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Demographics

Local ID __________

NMDP Recipient ID (RID) in dashes format (XXX-XXX-X) __________

Date of birth __________

Date 15-MMUD informed consent signed __________

Age __________
(Field is automatically generated by Rave)

Sex
• Male
• Female

Does the patient have documentation of confirmed HIV-1 infection?
• Yes
• No

System generated answers
Subject ID

Subject status
• Screening
• Screen Failed
• Enrolled
• Early Terminated
• Completed
Inclusion / Exclusion

Inclusion criteria
Is the patient greater than or equal to 15 years and less than or equal to 70 years old?
- Yes
- No

Does the patient have a partially HLA-mismatched unrelated donor (MMUD) with a minimum match of 4/8 at -A, -B, -C and -DRB1 alleles by high-resolution testing?
- Yes
- No

Is the planned product bone marrow?
- Yes
- No

Is the patient being treated for one of the allowed diseases listed in the protocol?
- Yes
- No

Disease and disease status
- Acute Leukemias (or T lymphoblastic lymphoma) in first or subsequent complete remission
- De novo Myelodysplastic Syndrome (MDS) with Intermediate-2 or High risk disease as determined by the IPSS, a bone marrow aspirate within 60 days prior to informed consent showing <20% blasts and planned conditioning is myeloablative
- Chronic Lymphocytic Leukemia (CLL) in complete remission and planned conditioning is reduced intensity
- Chronic Lymphocytic Leukemia (CLL) in complete remission or partial remission and planned conditioning is myeloablative
- Chemotherapy-sensitive lymphoma in status other than first complete remission

Has the 15-MMUD informed consent form been signed by the patient or legal guardian?
- Yes
- No

Does the patient have a Karnofsky Performance score or Lansky Play-Performance Scale score of ≥ 60%?
- Yes
- No

Does the patient have adequate cardiac function defined as LVEF at rest ≥ 35% (reduced intensity cohort) or LVEF at rest ≥ 40% (full intensity cohort), or LVFS ≥ 25% with either cohort?
- Yes
- No

Does the patient have adequate pulmonary function defined as DLCO, FEV₁, FVC ≥ 50% predicted by pulmonary function tests (PFTs)?
- Yes
- No

Does the patient have adequate hepatic function defined as total bilirubin ≤ 2.5 mg/dl, and ALT, AST, and ALP < 5 x ULN (unless ALT, AST, and/or ALP are disease related)?
• Yes
• No

Does the patient have adequate renal function defined as serum creatinine within normal range for age?

• Yes
• No

  If serum creatinine is outside the normal range, does the patient have a creatinine clearance > 40 mL/min/1.73m² (measured by 24-hour urine specimen, nuclear medicine glomerular filtration rate (GFR))?

  • Yes
  • No

Does the patient have documentation of confirmed HIV-1 infection?

• Yes
• No

**Exclusion criteria**

Does the patient have an HLA-matched related or 8/8 allele matched (HLA-A, -B, -C, -DRB1) unrelated donor available?

• Yes
• No
• Not applicable, HIV-positive

Did the patient have an autologous HCT < 3 months from the informed consent date?

• Yes
• No

Is the patient pregnant or breast feeding?

• Yes
• No
• Not applicable, male or female of non-childbearing potential

  Date of pregnancy test __________

Does the patient have a current uncontrolled bacterial, viral or fungal infection?

• Yes
• No

Has the patient ever received a prior allogeneic HCT?

• Yes
• No

Does the patient have a history of primary idiopathic myelofibrosis?

• Yes
• No

If the patient has MDS and is not HIV-positive are they greater than or equal to 50 years old at the time of informed consent?

• Yes
• No
• Not applicable
Is the patient eligible for BMT CTN 1101 and has agreed to participate in that study?
- Yes
- No

Is the patient positive for donor-specific anti-HLA antibodies (antibodies against a mismatched allele in the selected donor)?
- Yes
- No

HIV-positive patients ONLY
HIV-positive inclusion criteria
Is the patient willing to comply with an effective Antiretroviral Therapy (ARV)?
- Yes
- No

Does the patient have hepatitis C?
- Yes
- No

Has the patient achieved a sustained virologic response for 12 weeks after cessation of antiviral treatment?
- Yes
- No

Will the patient receive the reduced intensity regimen (Regimen A: Flu/Cy/TBI)?
- Yes
- No

HIV-positive exclusion criteria
Does the patient have an excessive risk for transplantation-related morbidity due to AIDS-related syndromes or symptoms?
- Yes
- No

Does the patient have untreatable HIV due to multidrug antiretroviral resistance?
- Yes
- No

Is the patient currently prescribed ritonavir, cobacistat or zidovudine?
- Yes
- No

System generated answers (NO RESPONSE REQUIRED)
Is the patient eligible for enrollment?
- Yes
- No

Enrollment date __________
Screen failure date __________
Medical History

Date complete history and physical performed __________

Height _______ cm
   Date measured __________

Weight _______ kg
   Date measured __________

CMV serostatus
   • Positive
   • Negative
   Date tested __________

ABO group
   • A
   • B
   • AB
   • O

What scale was used to determine the subject’s functional status?
   • Karnofsky Performance Scale
   • Lansky Play-Performance Scale

Functional status (List populates based on scale selected in previous question)
   • 100 Normal; no complaints; no evidence of disease
   • 90 Able to carry on normal activity
   • 80 Normal activity with effort
   • 70 Cares for self; unable to carry on normal activity or to do active work
   • 60 Requires occasional assistance but is able to care for most needs
   • 100 Fully active
   • 90 Minor restriction in physically strenuous play
   • 80 Restricted in strenuous play, tires more easily, otherwise active
   • 70 Both greater restrictions of, and less time spent in, active play
   • 60 Ambulatory up to 50% of time, limited active play with assistance / supervision

   Date functional status evaluated __________

Date of bone marrow aspirate __________

For lymphoma and CLL subjects, date of imaging (e.g. CT/PET/MRI) __________

Date of echocardiogram or multiple-gated acquisition scan (MUGA) __________

Date of pulmonary function tests __________

Date of CBC with differential sample collection __________
Date of serum creatinine sample collection __________

Date of creatinine clearance sample collection __________

Date of AST sample collection __________

Date of ALT sample collection __________

Date of ALP sample collection __________

Date of total bilirubin sample collection __________

Has the subject signed an IRB-approved informed consent form to donate research blood samples to the CIBMTR Biorepository?
  - Yes
  - No

Was the Biorepository sample collected for the subject?
  - Yes
  - No

Ethnicity
  - Hispanic or Latino
  - Not Hispanic or Latino
  - Not applicable, not a resident of the USA
  - Unknown

Race
Add a new log line for each race.

<table>
<thead>
<tr>
<th>Race</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian or Alaska Native</td>
</tr>
<tr>
<td>Asian</td>
</tr>
<tr>
<td>Black or African American</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Not reported</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>
Conditioning regimen

CIBMTR Research ID (CRID) _______________

Dosing body weight used for conditioning regimen _____ kg

Which conditioning regimen was chosen?

- Regimen A (reduced intensity)
- Regimen B (full intensity, busulfan with cyclophosphamide)
- Regimen B (full intensity, busulfan with fludarabine)
- Regimen C (full intensity)
Regimen A

Fludarabine day 1: date administered __________
Fludarabine day 1: total dose ________ mg
Fludarabine day 2: date administered __________
Fludarabine day 2: total dose ________ mg
Fludarabine day 3: date administered __________
Fludarabine day 3: total dose ________ mg
Fludarabine day 4: date administered __________
Fludarabine day 4: total dose ________ mg
Fludarabine day 5: date administered __________
Fludarabine day 5: total dose ________ mg
Cyclophosphamide day 1: date administered __________
Cyclophosphamide day 1: total dose ________ mg
Cyclophosphamide day 2: date administered __________
Cyclophosphamide day 2: total dose ________ mg
Total body irradiation day 1: date administered __________
Total body irradiation day 1: total dose ________ cGy
Regimen B with Cy

Busulfan day 1: date administered __________
Busulfan day 1: total daily dose _______ mg
Busulfan day 2: date administered __________
Busulfan day 2: total daily dose _______ mg
Busulfan day 3: date administered __________
Busulfan day 3: total daily dose _______ mg
Busulfan day 4: date administered __________
Busulfan day 4: total daily dose _______ mg
Cyclophosphamide day 1: date administered __________
Cyclophosphamide day 1: total dose _______ mg
Cyclophosphamide day 2: date administered __________
Cyclophosphamide day 2: total dose _______ mg

Was busulfan PK monitoring done?
- Yes
- No

Was an average daily busulfan AUC target of 4800-5300 μM*min achieved?
- Yes
- No
Regimen B with Flu

Busulfan day 1: date administered __________
Busulfan day 1: total daily dose _______ mg
Busulfan day 2: date administered __________
Busulfan day 2: total daily dose _______ mg
Busulfan day 3: date administered __________
Busulfan day 3: total daily dose _______ mg
Busulfan day 4: date administered __________
Busulfan day 4: total daily dose _______ mg
Fludarabine day 1: date administered __________
Fludarabine day 1: total dose _______ mg
Fludarabine day 2: date administered __________
Fludarabine day 2: total dose _______ mg
Fludarabine day 3: date administered __________
Fludarabine day 3: total dose _______ mg
Fludarabine day 4: date administered __________
Fludarabine day 4: total dose _______ mg
Fludarabine day 5: date administered __________
Fludarabine day 5: total dose _______ mg

Was busulfan PK monitoring done?
  - Yes
  - No

Was an average daily busulfan AUC target of 4800-5300 μM*min achieved?
  - Yes
  - No
Regimen C

Cyclophosphamide day 1: date administered __________
Cyclophosphamide day 1: total dose _______ mg
Cyclophosphamide day 2: date administered __________
Cyclophosphamide day 2: total dose _______ mg
Total body irradiation day 1: date administered __________
Total body irradiation day 1: total daily dose _______ cGy
Total body irradiation day 2: date administered __________
Total body irradiation day 2: total daily dose _______ cGy
Total body irradiation day 3: date administered __________
Total body irradiation day 3: total daily dose _______ cGy
Infusion

Date of infusion of non-T-cell depleted bone marrow __________

Infused total nucleated cells ______ x10^6 /kg

Infused CD34+ cells ______ x10^6 /kg

Was the entire fresh product cryopreserved at your facility prior to infusion?
- Yes
- No

Was the bone marrow product manipulated?
- Yes
- No

<table>
<thead>
<tr>
<th>Specify reason</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor ABO mismatch</td>
<td>Diluted</td>
</tr>
<tr>
<td>Major ABO mismatch</td>
<td>Plasma reduced</td>
</tr>
<tr>
<td>Volume reduction</td>
<td>RBC reduced</td>
</tr>
<tr>
<td>Other, specify _______</td>
<td>Other, specify_________</td>
</tr>
</tbody>
</table>
Follow up

Date of evaluation __________

Survival status
- Alive
- Dead

Main cause of death
- Recurrence / persistence / progression of disease
- Acute GVHD
- Chronic GVHD
- Graft rejection or failure
- Cytokine release syndrome
- Infection, organism not identified
- Bacterial infection
- Fungal infection
- Viral infection
- Protozoal infection
- Other infection, specify __________
- Idiopathic pneumonia syndrome (IPS)
- Pneumonitis due to Cytomegalovirus (CMV)
- Pneumonitis due to other virus
- Other pulmonary syndrome (excluding pulmonary hemorrhage), specify __________
- Diffuse alveolar damage (without hemorrhage)
- Adult respiratory distress syndrome (ARDS) (other than IPS)
- Liver failure (not VOD)
- Veno-occlusive disease (VOD) / sinusoidal obstruction syndrome (SOS)
- Cardiac failure
- Pulmonary failure
- Central nervous system (CNS) failure
- Renal failure
- Gastrointestinal (GI) failure (not liver)
- Multiple Organ Failure
- Other organ failure, specify __________
- New malignancy, specify __________
- Prior malignancy
- Pulmonary hemorrhage
- Diffuse alveolar hemorrhage (DAH)
- Intracranial hemorrhage
- Gastrointestinal hemorrhage
- Hemorrhagic cystitis
- Other hemorrhage, specify __________
- Thromboembolic
- Disseminated intravascular coagulation (DIC)
- Thrombotic microangiopathy (TMA) (Thrombotic thrombocytopenic purpura (TTP)/Hemolytic Uremic Syndrome (HUS))
- Other vascular, specify __________
- Accidental death, specify __________
- Suicide
- Other cause, specify __________

Has the disease relapsed or progressed since last reported for the study?
• Yes
• No

Did acute GVHD occur or persist since last reported for the study?
• Yes
• No

Did chronic or overlap GVHD develop since last reported for the study?
• Yes
• No

Did chronic or overlap GVHD persist since last reported for the study?
• Yes
• No

Did the subject receive a donor cellular infusion since last reported for the study?
• Yes
• No

Did the subject receive a subsequent transplant since last reported for the study?
• Yes
• No

Date of subsequent transplant __________

Subsequent transplant source:
• Autologous
• Allogeneic, unrelated
• Allogeneic, related
• Syngeneic

Toxicities

Was there any incidence of viral reactivations or infections as indicated in the protocol since last reported for the study?
• Yes
• No

Did thrombotic microangiopathy (TMA) occur since last reported for the study?
• Yes
• No

Did Hepatic veno-occlusive disease (VOD)/ sinusoidal obstruction syndrome (SOS) occur since last reported for the study?
• Yes
• No

Was there unresolved VOD at the last report?
• Yes
• No
Laboratory tests

Date of CBC with differential sample collection __________
Date of serum creatinine sample collection __________
Date of AST sample collection __________
Date of ALT sample collection __________
Date of ALP sample collection __________
Date of total bilirubin sample collection __________

Maintenance therapy
–Required at Day 21 – 1 year, optional at Day 7 and Day 14
Was any post-transplant maintenance therapy given to prevent relapse or progression since last reported for the study?
  • Yes
  • No

Add a new log line for each post-transplant maintenance therapy given since last reported for this study.

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Date started</th>
</tr>
</thead>
<tbody>
<tr>
<td>DNA-methyltransferase inhibitor</td>
<td></td>
</tr>
<tr>
<td>Tyrosine kinase inhibitor</td>
<td></td>
</tr>
<tr>
<td>Rituximab for CD20+ malignancy</td>
<td></td>
</tr>
<tr>
<td>Intrathecal chemotherapy</td>
<td></td>
</tr>
<tr>
<td>Consolidative radiation therapy</td>
<td></td>
</tr>
<tr>
<td>Other, specify __________</td>
<td></td>
</tr>
</tbody>
</table>
Post-transplant treatments

--Day 7

**DAY + 3**

Date cyclophosphamide administered Day + 3 __________

Total daily dose for cyclophosphamide Day + 3 __________ mg

Was mesna administered pre- and post-cyclophosphamide?
- Yes
- No

Date first mesna dose administered __________

Total dose of mesna administered __________ mg

**DAY + 4**

Date cyclophosphamide administered Day + 4 __________

Total daily dose for cyclophosphamide Day + 4 __________ mg

Was mesna administered pre- and post-cyclophosphamide?
- Yes
- No

Date first mesna dose administered __________

Total dose of mesna administered __________ mg

Were systemic immunosuppressive agents (including corticosteroids) given within 24 hours of completion of post-transplant cyclophosphamide?
- Yes
- No

Date sirolimus started __________

Were 4 or more sirolimus doses omitted during this reporting period?
- Yes
- No
- Not applicable; sirolimus not administered during this reporting period

Date MMF started __________

Growth factors
Date G-CSF or biosimilar started __________
Sirolimus
--Day 14 through 270 Days

Has the subject remained on sirolimus?
  • Yes
  • No

  Date sirolimus was discontinued _________

Were 4 or more sirolimus doses omitted since last reported for the study?
  • Yes
  • No

Was a sirolimus concentration level performed since last reported for the study?
  • Yes
  • No

  Was the sirolimus concentration level between 5-15 ng/mL?
    • Yes
    • No

  Was the sirolimus dose adjusted to maintain a level between 5-15 ng/mL?
    • Yes
    • No
MMF
--Day 14 through Day 42

Has the subject remained on MMF?
- Yes
- No

Date MMF was discontinued __________
Hematopoietic recovery
--Day 7 through Day 56

Was an ANC of \( \geq 0.5 \times 10^9/L \) achieved on 3 consecutive laboratory values?

- Yes
- No
- Not applicable, ANC never dropped below 500/mm\(^3\) at any time after the start of the conditioning regimen

If yes, first date of 3 consecutive laboratory values __________

Was an ANC \( \geq 1,000/mm^3 \) achieved for 3 consecutive days?

- Yes
- No

Was G-CSF given until ANC \( \geq 1,000/mm^3 \) for 3 consecutive days?

- Yes
- No

Date G-CSF was discontinued __________ □ Ongoing

--Day 7 – 1 year

Was an initial platelet count \( \geq 20 \times 10^9/L \) achieved?

- Yes
- No
- Not applicable, platelet count never dropped below 20 \( \times 10^9/L \) and never received a platelet transfusion at any time after the start of the conditioning regimen

If yes, date platelets \( \geq 20 \times 10^9/L \) __________

--Day 28

Date of bone marrow aspirate __________

--Day 56

Did primary graft failure occur?

- Yes
- No
Protocol-specified sample collections

-- Day 21, 100, 180
Was the protocol-specified sample collected for gene expression profile?

• Yes
• No

Date gene expression profile sample collected __________

--Day 100 and 365
Was the protocol-specified sample collected for immune reconstitution?

• Yes
• No

Date of immune reconstitution sample collection __________

Was the protocol-specified sample collected for donor clonal hematopoiesis assessment?

• Yes
• No

Date of donor clonal hematopoiesis assessment bone marrow sample collection __________
Peripheral blood chimerism

--Day 28, 56, 100, 180, and 365

Date chimerism sample collected __________

Whole blood chimerism _____ % donor

CD3 _____ % donor

CD33 _____ % donor
DCI

Add a new log line for each DCI given since last reported for the study

<table>
<thead>
<tr>
<th>Indication for DCI</th>
<th>Date of DCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Treatment for relapsed, persistent or progressive disease</td>
<td></td>
</tr>
<tr>
<td>Treatment for B cell lympho-proliferative disorder (PTLD, EBV lymphoma)</td>
<td></td>
</tr>
<tr>
<td>Treatment for GVHD</td>
<td></td>
</tr>
<tr>
<td>Viral infection</td>
<td></td>
</tr>
<tr>
<td>Stable, mixed chimerism</td>
<td></td>
</tr>
<tr>
<td>Loss of / decreased donor T-cell chimerism</td>
<td></td>
</tr>
<tr>
<td>Other, specify ________________</td>
<td></td>
</tr>
</tbody>
</table>
Disease evaluation

Used for relapse and at 100, 180, 365
Date of bone marrow aspirate __________

For lymphoma and CLL subjects, date of imaging (e.g. CT/PET/MRI) __________

For lymphoma and CLL subjects, date of lymph node biopsy __________ (optional)

Was relapse or progression detected?
  • Yes
  • No

Date relapse or progression first detected _______________

Was a disease relapse detected by molecular testing (e.g. PCR)?
  • Yes
  • No

Was a disease relapse detected via flow cytometry?
  • Yes
  • No

Was a disease relapse detected via FISH?
  • Yes
  • No

Was a disease relapse detected via conventional cytogenetics?
  • Yes
  • No

Was a disease relapse detected by clinical / hematologic assessment?
  • Yes
  • No

Was a disease relapse detected by radiologic assessment?
  • Yes
  • No

Indicate all site(s) of relapse or progression

<table>
<thead>
<tr>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
</tr>
<tr>
<td>Bone marrow</td>
</tr>
<tr>
<td>Central nervous system</td>
</tr>
<tr>
<td>Lymph nodes</td>
</tr>
<tr>
<td>Skin</td>
</tr>
<tr>
<td>Soft tissue</td>
</tr>
<tr>
<td>Spleen</td>
</tr>
<tr>
<td>Other site, specify ______</td>
</tr>
</tbody>
</table>

Current disease status
Acute leukemia
What is the current disease status?
- Complete remission (CR)
- Not in complete remission
- Not assessed, specify _______________

MDS
What is the current disease status?
- Complete remission (CR)
- Stable disease (SD)
- Progressive disease (PD)
- Relapse from complete remission (Rel from CR)
- Progression to AML
- Not assessed, specify____________

CLL
What is the current disease status?
- Complete remission (CR)
- Partial remission (PR)
- Stable disease (SD)
- Progressive disease (PD)
- Relapse from complete remission (Rel from CR)
- Not assessed, specify_________

Lymphoma
What is the current disease status?
- Continued complete remission (CCR)
- Complete remission (CR)
- Partial remission (PR)
- Stable disease (SD)
- Progressive disease (PD)
- Relapse from complete remission (Rel from CR)
- Not assessed, specify_______
**AE assessment**

**Adverse event date of onset**

**Date center became aware of the event**

**Is this adverse event unexpected?**
- Yes (only grade 3-5, unexpected events require reporting)
- No (only grade 5, expected events require reporting)
- No, but occurred at an unexpected rate or severity compared to subjects undergoing similar transplants

**Does this adverse event meet the protocol definition of a serious adverse event?**
- Yes
- No

**Serious adverse event outcome**
- Death
- Life-threatening adverse event
- Requires hospitalization or prolongs an existing hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Other, specify______________

**What is the relationship between the reported adverse event and the study procedures?**
- Unrelated
- Unlikely
- Possible
- Probable
- Definite

**CTCAE primary category** [Search list for CTCAE v4.03](#)

**CTCAE primary event** [DSL based on category](#)

**CTCAE grade (most severe)**
- Grade 1
- Grade 2
- Grade 3
- Grade 4
- Grade 5

**Has this adverse event resolved at the time of this report?**
- Yes
- No

**Date of resolution**

**Type of resolution**
- Complete recovery from adverse event
- Resolved, but with residual effects
- Fatal adverse event
- Death unrelated to this adverse event
AE summary

Adverse event description ___ ________

Was the subject taking any relevant concomitant medications?
  • Yes
  • No

Were relevant laboratory tests performed?
  • Yes
  • No

Were relevant diagnostic tests or procedures performed?
  • Yes
  • No

Does the subject have any relevant past medical history, including pre-existing conditions?
  • Yes
  • No

Indicate any relevant past medical history, including pre-existing conditions:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Date of onset</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
AE meds

Indicate any relevant concomitant medications.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Indication</th>
<th>Start date</th>
<th>Stop date</th>
<th>Ongoing</th>
<th>Dose, Route, Schedule</th>
</tr>
</thead>
</table>
| • Discontinued due to AE  
• Treatment of adverse event  
• Other |            |            |           |         |                       |
## AE laboratory values

Indicate any relevant laboratory tests.

<table>
<thead>
<tr>
<th>Test</th>
<th>Collection date</th>
<th>Result (include units)</th>
<th>Site normal range (include units)</th>
<th>Lab value previous to this adverse event (include units)</th>
<th>Collection date of previous lab</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15-MMUD Study CRFs v3.1
AE tests

Indicate any relevant diagnostic tests or procedures.

<table>
<thead>
<tr>
<th>Diagnostic test or procedure</th>
<th>Date performed</th>
<th>Results/Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
AE review

–Not visible to external user roles, visible and entered by Safety role
Has this event been determined to be a grade 3-5, unexpected adverse event or grade 5, expected event?
  • Yes
  • No

Does this adverse event meet the protocol definition of a serious adverse event?
  • Yes
  • No

  Serious adverse event outcome
  o Death
  o Life-threatening adverse event
  o Requires hospitalization or prolongs an existing hospitalization
  o Persistent or significant disability/incapacity
  o Congenital anomaly/birth defect
  o Other, specify___________________

What is the relationship between the reported adverse event and the study procedures?
  • Unrelated
  • Unlikely
  • Possible
  • Probable
  • Definite

CTCAE primary category Search list for CTCAE v4

CTCAE primary event DSL based on category

CTCAE grade (most severe)
  • Grade 1
  • Grade 2
  • Grade 3
  • Grade 4
  • Grade 5

Does this adverse event require expedited reporting to the Data Safety Monitoring Board?
  • Yes
  • No

  Date of determination ___________
UPIRSO

Start of unanticipated problem ____________

Date center became aware of the unanticipated problem ____________

Type of unanticipated problem (check all that apply)

☐ Breach of confidentiality
☐ New data indicating a risk higher than previously thought
☐ An unexpected event related or possibly related to participation in the research that puts the subject or others at greater risk of harm than was previously known
☐ Other

Unanticipated problem description ______

Plan of action taken to address unanticipated problem _____

Updates (complete as needed after initial submission of unanticipated problem)

<table>
<thead>
<tr>
<th>Date of update</th>
<th>Update description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medical monitor review (NO SITE RESPONSE REQUIRED)

Does this event meet the protocol definition of an unanticipated problem (UPIRSO)?

- Yes
- No

No, specify _________________

Description _________________

Is additional information required?

- Yes
- No

Yes, specify __________

Are protocol modifications or other intervention(s) required to address the unanticipated problem?

- Yes
- No

Describe the actions taken as a result of the unanticipated problem and the final determination on the relevance to the 15-MMUD study ________________

Date of determination ____________
Study exit

Did the subject complete the study per protocol?
  • Yes
  • No

  Completion date __________

Reason participation ended before study completion
  • Death
  • Discontinued per medical discretion of the P.I. or Medical Monitor, specify
  • Subject determined ineligible by the study team after initial enrollment
  • Subject withdrawal
  • Donor cannot provide bone marrow as planned
  • Insufficient dose of bone marrow obtained
  • Transplant canceled, donor reason, specify
  • Transplant canceled, subject reason, specify
  • Lost to follow-up

  Date of study exit event __________

Describe reason participation ended _____
Acute GVHD assessment

Date of acute GVHD diagnosis __________ □ Check if previously reported

Maximum overall grade since last reported for the study
- I
- II
- III
- IV

Date maximum grade reached __________

Maximum severity of organ involvement since last reported for the study

Skin
- Stage 0 – no rash, or no rash attributable to acute GVHD
- Stage 1 – < 25% of body surface area
- Stage 2 – 25–50% of body surface area
- Stage 3 – >50% of body surface area
- Stage 4 – generalized erythroderma with bullae formation

Lower intestinal tract
- Stage 0 – no diarrhea, or diarrhea ≤ 500 mL/day, or no diarrhea attributable to acute GVHD
- Stage 1 – diarrhea > 500 mL/day
- Stage 2 – diarrhea > 1000 mL/day
- Stage 3 – diarrhea > 1500 mL/day
- Stage 4 – large volume diarrhea and severe abdominal pain, with or without ileus

Upper intestinal tract
- Stage 0 – no persistent nausea or vomiting
- Stage 1 – persistent nausea or vomiting

Liver
- Stage 0 – bilirubin < 2.0 mg/dL, or no liver acute GVHD
- Stage 1 – bilirubin 2.0–3.0 mg/dL
- Stage 2 – bilirubin 3.1–6.0 mg/dL
- Stage 3 – bilirubin 6.1–15.0 mg/dL
- Stage 4 – bilirubin > 15.0 mg/dL

Other, specify_______________________

Add a new log line for each therapy given to treat acute GVHD since last reported for this study.

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Date started</th>
<th>Dose for ALG, ALS, ATG, ATS</th>
<th>Source for ALG, ALS, ATG, ATS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• ALS, ALG, ATS, ATG</td>
<td></td>
<td></td>
<td>• ATGAM (horse)</td>
</tr>
<tr>
<td>• Corticosteroids (systemic)</td>
<td></td>
<td></td>
<td>• ATG – Fresnius (rabbit)</td>
</tr>
<tr>
<td>• Corticosteroids (topical)</td>
<td></td>
<td></td>
<td>• Thymoglobulin (rabbit)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Other, specify_____________</td>
</tr>
</tbody>
</table>
- Cyclosporine (CSA) (Sandimmune, Neoral)
- ECP (extra-corporeal photopheresis)
- FK 506 (Tacrolimus, Prograf)
- Anti CD25 – Zenapax
- Anti CD25 – Daclizumab
- Anti CD25 – AntiTAC
- Campath
- Etanercept (Enbrel)
- Infliximab (Remicade)
- Other in vivo monoclonal antibody
- In vivo immunotoxin
- Methotrexate (MTX) (Amethopterin)
- Mycophenolate mofetil (MMF) (CellCept)
- Sirolimus (Rapamycin, Rapamune)
- Tocilizumab
- Ursodiol
- Blinded randomized trial
- Other agent
Chronic or Overlap GVHD

--Triggered from the follow-up form if chronic GVHD question = Yes, asked at each time point
Date of chronic GVHD diagnosis

Onset of chronic GVHD was
- Progressive (acute GVHD present within 2 weeks prior to onset of chronic GVHD)
- Interrupted (acute GVHD resolved, then chronic GVHD developed)
- De novo (acute GVHD never developed)

Were signs of acute GVHD present at the time of chronic GVHD diagnosis (overlap syndrome)?
- Yes
- No

What scale was used to determine the subject’s functional status?
- Karnofsky Performance Scale
- Lansky Play-Performance Scale

Functional status (List populates based on scale selected in previous question)
- 100 Normal; no complaints; no evidence of disease
- 90 Able to carry on normal activity
- 80 Normal activity with effort
- 70 Cares for self; unable to carry on normal activity or to do active work
- 60 Requires occasional assistance but is able to care for most needs
- 50 Requires considerable assistance and frequent medical care
- 40 Disabled; requires special care and assistance
- 30 Severely disabled; hospitalization indicated, although death not imminent
- 20 Very sick; hospitalization necessary
- 10 Moribund; fatal process progressing rapidly
- 100 Fully active
- 90 Minor restriction in physically strenuous play
- 80 Restricted in strenuous play; tires more easily, otherwise active
- 70 Both greater restrictions of, and less time spent in, active play
- 60 Ambulatory up to 50% of time, limited active play with assistance / supervision
- 50 Considerable assistance required for any active play; fully able to engage in quiet play
- 40 Able to initiate quiet activities
- 30 Needs considerable assistance for quiet activity
- 20 Limited to very passive activity initiated by others (e.g., TV)
- 10 Completely disabled, not even passive play

Platelets at diagnosis of chronic GVHD _______________ x 10^6/L
Total serum bilirubin at diagnosis of chronic GVHD _______ mg/dL

Was chronic GVHD evaluated by biopsy (histology) at diagnosis?
- Yes
- No

Skin
- Positive
- Suggestive
- Negative
- Inconclusive / equivocal
- Not done

**Lower gastrointestinal (GI)**
- Positive
- Suggestive
- Negative
- Inconclusive/ equivocal
- Not done

**Upper gastrointestinal (GI)**
- Positive
- Suggestive
- Negative
- Inconclusive/ equivocal
- Not done

**Liver**
- Positive
- Suggestive
- Negative
- Inconclusive/ equivocal
- Not done

**Lung**
- Positive
- Suggestive
- Negative
- Inconclusive/ equivocal
- Not done

**Other site**
- Positive
- Suggestive
- Negative
- Inconclusive/ equivocal
- Not done

Specify other site ______________________________
Chronic or Overlap GVHD organ involvement at diagnosis

Form triggered at the same time as other chronic GVHD forms and contained within the same folder
Specify organs involved and NIH scoring at diagnosis of chronic GVHD

Skin
- Yes
- No

Skin score percent BSA involved
- Score 0 – No BSA involved, no sclerotic features
- Score 1 – 1-18% BSA
- Score 2 – 19-50% BSA, or superficial sclerotic features "not hidebound" (unable to pinch)
- Score 3 - >50% BSA, deep sclerotic features, hidebound, impaired mobility, or ulceration

Skin features score
- No sclerotic features
- Superficial sclerotic features “not hidebound” (able to pinch)
- Deep sclerotic features, hidebound (unable to pinch), impaired mobility, or ulceration

Specify skin GVHD features present at diagnosis of chronic GVHD
Maculopapular rash / erythema
- Yes
- No

Lichen planus-like features
- Yes
- No

Papulosquamous lesions or ichthyosis
- Yes
- No

Keratosis pilaris-like GVHD
- Yes
- No

Specify if any skin abnormalities were present, but explained entirely by non-GVHD causes
Abnormality present but explained entirely by non-GVHD documented cause
- Yes
- No

Specify cause _________________________

Mouth
- Yes
- No

Mouth score
- Score 0 – No symptoms
- Score 1 – Mild symptoms with disease signs but not limiting oral intake significantly
- Score 2 – Moderate symptoms with disease signs with partial limitation of oral intake
- Score 3 – Severe symptoms with disease signs on examination with major limitation of oral intake
Lichen planus-like features
- Yes
- No

Specify if any mouth abnormalities were present, but explained entirely by non-GVHD causes
Abnormality present but explained entirely by non-GVHD documented cause
- Yes
- No

Specify cause _____________________________

Eyes
- Yes
- No

Eyes score
- Score 0 – No symptoms
- Score 1 – Mild dry eye symptoms not affecting ADL (requirement of lubricant eye drops ≤ 3x per day)
- Score 2 – Moderate dry eye symptoms partially affecting ADL (requiring lubricant eye drops >3x per day or punctal plugs), without new vision impairment due to KCS
- Score 3 – Severe dry eye symptoms significantly affecting ADL (special eyewear to relieve pain) OR unable to work because of ocular symptoms OR loss of vision due to KCS

Keratoconjunctivitis sicca (KCS) confirmed by ophthalmologist?
- Yes
- No
- Not done

Specify if any eye abnormalities were present, but explained entirely by non-GVHD causes
Abnormality present but explained entirely by non-GVHD documented cause
- Yes
- No

Specify cause ______________________

Gastrointestinal (GI) Tract
- Yes
- No

Gastrointestinal (GI) tract score
- Score 0 – No symptoms
- Score 1 – Symptoms without significant weight loss (<5%)
- Score 2 – Symptoms associated with mild to moderate weight loss (5-15%) OR moderate diarrhea without significant interference with daily living
- Score 3 – Symptoms associated with significant weight loss (>15%), requires nutritional supplementation for most calorie needs OR esophageal dilation OR severe diarrhea with significant interference with daily living

Esophageal web/proximal stricture or ring
- Yes
- No

Dysphagia
- Yes
- No

**Anorexia**
- Yes
- No

**Nausea**
- Yes
- No

**Vomiting**
- Yes
- No

**Diarrhea**
- Yes
- No

**Weight loss ≥ 5%**
- Yes
- No

**Failure to thrive**
- Yes
- No

Specify if any GI abnormalities were present, but explained entirely by non-GVHD causes
Abnormality present but explained entirely by non-GVHD documented cause
- Yes
- No

Specify cause ________________________

**Liver dysfunction**
- Yes
- No

**Liver score**
- Score 0 – Normal total bilirubin and ALT or AP <3 x ULN
- Score 1 – Normal total bilirubin with ALT ≥3 to 5 x ULN or AP ≥3 x ULN
- Score 2 – Elevated total bilirubin but ≤3 mg/dL or ALT >5 ULN
- Score 3 – Elevated total bilirubin > 3 mg/dL

Specify if any liver abnormalities were present, but explained entirely by non-GVHD causes
Abnormality present but explained entirely by non-GVHD documented cause
- Yes
- No

Specify cause ________________________

**Lung dysfunction**
- Yes
- No
Lung score
- Score 0 – No symptoms
- Score 1 – Mild symptoms (shortness of breath after climbing one flight of steps)
- Score 2 – Moderate symptoms (shortness of breath after walking on flat ground)
- Score 3 – Severe symptoms (shortness of breath at rest; requiring oxygen)

Were pulmonary function tests performed?
- Yes
- No

Specify FEV1 percent _____ %

Specify if any lung abnormalities were present, but explained entirely by non-GVHD causes
Abnormality present but explained entirely by non-GVHD documented cause
- Yes
- No

Specify cause _________________________

Joint and fascia symptoms
- Yes
- No

Joint and fascia score
- Score 0 – No symptoms
- Score 1 – Mild tightness of arms or legs, normal or mild decreased range of motion (ROM) AND not affecting ADL
- Score 2 – Tightness of arms or legs OR joint contractures, erythema thought due to fasciitis, moderate decrease ROM AND mild to moderate limitation of ADL
- Score 3 – Contractures WITH significant decrease ROM AND significant limitation of ADL (e.g. unable to tie shoes, button shirts, dress self, etc.)
- Not applicable – abnormality present but explained entirely by non-GVHD documented cause

Specify if any joint or fascia abnormalities were present, but explained entirely by non-GVHD causes
Abnormality present but explained entirely by non-GVHD documented cause
- Yes
- No

Specify cause _________________________

Genital tract dysfunction
- Yes
- No

Genital tract score
- Score 0 – No signs
- Score 1 – Mild signs and females with or without discomfort on exam
- Score 2 – Moderate signs and may have symptoms with discomfort on exam
- Score 3 – Severe signs with or without symptoms

Currently sexually active?
- Yes
- No
Specify if any genital tract abnormalities were present, but explained entirely by non-GVHD causes
Abnormality present but explained entirely by non-GVHD documented cause
• Yes
• No
Specify cause ________________________
Chronic or Overlap GVHD status

Indicate responses since last reported for the study

Maximum grade of chronic GVHD according to best clinical judgment
- Mild
- Moderate
- Severe
- Unknown

Specify if chronic GVHD was limited or extensive
- Limited
- Extensive

Date of maximum grade of chronic GVHD __________

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

Sclerosis of skin or fascia (e.g., scleroderma, fasciitis, morphea)
- Yes
  - No

Erythematous skin rash
- Yes
  - No

Joint contractures
- Yes
  - No

Other skin or hair involvement (ulcers, pruritus or itching, dyspigmentation, alopecia, lichenoid skin changes, etc.)
- Yes
  - No

Eyes (xerophthalmia (dry eyes), abnormal Schirmer's test, abnormal slit lamp, corneal erosion / conjunctivitis, etc.)
- Yes
  - No

Mouth (lichenoid changes, mucositis / ulcers, erythema, etc.)
- Yes
  - No

Bronchiolitis obliterans
- Yes
  - No

Other lung involvement
- Yes
  - No

Upper gastrointestinal tract (esophageal involvement, chronic nausea / vomiting)
- **Yes**
- **No**

Lower gastrointestinal tract (chronic diarrhea, malabsorption, abdominal pain / cramps, etc.)
- **Yes**
- **No**

Diarrhea
- **Yes**
- **No**

Liver
- **Yes**
- **No**

Genitourinary tract (vaginitis / stricture, etc.)
- **Yes**
- **No**

Musculoskeletal (arthritis, myositis, etc.)
- **Yes**
- **No**

Thrombocytopenia (< 100 x 10^9/L)
- **Yes**
- **No**

Eosinophilia
- **Yes**
- **No**

Serositis (e.g., pleural effusion, ascites, pericardial effusion)
- **Yes**
- **No**

Other organ involvement
- **Yes, specify ____________________________**
- **No**
Chronic or Overlap GVHD therapy

Add a new log line for each therapy given to treat the chronic GVHD since last reported for this study.

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Date started</th>
<th>Dose for ALG, ALS, ATG, ATS</th>
<th>Source for ALG, ALS, ATG, ATS</th>
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<tbody>
<tr>
<td>ALG, ALS, ATG, ATS</td>
<td></td>
<td></td>
<td>ATGAM (horse)</td>
</tr>
<tr>
<td>Aldesleukin (interleukin-2, IL-2)</td>
<td></td>
<td></td>
<td>ATG – Fresnius (rabbit)</td>
</tr>
<tr>
<td>Alemtuzumab (Campath)</td>
<td></td>
<td></td>
<td>Thymoglobulin (rabbit)</td>
</tr>
<tr>
<td>Anti CD25 – Zenapax</td>
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<td></td>
<td>Other, specify</td>
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<tr>
<td>Anti CD25 – Daclizumab</td>
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<tr>
<td>Anti CD25 – AntiTAC</td>
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<tr>
<td>Azathioprine</td>
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<tr>
<td>Bortezomib (Velcade)</td>
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<tr>
<td>Corticosteroids (systemic) (e.g. prednisone, dexamethasone)</td>
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<tr>
<td>Cyclosporine (CSA, Neoral, Sandimmune)</td>
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<tr>
<td>Interleukin inhibitors – Anti-IL2</td>
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<tr>
<td>Interleukin inhibitors – Anti-IL6</td>
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<tr>
<td>Interleukin inhibitors – Other, specify</td>
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<tr>
<td>Extra-corporeal photopheresis (ECP)</td>
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<tr>
<td>Mycophenolate mofetil (MMF) (CellCept, Myfortic)</td>
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<tr>
<td>Pentostatin (Nipent)</td>
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<tr>
<td>UV therapy – PUVA (Psoralen and UVA)</td>
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<tr>
<td>UV therapy – UVB</td>
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<tr>
<td>Rituximab (Rituxan, MabThera)</td>
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<tr>
<td>Sirolimus (Rapamycin, Rapamune)</td>
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<tr>
<td>Tyrosine kinase inhibitors (TKI) – Imatinib mesylate (Gleevec)</td>
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<tr>
<td>Tyrosine kinase inhibitors (TKI) – Other, specify</td>
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<tr>
<td>JAK 2 inhibitors – Ruxolitinib (Jakafi)</td>
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<tr>
<td>JAK 2 inhibitors – Other, specify</td>
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<tr>
<td>Blinded randomized trial, specify</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Other agent, specify</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Viral reactivations or infections

Is there evidence of CMV reactivation (defined as a positive PCR for CMV in the peripheral blood) or infection post-transplant?
- Yes
- No
- Not tested

Is the reactivation or infection new or ongoing since last reported for the study?
- New
- Ongoing

Date of diagnosis__________

Grade since last reported for the study
- Grade 1
- Grade 2 based on viremia criteria
- Grade 2 based on clinically active CMV infection

Is there evidence of grade 3 CMV infection defined as end organ damage due to CMV?
- Yes
- No
- Not tested

Is the infection new or ongoing since last reported for the study?
- New
- Ongoing

Date of diagnosis __________

Lung (pneumonitis)
- Yes
- No

Intestine (enteritis)
- Yes
- No

Eye (retinitis)
- Yes
- No

Other organ involvement
- Yes
- No

Specify other organ _____________________

Is there evidence of EBV reactivation (defined as a positive PCR for EBV in the peripheral blood) or PTLD post-transplant?
- Yes
- No
• Not tested

Is the reactivation or infection new or ongoing since last reported for the study?
• New
• Ongoing

Date of diagnosis __________

Grade since last reported for the study
• Grade 1, not treated with rituximab
• Grade 2, treated with rituximab
• Grade 3, evidence of post-transplant lymphoproliferative disorder (PTLD)

Date of PTLD diagnosis __________

Was PTLD confirmed by a biopsy?
• Yes
• No

Is there evidence of a positive PCR for BK virus in the plasma and/or urine post-transplant?
• Yes
• No
• Not tested

Is the reactivation or infection new or ongoing since last reported for the study?
• New
• Ongoing

Date of diagnosis __________

Grade since last reported for the study
• Grade 1
• Grade 2

Is there evidence of a positive PCR for Adenovirus in the plasma, stool and/or urine or biopsy material from any organ post-transplant?
• Yes
• No
• Not tested

Specify site(s) _______________

Is the reactivation or infection new or ongoing since last reported for the study?
• New
• Ongoing

Date of diagnosis __________

Grade since last reported for the study
• Grade 1
• Grade 2
• Grade 3
Is there evidence of a positive PCR for HHV-6 in any anatomical specimen (e.g. CSF, blood) post-transplant requiring therapy?

- Yes
- No
- Not tested

Specify site(s)____

Is the reactivation or infection new or ongoing since last reported for the study?

- New
- Ongoing

Date of diagnosis _________

Grade since last reported for the study

- Grade 1
- Grade 2
Thrombotic microangiopathy (TMA) assessment

Date of diagnosis __________

Specify signs and symptoms

RBC fragmentation and >2 schistocytes per high-power field on peripheral smear
  • Yes
  • No

Increased serum LDH above institutional baseline
  • Yes
  • No

Renal dysfunction without other explanation (doubling of serum creatinine from baseline, OR 50% decrease in creatinine clearance from baseline)
  • Yes
  • No

Neurologic dysfunction without other explanation
  • Yes
  • No

Negative direct and indirect Coombs test results
  • Yes
  • No

Was TMA evaluated by biopsy?
  • Yes
  • No

Kidney
  o Positive
  o Suggestive
  o Negative
  o Inconclusive / equivocal
  o Not done

Other site
  o Positive
  o Suggestive
  o Negative
  o Inconclusive / equivocal
  o Not done

Specify other site ________________________

Therapy for TMA

Was therapy given for TMA?
  • Yes
  • No
<table>
<thead>
<tr>
<th>Therapy</th>
<th>Prescribed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defibrotide</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Eculizumab (Soliris)</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Rituximab (Rituxan, MabThera)</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Plasma exchange / plasmapheresis</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Other therapy, specify__________</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

Did the TMA resolve?

- Yes
- No

Date of resolution ____________
Hepatic veno-occlusive disease (VOD)/ sinusoidal obstruction syndrome (SOS) assessment

Date of diagnosis __________

Specify how the diagnosis was made

Was ultrasonography (with doppler) performed?

- Yes
- No

Provide a de-identified copy of the ultrasound report. Report must reference the subject's 15-MMUD study ID number. [file upload]

Date performed __________

Normal results

- Yes
- No

Reversal of portal venous flow (in at least 1 vein)

- Yes
- No

Other abnormality

- Yes, specify ________________
- No

Liver biopsy

- Positive for signs of VOD
- Negative for signs of VOD
- Inconclusive
- Not done

Provide a de-identified copy of the biopsy report. Report must reference the subject's 15-MMUD study ID number. [file upload]

Was an autopsy performed?

- Yes
- No

Provide a de-identified copy of the autopsy report. Report must reference the subject's 15-MMUD study ID number. [file upload]
VOD/ SOS evaluations at diagnosis

Signs and symptoms at diagnosis

Ascites
- Yes
- No

Hepatomegaly
- Yes
- No

Right upper quadrant pain
- Yes
- No

Weight gain (>2% over baseline at time of diagnosis of VOD / SOS)
- Yes
- No

Was there concurrent organ dysfunction at the time of diagnosis?
- Yes
- No

Kidney
- Yes
- No

Did the subject require renal replacement therapy?
- Yes
- No

Lungs
- Yes
- No

Specify the oxygen requirements at diagnosis of VOD / SOS
- Room air
- Supplemental oxygen
- Mechanical ventilation
- Other, specify _________________________

Mechanical ventilation start date __________

Was the subject successfully extubated?
- Yes
- No (mechanical ventilation ongoing)

Date extubated __________

Other organ
- Yes, specify _________________________
- No

Subject weight at diagnosis of VOD / SOS ______ kg

15-MMUD Study CRFs v3.1
Laboratory tests at diagnosis
Total serum bilirubin at diagnosis of VOD / SOS _______ mg/dL
  Date sample collected __________
Serum creatinine at diagnosis of VOD / SOS _______ mg/dL
  Date sample collected __________
AST (SGOT) at diagnosis of VOD / SOS _______ U/L
  Date sample collected __________
  Upper limit of normal for your institution _______ U/L
ALT (SGPT) at diagnosis of VOD / SOS _______ U/L
  Date sample collected __________
  Upper limit of normal for your institution _______ U/L

VOD toxicity prophylaxis
Was specific therapy used to prevent VOD toxicity?
  • Yes
  • No

Defibrotide
  • Yes
  • No

N-acetylcysteine
  • Yes
  • No

Tissue plasminogen activator (TPA)
  • Yes
  • No

Ursodiol
  • Yes
  • No

Other therapy
  • Yes
  • No

Specify other therapy: _______________

VOD/ SOS therapy
Was therapy given?
• Yes
• No

Defibrotide
• Yes
• No

Planned total daily dose ___________ mg

Date started __________

Date stopped ____________             □Ongoing

Subject weight at initiation of therapy ________ kg

Specify the lab results on the therapy start date

Total serum bilirubin _______ mg/dL

Serum creatinine _______ mg/dL

Specify the oxygen requirements at start of therapy
• Room air
• Supplemental oxygen
• Mechanical ventilation
• Other, specify ____________________

Reason therapy stopped
• Complete resolution
• Completed prescribed course/end of treatment protocol
• Discharge from hospital
• Side effect(s)
• Other, specify ____________________

Bleeding as side effect
• Yes
• No

Specify site(s) of bleeding

Central nervous system (CNS)
• Yes
• No

Gastrointestinal (GI)
• Yes
• No

Pulmonary
• Yes
• No
Other site
  - Yes, specify _________________
  - No

Other side effect
  - Yes, specify _________________
  - No

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Prescribed</th>
<th>Total dose</th>
<th>Date started</th>
<th>Date stopped</th>
<th>Ongoing at last contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-thrombin III</td>
<td>Yes/No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diuretics</td>
<td>Yes/No</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Heparin</td>
<td>Yes/No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methylprednisolone</td>
<td>Yes/No</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>N-acetylcysteine</td>
<td>Yes/No</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Tissue plasminogen activator (TPA)</td>
<td>Yes/No</td>
<td></td>
<td></td>
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<tr>
<td>Ursodiol</td>
<td>Yes/No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other therapy, specify</td>
<td>Yes/No</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
VOD/ SOS maximum severity

Maximum subject weight in this reporting period ______ kg

Maximum total serum bilirubin in this reporting period ______ mg/dL
  Date sample collected ______

Maximum serum creatinine in this reporting period ______ mg/dL
  Date sample collected ______

Was the subject placed on dialysis?
  • Yes
  • No
  Date started ______
  Date stopped ______
  Ongoing at the date of last contact □

Specify the maximum oxygen requirements in this reporting period?
  • Room air
  • Supplemental oxygen
  • Mechanical ventilation
  • Other, specify __________________
VOD/ SOS current status

Most recent subject weight _______ kg
   Date documented _______________

Total serum bilirubin at the date of last contact _______ mg/dL
   Date sample collected __________

Serum creatinine at the date of last contact _______ mg/dL
   Date sample collected __________

Specify the oxygen requirements at the date of last contact
   • Room air
   • Supplemental oxygen
   • Mechanical ventilation
   • Other, specify ____________________

Did VOD / SOS resolve?
   • Yes
   • No
   Date of resolution __________

Did VOD / SOS recur?
   • Yes
   • No
   Date of recurrence __________

VOD / SOS symptoms at recurrence

Increased bilirubin
   • Yes
   • No

Ascites
   • Yes
   • No

Weight gain (>2% over baseline at time of recurrence)
   • Yes
   • No

Hepatomegaly
   • Yes
   • No

Right upper quadrant pain
   • Yes
   • No
Other symptom
- Yes, specify __________________________
- No

Was therapy given for recurrent VOD?
- Yes
- No

Anti-thrombin III
- Yes
- No

Defibrotide
- Yes
- No

Diuretics
- Yes
- No

Heparin
- Yes
- No

Methylprednisolone
- Yes
- No

N-acetylcysteine
- Yes
- No

Tissue plasminogen activator (TPA)
- Yes
- No

Ursodiol
- Yes
- No

Other therapy, specify
- Yes, specify __________________________
- No

Management of late sequelae

Was management of late sequelae required?
- Yes
- No

Variceal banding
- Yes
• No

Transjugular Intrahepatic Portosystemic Shunt (TIPS)
• Yes
• No

Paracentesis
• Yes
• No

Thoracentesis
• Yes
• No

Was the subject dialysis dependent?
• Yes
• No

Other late sequelae
• Yes, specify ______________________
• No

Hospital stay

Was the subject admitted to ICU during their hospital stay?
• Yes
• No

Discharge status
• Discharged to home
• Hospice
• Rehabilitation
• Died during hospital stay
• Other, specify ______________
Donor form

Date of preliminary search ________
Date of formal donor/CBU activation __________

Demographics

NMDP donor ID (DID) __________
Date of donor work-up request __________
Date donor cleared for donation __________
Donor age at time of donation _______
Donor weight ______ kg

Donor sex
• Male
• Female, nulliparous
• Female, 1 or more pregnancies

Ethnicity
• Hispanic or Latino
• Not Hispanic or Latino

<table>
<thead>
<tr>
<th>Race</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian or Alaska Native</td>
</tr>
<tr>
<td>Asian</td>
</tr>
<tr>
<td>Black or African American</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Not reported</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
</tbody>
</table>

Donor CMV serostatus
• Positive
• Negative

ABO group
• A
• B
• AB
• O
HLA typing

Overall allele match at A, B, C and DRB1
- 4/8
- 5/8
- 6/8
- 7/8

HLA-A Locus high resolution matching
- Zero matched
- One matched
- Two matched

HLA-B Locus high resolution matching
- Zero matched
- One matched
- Two matched

HLA-C Locus high resolution matching
- Zero matched
- One matched
- Two matched

HLA-DRB1 Locus high resolution matching
- Zero matched
- One matched
- Two matched

HLA-DQB1 Locus high resolution matching
- Zero matched
- One matched
- Two matched

HLA-DPB1 Locus high resolution matching
- Zero matched
- One matched
- Two matched

HLA-DPB1 Locus TCE matching
- Allele/High resolution match
- Permissive TCE mismatch
- Non-Permissive TCE mismatch
HIV-positive pre-conditioning

Hepatitis B

Were Hepatitis B core antibody test results obtained within 6 months prior to the start of conditioning?
- Yes
- No

Hepatitis B core antibody sample collection date __________
Hepatitis B core antibody sample test date __________

Hepatitis B core antibody results
- Positive
- Negative

Hepatitis B DNA PCR sample collection date __________
Hepatitis B DNA PCR sample test date __________

Hepatitis B DNA PCR qualitative results
- Undetected
- Detected

Hepatitis B DNA PCR quantitative results __________ IU/mL

Hepatitis C

Were Hepatitis C antibody test results obtained within 6 months prior to the start of conditioning?
- Yes
- No

Hepatitis C antibody sample collection date __________
Hepatitis C antibody sample test date __________

Hepatitis C antibody results
- Positive
- Negative

Hepatitis C RNA PCR sample collection date __________
Hepatitis C RNA PCR sample test date __________

Hepatitis C RNA PCR qualitative results
- Undetected
- Detected

Hepatitis C RNA PCR quantitative results __________ IU/mL

CMV
Was CMV PCR assay obtained within 8 weeks prior to the start of conditioning?
- Yes
- No

CMV PCR sample collection date __________
CMV PCR sample test date __________

CMV PCR qualitative results
- Undetected
- Detected

CMV PCR quantitative results __________ IU/mL

Was CMV antigenemia assay obtained within 8 weeks prior to the start of conditioning?
- Yes
- No

CMV antigenemia assay sample collection date __________
CMV antigenemia assay sample test date __________

CMV antigenemia results
- Positive
- Negative

HIV-1 RNA

Was a HIV-1 RNA PCR level (HIV viral load by standard assay) obtained within 8 weeks prior to the start of conditioning?
- Yes
- No

HIV-1 RNA PCR level sample collection date __________
HIV-1 RNA PCR level sample test date __________

HIV-1 RNA PCR qualitative results
- Undetected
- Detected

HIV-1 RNA PCR quantitative results __________ copies/mL

CD4

Was a CD4 count obtained within 8 weeks prior to the start of conditioning?
- Yes
- No

CD4 sample collection date __________
CD4 sample test date __________
CD4 test results _________ cells/mm³

Was a protocol-specified sample collected for Latent HIV Cellular Reservoir Analysis within 8 weeks prior to the start of conditioning?

- Yes
- No

Date of Latent HIV Cellular Reservoir Analysis sample collection __________
HIV-positive post-transplant

--Day 180 and 365
Was a protocol-specified sample collected for Latent HIV Cellular Reservoir Analysis?
- Yes
- No

Date of Latent HIV Cellular Reservoir Analysis sample collection __________

--Day 100, 180, 270, 365
Was a CD4 count obtained?
- Yes
- No

CD4 sample collection date __________
CD4 sample test date __________
CD4 test results __________ cells/mm³