

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
yyyy - mm - dd

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: _____ Sex: Male Female
yyyy - mm - dd (at birth)

Primary Disease Diagnosis

Date of initial diagnosis: _____
yyyy - mm - dd

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

<input type="checkbox"/> Acute Leukaemia <input type="checkbox"/> Acute Myelogenous Leukaemia (AML) related Precursor Neoplasms <input type="checkbox"/> Precursor Lymphoid Neoplasms (old ALL) <input type="checkbox"/> Therapy related myeloid neoplasms (old Secondary Acute Leukaemia) <input type="checkbox"/> Chronic Leukaemia <input type="checkbox"/> Chronic Myeloid Leukaemia (CML) <input type="checkbox"/> Chronic Lymphocytic Leukaemia (CLL) <input type="checkbox"/> Lymphoma <input type="checkbox"/> Non Hodgkin <input type="checkbox"/> Hodgkin's Disease	<input type="checkbox"/> Myeloma/Plasma cell disorder <input type="checkbox"/> Solid Tumour <input type="checkbox"/> Myelodysplastic syndromes / Myeloproliferative neoplasm <input type="checkbox"/> MDS <input type="checkbox"/> MDS/MPN <input type="checkbox"/> Myeloproliferative neoplasm <input type="checkbox"/> Bone marrow failure including Aplastic anaemia <input type="checkbox"/> Inherited disorders <input type="checkbox"/> Primary immune deficiencies <input type="checkbox"/> Metabolic disorders	<input type="checkbox"/> Histiocytic disorders <input type="checkbox"/> Autoimmune disease <input type="checkbox"/> Juvenile Idiopathic Arthritis <input type="checkbox"/> Multiple Sclerosis <input type="checkbox"/> Systemic Lupus <input type="checkbox"/> Systemic Sclerosis <input type="checkbox"/> Haemoglobinopathy
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Other diagnosis, specify: _____

MYELODYSPLASTIC SYNDROME (MDS)(main disease code 6)**Disease**Date of Initial Diagnosis:
yyyy - mm - dd

Select only one

WHO Classification at diagnosis:

- Refractory anaemia (*without ring sideroblasts*) (RA)
- RA with ring sideroblasts (RARS)
- MDS associated with isolated del(5q)
- Refractory cytopenia with multilineage dysplasia (RCMD)
- RCMD with ringed sideroblasts (RCMD-RS)
- RA with excess of blasts-1 (RAEB-1)
- RA with excess of blasts-2 (RAEB-2)
- Childhood myelodysplastic syndrome (*Refractory cytopenia of childhood (RCC)*)
- MDS Unclassifiable (MDS-U)

Secondary Origin?**Therapy related MDS:**
(*Secondary origin*)

- Yes : Disease related to prior exposure to therapeutic drugs or radiation
- No
- Unknown

IF THE PATIENT HAS RECEIVED AN ALLOGRAFT PRIOR TO THE DIAGNOSIS OF MDS, ANSWER THE FOLLOWING QUESTION

Is this a donor cell leukaemia

- No Yes Not evaluated

MYELODYSPLASTIC SYNDROME (MDS)(main disease code 6)**Chromosome Analysis at Diagnosis****Chromosome analysis at diagnosis** (All methods including FISH)

Normal Abnormal Not done or failed Unknown

If abnormal:

Complex karyotype: No Yes Unknown
(3 or more abnormalities)

You can transcribe the complete karyotype:
OR

Indicate below those abnormalities that have been evaluated and whether they were Absent or Present:

del Y (-Y)	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
abn 5 type <i>Fill only if abn 5 is Present</i>	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
<i>del5q (5q-)</i>	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
Other abn 5, specify _____	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
del 20q (20q-)	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
abn 7 type <i>Fill only if abn 7 is Present:</i>	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
<i>del 7q (7q-)</i>	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
<i>Other abn 7, specify</i>	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
abn 3 type <i>Fill only if abn 3 is Present:</i>	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
<i>inv(3)</i>	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
<i>t(3q;3q)</i>	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
<i>del(3q)</i>	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
Other abn 3, specify _____	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
del11q	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
trisomy 8	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
trisomy 19	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
i(17q)	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated
Other, specify _____	<input type="checkbox"/> Absent	<input type="checkbox"/> Present	<input type="checkbox"/> Not evaluated

Molecular Markers at Diagnosis**Marker analysis at diagnosis**

- Not evaluated
 Evaluated: Absent
 Evaluated: Present
 Unknown

If you are entering an **AML with myelodysplasia related changes**, return to the Acute Leukaemia to continue

MYELODYSPLASTIC SYNDROME (MDS)(main disease code 6)**Status at HSCT**Date of this HSCT:
yyyy - mm - dd

Select only one

WHO Classification at HSCT:

- Refractory anaemia (RA) (without ring sideroblasts)
- RA with ring sideroblasts (RARS)
- MDS associated with isolated del(5q)
- Refractory cytopenia with multilineage dysplasia (RCMD)
- RCMD with ringed sideroblasts (RCMD-RS)
- RA with excess of blasts-1 (RAEB-1)
- RA with excess of blasts-2 (RAEB-2)
- Childhood myelodysplastic syndrome (Refractory cytopenia of childhood (RCC))
- MDS Unclassifiable (MDS-U)

STATUS	NUMBER
Treated with chemotherapy: <input type="checkbox"/> Primary refractory phase (no change)	
<input type="checkbox"/> Complete remission (CR)	<input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher
<input type="checkbox"/> Improvement but no CR	
<input type="checkbox"/> Relapse (after CR)	<input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher
<input type="checkbox"/> Progression/worse <input type="checkbox"/> Never treated (Supportive care or treatment without chemotherapy)	

HSCT

Performance score

 system used Karnofsky

 Lansky

 Score 10 20 30 40 50 60 70 80 90 100

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

Comorbidity Index

 Sorror et al., Blood, 2005 Oct 15; 106(8): 2912-2919: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1895304/>

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

 No Yes

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

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

Peripheral blood

Cord 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 (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:				
DRUG (given before day 0)	DOSE	UNITS		
<input type="checkbox"/> Ara-C (cytarabine)		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> ALG, ATG (ALS/ ATS) Animal origin: <input type="checkbox"/> Horse <input type="checkbox"/> Rabbit <input type="checkbox"/> Other, specify		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Bleomycin		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Busulfan <input type="checkbox"/> Oral <input type="checkbox"/> IV <input type="checkbox"/> Both		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	<input type="checkbox"/> mg x hr/L <input type="checkbox"/> micromol x min/L <input type="checkbox"/> mg x min/mL
<input type="checkbox"/> BCNU		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Bexxar (radio labelled MoAB)		<input type="checkbox"/> mCi	<input type="checkbox"/> MBq	
<input type="checkbox"/> CCNU		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Campath (AntiCD 52)		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Carboplatin		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	<input type="checkbox"/> mg x hr/L <input type="checkbox"/> micromol x min/L <input type="checkbox"/> mg x min/mL
<input type="checkbox"/> Cisplatin		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Clofarabine		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Corticosteroids		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Cyclophosphamide		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Daunorubicin		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Doxorubicin (adriamycine)		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Epirubicin		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Etoposide (VP16)		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Fludarabine		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Gemtuzumab		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Idarubicin		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Ifosfamide		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Imatinib mesylate		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Melphalan		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Mitoxantrone		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Paclitaxel		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Rituximab (mabthera, antiCD20)		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Teniposide		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Thiotepa		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Treosulphan		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Zevalin (radiolabelled MoAB)		<input type="checkbox"/> mCi	<input type="checkbox"/> MBq	
<input type="checkbox"/> Other radiolabelled MoAB Specify		<input type="checkbox"/> mCi	<input type="checkbox"/> MBq	
<input type="checkbox"/> Other MoAB, specify		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	
<input type="checkbox"/> Other, specify		<input type="checkbox"/> mg/m ²	<input type="checkbox"/> mg/kg	

*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

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 Venous occlusive disorder (VOD)
 Haemorrhage
 Cardiac toxicity
 Central nervous system (CNS) toxicity
 Gastrointestinal (GI) toxicity
 Skin toxicity
 Renal failure
 Multiple organ failure
 Other, specify