function and do not progress once appropriately treated with local therapy or standard systemic therapy (corticosteroids and/or cyclosporine or FK 506)
- moderate – signs and symptoms of chronic GVHD interfere somewhat with function despite appropriate therapy or are progressive through first line systemic therapy (corticosteroids and/or cyclosporine or FK 506)
- severe – signs and symptoms of chronic GVHD limit function substantially despite appropriate therapy or are progressive through second line therapy

### Organ Involvement

**Indicate if there was organ involvement with chronic GVHD from the list below:**

**196** Sclerosis of skin

yes no

**197** Was involvement proven by biopsy?

yes no

**198** Other skin or hair involvement (rash, ulcers, pruritus or itching, dyspigmentation, alopecia, lichenoid skin changes, etc.)

yes no

**199** Was involvement proven by biopsy?

yes no

**200** Eyes (xerophthalmia (dry eyes), abnormal Schirmer's test, abnormal slit lamp, corneal erosion / conjunctivitis, etc.)

yes no

**201** Was involvement proven by biopsy?

yes no

**202** Mouth (lichenoid changes, mucositis / ulcers, erythema, etc.)

yes no

**203** Was involvement proven by biopsy?

yes no

**204** Bronchiolitis obliterans

yes no

**205** Was involvement proven by biopsy?

yes no

**206** Other lung involvement

yes no

**207** Was involvement proven by biopsy?

yes no

**208** Gastrointestinal tract (esophageal involvement, chronic nausea / vomiting, chronic diarrhea, malabsorption, abdominal pain / cramps, etc.)

yes no

**209** Was involvement proven by biopsy?

yes no

**210** Liver

yes no

**211** Was involvement proven by biopsy?

yes no

**212** Genitourinary tract (vaginitis / stricture, etc.)

yes no

**213** Was involvement proven by biopsy?

yes no

**214** Musculoskeletal (arthritis, contractures, myositis, myasthenia, etc.)

yes no

**215** Was involvement proven by biopsy?

yes no

**216** Thrombocytopenia (< 100 x 10^9/L)

yes no

**217** Eosinophilia

yes no

**218** Autoantibodies

yes no

**219** Other hematologic involvement

yes no

**220** Serositis

yes no

**221** Was involvement proven by biopsy?

yes no

**222** Weight loss

yes no

**223** Other organ involvement from chronic GVHD

yes no

**224** Specify site: _____

**225** Was involvement proven by biopsy?

yes no

**226** Was specific therapy used to treat chronic GVHD?

yes no

**Specify:**

**227** ALS, ALG, ATS, ATG

yes no

**228** Specify source:

Horse Rabbit Other

**229** Specify source: _____

**230** Azathioprine

yes no

**231** Corticosteroids (systemic)

yes no

**232** Corticosteroids (topical)

yes no

**233** Cyclosporine (CSA) (Sandimmune, Neoral)

yes no

**234** ECP (extracorporeal photopheresis)

yes no

**235** Hydroxychloroquine (Plaquenil)

yes no

**236** Etretinate

yes no

**237** FK 506 (Tacrolimus, Prograf)

yes no

**238** In vivo monoclonal antibody

yes no

**Specify:**

**239** Anti CD 25 (Zenapax, Daclizumab, AntiTAC)

yes no

**240** Specify anti CD25: _____

**241** Campath

yes no

**242** Etanercept (Enbrel)

yes no

**243** Infliximab (Remicade)

yes no

**244** Other in vivo monoclonal antibody

yes no

**245** Specify antibody: _____

**246** Lamprene (Clofazimine)

yes no

**247** Mycophenolate mofetil (MMF) (CellCept)

yes no

**248** Pentostatin

yes no

**249** PUVA (Psoralen and UVA)

yes no

**250** Sirolimus (Rapamycin, Rapamune)

yes no

**251** Thalidomide

yes no

**252** Ursodiol

yes no

**253** Blinded randomized trial

yes no

**254** Specify trial agent: _____

**255** Other agent:

yes no

**256** Specify other agent: _____

**257** Are symptoms of chronic GVHD still present on the date of actual contact (or present at the time of death)?

yes no

**258** Is the recipient still taking immunosuppressive agents (including PUVA) to treat or prevent GVHD?

yes no Unknown

**259** Date final treatment administered: __ __ __ __ - __ __- __ __ Date unknown

## Infection

**Questions: 260 - 297**

**260** Did the recipient receive any of the following agents for infection prophylaxis after the start of the preparative regimen?
*(report prophylaxis immunoglobulins at questions 63–64)*

yes no Unknown

**Specify agent(s) given:**

**261** Systemic antibacterial antibiotics

yes no

**262** Nonabsorbable oral antibiotics

yes no

**263** Amphotericin (Fungizone) *(non-lipid formulation)*

yes no

**264** Amphotericin (e.g. Abelcet, AmBisome, Amphotec) *(lipid formulation)*

yes no

**265** Caspofungin

yes no

**266** Fluconazole

yes no

**267** Itraconazole
yes no

**268** Micafungin
yes no

**269** Posaconazole
yes no

**270** Ravuconazole
yes no

**271** Voriconazole
yes no

**272** Other systemic antifungal agent
yes no

**273** Specify other antifungal agent: _____

**274** Acyclovir
yes no

**275** Foscarnet
yes no

**276** Ganciclovir (DHPG)
yes no

**277** Valganciclovir (Valcyte)
yes no

**278** Valacyclovir
yes no

**279** Other antiviral agent
yes no

**280** Specify other antiviral agent: _____

**281** Atovaquone (Mepron)
yes no

**282** Dapsone
yes no

**283** Pentamidine inhaled
yes no

**284** Pentamidine IV
yes no

**285** Trimethoprim/sulfamethoxazole (Bactrim/Septra)
yes no

**286** Other pneumocystis prophylaxis
yes no

**287** Specify other pneumocystis agent: _____

**288** Other prophylaxis agent

yes no

**289** Specify other prophylaxis agent: _____

**290** Did the recipient receive irradiated granulocyte infusions after the start of the preparative regimen to 60 days post-HSCT?

yes no

**291** Did the recipient develop a clinically significant infection after the start of the preparative regimen?

yes no

**Clinically significant infections (1)** **Questions: 292 - 295**

**Report each infection organism, site and date of diagnosis.**

**292** Organism _____

**The codes for "other organism, specify" should rarely be needed; check with your microbiology lab or HSCT physician before using them.**

**293** If other, specify: _____

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

**294** Site _____

**295** __ __ __ __ - __ __- __ __

**296** Did the recipient develop more than 7 infections post-HSCT?

yes no

**297** Are extra pages attached?

yes no

## Organ Function

**Questions: 298 - 449**

**298** Did the recipient develop interstitial pneumonitis (IPn or ARDS) / idiopathic pneumonia syndrome (IPS) after the start of preparative regimen to date of last contact (question 1)?

**Interstitial pneumonitis/idiopathic pneumonia syndrome is characterized on chest x-ray by hypoxia and diffuse interstitial infiltrates not caused by fluid overload.**

***(Report bacterial and fungal pneumonia in Infection section (questions 291-295))***

yes no

**Pulmonary function (1)** **Questions: 299 - 320**

**299** Date of diagnosis of IPn / IPS: __ __ __ __ - __ __- __ __

**300** Were diagnostic tests done (other than radiographic studies)?

yes no

**Diagnosis was evaluated by:**

**301** bronchoalveolar lavage (BAL)

yes no

**302** transbronchial biopsy

yes no

**303** open / thoracopic (VATS) lung biopsy

yes no

**304** autopsy

yes no

**305** Other test

yes no

**306** Specify other test: _____

**307** Was an organism isolated?

Yes no / idiopathic

**Etiology:**

**308** adenovirus

yes no

**309** cytomegalovirus (CMV)

yes no

**310** herpes simplex (HSV1, HSV2)

yes no

**311** human herpes virus type 6 (HHV6)

yes no

**312** parainfluenza

yes no

**313** respiratory syncytial virus (RSV)

yes no

**314** toxoplasma

yes no

**315** other virus

yes no

**316** Specify other virus: _____

**317** other organism

yes no

**318** Specify organism: _____

**319** Did the recipient experience two or more episodes of IPn / IPS after the start of preparative regimen to date of last contact (question 1)?

yes no

**320** Are extra pages attached?

yes no

**321** Did the recipient develop non-infectious pulmonary abnormalities (other than IPn / IPS / ARDS) after the start of preparative regimen to date of last contact (question 1)?

yes no

**322** Did the recipient develop bronchiolitis obliterans after the start of preparative regimen to date of last contact (question 1)?

yes no

**323** Date of diagnosis: __ __ __ __ - __ __- __ __

**324** Were diagnostic tests done?

yes no

**Diagnosis was evaluated by:**

**325** bronchoalveolar lavage (BAL)

yes no

**326** transbronchial biopsy

yes no

**327** open / thorascopic (VATS) lung biopsy

yes no

**328** autopsy

yes no

**329** Other

yes no

**330** Specify: _____

**331** Did the recipient develop pulmonary hemorrhage?

yes no

**332** Date of diagnosis: __ __ __ __ - __ __- __ __

**333** Were diagnostic tests done?

yes no

**Diagnosis was evaluated by:**

**334** bronchoalveolar lavage (BAL)

yes no

**335** transbronchial biopsy

yes no

**336** open / thorascopic (VATS) lung biopsy

yes no

**337** autopsy

yes no

**338** Other

yes no

**339** Specify: _____

**340** Did the recipient develop cryptogenic organizing pneumonia (COP)?

yes no

**341** Date of diagnosis: __ __ __ __ - __ __- __ __

**342** Were diagnostic tests done?

yes no

**Diagnosis was evaluated by:**

**343** bronchoalveolar lavage (BAL)

yes no

**344** transbronchial biopsy

yes no

**345** open / thorascopic (VATS) lung biopsy

yes no

**346** autopsy

yes no

**347** Other

yes no

**348** Specify: _____

**349** Did the recipient develop any other non-infectious pulmonary abnormalities?

yes no

**350** Specify other pulmonary abnormality: _____

**351** Did the recipient receive endotracheal intubation or mechanical ventilation post-HSCT?

yes no

**Liver Function**

**352** Did the recipient develop non-infectious liver toxicity (excluding GVHD) after the start of preparative regimen to date of last contact (question 1)?

yes no

**353** Date of diagnosis: __ __ __ __ - __ __- __ __

**Etiology:**

**354** cirrhosis

yes no

**355** veno-occlusive disease (VOD) / sinusodial obstruction syndrome (SOS)

yes no

**356** Did the recipient receive treatment for VOD?

yes no

**357** Specify: _____

**358** Did VOD resolve by day 100?

yes no

**359** Maximum bilirubin in first 100 days: _____

**360** Other

yes no

**361** Specify other etiology: _____

**362** Unknown

yes no

**Specify diagnosis of liver toxicity by clinical signs and symptoms/evaluation:**

**363** ascites

yes no

**364** autopsy

yes no

**365** bilirubin > 2.0 mg

yes no

**366** biopsy

yes no

**367** elevated hepatic venous pressure gradient

yes no

**368** elevated liver enzymes ( e.g., alkaline phosphatase, ALT, AST, LDH, GGT)

yes no

**369** hepatomegaly

yes no

**370** right upper quadrant pain or tenderness

yes no

**371** ultrasonography / doppler (abnormal portal vein flow)

yes no

**372** weight gain > 5%

yes no

**373** Other

yes no

**374** Specify other evaluation: _____

**Other Organ Impairment/Disorder**

**375** Has the recipient developed any other clinically significant organ impairment or disorder after the start of preparative regimen to date of last contact (question 1)?

yes no

**Specify impairment/disorder:**

**376** avascular necrosis

yes no

**377** Date of diagnosis: __ __ __ __ - __ __- __ __

**378** cataracts

yes no

**379** Date of diagnosis: __ __ __ __ - __ __- __ __

**380** congestive heart failure (EF < 40%)

yes no

**381** Date of diagnosis: __ __ __ __ - __ __- __ __

**382** diabetes / hyperglycemia

yes no

**383** Date of diagnosis: __ __ __ __ - __ __- __ __

**384** gonadal dysfunction / infertility requiring hormone replacement (testosterone or estrogen)

yes no

**385** Date of diagnosis: __ __ __ __ - __ __- __ __

**386** growth hormone deficiency / growth disturbance

yes no

**387** Date of diagnosis: __ __ __ __ - __ __- __ __

**388** hemorraghic cystitis / hematuria requiring medical intervention (catheterization of bladder, extra transfusions, urology consult)

yes no

**389** Date of diagnosis: __ __ __ __ - __ __- __ __

**390** hypothyroidism

yes no

**391** Date of diagnosis: __ __ __ __ - __ __- __ __

**392** myocardial infarction

yes no

**393** Date of diagnosis: __ __ __ __ - __ __- __ __

**394** pancreatitis

yes no

**395** Date of diagnosis: __ __ __ __ - __ __- __ __

**396** post-transplant microangiopathy-thrombotic thrombocytopenic purpura (TTP), hemolytic uremic syndrome (HUS), or similar syndrome

yes no

**397** Date of diagnosis: __ __ __ __ - __ __- __ __

**398** Did the recipient receive plasmapheresis?

yes no

**399** renal failure severe enough to warrant dialysis

yes no

**400** Date of diagnosis: __ __ __ __ - __ __- __ __

**401** Did the recipient receive dialysis?

yes no

**402** stroke / seizure

yes no

**403** Date of diagnosis: __ __ __ __ - __ __- __ __

**404** Other impairment or disorder

yes no

**405** Date of diagnosis: __ __ __ __ - __ __- __ __

**406** Specify other impairment / disorder: _____

**New Malignancy**

**407** Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear that is different from the disease for which the HSCT was performed?

yes no

**408** For all new malignancies except for "other skin malignancy (basal cell, squamous)," was testing performed to determine the cell of origin?

Yes

No

the only new malignancy in this reporting period was "other skin malignancy (basal cell, squamous)"

**409** Specify the cell origin of the new malignancy:

recipient (host) donor origin unknown

**410** Is a copy of the cell origin evaluation (VNTR, cytogenetics, FISH) attached?

yes **Attach a copy of the report with all identifiers removed, except for birth date and ID numbers. Reference question 410 on the report.**

no

**Specify which new disease(s) occurred:**

**411** Acute myeloid leukemia (AML / ANLL)

yes no

**412** Date of diagnosis __ __ __ __ - __ __- __ __

**413** Other leukemia, including ALL

yes no

**414** Date of diagnosis: __ __ __ __ - __ __- __ __

**415** Specify other leukemia: _____

**416** Breast cancer

yes no

**417** Date of diagnosis __ __ __ __ - __ __- __ __

**418** Central nervous system (CNS) malignancy (glioblastoma, astrocytoma)

yes no

**419** Date of diagnosis __ __ __ __ - __ __- __ __

**420** Clonal cytogenetic abnormality without leukemia or MDS

yes no

**421** Date of diagnosis __ __ __ __ - __ __- __ __

**422** Gastrointestinal malignancy (colon, rectum, stomach, pancreas, intestine)

yes no

**423** Date of diagnosis __ __ __ __ - __ __- __ __

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

yes no

**425** Date of diagnosis __ __ __ __ - __ __- __ __

**426** Hodgkin disease

yes no

**427** Date of diagnosis __ __ __ __ - __ __- __ __

**428** Lung cancer

yes no

**429** Date of diagnosis __ __ __ __ - __ __- __ __

**430** Lymphoma or lymphoproliferative disease

yes no

**431** Date of diagnosis __ __ __ __ - __ __- __ __

**432** Is the tumor EBV positive?

yes no

**433** Melanoma

yes no

**434** Date of diagnosis __ __ __ __ - __ __- __ __

**435** Other skin malignancy (basal cell, squamous)

yes no

**436** Date of diagnosis __ __ __ __ - __ __- __ __

**437** Specify other skin malignancy: _____

**438** Myelodysplasia (MDS) / myeloproliferative (MPS) disorder

yes no

**439** Date of diagnosis __ __ __ __ - __ __- __ __

**440** Oropharyngeal cancer (tongue, buccal mucosa)

yes no

**441** Date of diagnosis __ __ __ __ - __ __- __ __

**442** Sarcoma

yes no

**443** Date of diagnosis __ __ __ __ - __ __- __ __

**444** Thyroid cancer

yes no

**445** Date of diagnosis __ __ __ __ - __ __- __ __

**446** Other new malignancy

yes no

**447** Date of diagnosis __ __ __ __ - __ __- __ __

**448** Specify other new malignancy: _____

**449** Is a pathology / autopsy report or other documentation attached?

yes **-Attach a copy of the report with all identifiers removed, except for birth date and ID numbers. Reference question 449 on the report.**

no

## Functional Status

**Questions: 450 - 453**

**450** Was the recipient discharged from the hospital after HSCT?

Yes

No

not applicable, therapy and HSC infusion given as outpatient

**451** Date first discharged from hospital post-HSCT: __ __ __ __ - __ __- __ __

**452** Total number of inpatient days (day 0 to day 100) in first 100 days post-HSCT _____

**If the recipient is 16 years of age or older, complete the Karnofsky Scale. If the recipient is younger than 16 years of age, complete the Lansky Scale.**

**453** Which scale was used, Karnofsky or Lansky?

Karnofsky Lansky

Specify the functional status of the recipient on the date of last actual contact. _____

## Subsequent HSCT

**Questions: 454 - 461**

**454** Date of subsequent HSCT: __ __ __ __ - __ __- __ __

**455** Was the subsequent HSCT performed at a different institution?

yes no

**Specify the institution that performed the subsequent HSCT:**

**456** Name: _____

City: _____ State / Country: _____

**457** What was the indication for subsequent HSCT? _____

**Subsequent autologous HSCTs performed for engraftment reasons (options 1–3) do not require separate report forms to be completed.**

**All other subsequent HSCTs will require a separate follow-up report form completed for each infusion.**

**458** Specify other indication: _____

### Subsequent Product(s) Information (1)

**Questions: 459 - 461**

**459** Source of HSCs:

- Allogeneic, related
- Allogeneic, unrelated
- Autologous

**460** Was the same donor used?

yes no

**461** Specify:

- fresh, original NMDP donor bone marrow
- fresh, original non-NMDP donor bone marrow
- fresh, new NMDP donor bone marrow
- fresh, new non-NMDP donor bone marrow
- fresh, original NMDP donor mobilized peripheral blood stem cells
- fresh, original non-NMDP donor mobilized peripheral blood stem cells
- fresh, new NMDP donor mobilized peripheral blood stem cells
- fresh, new non-NMDP donor mobilized peripheral blood stem cells
- NMDP cord blood
- non-NMDP cord blood
- cryopreserved original donor bone marrow
- cryopreserved original donor mobilized peripheral blood stem cells

## Donor Cellular Infusion (DCI) Information

**Questions: 462 - 560**

### DCI (1)

**Questions: 462 - 560**

**462** Date the first DCI was given: __ __ __ __ - __ __- __ __

**463** Specify the number of cell infusions given within 10 weeks of the first DCI: _____

**464** Was the DCI infusion performed at a different institution?

yes no

**Specify the institution that performed the DCI:**

**465** Name: _____

City: _____ State / Country: _____

**466** Indication for DCI:

- planned as part of initial HSCT protocol
- treatment for relapsed, persistent or progressive disease
- treatment for B cell lympho-proliferative disorder (PTLD, EBV lymphoma)
- treatment for GVHD
- viral infection
- stable, mixed chimerism
- loss of / decreased donor T-cell chimerism
- Other

**Specify the method(s) of disease detection below. For each method used, if the result was positive report the first date the disease was detected; if the result was negative report the last date the method was used prior to DCI (question 462).**

**467** Molecular

Positive Negative not done / unknown

**468** Date: __ __ __ __ - __ __- __ __

**469** Cytogenetic

Positive Negative not done / unknown

**470** Date: __ __ __ __ - __ __- __ __

**471** clinical evidence / hematologic

Positive Negative not done / unknown

**472** Date: __ __ __ __ - __ __- __ __

**473** Was chemotherapy used to attempt to induce disease response prior to the first DCI?

yes no

**474** Date of administration of final chemotherapy dose: __ __ __ __ - __ __- __ __

**475** Specify viral organism code: _____

**476** Date documented: __ __ __ __ - __ __- __ __ *(document chimerism testing beginning at question 81 or question 91)*

**477** Specify other indication: _____

**478** What was the recipient's disease status immediately prior to the first DCI?

- first complete remission post-HSCT (no hematologic evidence of disease)
- therapy-induced complete remission after persistent disease or relapse post-HSCT
- Relapse or progression
- Persistent disease
- not evaluated post-HSCT

**479** Date disease status was established prior to the first DCI: __ __ __ __ - __ __- __ __

**If the recipient is 16 years or older, complete the Karnofsky Scale. If the recipient is younger than 16 years of age, complete the Lansky Scale.**

**480** Specify the functional status of the recipient immediately prior to the first DCI: _____

**Specify DCI source:**

**481** collected at the time of PBSC mobilization and collection

yes no

**482** negative fraction of CD34 selected PBSC

yes no

**483** negative fraction of CD34 selected bone marrow

yes no

**484** apheresis at a different time than collection of PBSC used for allogeneic HSCT

yes no

**485** Date of Apheresis: __ __ __ __ - __ __- __ __

**486** isolated from a unit(s) of whole blood

yes no

**487** Specify number of units: _____

**488** Were the donor cells collected by leukapheresis?

yes no

**489** Date of first leukapheresis: __ __ __ __ - __ __- __ __

**490** Date of last leukapheresis: __ __ __ __ - __ __- __ __

**491** Number of leukaphereses: _____

**492** Did the donor receive treatment to enhance cell collection prior to donation?

yes no

**Specify treatment(s) given:**

**493** Growth factors

yes no

**Specify agent:**

**494** G-CSF

yes no

**495** GM-CSF

yes no

**496** Other agent

yes no

**497** Specify other agent: _____

**498** Other treatment

yes no

**499** Specify other treatment: _____

**For each DCI given, report the total number of cells infused. If the cells were cryopreserved, report the totals after processing, but before cryopreservation.**

**500** CD3+ cells not tested

CD3+ cells: _____ x10 Specify exponent: _____

**501** CD4+ cells not tested

CD4+ cells: _____ x10 Specify exponent: _____

**502** CD8+ cells not tested

CD8+ cells: _____ x10 Specify exponent: _____

**503** CD34+ cells not tested

CD34+ cells: _____ x10 Specify exponent: _____

**504** NK cells not tested

NK cells: _____ x10 Specify exponent: _____

**505** Nucleated cells not tested

Nucleated cells: _____ x10 Specify exponent: _____

**506** Mesenchymal cells not tested

Mesenchymal cells: _____ x10 Specify exponent: _____

**507** Were dendritic cells infused?

yes no

**508** Were fibroblasts infused?

yes no

**509** Were any other cell types infused?
(not including cell types reported in questions 500-508)

yes no

**510** Specify other cell type(s): _____

**511** Were the cells cryopreserved prior to infusion?

yes no

**512** Specify portion cryopreserved:

all cells portion of cells

**513** Were the cells manipulated prior to infusion?

yes no

**514** Specify portion manipulated:

all cells portion of cells

**Specify all methods used to manipulate the cells:**

**515** ABO incompatibility

yes no

**Specify method:**

**516** buffy coat preparation

yes no

**517** cell separator (i.e., COBE Spectra)

yes no

**518** density gradient separation (i.e., Ficoll)

yes no

**519** plasma removal

yes no

**520** sedimentation (i.e., hetastarch)

yes no

**521** other

yes no

**522** Specify other method: _____

**523** dextran-albumin wash

yes no

**524** ex-vivo expansion

yes no

**525** genetic manipulation (gene transfer / transduction)

yes no

**526** volume reduction

yes no

**527** CD34+ selection

yes no

**528** Specify manufacturer:

CliniMACS / CliniMax Isolex other manufacturer

**529** Specify other manufacturer: _____

**530** T-cell depletion

yes no

**Specify method:**

**531** Antibody affinity column

yes **-Report antibodies used for T-cell depletion at question 543.**

no

**532** Antibody coated plates

yes **-Report antibodies used for T-cell depletion at question 543.**

no

**533** Antibody coated plates and soybean lectin

yes **-Report antibodies used for T-cell depletion at question 543.**

no

**534** Antibody + complement

yes **-Report antibodies used for T-cell depletion at question 543.**

no

**535** Antibody + toxin

yes **-Report antibodies used for T-cell depletion at question 543.**

no

**536** Immunomagnetic beads

yes **-Report antibodies used for T-cell depletion at question 543.**

no

**537** Elutriation

yes no

**538** CD34 affinity column plus sheep red blood cell rosetting

yes no

**539** Other

yes no

**540** Specify other method: _____

**541** Other cell manipulation

yes no

**542** Specify other cell manipulation: _____

**543** Were antibodies used during graft manipulation?

yes no

**Specify antibodies:**

**544** Anti CD2

yes no

**545** Anti CD4

yes no

**546** Anti CD5

yes no

**547** Anti CD6

yes no

**548** Anti CD7

yes no

**549** Anti CD8

yes no

**550** Anti CD34

yes no

**551** Anti TCR alpha / beta (T10-B9)

yes no

**552** OKT-3

yes no

**553** Other CD3

yes no

**554** Specify other CD3: _____

**555** Anti CD52

yes no

**Specify antibodies:**

**556** campath-NOS

yes no

**557** campath-1G

yes no

**558** campath-1H

yes no

**559** Other antibody

yes no

**560** Specify other antibody: _____

First Name: _____ Last Name: _____

Phone number: _____ Fax number: _____

E-mail address: _____