

HSCT - Minimum Essential Data - A

REGISTRATION - DAY 0

Centre Identification

EBMT Code (CIC): Contact person:

Hospital: Unit: Email:

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

 Other diagnosis, specify:

SOLID TUMOURS (main disease code 5)**Disease**Date of initial diagnosis:
yyyy - mm - dd**Classification:**

- | | |
|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| <input type="checkbox"/> Bone sarcoma (excluding Ewing sarcoma/PNET) | <input type="checkbox"/> Melanoma |
| <input type="checkbox"/> Breast | <input type="checkbox"/> Neuroblastoma |
| <input type="checkbox"/> Central nervous system tumours (include CNS PNET) | <input type="checkbox"/> Ovarian (carcinoma) |
| <input type="checkbox"/> Colorectal | <input type="checkbox"/> Pancreatic |
| <input type="checkbox"/> Ewing sarcoma (ES)/PNET, extra-skeletal | <input type="checkbox"/> Prostate |
| <input type="checkbox"/> Ewing sarcoma(ES)/PNET, skeletal | <input type="checkbox"/> Renal cell |
| <input type="checkbox"/> Germ cell tumour, extragonadal only | <input type="checkbox"/> Retinoblastoma |
| <input type="checkbox"/> Head and neck | <input type="checkbox"/> Rhabdomyosarcoma |
| <input type="checkbox"/> Hepatobiliary | <input type="checkbox"/> Soft tissue sarcoma (excluding Rhabdo. and extra-skeletal ES) |
| <input type="checkbox"/> Kidney cancer excluding Wilm's tumour | <input type="checkbox"/> Germ cell tumour, gonadal |
| <input type="checkbox"/> Lung cancer, non-small cell | <input type="checkbox"/> Thymoma |
| <input type="checkbox"/> Lung cancer, small cell | <input type="checkbox"/> Wilm's tumour |
| <input type="checkbox"/> Medulloblastoma | |
| <input type="checkbox"/> Other, specify: | |

TNM classification

Type:	<input type="checkbox"/> Clinical	<input type="checkbox"/> Pathological						
	0	1	2	3	4	X	Not evaluated	Unknown
Tumour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nodes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Metastases*	<input type="checkbox"/>	<input type="checkbox"/>				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

* For metastases, 0 indicates "No metastasis", 1 indicates "Metastasis" and X indicates "Not evaluable"

Disease-specific staging

I	II	III	IV	Not evaluated	unknown
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Risk Factors/Staging at Diagnosis**Breast carcinoma only**

Receptor status:

Estrogen (ER): Negative Positive Not evaluatedProgesteron (PgR): Negative Positive Not evaluatedHER2/neu (c-erb-B2): Negative Positive Not evaluated

Axillary lymph nodes at surgery: N° positive / N° examined = /

Sentinel Node Negative Positive Not evaluated

Carcinoma type (tick only one)

 Ductal carcinoma Lobular carcinoma

Proliferation index (activity by Ki67 or MiB1 immunostaining) (% of positive cells).....

Germ cell tumours only**Histological classification** Seminoma Non-seminoma**Site of origin** Gonadal Extragonadal: retroperitoneal mediastinal Other sites specify:.....

SOLID TUMOURS (main disease code 5)

Status At HSCT

Date of this HSCT:
yyyy - mm - dd

Germ cell tumours

Risk category at disease recurrence (or platinum refractoriness) following first line CT

- Very low
 Low
 Intermediate
 High
 Very High
 Not evaluated

STATUS		
<input type="checkbox"/> Adjuvant <input type="checkbox"/> Never treated (upfront) <input type="checkbox"/> Stable disease/no response		
<input type="checkbox"/> Complete remission (CR) <input type="checkbox"/> Unconfirmed (CRU*) <small>*CRU – complete response with persistent scan abnormalities of unknown significance</small> <input type="checkbox"/> Confirmed	NUMBER	
	<input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher	
<input type="checkbox"/> 1st Partial response (PR1)		
<input type="checkbox"/> Relapse	NUMBER	SENSITIVITY TO CHEMOTHERAPY
	<input type="checkbox"/> 1st <input type="checkbox"/> 2nd <input type="checkbox"/> 3rd or higher	<input type="checkbox"/> Sensitive <input type="checkbox"/> Resistant <input type="checkbox"/> Untreated
<input type="checkbox"/> Progressive disease (PD)		

Organs involved (complete only if not in CR)

- | | |
|-----------------------------------------------|--------------------------------------|
| <input type="checkbox"/> Nodes | <input type="checkbox"/> Bone |
| <input type="checkbox"/> CNS | <input type="checkbox"/> Lung |
| <input type="checkbox"/> Liver | <input type="checkbox"/> Soft Tissue |
| <input type="checkbox"/> Other, specify:..... | |

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