HSCT - Minimum Essential Data - A
REGISTRATION - DAY 0

Centre Identification

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

Patient Data

Date of this report: .......................... yyyy - mm - dd
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: .......................... yyyy - mm - dd
(at birth) Sex: ☐ Male ☐ Female

Primary Disease Diagnosis

Date of initial diagnosis: .......................... yyyy - mm - dd

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
  ☐ Solid Tumour
  ☐ 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: ................................................
CHRONIC LEUKAEMIAS (main disease code 2)
Chronic Myelogenous Leukaemias (CML)

Disease

Date of Initial Diagnosis: 

Classification: (CML is not a CML but MDS/MPN)
At least one investigation must be positive

Translocation (9;22) 
Absent  
Present  
Not evaluated

bcr-abl 
Absent  
Present  
Not evaluated

Treatment Pre-HSCT

Treatment pre-HSCT (primary treatment)

☐ No  - Includes supportive care or treatment without Tyrosine Kinase Inhibitor (TKI) or chemotherapy
☐ Yes  Date Treatment started 

Tyrosine Kinase Inhibitor (TKI):

☐ No
☐ Yes

Imatinib mesylate
Nilotinib
Dasatinib
Bosutinib
Ponatinib
Other TKI, specify:_________

☐ Other chemotherapy, specify:_________

Status at HSCT

Date of this HSCT: 

PHASE

NUMBER

TYPE OF REMISSION

HAEMATOLOGICAL

No
Yes
Not evaluated
Unknown

CYTOGENETIC

No
Yes
Not evaluated
Not Applicable*
Unknown

MOLECULAR

No
Yes
Not evaluated
Not Applicable*
Unknown

* No abnormalities detected prior to this time point
### HSCT

**Performance score**
- System used: □ Karnofsky
- □ Lansky

**Score**
- □ 10
- □ 20
- □ 30
- □ 40
- □ 50
- □ 60
- □ 70
- □ 80
- □ 90
- □ 100

**Weight (kg):** ....................  
**Height (cm):** ....................

### 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>
</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>
</tr>
<tr>
<td>Inflammatory bowel disease</td>
<td>Crohn's disease or ulcerative colitis</td>
</tr>
<tr>
<td>Rheumatologic</td>
<td>SLE, RA, polymyositis, mixed CTD, or polymyalgia rheumatica</td>
</tr>
<tr>
<td>Infection</td>
<td>Requiring continuation of antimicrobial treatment after day 0</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Requiring treatment with insulin or oral hypoglycaemics but not diet alone</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>
</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>
</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>
</tr>
<tr>
<td>Arrhythmia</td>
<td>Atrial fibrillation or flutter, sick sinus syndrome, or ventricular arrhythmias</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>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>Transient ischemic attack or cerebrovascular accident</td>
</tr>
<tr>
<td>Heart valve disease</td>
<td>Except mitral valve prolapse</td>
</tr>
<tr>
<td>Pulmonary: moderate severe</td>
<td>DLco and/or FEV1 66-80% or dyspnoea on slight activity</td>
</tr>
<tr>
<td>severe</td>
<td>DLco and/or FEV1 ≤ 65% or dyspnoea at rest or requiring oxygen</td>
</tr>
<tr>
<td>Obesity</td>
<td>Patients with a body mass index &gt; 35 kg/m²</td>
</tr>
<tr>
<td>Peptic ulcer</td>
<td>Requiring treatment</td>
</tr>
<tr>
<td>Psychiatric disturbance</td>
<td>Depression or anxiety requiring psychiatric consultation or treatment</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)

<table>
<thead>
<tr>
<th>Chronological number of HSCT for this patient?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>If &gt;1, date of last HSCT before this one</td>
<td>yyyy-mm-dd</td>
</tr>
<tr>
<td>If &gt;1, type of last HSCT before this one</td>
<td>□ Allo □ Auto</td>
</tr>
<tr>
<td>If &gt;1, was last HSCT performed at another institution?</td>
<td>□ No □ Yes: CIC if known</td>
</tr>
<tr>
<td>Name of the institution</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
</tbody>
</table>

> 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 *(Usually Paed Inherited Disorders only)* Go to GvHD Prophylaxis
- □ Yes

**Drugs**

- □ No
- □ Yes
- □ Unknown

*(include any active agent be it chemo, monoclonal antibody, polyclonal antibody, serotherapy, etc.)*
### Specification and dose of the preparative regimen

**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>
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</tr>
<tr>
<td>□ Both</td>
<td></td>
<td></td>
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<tr>
<td>□ BCNU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Bexxar (radio labelled MoAB)</td>
<td></td>
<td></td>
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<tr>
<td>□ CCNU</td>
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<td></td>
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<tr>
<td>□ Campath (AntICD 52)</td>
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<td></td>
</tr>
<tr>
<td>□ Carboplatin</td>
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<td></td>
</tr>
<tr>
<td>□ Cisplatin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Clofarabine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Corticosteroids</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Cyclophosphamide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Daunorubicin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Doxorubicin (adriamycine)</td>
<td></td>
<td></td>
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<tr>
<td>□ Epirubicin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Etoposide (VP16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Fludarabine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Gemtuzumab</td>
<td></td>
<td></td>
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<tr>
<td>□ Idarubicin</td>
<td></td>
<td></td>
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<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>
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<tr>
<td>□ Mitoxantrone</td>
<td></td>
<td></td>
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<tr>
<td>□ Paclitaxel</td>
<td></td>
<td></td>
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<tr>
<td>□ Rituximab (mabthera, antiCD20)</td>
<td></td>
<td></td>
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<tr>
<td>□ Teniposide</td>
<td></td>
<td></td>
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<tr>
<td>□ Thiotepa</td>
<td></td>
<td></td>
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<tr>
<td>□ Treosulphan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Zevalin (radiolabelled MoAB)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Other radiolabelled MoAB</td>
<td></td>
<td></td>
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<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>
<td></td>
<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
Hospital UPN:  
Patient UIC:  
HSCT Date:  

Total Body Irradiation (TBI)  
☐ No  ☐ Yes  
Total prescribed radiation dose as per protocol:  
Gy  
Number of fractions:  
over  
radiation days

TLI, TNI, TAI  
☐ No  ☐ Yes  
Total prescribed radiation dose as per protocol:  
Gy

(lymphoid, nodal, abdominal)

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 ...............................................................

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 ...................................................