Blood and Marrow Transplant Clinical Trials Network

C-1506: Busulfan Pharmacokinetics Sample Submission Form (BPK)

Web Version: 1.0; 2.01; 04-23-10

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

As of Version 6.0 of the protocol, the form is no longer in use.

C-1506: BUSULFAN PHARMACOKINETICS SAMPLE SUBMISSION FORM

ADDITIONAL INSTRUCTIONS: Submit a copy of this form along with the samples. Submit a copy to CALGB Data Operations. Fax a copy to Dr. Merrill Egorin's lab at 412-623-1212. Retain a copy for your records.

Were pharmacokinetic samples collected? *(PKSAMPLE)* ☐ 2 - No ☐ 1 - Yes

If No, specify reason: *(PKSMPLNO)* _____

Route of busulfan dosing *(RTBUDOSE)* ☐ 1 - IV ☐ 2 - Oral

Is the patient receiving Dilantin? *(RCVDILA)* ☐ 2 - No ☐ 1 - Yes

If Yes, specify dose: *(DILADOSE)* _____ *(xxx)* mg/day

The patient is currently receiving Voriconazole *(RCVVORI)* ☐ 2 - No ☐ 1 - Yes

The patient is currently receiving Itraconazole *(RCVITRA)* ☐ 2 - No ☐ 1 - Yes

The patient is currently receiving Acetaminophen *(RCVACETA)* ☐ 2 - No ☐ 1 - Yes

If the patient is receiving other agents, specify *(RCVOTHER)* _____

Actual weight *(ACTWGT)* _____ *(xxx.x)* kg

Dosing weight *(DOSEWGT)* _____ *(xxx.x)* kg
(ABW, IBW, AIBW)

Height *(PKHGT)* _____ *(xxx)* cm

Busulfan dose *(BUDOSE)* _____ *(xxx)* mg per dose

SAMPLE COLLECTION AND INFUSION DOCUMENTATION

	Collection date	Planned time of draw	Actual time of draw
1) Baseline sample (prior to busulfan infusion)	*(BLSMPLDT)* *(mm/dd/yyyy)*	*(BLSMPLPT)* *(hh:mm)*	*(BLSMPLAT)* *(hh:mm)*
2) 1 hour into 2-hour busulfan infusion	*(PKONEDT)* *(mm/dd/yyyy)*	*(PKONEPT)* *(hh:mm)*	*(PKONEAT)* *(hh:mm)*
3) 1 hour and 55 minutes into 2-hour busulfan infusion	*(PKONEFDT)* *(mm/dd/yyyy)*	*(PKONEFPT)* *(hh:mm)*	*(PKONEFAT)* *(hh:mm)*
4) 3 hours after initiation of busulfan infusion (i.e., 1 hour after completion of busulfan infusion)	*(PKTHRDT)* *(mm/dd/yyyy)*	*(PKTHRPT)* *(hh:mm)*	*(PKTHRAT)* *(hh:mm)*
5) 4 hours after initiation of busulfan infusion (i.e., 2 hours after completion of busulfan infusion)	*(PKFRDT)* *(mm/dd/yyyy)*	*(PKFRPT)* *(hh:mm)*	*(PKFRAT)* *(hh:mm)*
6) 5 hours after initiation of busulfan infusion (i.e., 3 hours after completion of busulfan infusion)	*(PKFVDT)* *(mm/dd/yyyy)*	*(PKFVPT)* *(hh:mm)*	*(PKFVAT)* *(hh:mm)*
7) 5 hours and 55 minutes after initiation of busulfan infusion (i.e., immediately prior to the subsequent dose of busulfan)	*(PKFVFFDT)* *(mm/dd/yyyy)*	*(PKFVFFPT)* *(hh:mm)*	*(PKFVFFAT)* *(hh:mm)*

Condition of samples at time of shipment *(PKCOND)* ☐ 1 - Frozen ☐ 2 - Thawed

Contact Name *(PKCONTCT)* _____

Fax No. *(PKFAX)* _____

Email Address *(PKEMAIL)* _____

Phone No. *(PKPHONE)* _____

Date sample shipped *(PKSHIP)* _____ *(mm/dd/yyyy)*

Tracking No. *(PKTRACK)* _____

Carrier *(PKCARR)* _____

COMMENTS (unusual circumstances during collection/ processing of samples) *(PKCMMNT)*

Blood and Marrow Transplant Clinical Trials Network

C-1092: Adverse Event Form (CAE)

Web Version: 1.0; 2.01; 03-15-11

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

C-1092: ADVERSE EVENT (AE) FORM

CTC adverse event report begin date *(CAEBEGDT)* _____ *(mm/dd/yyyy)*

CTC adverse event report end date *(CAEENDDT)* _____ *(mm/dd/yyyy)*

Has an AdEERS been filed with *Central Office based on an event reported below? (ADEERFIL)* ☐ 2 - No ☐ 1 - Yes

[1]Use **NCI CTCAE v3.x** or most current version with MedDRA codes posted at http://www.calgb.org to grade each adverse event. Grade = 0 if category evaluated but event not reported.

[2]AE is defined as adverse event.

[3]**TREATMENT ATTRIBUTION CODES:** 1 = unrelated, 2 = unlikely, 3 = possible, 4 = probable, 5 = definite

EXPECTED ADVERSE EVENTS

MedDRA code [1]	CTC adverse event term	CTC AE [2] grade [1]	CTC AE [2] Attribution Code [3]
10029363	ANC	*(ANCAEGR)* 0-0 -None 1-1 -< LLN -1500/mm^3 2-2 -< 1500 -1000/mm^3 3-3 -< 1000 -500/mm^3 4-4 -< 500/mm^3 *Additional Options Listed Below	*(ANCAEATR)* 1-1 -Unrelated 2-2 -Unlikely 3-3 -Possible 4-4 -Probable 5-5 -Definite
10035528	Platelets	*(PLTAEGRD)* 0-0 -None 1-1 -< LLN -75,000/mm^3 2-2 -< 75,000 -50,000/mm^3 3-3 -< 50,000 -25,000/mm^3 4-4 -< 25,000/mm^3 *Additional Options Listed Below	*(PLTAEATR)* 1-1 -Unrelated 2-2 -Unlikely 3-3 -Possible 4-4 -Probable 5-5 -Definite
10047899	Weight gain	*(WTGNAEGR)* 0-0 -None 1-1 -5 -< 10% of baseline 2-2 -10 -< 20% of baseline 3-3 -> or= 20% of baseline	*(WTGNAEAT)* 1-1 -Unrelated 2-2 -Unlikely 3-3 -Possible 4-4 -Probable 5-5 -Definite
10012457	Rash	*(RASHAEGR)* 0-0 -None 1-1 -Macular/papular eruption; erythema without associated symptoms 2-2 -Macular/papular eruption; erythema with pruritus or other associated symptoms 3-3 -Severe, generalized erythroderma; macular, papular or vesicular eruption 4-4 -Generalized exfoliative, ulcerative, or bullous dermatitis *Additional Options Listed Below	*(RASHARAT)* 1-1 -Unrelated 2-2 -Unlikely 3-3 -Possible 4-4 -Probable 5-5 -Definite
10012745	Diarrhea	*(DIARAEGR)* 0-0 -None 1-1 -Increase of < 4 stools per day over baseline 2-2 -Increase of 4 - 6 stools per day over baseline; IV fluids indicated < 24 hrs 3-3 -Increase of > or= 7 stools per day over baseline; IV fluids > or= 24 hrs 4-4 -Life-threatening consequences (e.g., hemodynamic collapse) *Additional Options Listed Below	*(DIARAEAT)* 1-1 -Unrelated 2-2 -Unlikely 3-3 -Possible 4-4 -Probable 5-5 -Definite

10005364 Bilirubin

(BILIAEGR)

0-0 - None
1-1 - > ULN - 1.5 x ULN
2-2 - > 1.5 - 3.0 x ULN
3-3 - > 3.0 - 10.0 x ULN
4-4 - > 10.0 x ULN

(BILIAEAT)

1-1 - Unrelated
2-2 - Unlikely
3-3 - Possible
4-4 - Probable
5-5 - Definite

10035755 Pneumonitis/Pulm Infiltrates

(PULMAEGR)

0-0 - None
1-1 - Asymptomatic; radiographic findings only
2-2 - Symptomatic; not interfering with ADL
3-3 - Symptomatic; interfering with ADL; oxygen indicated
4-4 - Life-threatening; ventilator support indicated
*Additional Options Listed Below

(PULMAEAT)

1-1 - Unrelated
2-2 - Unlikely
3-3 - Possible
4-4 - Probable
5-5 - Definite

10016288 Febrile neutropenia

(NEUTAEGR)

0-0 - None
3-3 - Present
4-4 - Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis)
5-5 - Death

(NEUTAEAT)

1-1 - Unrelated
2-2 - Unlikely
3-3 - Possible
4-4 - Probable
5-5 - Definite

10013968 Dyspnea

(DYSPAEGR)

0-0 - None
1-1 - Dyspnea on exertion
2-2 - Dyspnea on exertion; unable to walk 1 flight of stairs
3-3 - Dyspnea with ADL
4-4 - Dyspnea at rest; intubation or ventilator indicated
*Additional Options Listed Below

(DYSPAEAT)

1-1 - Unrelated
2-2 - Unlikely
3-3 - Possible
4-4 - Probable
5-5 - Definite

10021143 Hypoxia

(HYPXAEGR)

0-0 - None
2-2 - Decreased oxygen saturation with exercise
3-3 - Decreased oxygen saturation at rest; continuous oxygen indicated
4-4 - Life-threatening; intubation or ventilation indicated
5-5 - Death

(HYPXAEAT)

1-1 - Unrelated
2-2 - Unlikely
3-3 - Possible
4-4 - Probable
5-5 - Definite

10021099 Hypotension

(LOBPAEGR)

0-0 - None
1-1 - Changes; intervention not indicated
2-2 - Brief (< 24 hrs) fluid replacement or other therapy
3-3 - Sustained (> or = 24 hrs) therapy; resolves without persisting physiologic consequences
4-4 - Shock (e.g., acidemia; impairment of vital organ function)
*Additional Options Listed Below

(LOBPAEAT)

1-1 - Unrelated
2-2 - Unlikely
3-3 - Possible
4-4 - Probable
5-5 - Definite

10020782 Hypertension

(HIBPAEGR)

0-0 - None
1-1 - Asymptomatic; transient (< 24 hrs) increase by > 20 mm Hg (diastolic)
2-2 - Recurrent or persistent; (> or = 24 hrs) symptomatic increase by > 20 mm Hg (diastolic)
3-3 - Requiring more than one drug or more intensive therapy than previously
4-4 - Life-threatening consequences (e.g., hypertensive crisis)
*Additional Options Listed Below

(HIBPAEAT)

1-1 - Unrelated
2-2 - Unlikely
3-3 - Possible
4-4 - Probable
5-5 - Definite

10024119 Left ventricular systolic dysfunction

(SYSTAEGR)

0-0 - None
1-1 - Asymptomatic; resting EF < 60 - 50%; SF < 30 - 24%
2-2 - Asymptomatic; resting EF < 50 - 40%; SF < 24 - 15%
3-3 - Symptomatic CHF responsive to intervention; EF < 40 - 20%; SF < 15%
4-4 - Refractory CHF or poorly controlled; intervention with ventricular assist device
*Additional Options Listed Below

(SYSTAEAT)

1-1 - Unrelated
2-2 - Unlikely
3-3 - Possible
4-4 - Probable
5-5 - Definite

10052337 Left ventricular diastolic dysfunction

(DIASAEGR)

0-0 - None
1-1 - Asymptomatic; intervention not indicated
2-2 - Asymptomatic; intervention indicated
3-3 - Symptomatic CHF responsive to intervention
4-4 - Refractory CHF, poorly controlled
*Additional Options Listed Below

(DIASAEAT)

1-1 - Unrelated
2-2 - Unlikely
3-3 - Possible
4-4 - Probable
5-5 - Definite

Specify any other events that occurred during this time period. Report secondary malignancies other than AML/MDS here and on Form C-1001.
Include infection w/ grade 3 or 4 neutropenia, mucositis/stomatitis
*Report all **Select-Site** adverse events listed below, if Grade 1 or higher, using MedDRA code corresponding to each specific site. If more than one site is involved,*

report each site separately.

MedDRA code [1]	CTC adverse event term	CTC AE [2] grade[1]	CTC AE [2] Attribution Code[3]
(MEDR1COD) *(xxxxxxxx)*	*(CTC1TERM)*	*(CTC1GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC1ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MEDR2COD) *(xxxxxxxx)*	*(CTC2TERM)*	*(CTC2GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC2ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MEDR3COD) *(xxxxxxxx)*	*(CTC3TERM)*	*(CTC3GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC3ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MEDR4COD) *(xxxxxxxx)*	*(CTC4TERM)*	*(CTC4GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC4ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MEDR5COD) *(xxxxxxxx)*	*(CTC5TERM)*	*(CTC5GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC5ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MEDR6COD) *(xxxxxxxx)*	*(CTC6TERM)*	*(CTC6GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC6ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MEDR7COD) *(xxxxxxxx)*	*(CTC7TERM)*	*(CTC7GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC7ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MEDR8COD) *(xxxxxxxx)*	*(CTC8TERM)*	*(CTC8GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC8ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MEDR9COD) *(xxxxxxxx)*	*(CTC9TERM)*	*(CTC9GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC9ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite

(MDR10COD) *(xxxxxxxx)*	*(CTC10TRM)*	*(CTC10GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC10ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MDR11COD) *(xxxxxxxx)*	*(CTC11TRM)*	*(CTC11GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC11ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MDR12COD) *(xxxxxxxx)*	*(CTC12TRM)*	*(CTC12GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC12ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MDR13COD) *(xxxxxxxx)*	*(CTC13TRM)*	*(CTC13GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC13ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MDR14COD) *(xxxxxxxx)*	*(CTC14TRM)*	*(CTC14GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC14ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite
(MDR15COD) *(xxxxxxxx)*	*(CTC15TRM)*	*(CTC15GRD)* 1-1- Grade 1 2-2- Grade 2 3-3- Grade 3 4-4- Grade 4 5-5- Grade 5	*(CTC15ATR)* 1-1 - Unrelated 2-2 - Unlikely 3-3 - Possible 4-4 - Probable 5-5 - Definite

Comments: *(CAECOMNT)*

Additional Selection Options for CAE

ANC AE Grade
5-5 - Death

Platelets AE Grade
5-5 - Death

Rash AE Grade
5-5 - Death

Diarrhea AE Grade
5-5 - Death

Pulm Infiltrates AE Grade
5-5 - Death

Dyspnea AE Grade
5-5 - Death

Hypotensn (Lo BP) AE Grd
5-5 - Death

Hypertensn (Hi BP) AE Grd
5-5 - Death

Left Ventr Systolic AE Gr
5-5 - Death

Left Ventr Diastol AE Grd
5-5 - Death

Blood and Marrow Transplant Clinical Trials Network

C-1740: Chimerism Results Form (CHM)

Web Version: 1.0; 1.01; 11-29-10

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

C-1740: CHIMERISM RESULTS FORM

	Whole blood	Bone marrow
Sample collection date	*(CHMWBDT)* *(mm/dd/yyyy)*	*(CHMBMDT)* *(mm/dd/yyyy)*
CD3+ chimerism results	*(CHMWBCD)* *(xxx)* %	*(CHMBMCD)* *(xxx)* %
Total chimerism results	*(CHMWBTCH)* *(xxx)* %	*(CHMBMTCH)* *(xxx)* %

Blood and Marrow Transplant Clinical Trials Network

C-703: Chimerism Sample Submission Form (CSS)

Web Version: 1.0; 2.00; 03-02-10

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

C-703: CHIMERISM SAMPLE SUBMISSION FORM

For version 6.0 of the BMT CTN 0502 protocol, the C-703 chimerism form is no longer required. Please report all in-house chimerism data via the C-1704 form.

Date samples drawn *(DATSMPLD)* *(mm/dd/yyyy)*

Samples drawn from *(SPLPTDON)* ☐ 1 - Patient ☐ 2 - Donor

Sample collection period (code "0" for pre-study) *(SMPLCOLL)*

Types of samples submitted *(TYPESAMP)*

1-1 - Peripheral Blood
2-2 - Bone Marrow Aspirate
3-3 - Both

Date samples sent *(DATSMPST)* *(mm/dd/yyyy)*

Date of transplant (Day 0) *(DATETXP)* *(mm/dd/yyyy)*

Were any platelet transfusions performed within one week of sample collection? *(CSSPLATL)* ☐ 2 - No ☐ 1 - Yes

Were any RBC transfusions performed within one week of sample collection? *(CSSRBC)* ☐ 2 - No ☐ 1 - Yes

Name of person sending samples *(NMSNDSPL)*

Phone number *(PHONENMB)*

Fax number *(FAXNUMBR)*

INSTITUTION LAB RESULTS:

WBC (mm^3) *(CSSWBC)* *(xxx.x)*

Granulocytes (%) *(GRANULCT)* *(xx)*

Lymphocytes (%) *(LYMPHOCT)* *(xx)*

Date performed *(INSLABDT)* *(mm/dd/yyyy)*

Comments: *(CSSCOMMT)*

Blood and Marrow Transplant Clinical Trials Network

C-702: Donor Cell Product Form (DCP)

Web Version: 1.0; 2.00; 04-20-09

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

C-702: DONOR CELL PRODUCT FORM

Reporting Period From: *(DCPFRMDT)* _____ *(mm/dd/yyyy)*
Reporting Period To: *(DCPTODT)* _____ *(mm/dd/yyyy)*

Donor age (years): *(DCPAGE)* _____ *(xx)* Sex of donor: *(DCPSEX)* ☐ 1 - Male ☐ 2 - Female

TOTAL NUMBER OF CELLS INFUSED DURING THIS REPORTING PERIOD:

CD34+ Cell Dose *(DCPCD34C)* _____ *(xx.x)* x 10^6 / kg

CD3+ Cell Dose *(DCPCD3PC)* _____ *(xx.x)* x 10^7 / kg

Total number of collections during this time period (List each one below separately) *(DCPCOLNO)* _____ *(x)*

Date of Infusion *(DCPINFDT)* _____ *(mm/dd/yyyy)*

FIRST COLLECTION DURING THIS REPORTING PERIOD:

Date of first collection *(DCP1DATE)* _____ *(mm/dd/yyyy)*

Was the donor receiving G-CSF? *(DCP1YNGC)* ☐ 2 - No ☐ 1 - Yes

G-CSF schedule *(DCP1SCHG)* 1-Once a day 2-Twice a day

G-CSF dosing per day *(DCP1DOSE)* _____ *(xx)* µg/kg/d

Number of cells collected for the first collection:

CD34+ Cell Dose *(DCP134CD)* _____ *(xx.x)* x 10^6 / kg

CD3+ Cell Dose *(DCP1CD3P)* _____ *(xx.x)* x 10^7 / kg

Were the cells cryopreserved? *(DCP1CRYO)* ☐ 2 - No ☐ 1 - Yes

SECOND COLLECTION DURING THIS REPORTING PERIOD:

Date of second collection *(DCP2DATE)* _____ *(mm/dd/yyyy)*

Was the donor receiving G-CSF? *(DCP2YNGC)* ☐ 2 - No ☐ 1 - Yes

G-CSF schedule *(DCP2SCHG)* 1-Once a day 2-Twice a day

G-CSF dosing per day *(DCP2DOSE)* _____ *(xx)* µg/kg/d

Number of cells collected for the second collection:

CD34+ Cell Dose *(DCP234CD)* _____ *(xx.x)* x 10^6 / kg

CD3+ Cell Dose *(DCP2CD3P)* _____ *(xx.x)* x 10^7 / kg

Were the cells cryopreserved? *(DCP2CRYO)* ☐ 2 - No ☐ 1 - Yes

THIRD COLLECTION DURING THIS REPORTING PERIOD:

Date of third collection *(DCP3DATE)* _____ *(mm/dd/yyyy)*

Was the donor receiving G-CSF? *(DCP3YNGC)* ☐ 2 - No ☐ 1 - Yes

G-CSF schedule *(DCP3SCHG)* 1-Once a day 2-Twice a day

G-CSF dosing per day *(DCP3DOSE)* _____ *(xx)* µg/kg/d

Number of cells collected for the third collection:

CD34+ Cell Dose *(DCP334CD)* _____ *(xx.x)* x 10^6 / kg

CD3+ Cell Dose *(DCP3CD3P)* _____ *(xx.x)* x 10^7 / kg

Were the cells cryopreserved? *(DCP3CRYO)* ☐ 2 - No ☐ 1 - Yes

FOURTH COLLECTION DURING THIS REPORTING PERIOD:

Date of fourth collection *(DCP4DATE)* _____ *(mm/dd/yyyy)*

Was the donor receiving G-CSF? *(DCP4YNGC)* ☐ 2 - No ☐ 1 - Yes

G-CSF schedule *(DCP4SCHG)* 1-Once a day 2-Twice a day

G-CSF dosing per day *(DCP4DOSE)* _____ *(xx)* µg/kg/d

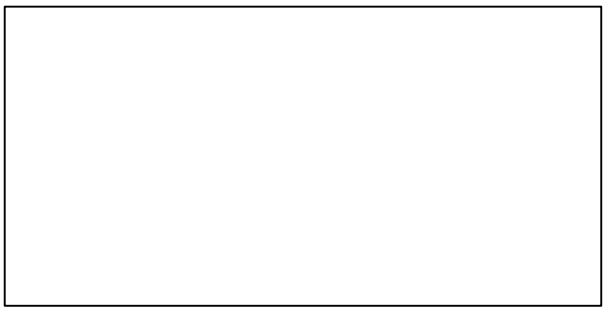
Number of cells collected for the fourth collection:

CD34+ Cell Dose *(DCP434CD)* _____ *(xx.x)* x 10^6 / kg

CD3+ Cell Dose *(DCP4CD3P)* _____ *(xx.x)* x 10^7 / kg

Were the cells cryopreserved? *(DCP4CRYO)* ☐ 2 - No ☐ 1 - Yes

Comments: *(DCPCOMNT)*



Blood and Marrow Transplant Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 6.00; 06-22-11

1. Name Code: *(NAMECODE)*
2. IUBMID # (if available): *(IUBMID)*
3. CRID # (CIBMTR Recipient ID): *(CRIDNUM)* *(xxxxxxxxxx)*

Do NOT use IUBMID/UPN numbers in the CRID field.

4. Gender: *(GENDER)* ☐ 1 - Male ☐ 2 - Female
5. Date of Birth: *(DOB)* *(mm/dd/yyyy)*
6. Ethnicity: *(ETHNIC)*

1-1 - Hispanic or Latino
2-2 - Not Hispanic or Latino
8-8 - Unknown
9-9 - Not Answered

7. Race: *(RACE)*

-White
10-10 - White (Not Otherwise Specified)
11-11 - European (Not Otherwise Specified)
13-13 - Mediterranean
14-14 - White North American
*Additional Options Listed Below

Specify race: *(RACESP)*

8. Secondary Race: *(RACE2)*

-White
10-10 - White (Not Otherwise Specified)
11-11 - European (Not Otherwise Specified)
13-13 - Mediterranean
14-14 - White North American
*Additional Options Listed Below

Specify secondary race: *(RACE2SP)*

Comments: *(DEMCOMM1)*

Additional Selection Options for DEM

Race:
15-15 - South or Central American
16-16 - Eastern European
17-17 - Northern European
18-18 - Western European
81-81 - White Caribbean
82-82 - North Coast of Africa
83-83 - Middle Eastern
-Black
20-20 - Black (Not Otherwise Specified)
21-21 - African American
22-22 - African Black (Both Parents Born in Africa)
23-23 - Caribbean Black
24-24 - South or Central American Black
29-29 - Black, Other Specify
-Asian
30-30 - Asian (Not Otherwise Specified)
31-31 - Indian/South Asian
32-32 - Filipino (Pilipino)
34-34 - Japanese
35-35 - Korean
36-36 - Chinese
37-37 - Other Southeast Asian
38-38 - Vietnamese
-American Indian or Alaska Native
50-50 - Native American (Not Otherwise Specified)
51-51 - Native Alaskan/Eskimo/Aleut
52-52 - American Indian (Not Otherwise Specified)
53-53 - North American Indian
54-54 - South or Central American Indian
55-55 - Caribbean Indian
-Native Hawaiian or Other Pacific Islander
60-60 - Native Pacific Islander (Not Otherwise Specified)
61-61 - Guamanian
62-62 - Hawaiian
63-63 - Samoan
-Other
88-88 - Unknown
90-90 - Other, Specify
99-99 - Not Answered

Blood and Marrow Transplant Clinical Trials Network

C-113: Notification of Death (DET)

Web Version: 1.0; 2.00; 04-20-09

C-113: NOTIFICATION OF DEATH

INSTRUCTIONS: This form is to be submitted in the event of a patient's death due to any cause. It is to be submitted within four (4) weeks of death, along with copies of death certificate/autopsy report (if available). If appropriate, include other required CALGB forms if they have not already been submitted. If death has been reported via a monthly delinquency reminder list, this form must still be submitted if required by the protocol. This form is not applicable for most non-treatment studies, such as companions, psychiatric assessments, laboratory evaluations and cancer control studies.

Date of Death *(DATDEATH)* *(mm/dd/yyyy)*

Cause of Death *(CAUSEDET)*

- 1.0-1.0 - Graft Rejection or Failure
- Infection (Other than Interstitial Pneumonia)
- 1.1-1.1 - Autologous Recovery
- 1.2-1.2 - Rejection
- 2.1-2.1 - Bacterial
- *Additional Options Listed Below

If other, specify *(DETOTHER)*

Relation to Protocol *(DTHRELTD)*

- 1-1 - Protocol Treatment Related
- 2-2 - Protocol Disease Related
- 3-3 - Not Related to Protocol Treatment or Protocol Disease

Comments: *(DETCOMMT)*

Additional Selection Options for DET

Cause of Death
2.2-2.2 - Fungal
2.3-2.3 - Viral
2.4-2.4 - Protozoal
2.5-2.5 - Other, Specify Below
2.9-2.9 - Organism Not Identified
-Interstitial Pneumonia
3.1-3.1 - Viral, CMV
3.2-3.2 - Viral, Other
3.3-3.3 - Pneumocystis
3.4-3.4 - Other, Specify Below
3.9-3.9 - Idiopathic
4.0-4.0 - Adult Respiratory Distress Syndrome
5.0-5.0 - Acute GVHD
6.0-6.0 - Chronic GVHD
7.0-7.0 - Recurrence or Persistence of Leukemia/Malignancy/MDS
7.1-7.1 - Persistent Disease
-Organ Failure (Not Due to GVHD or Infection)
8.1-8.1 - Liver
8.2-8.2 - Cardiac (Cardiomyopathy)
8.3-8.3 - Pulmonary
8.4-8.4 - CNS
8.5-8.5 - Renal
8.6-8.6 - Other, Specify Below
8.7-8.7 - Multiple Organ Failure, Specify Below
8.8-8.8 - Secondary Graft Failure
9.0-9.0 - Secondary Malignancy
9.1-9.1 - EBV
9.2-9.2 - Other, Specify Below
-Hemorrhage
10.1-10.1 - Pulmonary
10.2-10.2 - Intracranial
10.3-10.3 - Gastrointestinal
10.4-10.4 - Hemorrhage Not Specified
10.5-10.5 - Other, Specify Below
-Vascular
11.1-11.1 - Thromboembolic
11.2-11.2 - Disseminated Intravascular Coagulation (DIC)
11.3-11.3 - Gastrointestinal
11.4-11.4 - Thrombotic Thrombocytopenic Purpura
11.5-11.5 - Vascular Not Specified
11.9-11.9 - Other, Specify Below
12.0-12.0 - Accidental Death
13.0-13.0 - Other, Specify Below

Blood and Marrow Transplant Clinical Trials Network

Eligibilty Checklist - 0502 (ELG)

Web Version: 1.0; 2.00; 09-28-10

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

CALGB 100103 ELIGIBILITY CHECKLIST

INSTRUCTIONS: Complete all information on this form. Do not leave any entries blank.

Patient meets all of the following eligibility criteria (please check each one):

Patient has AML in CR1 *(AMLCRONE)*	☐ 2 - No	☐ 1 - Yes
Patient does not have FAB M3 *(NOFABMTH)*	☐ 2 - No	☐ 1 - Yes
Patient has no extramedullary leukemia *(NOXMDLEU)*	☐ 2 - No	☐ 1 - Yes
Patient achieved CR after no more than two cycles of induction chemotherapy or no more than 4 cycles of a hypomethylating agent containing regimen including either 5-azacytadine or decitabine *(CRICHEMO)*	☐ 2 - No	☐ 1 - Yes
Consolidation therapy did not require a transplant *(CTNOTXP)*	☐ 2 - No	☐ 1 - Yes
Less than 6 months elapsed between achieving CR and date of transplant on this study *(TIMCRTXP)*	☐ 2 - No	☐ 1 - Yes
Identification of HLA identical sibling donor or a 10/10 unrelated donor *(HLAIDSIB)*	☐ 2 - No	☐ 1 - Yes
≥ 4 weeks since prior chemotherapy, radiation, or surgery *(PCHRADSX)*	☐ 2 - No	☐ 1 - Yes
Age ≥ 60 years and < 75 years *(AGEYEARS)*	☐ 2 - No	☐ 1 - Yes
Performance Status 0-2 *(PERFSTAT)*	☐ 2 - No	☐ 1 - Yes
DLCO > 40% with no symptomatic pulmonary disease *(DLCONOPD)*	☐ 2 - No	☐ 1 - Yes
LVEF by MUGA ≥ 30% *(LVEFMUGA)*	☐ 2 - No	☐ 1 - Yes
No uncontrolled diabetes mellitus or serious infection requiring antibiotics *(NODIBINF)*	☐ 2 - No	☐ 1 - Yes
No known hypersensitivity to E.coli-derived products *(NOECSENS)*	☐ 2 - No	☐ 1 - Yes
No HIV disease *(NOHIV)*	☐ 2 - No	☐ 1 - Yes

Initial required laboratory values completed within 16 days before registration:

ANC > 1000/µl *(ELGANCDT)*	Date Obtained	*(mm/dd/yyyy)*
Platelets > 100,000/µl *(ELGPLTDT)*	Date Obtained	*(mm/dd/yyyy)*
Calculated Creatinine Clearance ≥ 40 cc/min *(ELGCRTDT)*	Date Obtained	*(mm/dd/yyyy)*
Total Bilirubin < 2 mg/dL *(ELGBILDT)*	Date Obtained	*(mm/dd/yyyy)*
AST < 3x ULN *(ELGASTDT)*	Date Obtained	*(mm/dd/yyyy)*

Donor meets all of the following eligibility criteria (please check each one):

Donor is an HLA-matched sibling (6/6) or a 10/10 unrelated donor *(DHLASIB)*	☐ 2 - No	☐ 1 - Yes
Donor is healthy and meets all institutional criteria for marrow or blood stem cell donation *(DHEALTH)*	☐ 2 - No	☐ 1 - Yes
Donor has no significant cardiopulmonary, renal, endocrine, or hepatic disease *(DNOSIGDX)*	☐ 2 - No	☐ 1 - Yes
Donor is not syngeneic *(DNOSYNG)*	☐ 2 - No	☐ 1 - Yes

Comments: *(ELGCOMM)*

Blood and Marrow Transplant Clinical Trials Network

0502A (ENR)

Web Version: 1.0; 4.01; 03-15-11

CALGB 100103 REGISTRATION WORKSHEET

A Phase II Study of Allogeneic Transplant for Older Patients with AML in First Morphologic Complete Remission Using a Non-Myeloablative Preparative Regimen

Institution *(INST)*

Physician of Record *(MD)*

Affiliate/Treating Institution *(AFFINST)*

Participating Group Name *(GRPNAM)*

If the patient has been on a previous CALGB protocol, specify CALGB Patient ID *(EXISTID)*

Protocol Administration

IRB Approval Date *(IRBAPPDT)* *(mm/dd/yyyy)* Responsible Contact *(RESPCNCT)*

Date Informed Consent Signed *(CACNSTDT)* *(mm/dd/yyyy)*

Projected Treatment Start Date *(PRXSTDT)* *(mm/dd/yyyy)* Phone *(RESPPHON)*

HIPAA Authorization Date *(HIPAADT)* *(mm/dd/yyyy)* FAX *(RESPFAX)*

Patient Demographics/Pre-Treatment Characteristics

Patient Initials *(PTINTL)* Social Security Number *(PTSSN)*

Last, First Middle

Birth Date *(CAPTDOB)* *(mm/dd/yyyy)* Patient Hospital No. *(PTHOSPNO)*

Gender *(CAGENDER)* ☐ 1 - Male ☐ 2 - Female

Race *(CA1RACE)*

1-1 - American Indian or Alaskan Native
2-2 - Asian
3-3 - Black or African American
4-4 - Native Hawaiian or Other Pacific Islander
5-5 - Unknown
*Additional Options Listed Below

Specify race: *(CA1RASP)*

Race 2 *(CA2RACE)*

1-1 - American Indian or Alaskan Native
2-2 - Asian
3-3 - Black or African American
4-4 - Native Hawaiian or Other Pacific Islander
5-5 - Unknown
*Additional Options Listed Below

Specify race 2: *(CA2RASP)*

Ethnicity *(mark one) (CAETHN)*

1-1 - Hispanic or Latino
2-2 - Non-Hispanic
8-8 - Unknown

ECOG Performance Status *(ECOG/Zubrod scale) (ECOGPS)*

0-0 - Fully active, able to carry on all pre-disease performance without restriction
1-1 - Restricted in physically strenuous activity but ambulatory, e.g. light house work, office work
2-2 - Ambulatory and capable of all self care but unable to carry out any work activities
3-3 - Capable of only limited self care, confined to bed or chair more than 50% of waking hours
4-4 - Completely disabled. Can not carry on self care. Totally confined to bed or chair.
*Additional Options Listed Below

Height *(CAHGT)* *(xxx)* *cm* Weight *(CAWGT)* *(xxx.x)* *kg* BSA *(CABSA)* *(x.xx)* m^2

Method of Payment *(MTHPAY)*

01-01 - Medicaid
02-02 - Medicaid and Medicare
03-03 - Medicare
04-04 - Medicare and Private Insurance
05-05 - Military (including CHAMPUS)
*Additional Options Listed Below

Disease *(CADIS)*

1-1 - Acute Myelogenous Leukemia

Pathologic Type *(CAPTHTYP)*

Patient's Zip Code *(PTZIP)* - *(PTZIP2)*

Country of Residence *(If not USA) (PTCNTRY)*

Certification Of Eligibility

Is the patient eligible? *(PTELIG)*

☐ 2 - No ☐ 1 - Yes

Protocol Design

Assigned Treatment Arm: 1 = Stem cell infusion

Comments: *(CACOMMTS)*

Additional Selection Options for ENR

Race
6-6 - White
9-9 - Other, specify

ECOG Performance Status
(ECOG/Zubrod scale)
5-5 - Dead

Method of Payment
06-06 - No means of payment (no insurance)
07-07 - Other
08-08 - Private insurance (Aetna, Blue Cross, Kaiser Permanente and employer-sponsored insurers)
09-09 - Self Pay (no insurance)
10-10 - Unknown
11-11 - Veterans Administration Sponsored

Blood and Marrow Transplant Clinical Trials Network

C-1091: Follow-Up Form (FUF)

Web Version: 1.0; 2.02; 03-15-11

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

C-1091: FOLLOW-UP FORM

Reporting period start date *(RPSTDT)* *(mm/dd/yyyy)*

Reporting period end date *(RPENDDT)* *(mm/dd/yyyy)*

SURVIVAL STATUS *(SUVSTAT)*

1-1 - Alive
2-2 - Dead
3-3 - Lost to follow-up

TREATMENT DATA

Record the type of treatment covered by this form. This should reflect the patient's treatment at the beginning of this reporting period. Do NOT report more than one treatment type or more than one infusion per reporting period.

Treatment type *(TXTYPE)*

1-1 - Allogeneic transplant
2-2 - Donor lymphocyte infusion (DLI)
3-3 - Follow-up off treatment
4-4 - Other

Treatment type *(TXTYPE)*

1-1 - Allogeneic transplant
2-2 - Donor lymphocyte infusion (DLI)
3-3 - Follow-up off treatment
4-4 - Other

If other, specify: *(TXOTHR)*

If the patient received their transplant during this reporting period, day 0 of the transplant will be recorded. If there was no transplant performed during this reporting period, leave the date blank.

Transplant date *(TRNSPDT)* *(mm/dd/yyyy)*

If tacrolimus taper was started before day +90 or completed in less than 60 days, give reason.

Tacrolimus taper *(TACTAPR)*

1-1 - Not given during this reporting period
2-2 - Not applicable (given according to protocol)
3-3 - Disease progression
4-4 - Poor donor chimerism
5-5 - Toxicity due to tacrolimus
*Additional Options Listed Below

If tacrolimus was tapered due to toxicity, specify: *(TACTOX)*

If tacrolimus was tapered due to other, specify: *(TACOTHR)*

Donor Lymphocyte Infusion (DLI)

If the patient received a donor lymphocyte infusion (DLI) during this reporting period, record the date of the DLI. If a DLI was performed, continue to follow the patient for response.

DLI Date *(DLIDATE)* *(mm/dd/yyyy)*

DLI number *(DLINO)*

1-1 - First
2-2 - Second
3-3 - Third

Reason DLI given *(DLIGVN)*

1-1 - Disease progression
2-2 - Poor chimerism

Was the patient on an immunosuppressive agent during this reporting period? *(IMMUAGNT)* ☐ 2 - No ☐ 1 - Yes ☐ 9 - Unknown

If yes, specify date of last immunosuppressive agent *(IMMUDT)* *(mm/dd/yyyy)*

Did the patient receive the following immunosuppressive agent?

Corticosteroids (systemic) *(IMMCORT)* ☐ 2 - No ☐ 1 - Yes

Tacrolimus (FK506) *(IMMTAC)* ☐ 2 - No ☐ 1 - Yes

Mycophenolate mofetil *(IMMMYCO)* ☐ 2 - No ☐ 1 - Yes

Cyclosporin A *(IMMCYCLO)* ☐ 2 - No ☐ 1 - Yes

Azathioprine *(IMMAZA)* ☐ 2 - No ☐ 1 - Yes

Rapamycin *(IMMRAP)* ☐ 2 - No ☐ 1 - Yes

Other *(IMMOTHER)* ☐ 2 - No ☐ 1 - Yes

Specify other agent used *(IMMSPEC)*

Did the patient receive preemptive therapy for CMV reactivation during this reporting period? *(PRECMV)* ☐ 2 - No ☐ 1 - Yes ☐ 9 - Unknown

If yes, specify *(PRECMVAG)*

Did the patient receive non-protocol treatment during this reporing period? *(NONPRTX)* ☐ 2 - No ☐ 1 - Yes ☐ 9 - Unknown

If yes, record dosing and dates on the flow sheet and complete the following:

Date non-protocol treatment started *(NONPRDT)* *(mm/dd/yyyy)*

Type of non-protocol treatment *(NONPRTYP)*

LAB VALUES

Record the highest and lowest values for the following labs that were performed during this reporting period.

	Peak		Nadir	
Serum Creatinine (mg/dL)	*(SCPEAK)*	*(x.x)*	*(SCNAD)*	*(x.x)*
Bilirubin (mg/dL)	*(BILIPEAK)*	*(x.x)*	*(BILINAD)*	*(x.x)*
Alkaline phosphatase (U/L)	*(ALKPEAK)*	*(xxxx)*	*(ALKNAD)*	*(xxxx)*
AST (U/L)	*(ASTPEAK)*	*(xxx)*	*(ASTNAD)*	*(xxx)*

Hematologic Recovery

Record the dates ANC and platelets first fell below the indicated levels and first recovered.

	From		To	
ANC < 500/µl	*(ANC1STDT)*	*(mm/dd/yyyy)*	*(ANC1ENDT)*	*(mm/dd/yyyy)*
ANC < 1,000/µl	*(ANC2STDT)*	*(mm/dd/yyyy)*	*(ANC2ENDT)*	*(mm/dd/yyyy)*
Platelets < 20,000/ul	*(PLT1STDT)*	*(mm/dd/yyyy)*	*(PLT1ENDT)*	*(mm/dd/yyyy)*
Platelets < 50,000/ul	*(PLT2STDT)*	*(mm/dd/yyyy)*	*(PLT2ENDT)*	*(mm/dd/yyyy)*
Platelets < 100,000/ul	*(PLT3STDT)*	*(mm/dd/yyyy)*	*(PLT3ENDT)*	*(mm/dd/yyyy)*

PATIENT RECOVERY

Record the total number of platelet transfusions, RBC units transfused, days of TPN, and days on narcotics for this reporting period. The total number of days hospitalized should include the day(s) hospitalized for the transplant or DLI, if applicable.

Total number of platelet transfusions	*(TOTPLT)*	*(xxx)*
Total number of RBC units transfused	*(TOTRBC)*	*(xxx)*
Total number of days on Total Parenteral Nutrition (TPN)	*(TOTTPN)*	*(xxx)*
Total number of days on narcotics (IV, SC, or PO)	*(TOTNARC)*	*(xxx)*
Total number of days hospitalized during this reporting period (include transplant or DLI, if applicable)	*(TOTHOSP)*	*(xxx)*

GVHD STATUS

Signs of acute or chronic GVHD exhibited by the patient (maximum stage) during this reporting period should be indicated on this form. Staging criteria for the GVHD symptoms can be found in the protocol.

Acute GVHD

Staging for skin

(GRSKIN)

0-0 - No Rash
1-1 - Maculopapular Rash, <25% of Body Surface
2-2 - Maculopapular Rash, 25-50% of Body Surface
3-3 - Generalized Erythroderma
4-4 - Generalized Erythroderma with Bullus Formation and Desquamation

Staging for bilirubin

(GRBILI)

0-0 - Bilirubin <2.0 mg/dL
1-1 - Bilirubin 2.0-3.0 mg/dL
2-2 - Bilirubin 3.1-6.0 mg/dL
3-3 - Bilirubin 6.1-15.0 mg/dL
4-4 - Bilirubin >15.0 mg/dL

Staging for diarrhea

0-0 - No Diarrhea
1-1 - Diarrhea Less Than or Equal to 500 mL/day or <280 mL/m^2
2-2 - Diarrhea >500 but Less Than or Equal to 1000 mL/day or 280-555 mL/m^2
3-3 - Diarrhea >1000 but Less Than or Equal to 1500 mL/day or 556-833 mL/m^2
4-4 - Diarrhea >1500 mL/day or >833 mL/m^2
*Additional Options Listed Below

(GRDIAR)

Overall grade *(GROVRLL)* _____ *(x)*

Date of acute GVHD onset (if applicable) *(GVHDDT)* _____ *(mm/dd/yyyy)*

Chronic GVHD *(CRGVHD)*

1-1 - None
2-2 - Limited
3-3 - Extensive

Date of chronic GVHD onset *(CRGVHDDT)* _____ *(mm/dd/yyyy)*

Were the following organs involved in chronic GVHD?

- Skin *(CRGVSKN)* ☐ 2 - No ☐ 1 - Yes
- Eyes *(CGVEYE)* ☐ 2 - No ☐ 1 - Yes
- Mouth *(CGVMOUTH)* ☐ 2 - No ☐ 1 - Yes
- Lung *(CGVLUNG)* ☐ 2 - No ☐ 1 - Yes
- Liver *(CRGVLIV)* ☐ 2 - No ☐ 1 - Yes
- Vagina *(CGVVAG)* ☐ 2 - No ☐ 1 - Yes
- Other *(CGORGOTH)* ☐ 2 - No ☐ 1 - Yes
  - Specify other organ(s) involved *(CGVOTHSP)* _____

DISEASE STATUS

Present status of disease *(DXSTAT)*

1-1 - Continues in remission
2-2 - Relapsed, no DLI given
3-3 - Relapsed, still with active disease following DLI
4-4 - Relapsed, disease free following DLI

If a patient relapsed during this reporting period, indicate the onset date below. Submit a copy of the C-1006 (Relapse Peripheral Blood and Bone Marrow Report Form) with this form in order to document relapse. Record the last date a disease assessment was performed and the patient was found to have achieved or maintained response or their disease was persistent.

- Date of bone marrow relapse onset *(BMRLPSDT)* _____ *(mm/dd/yyyy)*
- Date of non-marrow relapse onset *(NMRLPSDT)* _____ *(mm/dd/yyyy)*
- Date patient last known to be in remission or to have persistent disease *(REMPRSDT)* _____ *(mm/dd/yyyy)*

RELAPSE INFORMATION

If a patient relapsed in this reporting period, indicate the site(s) involved:

- Bone Marrow *(RLPSBM)* ☐ 2 - No ☐ 1 - Yes
- Peripheral blood *(RLPSPB)* ☐ 2 - No ☐ 1 - Yes
- Skin *(RLPSSKN)* ☐ 2 - No ☐ 1 - Yes
- CNS *(RLPSCNS)* ☐ 2 - No ☐ 1 - Yes
- Gonadal *(RLPSGNDL)* ☐ 2 - No ☐ 1 - Yes
- Other *(RLPSOTHR)* ☐ 2 - No ☐ 1 - Yes
  - Specify other site(s) involved *(RLPSSPEC)* _____

Was additional therapy given (other than DLI)? *(ADDTX)* ☐ 2 - No ☐ 1 - Yes ☐ 9 - Unknown

- If yes, describe treatment: *(SPECTX)* _____
  - Date additional therapy started *(TXSTDT)* _____ *(mm/dd/yyyy)*
  - Date additional therapy ended *(TXENDDT)* _____ *(mm/dd/yyyy)*
  - Outcome of additional therapy *(ADDTXOUT)*

1-1 - CR
2-2 - PR
3-3 - Persistent disease
4-4 - Died with no evidence of AML
5-5 - Unknown

INFECTION STATUS

Record the number of infections the patient experienced during this reporting period. *(INFSTAT)* _____ *(xx)*

If no infection documented during this reporting period, code as "0".

Comments: *(FUFCOMNT)*

Additional Selection Options for FUF

Tacrolimus taper
6-6 - Other
-

Staging for Diarrhea
5-5 - Severe Abdominal Pain with or without Ileus, or Stool with Frank Blood or Melena

Blood and Marrow Transplant Clinical Trials Network

C-1505: HLA Typing Form (HLA)

Web Version: 1.0; 2.00; 04-20-09

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

C-1505: HLA TYPING FORM

DONOR CHARACTERISTICS

Donor Weight: (DONRWGT) *(xxx)* kg

Donor blood type: (DNRBLDTP)
1-Type A
2-Type B
3-Type AB
4-Type O

Donor Rh type: (DNRRHTYP) ☐ Negative ☐ Positive

Donor CMV serology: (DNRCMVSR)
1-Negative
2-Positive
3-Unknown

Age: (DONRAGE) *(xx)* years

Sex: (DNRGEND)
1-Male
2-Female, nulliparous
3-Female, parous

Donor type: (DONORTYP)
1-HLA-identical sibling
2-10/10 unrelated donor

PATIENT CHARACTERISTICS

Patient Weight: *(PATIWGT)* *(xxx)* kg

Patient blood type: *(PTBLDTYP)*
1-Type A
2-Type B
3-Type AB
4-Type O

Patient Rh type: *(PTRHTYP)* ☐ Negative ☐ Positive

Patient CMV serology: *(PTCMVSRL)*
1-Negative
2-Positive
3-Unknown

DONOR HLA TYPING

Class I: (HLADNRI)
1-1-DNA Technology
2-2-Serology

A: (HLADNAI) , *(HLADNAII)*

B: (HLADNBI) , *(HLADNBII)*

C: (HLADNCI) , *(HLADNCII)*

Class II: (HLADNRII)
1-1-DNA Technology
2-2-Serology

DR: (HLADDRI) , *(HLADDRII)*

DQ: (HLADDQI) , *(HLADDQII)*

PATIENT HLA TYPING

Class I: *(HLAPTI)*
1-1-DNA Technology
2-2-Serology

A: *(HLAPTAI)* , *(HLAPTAII)*

B: *(HLAPTBI)* , *(HLAPTBII)*

C: *(HLAPTCI)* , *(HLAPTCII)*

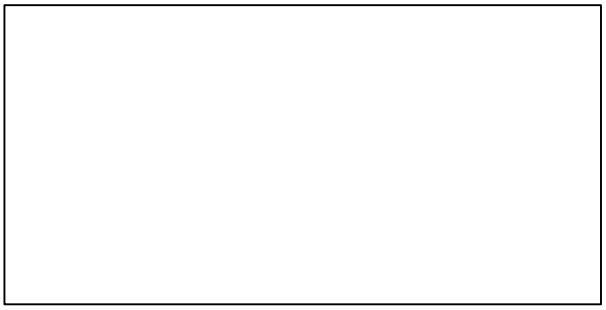
Class II: *(HLAPTII)*
1-1-DNA Technology
2-2-Serology

DR: *(HLAPDRI)* , *(HLAPDRII)*

DQ: *(HLAPDQI)* ,

(HLAPDQII)

Comments: *(HLACOMNT)*



Blood and Marrow Transplant Clinical Trials Network

C-664: Infectious Complications Form (ICF)

Web Version: 1.0; 2.00; 04-20-09

Segment *(PROTSEG)*:
Infection Site 0502 *(ICF0502S)*:
Infection Start Date *(INFSTDT)*:

C-664: INFECTIOUS COMPLICATIONS FORM

Indicate the site of the infection: *(ICFSITEO)*

INFECTION 1:

Causative agent *(ICF1CAGT)*
- 01-01 - Bacterial-Gram positive
- 02-02 - Bacterial-Gram negative
- 03-03 - Bacterial-other, specify
- 04-04 - Fungal-Candida
- 05-05 - Fungal-Aspergillus
- *Additional Options Listed Below

If other, specify: *(ICF1CAOT)*

Outcome of infection *(ICF1OUTC)*
- 1-1 - Resolved
- 2-2 - Improved
- 3-3 - Unresolved
- 4-4 - Death due to infection
- 5-5 - Death due to other causes
- *Additional Options Listed Below

If other, specify: *(ICF1OCOT)*

Treatment relation *(ICF1RELA)*
- 1-1 - Unrelated to treatment
- 2-2 - Unlikely related to treatment
- 3-3 - Possibly related to treatment
- 4-4 - Probably related to treatment
- 5-5 - Definitely related to treatment

INFECTION 2:

Causative agent *(ICF2CAGT)*
- 01-01 - Bacterial-Gram positive
- 02-02 - Bacterial-Gram negative
- 03-03 - Bacterial-other, specify
- 04-04 - Fungal-Candida
- 05-05 - Fungal-Aspergillus
- *Additional Options Listed Below

If other, specify: *(ICF2CAOT)*

Outcome of infection *(ICF2OUTC)*
- 1-1 - Resolved
- 2-2 - Improved
- 3-3 - Unresolved
- 4-4 - Death due to infection
- 5-5 - Death due to other causes
- *Additional Options Listed Below

If other, specify: *(ICF2OCOT)*

Treatment relation *(ICF2RELA)*
- 1-1 - Unrelated to treatment
- 2-2 - Unlikely related to treatment
- 3-3 - Possibly related to treatment
- 4-4 - Probably related to treatment
- 5-5 - Definitely related to treatment

INFECTION 3:

Causative agent *(ICF3CAGT)*
- 01-01 - Bacterial-Gram positive
- 02-02 - Bacterial-Gram negative
- 03-03 - Bacterial-other, specify
- 04-04 - Fungal-Candida
- 05-05 - Fungal-Aspergillus
- *Additional Options Listed Below

If other, specify: *(ICF3CAOT)*

Outcome of infection *(ICF3OUTC)*
- 1-1 - Resolved
- 2-2 - Improved
- 3-3 - Unresolved
- 4-4 - Death due to infection
- 5-5 - Death due to other causes
- *Additional Options Listed Below

If other, specify: *(ICF3OCOT)*

Treatment relation *(ICF3RELA)*
- 1-1 - Unrelated to treatment
- 2-2 - Unlikely related to treatment
- 3-3 - Possibly related to treatment
- 4-4 - Probably related to treatment
- 5-5 - Definitely related to treatment

Did the patient require hospitalization and / or parenteral antibiotics for this infection?
(ICFHOSP)

☐ 2 - No ☐ 1 - Yes ☐ 9 - Unknown

LABS AT TIME OF INFECTION

WBC *(ICFWBC)* _____ *(xxx.x)* x10^3 / uL

Segs + bands *(ICFSEGS)* _____ *(xx)* (%)

Comments: *(ICFCOMNT)*

Additional Selection Options for ICF

Infection Site 0502 *(ICF0502S)* (key field):
01-Lower Respiratory Tract (LRT)
02-Upper Respiratory Tract (LRT)
03-Urinary tract
04-Skin / Soft Tissue
05-Blood
06-CNS
07-GI
08-Liver / Spleen
09-Bone / Joint
10-Eye
11-Ear
12-Reproductive system
13-Disseminated
99-Other, specify

Causative agent
06-06 - Fungal - other, specify
07-07 - Viral - Varicella Zoster (VZV)
08-08 - Viral - Herpes Simplex (HSV)
09-09 - Viral - Cytomegalovirus (CMV)
10-10 - Viral - other, specify
11-11 - Parasitic
12-12 - Pneumocystis (PCP)
13-13 - Negative Culture/Clinical infection
99-99 - Other, specify

Outcome of infection
9-9 - Other, specify

Blood and Marrow Transplant Clinical Trials Network

C-400: Long-Term Follow-Up Form (LTF)

Web Version: 1.0; 2.00; 04-20-09

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

C-400: LONG-TERM FOLLOW-UP FORM

From: *(LTFSTDT)* _____ *(mm/dd/yyyy)*

To: (date last known alive or date of death) *(LTFENDDT)* _____ *(mm/dd/yyyy)*

Survival status *(SURVST)*

1-1 - Alive
2-2 - Dead (Submit C-113.)
3-3 - Lost to follow-up
4-4 - Consent for survival follow-up withdrawn

(If consent for survival follow-up withdrawn, consent withdrawal statement signed by the patient or the patient's physician must be submitted to Data Operations. Submission of this form is no longer required once signed statement is received.)

CLINICAL DATA

Did the patient have a clinical assessment for this cancer during this reporting period? *(CLINASSM)* ☐ 2 - No ☐ 1 - Yes

If Yes, specify the date of last clinical assessment: *(CLINCDT)* _____ *(mm/dd/yyyy)*

Did relapse or progression occur during this reporting period? *(RLPSPRG)* ☐ 2 - No ☐ 1 - Yes

If Yes, specify the date of progression (relapse): *(RLPGDT)* _____ *(mm/dd/yyyy)*

(Submit required data forms and/or samples according to protocol instructions.)

Did the patient develop a new adverse event in this reporting period or did an existing adverse event continue or increase in severity? *(AENEWCON)* ☐ 2 - No ☐ 1 - Yes

If Yes, submit required data forms according to protocol instructions.

Has a new malignancy been diagnosed for the first time during this reporting period? *(NEWMALIG)* ☐ 2 - No ☐ 1 - Yes

If Yes, submit required CALGB: C-1001 New Malignancy Form.

Has a secondary AML/MDS been diagnosed for the first time during this reporting period? *(SCAMLMDS)* ☐ 2 - No ☐ 1 - Yes

If Yes, submit NCI/CTEP Secondary AML/MDS Report Form.

NON-PROTOCOL THERAPY GIVEN DURING THIS REPORTING PERIOD

Has the patient received any previously unreported non-protocol treatment during this reporting period? *(NONPRTTX)* ☐ 2 - No ☐ 1 - Yes

If Yes, specify date non-protocol treatment started: *(NPRTXDT)* _____ *(mm/dd/yyyy)*

Specify the type of non-protocol treatment given: *(NPRTXGVN)* _____

Comments:
(LTFCMNT)

Blood and Marrow Transplant Clinical Trials Network

C-1001: New Malignancy Form (NMF)

Web Version: 1.0; 2.00; 05-23-11

C-1001: NEW MALIGNANCY FORM

INSTRUCTIONS: Report any malignancy that is:
- A new histologic type
- A previous histologic type which is judged to be a new primary
- A secondary malignancy related to cancer treatment, including AML/MDS

Attach pathology and/or cytogenetic report(s) documenting the primary or new secondary malignancy along with this form.

DO NOT REPORT RECURRENCES ON THIS FORM

Diagnosis Date of New Malignancy *(NMFMALDT)* _____ *(mm/dd/yyyy)*

Record new malignancy type, site and histology below.

New Malignancy Type:		**Specify Site:**	**Specify Histologic Type:**
New Primary Malignancy	New Secondary Malignancy		
(NMFNPSMA) ☐	☐	*(NMFSCSTA)*	*(NMFSPHTA)*
(NMFNPSMB) ☐	☐	*(NMFSCSTB)*	*(NMFSPHTB)*
(NMFNPSMC) ☐	☐	*(NMFSCSTC)*	*(NMFSPHTC)*
(NMFNPSMD) ☐	☐	*(NMFSCSTD)*	*(NMFSPHTD)*

Secondary AML/MDS malignancies must also be reported to NCI/CTEP on NCI/CTEP Secondary AML/MDS Report Form.
Report non AML/MDS secondary malignancies on the CALGB: 100103 Adverse Event Form (CAE).

Comments: *(NMFCOMMT)*

Blood and Marrow Transplant Clinical Trials Network

C-1090: On-Study Form (OSF)

Web Version: 1.0; 3.00; 12-07-10

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

C-1090: ON-STUDY FORM

PATIENT INFORMATION

Height *(PTHEIGHT)* *(xxx)* cm

Present weight *(PTWEIGHT)* *(xxx)* kg

Present actual BSA *(ACTULBSA)* *(xx.x)* m^2

Present corrected BSA *(CORCTBSA)* *(xx.x)* m^2

Performance status at registration *(PERFSTRG)*

0-0 - Fully active, able to carry on all pre-disease performance without restriction
1-1 - Restricted in physically strenuous activity but ambulatory, e.g. light house work, office work
2-2 - Ambulatory and capable of all self care but unable to carry out any work activities
3-3 - Capable of only limited self care, confined to bed or chair more than 50% of waking hours
4-4 - Completely disabled. Can not carry on self care. Totally confined to bed or chair.
*Additional Options Listed Below

Age at initial diagnosis *(AGEDIAGN)* *(xx)*

Present age *(PRSNTAGE)* *(xx)*

LABORATORY DATA (at initial diagnosis)

WBC *(PNTWBC)* *(xxx.x)* ($x10^3$/ml)

Karyotype *(KARYOTYP)*

1-1 - Not Done or Inadequate
2-2 - Normal
3-3 - Abnormal

Abnormal, specify *(KARTPSPC)*

LABORATORY DATA (at registration for this study)

Creatinine Clearance Value *(CREATCLR)* *(xxx)* (mL/min)

Creatinine Clearance *(CREATCLM)* ☐ 1 - Calculated ☐ 2 - Measured

Serum Creatinine *(SERUMCRN)* *(xx.xx)* (mg/dL)

Serum Creatinine ULN *(SERMCULN)* *(xx.xx)* (mg/dL)

Bilirubin *(BILIRBIN)* *(xx.x)* (mg/dL)

Bilirubin ULN *(BILIBULN)* *(xx.x)* (mg/dL)

AST *(PATAST)* *(xxx)* (U/L)

AST ULN *(PTASTULN)* *(xxx)* (U/L)

Alkaline Phosphatase *(ALKIPHOS)* *(xxx)* (U/L)

Alkaline Phosphatase ULN *(ALKPHULN)* *(xxx)* (U/L)

LDH *(PATLDH)* *(xxxxx)* (U/L)

LDH ULN *(LDHULN)* *(xxxxx)* (U/L)

LVEF *(PATLVEF)* *(xxx)* %

DLCO (% of predicted) *(PATDLCO)* *(xxx)* %

HIV *(HIVPOSNG)* ☐ 2 - Negative ☐ 1 - Positive

CMV (IgG) *(PTCMVIGG)* ☐ 2 - Negative ☐ 1 - Positive

AML DIAGNOSIS INFORMATION

Date of initial AML diagnosis *(DGAMLDAT)* *(mm/dd/yyyy)*

WHO Leukemia Classification *(WHOLEUKC)*

1-1 - AML With t(8;21)(q22;q22)
2-2 - AML With inv(16)(p13q22) or t(16;16)(p13;q22)
3-3 - AML With 11q23 (MLL) Abnormalities
4-4 - AML With Multilineage Dysplasia With Prior MDS
5-5 - AML With Multilineage Dysplasia Without Prior MDS
*Additional Options Listed Below

Other, specify *(WHOLKSPC)*

Has the patient had an antecedent hematologic (bone marrow) disorder? *(HEMDIAGN)*

2-2 -No
1-1 -Yes
9-9 -Unknown

If yes, specify type of preceding hematologic disorder *(HMDISSPC)*

1-1 -RA
2-2 -RARS
3-3 -RCMD
4-4 -RAEB
5-5 -CMMOL
*Additional Options Listed Below

Other, specify *(HMDISOTH)*

Date of antecedent hematologic disorder diagnosis *(ANHEMDIS)* *(mm/dd/yyyy)*

INITIAL TREATMENT

Induction therapy given *(INDUCTHP)*

1-1 -Standard Dose Ara-C
2-2 -High Dose Ara-C (HiDAC :>1000 mg/m2/dose)
3-3 -Other Agents

Other agents, specify *(INDTHOTH)*

Second induction course given *(Note: Patient must have achieved a CR with no more than two courses of induction therapy.) (SECINDCR)*

1-1 -Not Given
2-2 -Standard Dose Ara-C
3-3 -High Dose Ara-C (HiDAC :>1000 mg/m2/dose
4-4 -Other Agents

Other agents, specify *(SCDINOTH)*

Induction therapy given with hypomethylating agent containing regimen: *(INDTHHYP)*

☐ 5 azacytidine ☐ decitabine

Number of cycles given: *(INDTHCYC)*

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ ≥ 5 (not eligible)

CONSOLIDATION THERAPY GIVEN

Standard Dose Ara-C *(CONSTARA)*

☐ 2 - No ☐ 1 - Yes

High Dose Ara-C (HiDAC: > 1000 mg/m^2/ dose) *(CONHIARA)*

☐ 2 - No ☐ 1 - Yes

Any other consolidation therapies *(CONCBOTH)*

☐ 2 - No ☐ 1 - Yes

Specify other consolidation therapies given *(CONOTHER)*

Number of consolidation cycles given *(NUMBCONS)*

☐ 0 ☐ 1 ☐ 2 ☐ > or = 3 (not eligible)

Start date of initial induction therapy *(STDTINTH)* *(mm/dd/yyyy)*

Date complete response was documented *(DTCRDOCM)* *(mm/dd/yyyy)*

Date of last chemotherapy (induction and/or consolidation) *(DATLSTCH)* *(mm/dd/yyyy)*

INFECTIOUS COMPLICATION

Has the patient had a life-threatening infectious complication since initial diagnosis of AML? *(LFTHRINF)*

2-2 -No
1-1 -Yes
9-9 -Unknown

If yes, indicate type of infection *(INFC1TYP)*

1-1 -Unknown
2-2 -Bacteria
3-3 -Fungal
4-4 -Viral
5-5 -Other

Other, specify *(INFC1OTH)*

Specify organism *(SPEC1ORG)*

Indicate type of the second infection (if applicable) *(INFC2TYP)*

1-1 -Unknown
2-2 -Bacteria
3-3 -Fungal
4-4 -Viral
5-5 -Other

Other, specify *(INFC2OTH)*

Specify organism *(SPEC2ORG)*

Indicate type of the third infection (if applicable) *(INFC3TYP)*

1-1 -Unknown
2-2 -Bacteria
3-3 -Fungal
4-4 -Viral
5-5 -Other

Other, specify *(INFC3OTH)*

Specify organism *(SPEC3ORG)*

Are the infections controlled without antibiotics at study entry? *(INFCANTI)*

☐ 2 - No ☐ 1 - Yes ☐ 9 - Unknown

(Note: Patients with uncontrolled infection(s) are not eligible for this study.)

Comments: *(OSFCOMMT)*

Additional Selection Options for OSF

Performance status at registration
5-5 - Dead

WHO Leukemia Classification
6-6 - Alkylating Agent Realted AML and MDS
7-7 - Topoisomerase II Inhibitor-Related AML and MDS
8-8 - AML, Minimally Differentiated (M0)
9-9 - AML Without Maturation (M1)
10-10 - AML With Maturation (M2)
11-11 - Acute Myelomonocytic Leukemia (M4)
12-12 - Acute Monoblastic And Monocytic Leukemia (M5)
13-13 - Acute Erythroid Leukemia (M6)
14-14 - Acute Megakaryoblastic Leukemia (M7)
15-15 - Other

If yes, specify type of preceding hematologic disorder
6-6 - Other

Blood and Marrow Transplant Clinical Trials Network

C-1006: Peripheral Blood and Bone Marrow Report Form (PBM)

Web Version: 1.0; 2.00; 04-20-09

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

C-1006: PERIPHERAL BLOOD AND BONE MARROW REPORT FORM

Date peripheral blood obtained *(PBOBTNDT)* _____ *(mm/dd/yyyy)*

(*Submit this form each time a disease assessment has been performed.*)

PERIPHERAL BLOOD DIFFERENTIAL

Hemoglobin *(HEMOGLOB)* _____ *(xx.x)* gm/dL

Platelets *(PLATLCNT)* _____ *(xxxx)* x 10^3

WBC *(WBCCNT)* _____ *(xxx.x)* x 10^3

% Segmented neutrophils and bands *(PBNEUBAN)* _____ *(xx)* %

% Metamyelocytes and myelocytes *(PBMETMYL)* _____ *(xx)* %

% Promyelocytes *(PBPROMYL)* _____ *(xx)* %

% Blasts *(PBBLASTS)* _____ *(xx)* %

% Lymphocytes *(PBLYMPHO)* _____ *(xx)* %

% Monocytes *(PBMONOCY)* _____ *(xx)* %

% Monoblasts *(PBMONOBL)* _____ *(xx)* %

% Eosinophils *(PBEOSINO)* _____ *(xx)* %

% Basophils *(PBBASOPH)* _____ *(xx)* %

% Erythroblasts *(PBERYTHR)* _____ *(xx)* %

BONE MARROW

Date Obtained *(BMROBDT)* _____ *(mm/dd/yyyy)*

Aspirate Cellularity *(ASPCELLU)*
1-Aplastic
2-Hypercellular
3-Hypocellular
4-Packed
5-Normocellular
*Additional Options Listed Below

Biopsy Cellularity (0-100%) *(BIOCELLU)* _____ *(xxx)* %

BONE MARROW DIFFERENTIAL

% Segmented neutrophils and bands *(BMNEUBAN)* _____ *(xx)* %

% Metamyelocytes and myelocytes *(BMMETMYL)* _____ *(xx)* %

% Promyelocytes *(BMPROMYL)* _____ *(xx)* %

% Myeloblasts *(BMMYLBLT)* _____ *(xx)* %

% Lymphocytes *(BMLYMPHO)* _____ *(xx)* %

% Monocytes *(BMMONOCY)* _____ *(xx)* %

% Monoblasts *(BMMONBLS)* _____ *(xx)* %

% Eosinophils *(BMEOSINO)* _____ *(xx)* %

% Basophils *(BMBASOPH)* _____ *(xx)* %

% Erythroblasts *(BMERYTHR)* _____ *(xx)* %

% Lymphoblasts *(BMLYMBLS)* _____ *(xx)* %

Megakaryocyte Number *(MEGKARNU)*
1-Absent
2-Decreased
3-Normal
4-Increased
5-Unknown

Comments *(PBMCOMMT)*

Additional Selection Options for PBM

Aspirate Cellularity
6-Dry tap or not able to aspirate

Blood and Marrow Transplant Clinical Trials Network

Transplant Form (TXP)

Web Version: 1.0; 11.01; 12-21-11

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

1. Record date of hematopoietic stem cell infusion: *(TXDTTXP)* _____ *(mm/dd/yyyy)*

2. IUBMID for this patient (if available): *(T_IUBMID)* _____

3. CRID # (CIBMTR Recipient ID): *(TXPCRID)* _____ *(xxxxxxxxx)*

Do NOT use IUBMID/UPN numbers in the CRID field.

Comments: *(COMMTXP1)*