HSCT - Minimum Essential Data - A
REGISTRATION - DAY 0

Centre Identification

EBMT Code (CIC): ................................................................. Contact person: ..........................................................
Hospital: .......................................................... Unit: .......................................................... Email: ..........................................................

Patient Data

Date of this report: .......................................................... First transplant for this patient: [ ] Yes [ ] No
Patient following national / international study / trial:
[ ] No [ ] Yes: Name of study / trial .......................................................... [ ] Unknown
Hospital Unique Patient Number or Code (UPN) ..........................................................
Compulsory, registrations will not be accepted without this item.
All transplants performed in the same patient must be registered with the same patient identification number or code as this belongs to the patient and not to the transplant.

Initials: ......................... ......................... (first name(s) _family name(s))
Date of birth: ......................... .......................... [ ] Male [ ] Female
(at birth)

Primary Disease Diagnosis

Date of initial diagnosis: ..........................................................

PRIMARY DISEASE DIAGNOSIS (CHECK THE DISEASE FOR WHICH THIS TRANSPLANT WAS PERFORMED)

- [ ] Acute Leukaemia
  - [ ] Acute Myelogenous Leukaemia (AML) related Precursor Neoplasms
  - [ ] Precursor Lymphoid Neoplasms (old ALL)
  - [ ] Therapy related myeloid neoplasms (old Secondary Acute Leukaemia)
- [ ] Chronic Leukaemia
  - [ ] Chronic Myeloid Leukaemia (CML)
  - [ ] Chronic Lymphocytic Leukaemia (CLL)
- [ ] Lymphoma
  - [ ] Non Hodgkin
  - [ ] Hodgkin's Disease
- [ ] Myeloma/Plasma cell disorder
- [ ] Myelodysplastic syndromes / Myeloproliferative neoplasm
  - [ ] MDS
  - [ ] MDS/MPN
  - [ ] Myeloproliferative neoplasm
- [ ] Bone marrow failure including Aplastic anaemia
  - [ ] Inherited disorders
  - [ ] Primary immune deficiencies
  - [ ] Metabolic disorders
- [ ] Histiocytic disorders
- [ ] Autoimmune disease
  - [ ] Juvenile Idiopathic Arthritis
  - [ ] Multiple Sclerosis
  - [ ] Systemic Lupus
  - [ ] Systemic Sclerosis
  - [ ] Haemoglobinopathy

[ ] Other diagnosis, specify: ..........................................................
**Hospital UPN:**  
**Patient UIC:**  
**CIC:**  
**HSCT Date:**  

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### ACUTE LEUKAEMIAS (main disease code 1)

**Other acute leukaemias**

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**Date of initial diagnosis:**  
_YYYY - MM - DD_

**Classification:**

**Acute Leukaemias of ambiguous lineage**

- [ ] Acute undifferentiated leukaemia
- [ ] Mixed phenotype NOS
  - [ ] Mixed phenotype B/myeloid, NOS
  - [ ] Mixed phenotype T/myeloid, NOS
- [ ] Natural killer (NK)- cell lymphoblastic leukaemia/lymphoma
- [ ] Other, specify.................................

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**Secondary Origin?**

**Secondary origin**
- Related to prior exposure to therapeutic drugs or radiation
  - [ ] No
  - [ ] Yes
  - [ ] Unknown

**Is this a donor cell leukaemia**
- [ ] No
- [ ] Yes
- [ ] Not evaluated

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**Status at HSCT**

**Date of this HSCT:**  
_YYYY - MM - DD_

<table>
<thead>
<tr>
<th>STATUS</th>
<th>NUMBER</th>
<th>TYPE OF REMISSION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>CYTOGENETIC REMISSION</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[ ] No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[ ] Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[ ] Not evaluated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[ ] Not Applicable*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>[ ] Unknown</td>
</tr>
</tbody>
</table>

- Primary induction failure
- Complete haematological remission (CR)
- Relapse

- 1st
- 2nd
- 3rd or higher

*No abnormalities detected prior to this time point*
### Performance score system used
- Karnofsky
- Lansky

<table>
<thead>
<tr>
<th>Score</th>
<th>10</th>
<th>20</th>
<th>30</th>
<th>40</th>
<th>50</th>
<th>60</th>
<th>70</th>
<th>80</th>
<th>90</th>
<th>100</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Weight (kg):</th>
<th>Height (cm):</th>
</tr>
</thead>
</table>

### Comorbidity Index

Was there any **clinically significant** co-existing disease or organ impairment at time of patient assessment just prior to the preparative regimen?

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>Definitions</th>
<th>No</th>
<th>Yes</th>
<th>N/E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid tumour, previously present</td>
<td>Treated at any time point in the patient's past history, excluding non-melanoma skin cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Indicate type</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>Definitions</th>
<th>No</th>
<th>Yes</th>
<th>N/E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammatory bowel disease</td>
<td>Crohn's disease or ulcerative colitis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rheumatologic</td>
<td>SLE, RA, polymyositis, mixed CTD, or polymyalgia rheumatica</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>Requiring continuation of antimicrobial treatment after day 0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>Requiring treatment with insulin or oral hypoglycaemics but not diet alone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal: moderate/severe</td>
<td>Serum creatinine &gt; 2 mg/dL or &gt;177 µmol/L, on dialysis, or prior renal transplantation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatic: mild</td>
<td>Chronic hepatitis, bilirubin between Upper Limit Normal (ULN) and 1.5 x the ULN, or AST/ALT between ULN and 2.5 x ULN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>moderate/ severe</td>
<td>Liver cirrhosis, bilirubin greater than 1.5 x ULN, or AST/ALT greater than 2.5 x ULN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>Atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac</td>
<td>Coronary artery disease, congestive heart failure, myocardial infarction, EF ≤ 50%, or shortening fraction in children (&lt;28%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>Transient ischemic attack or cerebrovascular accident</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart valve disease</td>
<td>Except mitral valve prolapse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary: moderate severe</td>
<td>DLco and/or FEV1 66-80% or dyspnoea on slight activity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>DLco and/or FEV1 ≤ 65% or dyspnoea at rest or requiring oxygen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obesity</td>
<td>Patients with a body mass index &gt; 35 kg/m²</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Peptic ulcer</td>
<td>Requiring treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatric disturbance</td>
<td>Depression or anxiety requiring psychiatric consultation or treatment</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Were there any other major clinical abnormalities prior to the preparative regimen? Specify...
Type of HSCT (Autologous)

☐ Autologous

Source of the Stem cells
(check all that apply):

☐ Bone marrow
☐ Cord blood
☐ Peripheral blood
☐ Other: ____________________________

Graft manipulation ex-vivo
other than for RBC removal or volume reduction

☐ No  ☑ Yes: Genetic manipulation of the graft: ☐ No  ☑ Yes:

IF AUTOLOGOUS, CONTINUE TO “CHRONOLOGICAL NUMBER OF HSCT”
**HSCT (Continued)**

| Chronological number of HSCT for this patient? | ☐  | ☐  |
| If >1, date of last HSCT before this one | yyyy - mm - dd |
| If >1, type of last HSCT before this one | ☐ Allo | ☐ Auto |
| If >1, was last HSCT performed at another institution? | ☐ No | ☐ Yes | CIC if known |
| | Name of the institution |  |
| | City |  |

If >1, please submit an Annual follow up form before proceeding, giving the date of the subsequent transplant as the date of last contact (This is so we can capture relapse data and other events between transplants).

**HSCT part of a planned multiple (sequential) graft protocol (program)?**

| ☐ No | ☐ Yes |

**Preparative Regimen**

**Preparative (conditioning) regimen given?**

| ☐ No | ☐ Yes |

(Usually Paed Inherited Disorders only) Go to GvHD Prophylaxis

**Drugs**

| ☐ No | ☐ Yes | ☐ Unknown |

(include any active agent be it chemo, monoclonal antibody, polyclonal antibody, serotherapy, etc.)
**TOTAL PRESCRIBED CUMULATIVE DOSE**

*as per protocol:

<table>
<thead>
<tr>
<th>DRUG (given before day 0)</th>
<th>DOSE</th>
<th>UNITS</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Ara-C (cytarabine)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ ALG, ATG (ALS/ATS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Animal origin:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Horse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Rabbit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Other, specify</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Bleomycin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Busulfan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ IV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Both</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ BCNU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Bexar (radio labelled MoAB)</td>
<td>mCi</td>
<td>MBq</td>
</tr>
<tr>
<td>□ CCNU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Campath (AntiCD 52)</td>
<td></td>
<td></td>
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<tr>
<td>□ Carboplatin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Cisplatin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Clofarabine</td>
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<td></td>
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<tr>
<td>□ Corticosteroids</td>
<td></td>
<td></td>
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<tr>
<td>□ Cyclophosphamide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Daunorubicin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Doxorubicin (adriamycine)</td>
<td>mCi</td>
<td>MBq</td>
</tr>
<tr>
<td>□ Epirubicin</td>
<td></td>
<td></td>
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<tr>
<td>□ Etoposide (VP16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Fludarabine</td>
<td></td>
<td></td>
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<tr>
<td>□ Gemtuzumab</td>
<td></td>
<td></td>
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<tr>
<td>□ Idarubicin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Ifosfamide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Imatinib mesylate</td>
<td></td>
<td></td>
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<tr>
<td>□ Melphalan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Mitoxantrone</td>
<td></td>
<td></td>
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<tr>
<td>□ Paclitaxel</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Rituximab (mabthera, antiCD20)</td>
<td>mCi</td>
<td>MBq</td>
</tr>
<tr>
<td>□ Teniposide</td>
<td></td>
<td></td>
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<tr>
<td>□ Thiotepa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Treosulphan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Zevalin (radiolabelled MoAB)</td>
<td>mCi</td>
<td>MBq</td>
</tr>
<tr>
<td>□ Other radiolabelled MoAB</td>
<td>mCi</td>
<td>MBq</td>
</tr>
<tr>
<td>Specify</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Other MoAB, specify</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Other, specify</td>
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<td></td>
</tr>
</tbody>
</table>

*Report the total prescribed cumulative dose as per protocol. Multiply daily dose in mg/kg or mg/m² by the number of days; e.g. for Busulfan given 4mg/kg daily for 4days, total dose to report is 16mg/kg

**AUC = Area under the curve**
Survival Status

Survival Status on date of HSCT

- Alive
- Dead
- Patient died between administration of the preparative regimen and date of HSCT

Main Cause of Death (check only one main cause):

- Relapse or Progression/Persistent disease
- HSCT Related Cause
- Unknown
- Other

Contribution Cause of Death (check as many as appropriate):

- GVHD
- Interstitial pneumonitis
- Pulmonary toxicity
- Infection:
  - bacterial
  - viral
  - fungal
  - parasitic
  - Unknown
- Rejection/Poor graft function
- History of severe Veno occlusive disorder (VOD)
- Haemorrhage
- Cardiac toxicity
- Central nervous system (CNS) toxicity
- Gastrointestinal (GI) toxicity
- Skin toxicity
- Renal failure
- Multiple organ failure
- Other, specify

Total Body Irradiation (TBI)

- No
- Yes: Total prescribed radiation dose as per protocol ____________ Gy
  Number of fractions ____________ over ____________ radiation days

TLI, TNI, TAI (lymphoid, nodal, abdominal)

- No
- Yes: Total prescribed radiation dose as per protocol ____________ Gy

GvHD prophylaxis or preventive treatment

Drugs (Immunosuppressive chemo)

- ALG, ALS, ATG, ATS: Animal origin:
- Anti CD25
- Campath
- Systemic corticosteroids
- Cyclosporine
- Cyclophosphamide
- Etanercept
- Extracorporeal photopheresis (ECP)
- FK 506
- Infliximab
- Methotrexate
- Mycophenolate
- Sirolimus
- Other, specify

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- Gastrointestinal (GI) toxicity
- Skin toxicity
- Renal failure
- Multiple organ failure
- Other, specify

Contributory Cause of Death (check as many as appropriate):

- GVHD
- Interstitial pneumonitis
- Pulmonary toxicity
- Infection:
  - bacterial
  - viral
  - fungal
  - parasitic
  - Unknown
- Rejection/Poor graft function
- History of severe Veno occlusive disorder (VOD)
- Haemorrhage
- Cardiac toxicity
- Central nervous system (CNS) toxicity
- Gastrointestinal (GI) toxicity
- Skin toxicity
- Renal failure
- Multiple organ failure
- Other, specify